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Comment

The European Media Freedom Act: Expanding European Union Media Regulation to Fundamental Rights and Values Protection

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Introduction

On 8 August 2025, most of the provisions of the European Media Freedom Act (EMFA or Regulation) became applicable in the Member States of the European Union ('EU' or the 'Union').[1] In this comment, I argue that the coming into effect of the EMFA marks the culmination of the EU's transformations into a rights- and values-oriented regulator in the media domain. Today, the Union's reliance on EU-level rules goes beyond the sole objective of developing a single market for media services on predominantly economic grounds. Instead, the Union also seeks to protect and promote media freedom and pluralism as ends in themselves, and by extension, to strengthen the protection of values enshrined in Article 2 Treaty on the European Union (TEU).

However, the Regulation's capacity to bring about a meaningful change on the ground remains uncertain, as most Member States are still in the process of adapting their national frameworks to the new EU minimum standards, and as the EMFA faces an open resistance, most notably in the form of Hungary's action of annulment before the Court of Justice of the European Union (CJEU).

Against this backdrop, I interpret the EMFA as part of a broader effort by the EU institutions and Member States to better prevent and address violations

1 Regulation 2024/1083/EU of the European Parliament and of the Council of 11 April 2024 establishing a common framework for media services in the internal market and amending Directive 2010/13/EU (European Media Freedom Act), OJ L, 2024/1083.

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of EU values through undermining media freedom and pluralism within the Union. The EMFA's adoption signals the EU institutions' preparedness to intervene when the national systems fail to uphold the Union's values. Moreover, where the institutions do not act, citizens and national courts may fulfil this role through preliminary references to the CJEU and subsequent case law.

I. A New Media Ecosystem and the EU's Shifting Regulatory Response

The regulation of public and private media had traditionally fallen within the competence of the Member States, which had long been reluctant to extend the EU's powers in this area. Consequently, national rules on media remained fragmented and not harmonised. However, in the past fifteen years, a gradual Europeanisation of EU media regulation has occurred. In the 2000s, EU media policy focused primarily on the single market for media services,[2] which led to the Audiovisual Media Services Directive (AVMSD or the Directive), adopted in 2010 and amended in 2018.[3] The Directive introduced a requirement of independence for national media regulatory authorities (Article 30 AVMSD), which introduced a limited, but significant, values-dimension to EU media policy. By codifying the independence of national media regulators, the EU started to establish minimum democratic guarantees within the media sphere. I argue that this was consistent with the protection of media freedom and pluralism under the EU Charter of Fundamental Rights[4] (Article 11.2), because national media regulators perform a key oversight function over the media ecosystem.

Since 2020, the European Commission, has classified media freedom and pluralism as one of the components of the rule of law.[5] In the 2020 European Democracy Action Plan,[6] the Commission stressed that EU citizens must be able to form their own political judgements, requiring an electoral environment in which a plurality of views can be expressed freely, and in which

2 Elda Brogi and Pier Luigi Parcu, 'Evolving Regulation for Media Freedom and Pluralism in the European Union', Utilities Policy 31 (2014), 256-265.

3 Directive 2018/1808/EU of the European Parliament and of the Council of 14 November 2018 amending Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) in view of changing market realities PE/33/2018/REV/1, OJ L 303.

4 Charter of Fundamental Rights of the European Union, OJ C 326.

5 European Commission, Annual Rule of Law Report 2020.

6 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the European Democracy Action Plan, COM/2020/790 final.

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independent media can operate. In the Action Plan, the Commission identified a number of threats to media freedom and pluralism as well as to democracy, including abusive legal actions against journalists and media outlets, national restrictions on media freedom introduced under the pretext of combating disinformation, or financial challenges for media arising from the digital transformation.

To address these threats, the EU has significantly harmonised the standards governing the media sphere. This process has been driven by the ambition to respond to technological change, notably regarding digitalisation and the resultant increasingly cross-border nature of media consumption, and to the growing dominance of online platforms in the media domain. Moreover, such a harmonisation has been motivated by the desire to strengthen the protection of the Union's values against internal and external threats, such as the politicisation of media regulators and public service media, private media capture – meaning, taking direct or indirect control over private media by political party –, and other adverse state measures towards independent media. Moreover, the EU has also sought to combat the harassment of journalists and media outlets through Strategic Lawsuits Against Public Participation (SLAPPs) and disinformation.

The Digital Services Act (DSA)[7] and the Digital Markets Act (DMA),[8] adopted in 2022 respectively, impact the media sphere through regulating very large online platforms (VLOPS) and very large online search engines (VLOSEs) with over 45 million users in the EU. In 2021, the Commission issued a Recommendation on safeguarding, ensuring the safety and empowerment of journalists and other media professionals.[9] To fight with the problem of SLAPPs, the Directive on the protection of persons who engage in public participation from manifestly unfounded or abusive court proceedings[10] was adopted in 2024.

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7 Regulation 2022/2065/EU of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act) (Text with EEA relevance), PE/30/2022/REV/1, OJ L 277, 27. October 2022, 1-102.

8 Regulation 2022/1925/EU of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives 2019/1937/EU and 2020/1828/EU (Digital Markets Act) (Text with EEA relevance), PE/17/2022/REV/1, OJ L 265, 12 October 2022.

9 Commission Recommendation 2021/1534/EU of 16 September 2021 on ensuring the protection, safety and empowerment of journalists and other media professionals in the European Union C/2021/6650, OJ L 331.

10 Directive 2024/1069/EU of the European Parliament and of the Council of 11 April 2024 on protecting persons who engage in public participation from manifestly unfounded claims or abusive court proceedings (Strategic lawsuits against public participation), PE/88/2023/REV/1, OJ L.

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Beyond these measures, the development of the EU's rights- and values-oriented media policy is particularly visible in the EMFA. Compared to the AVMSD, the EMFA covers a broader range of horizontal aspects of the media ecosystem. It applies not only to audiovisual media, but also to radio outlets and the press, and it moreover addresses some of the challenges posed by the distribution of media content via social media platforms. The Regulation addresses a wide range of stakeholders. It codifies in EU law the rights of recipients of media services, imposes both positive and negative obligations on Member States (discussed in Section III.), and establishes rights and duties for media service providers and VLOPs.

The EMFA was generally welcomed, however, with some reservations by civil society organisations. By contrast, the Regulation faced strong opposition from media publishers' associations, which criticised the EU rules on media ownership transparency and obligations to safeguard editorial independence.[11] Belgium, Denmark, France, Germany, Hungary, and Poland expressed concerns about the centralisation of media oversight at the EU level.[12] Germany, in particular, feared that the EMFA could lower its comparatively high, including Länder-level, standards of media freedom protection.[13] This criticism, however, has no basis in the Regulation, which sets only minimum standards. Recital 8 of the EMFA explicitly confirms that stricter national measures to enhance media pluralism and editorial independence are permitted, provided they comply with EU law and do not hinder the free movement of media services. Notably, the strongest opposition to the EMFA came from Hungary, which has brought an action for annulment against the Regulation (see Section II.).

11 'Views of the European Publishers Council on Controversial Proposals for a European Media Freedom Act', EPC, 20 February 2023, <https://www.epceurope.eu/post/views-of-the-european-publishers-council-on-controversial-proposals-for-a-european-media-freedom-act>, last access 2 December 2025.

12 Stefania Kolarz, 'Protection of Media Freedom Provokes Debate in the EU', Polish Institute of International Affairs (PISM), 25 June 2024 <https://pism.pl/publications/protection-of-media-freedom-provokes-debate-in-the-eu>, last access 2 December 2025.

13 Lennart Lünemann, 'Why EU Member States with Low Risks to Media Pluralism Are so Reluctant to Support the European Media Freedom Act', Centre for Media Pluralism and Media Freedom, 8 September 2023, <https://cmpf.eui.eu/why-eu-member-states-with-low-risks-to-media-pluralism-are-so-reluctant-to-support-the-european-media-freedom-act/>, last access 2 December 2025.

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II. How the EMFA Reorients EU Media Regulation Towards Rights and Values

The EMFA is grounded in the EU's internal market competence under Article 114 Treaty on the Functioning of the European Union (TFEU). In recent years, this provision has served as the legal basis for various legal acts addressing new dimensions of the digital economy, including the DSA and the DMA. These instruments have had significant implications for the media environment, imposing obligations on VLOPs and VLOSEs, which shape the distribution and monetisation of media content. The rationale for relying on Article 114 has been procedural, practical, and political. Without a Treaty amendment, the provision allows the EU to expand its competences in the name of harmonising the internal market. The EMFA is another example of this already well-established practice.[14]

The fact that the EMFA marks a shift in EU media regulation towards a rights- and values-based approach is evident from the Regulation's very title, the wording of its recitals preceding the operative provisions, and the substance of the rules.

The EMFA lays down requirements on various categories of stakeholders. First, the Regulation imposes a broad set of positive and negative obligations on Member States concerning public service media and the relationship between the state and the private media market. Second, the EMFA introduces EU-level rights and duties for media service providers, who are guaranteed the right to operate without undue interference. However, they are required to ensure transparency about the ownership and the amount of public funding received for state advertising. Moreover, the media service providers are mandated to introduce internal safeguards for editorial independence, which are elaborated in the Commission Recommendation.[15] Thirdly, the Regulation imposes new obligations on VLOPs regarding content posted by media service providers, requiring them to apply procedural safeguards before such content may be restricted.[16]

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14 On the use of Article 114 TFEU as a legal basis for the expansion of EU competence, see, in this issue, Christian Calliess, 'Filling the Gap in the Health Policy of the European Union (EU) – Lessons Learned from the Corona Crisis (Covid-19 Pandemic), HJIL 85 (2025), 1045-1074.

15 Commission Recommendation 2022/1634/EU of 16 September 2022 on internal safeguards for editorial independence and ownership transparency in the media sector C/2022/6536, OJ L 245, 22. September 2022, 56-65.

16 See Matteo Monti, 'The Missing Piece in the DSA Puzzle? Article 18 of the EMFA and the Media Privilege', Rivista italiana di informatica e diritto 6 (2024), 195-212.

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The Regulation establishes duties for Member States towards individuals and legal persons, public institutions, and media service providers. These duties, this comment argues, are anchored in and serve the objective of protecting EU values: fundamental rights and democracy. Owing to space constraints, the analysis engages with a selection of these obligations.

From the outset, the EMFA is framed within the values of Article 2 TEU. Its preamble is composed of 78 recitals and articulates the Regulation's normative foundations. Recital 1 uses the notion of 'independent media services', which frames media not only as economic operators within the internal market, but as institutions fulfilling a democratic function. Recital 2 understands media freedom and pluralism as 'two of the main pillars of democracy and of the rule of law' and, therefore, as essential to the functioning of the internal market for media services. The Recital further stresses that the Union must support the media sector in realising the opportunities of the internal market 'while at the same time protecting the values that are common to the Union and to its Member States, such as the protection of fundamental rights'.

Notably, the EMFA has a clear fundamental rights dimension, Enshrining in EU law the right of recipients of media services. Recital 8 introduces the notion of 'the right to a plurality of media content' produced in accordance with editorial freedom within the internal market. According to the EMFA's preamble, access to such content is a prerequisite of fostering public discourse and civic participation, and essential for cultural and linguistic diversity in the Union. Recital 14 underscores the direct impact which in particular news and current affairs content have on democratic participation and societal well-being. Accordingly, Article 3 EMFA mandates Member States to respect the right of recipients of media services, both natural persons and legal persons established in the EU, 'to have access to a plurality of editorially independent media content'. It also obliges Member States to guarantee framework conditions for the realisation of this right to 'the benefit of free and democratic discourse'.

Secondly, the EMFA invokes the value of democracy while emphasising the importance of public service media. Recital 27 highlights the public service media's essential role in upholding freedom of expression and information, providing diverse content, and serving as a forum for public debate and democratic participation. The EMFA emphasises that public service media's independence is especially crucial during electoral periods to ensure citizens' access to impartial, high-quality information. However, the Recital also acknowledges their structural vulnerability to political interference, given public service media proximity to the state and reliance on public funding. Recital 28 emphasises that the regulation of public service media across the Union is

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highly heterogeneous, with significant divergences in rules on balanced coverage, managerial appointments and dismissals, and the adequacy and stability of funding. In some Member States, the safeguards for editorial and governance independence are absent, insufficient, or ineffective in practice, and the recent reforms have, in certain cases, increased governmental control over public service media. According to the EMFA, such deficiencies heighten the risk of political interference in public service media. This undermines the access to independent and impartial media services, and consequently, negatively affects the right to freedom of expression under Article 11 of the Charter, while also distorting the competition within the internal market.

In the light of the above, the EU-level minimum standards on media regulators and public service media introduced by the EMFA must be read in light of their overarching purpose: to safeguard freedom of information and democratic standards. Because of this, Article 7 EMFA, building on Article 30 AVMSD, requires Member States to guarantee the independence of national media regulatory authorities and to provide them with adequate financial, human, and technical resources. Article 5 EMFA complements this by setting minimum standards for the governance and functioning of public service media. The EMFA requires Member States to ensure that providers of public service media operate with editorial and functional independence, and fulfil their public service remit impartially, ensuring a plurality of opinions and information available for audiences. Member States are mandated to establish clear and precise national rules governing the appointment and dismissal of persons or bodies responsible for determining or influencing the editorial strategy of public service media. Moreover, Member States must ensure transparent and objective criteria and procedures for the funding of public service media, so they can perform their public service mission defined in national law.

Thirdly, the EMFA underscores the importance of transparency in media ownership and state funding for democracy, and introduces related obligations on Member States. Recital 32 stresses that recipients of media services must know who owns and controls media outlets in order to identify potential conflicts of interest. According to the Regulation, this is an essential precondition for forming informed opinions and meaningfully participating in democratic life. In addition, the EMFA's standards on the transparency of state funding for media service providers and online platforms are, as Recital 72 explains, intended to protect the media sector from undue state influence or partial interests that could undermine the freedom to provide services and fundamental rights.

These rationales are, again, operationalised in concrete provisions. Article 6 EMFA requires Member States to establish a centralised national

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electronic database on media ownership, in which media service providers must disclose their ownership structures and the total annual amount of public funds they receive. Article 25 sets standards of transparency, objectivity, proportionality, and non-discrimination for the allocation of public funding and other state resources by Member States to media service providers and online platforms. Such funding must support media pluralism and may not bring unjustified or disproportionate advantages to particular media service providers.

A close reading of the recitals and operative provisions reveals that the Regulation introduces EU-level standards precisely because comparable safeguards are varied or lacking across Member States. In this sense, the EMFA not only identifies the structural deficiencies that endanger media freedom but also justifies the need for minimum EU standards as a means of reinforcing democracy, the rule of law and fundamental rights throughout the Union. At the same time, the EMFA's text makes explicit that the protection of media pluralism and freedom is neither separate from nor in tension with the functioning of the internal market. On the contrary: the measures aimed at safeguarding rights and values, such as insulating public service media from political influence or ensuring the fair allocation of state resources, simultaneously serve to secure effective competition in the media sector.

Not all stakeholders, however, share this logic. Hungary has brought an action for annulment against the EMFA,[17] arguing that Article 114 TFEU is an incorrect legal basis, and challenging its individual provisions.[18] In Hungary's view, media regulation falls within the exclusive competence of the Member States and cannot be harmonised under the internal market clause, given the EMFA's extensive referencing of protecting media freedom and pluralism and, consequently, EU values. Hungary argues that a directive should be considered instead of a regulation. While some commentators criticise such a broad reading of EU competences, others defend the EMFA's legal basis, arguing that the Court of Justice's established trend of interpreting Article 114 TFEU expansively is justified and consistent with safeguarding the fundamental freedoms necessary for democracy and the protection of the shared European values.[19]

17 CJEU, *Hungary v. Parliament and Council*, action brought on 10 July 2024, case no. C-486/24.

18 Hungary asks the CJEU to annul Article 2, point 3, and Article 5; Article 2, point 20, and Article 4; Article 6; Article 7; provisions relating to the European Board for Media Services; Articles 21 to 23; and Article 2, point 19, and Article 25.

19 For the doctrinal debate and arguments defending the EMFA's legal basis see Erik Longo, 'Grounding Media Freedom in the EU: The Legal Basis of the EMFA, Rivista italiana di informatica e diritto 7 (2024), 111-124.

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III. EMFA as a New Leverage for Protecting EU Values

Indeed, the EMFA is a part of a broader effort to equip the Union with tools to prevent and address violations of EU values within the Member States. Going further, I suggest that, by adopting the Regulation, the EU institutions have signalled their readiness to intervene where the national systems fail to effectively uphold Union values. However, if the EU institutions do not assume this role, it may instead be carried out from below by natural and legal persons bringing their cases to national courts and through preliminary references to the CJEU.

The manner and pace with which the EU institutions have used the existing mechanisms to enforce compliance with Article 2 TEU in Member States have long been the subject of extensive scholarly criticism.[20] The Commission is infamously reluctant to use the EU law infringements procedure against those Member States that do not fulfil the obligations arising from EU law.[21] Such a reluctance gains additional significance when viewed against the Commission's response to media-freedom and pluralism crises in rule-of-law backsliding Member States. In Hungary, for example, despite fifteen years of well-documented media-freedom and pluralism crisis, the Commission has initiated only a single media-related EU law infringement action (Article 258 TFEU). In 2023, the Commission brought Hungary before the CJEU in a case concerning the refusal by the Media Council of Hungary to renew Klubrádió's right to use radio frequencies.[22] According to the Commission, Hungary had breached the EU law by denying the extension on procedural grounds that were not applied in a non-discriminatory and proportionate manner. The Commission raised that, in doing so, Hungary had violated the provisions of EU electronic communications law and Article 11 of the EU Charter.

Against this backdrop of the Commission's limited legal response to the media freedom and pluralism crises in Member States, the EMFA provides a broad and enforceable legal basis for infringement actions across several areas. Since the EMFA's entry into force, a 'low-hanging fruit' for Commission enforcement consists of infringement proceedings under Article 7 EMFA and

20 Armin von Bogdandy and Michael Ioannidis, 'Systemic Deficiency in the Rule of Law: What It Is, What Has Been Done, What Can Be Done', CML Rev. 51 (2014), 59-96.

21 R. Daniel Kelemen and Tommaso Pavone, 'Where Have the Guardians Gone? Law Enforcement and the Politics of Supranational Forbearance in the European Union', Wld. Pol. 75 (2023), 779-825.

22 CJEU, *Commission v. Hungary (Right to provide media services in a radio frequency)*, Opinion of Advocate General Rantos delivered on 3 April 2025, case no. C-92/23, ECLI:EU:C:2025:233.

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Article 30 AVMSD against Member States whose media regulators lack functional independence. In several countries, such as Hungary, Poland, Italy, Slovakia, and Greece, political interference is evident in appointment procedures and in the substantive decision-making of media regulatory bodies.[23] Moreover, the Commission has a clear legal basis under Article 5 EMFA to initiate infringement actions against several Member States, such as Greece, Italy, Hungary, Slovakia, and Malta, that fail to ensure that public service media operate with editorial and functional independence and fulfil their remit impartially.

In December 2025, the European Commission initiated infringement proceedings against Hungary, alleging breaches of multiple obligations under the EMFA and the DSA. In its assessment under the EMFA, the Commission concluded that Hungary permits undue interference in the work of journalists and media outlets, notably through restrictions affecting their economic activities and editorial freedom. The Commission further found that Hungarian law fails to ensure adequate protection of journalistic sources and confidential communications, and does not provide effective judicial remedies where these rights are violated. In addition, the Commission identified noncompliance with EMFA requirements concerning public service media, transparency of media ownership, the assessment of media market concentrations, and the allocation of state advertising. The infringement proceedings also encompass alleged failures to comply with obligations relating to national media regulatory authorities under the AVMSD.[24]

This infringement action illustrates the synergies between existing EU media regulation and the EMFA and provides initial confirmation of the argument advanced in this comment, namely that EU institutions intend to make active use of the EMFA. For the time being, enforcement appears to be directed at the most glaring example of a Member State undergoing democratic backsliding within the EU. This is so notwithstanding the fact that other Member States score even lower than Hungary in media freedom rankings, most notably Greece, which has been identified as the worst performer in the Union.

Whether the EMFA will enable the Commission to address systemic media-freedom problems in the Member States ultimately depends on political factors, including the Commission's willingness to make full use of its enforcement powers and reaction of Member States governments. Still,

23 See the Annual Rule of Law Report 2025.

24 'Commission calls on Hungary to comply with European Media Freedom Act and Audiovisual Media Services Directive', European Commission, 11 December 2025, <https://digital-strategy.ec.europa.eu/en/news/commission-calls-hungary-comply-european-media-freedom-act-and-audiovisual-media-services-directive>, last access 22 December 2025.

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individuals and legal persons bringing actions before national courts, and those courts submitting preliminary references, may lead the CJEU to clarify the scope and application of the EMFA within the Member States. The first preliminary reference concerning provisions of the EMFA has been submitted to the CJEU by the Budapest Metropolitan Court on 9 December 2024 in *Orbán v. Editorial Board of 24.hu*.[25] The question was asked in the context of a defamation dispute initiated by the Hungarian Prime Minister against the online news portal 24.hu.[26] The dispute arose after the portal republished information originally disseminated by a media outlet based in another EU Member State. The preliminary reference concerns the interpretation of Article 3 EMFA (the rights of recipients of media services) in conjunction with Article 11 of the EU Charter (media freedom and pluralism). The Budapest court asked the CJEU whether a news media outlet in one EU Member State may refer to or report on media content published in another Member State, without being required to prove the truthfulness of that content, and whether imposing such a burden in national law is against EU law. This example indicates that even if the Commission under enforces the EMFA, the precise scope of the Regulation will be clarified through judicial dialogue between national courts and the CJEU.

The alignment of national legal frameworks with the EMFA varies considerably across the Union. The 2025 Annual Rule of Law Report presents a mixed assessment of the EMFA's immediate impact. Most Member States are still in the process of reviewing national legislation or drafting new national rules to implement the EMFA standards in specific areas. Comprehensive media law reforms are currently underway in several Member States.[27] There has been no progress recorded regarding media ecosystem improvements in Hungary. Notably, the EMFA in itself has not prevented some Member States from deteriorating in media freedom and pluralism. In Slovakia, for example, the measures adopted in 2024 contributed to the politicisation of public service broadcasting and a regression in its overall independence.[28] In 2025, concerns arose regarding the independence of the public service broadcaster in Lithuania following a legislative amendment that made it easier to

25 CJEU, *Viktor Orbán v. Editorial board of 24.hu*, case no. C-843/24.

26 CJEU, *Orbán v. 24.hu* (n. 25).

27 Bulgaria, Croatia, Estonia, Finland, France, Ireland, Luxembourg, Latvia, Malta, the Netherlands, Poland, Romania, Slovakia, Slovenia, and Spain.

28 'Slovakia: Media Capture Deepens as Government Tightens Grip on Public and Private Media', International Press Institute, 26 June 2025, <https://ipi.media/slovakia-media-capture-deepens-as-government-tightens-grip-on-public-and-private-media/>, last access 22 December 2025.

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remove the Director General of Lithuanian National Radio and Television (LRT).[29]

The introduction of the EMFA has also reinvigorated political tensions around media ecosystem reforms. For example, the government of Italy proposed a reform of appointments to the public broadcaster RAI governing board, which was criticised by constitutional scholars for the retained political control over the process.[30] In France, a heated debate is under way over the centralisation of public service media into a single entity, France Médias. Moreover, the opposition parties in several member states decry the established system of public service media for alleged bias. In France, the far-right the National Rally has advocated the privatisation of public broadcasting.[31] Similarly, the far-right party AfD in Germany has called for the abolition of public broadcasting, describing it as an instrument of an alleged 'indoctrination and propaganda'.[32] These examples indicate that compliance with the EMFA across national legal and regulatory frameworks may be uneven and partial, making robust EU-level enforcement of the Regulation all the more necessary.

IV. EMFA's Promise Is to Be Tested

The EMFA is a significant development in EU media regulation. It pursues a dual objective: on the one hand, advancing the integration of the internal market for media services, and on the other, safeguarding the Union's values in Member States through improved protection of media freedom and pluralism. These two rationales of the EMFA are mutually reinforcing. Provisions grounded in rights and values are intended to improve the functioning of the

29 'Lithuania: IPI Warns Over increasing Pressure on Independent Public Service Broadcasting', International Press Institute, 17 December 20205, <https://ipi.media/lithuania-ipi-warns-over-increasing-pressure-on-independent-public-service-broadcasting/>, last access 22 December 2025.

30 The provisions of the bill of 17 September 2025, adopted by the Senate's VIII Standing Committee has drawn criticism from constitutional law scholars in Italy, see: 'Una riforma della Rai che non rispetta né il Freedom Act né la Costituzione. Il pensiero di alcuni costituzionalisti. FIRMA L'APPELLO', Articolo 21, 29 September 2025, <https://www.articolo21.org/2025/09/una-riforma-della-rai-che-non-rispetta-ne-il-freedom-act-ne-la-costituzione-il-pensiero-di-alcuni-costituzionalisti/>, last access 2 December 2025.

31 'France: début des travaux de la commission d'enquête sur l'audiovisuel public', Radio France Internationale, 25 November 2025, <https://www.rfi.fr/fr/culture/20251124-france-d%C3%A9but-des-travaux-de-la-commission-d-enqu%C3%AAte-sur-l-audiovisuel-public>, last access on 2 December 2025.

32 Dirk Knipphals, 'Hier läuft etwas schief', TAZ.de, 20 April 2025, <https://taz.de/Debatte-ueber-Oeffentlich-Rechtliche/!6079414/>, last access 2 December 2025.

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media ecosystem as a whole, and in turn, to strengthen the single market for media services. Conversely, the existence of a robust, well-regulated market, with appropriate safeguards and requirements for media service providers, advances the EMFA's core objective of supporting media freedom and pluralism.

However, the true effectiveness of the EMFA remains uncertain as yet. A major challenge lies in ensuring consistent implementation of the Regulation, as uneven compliance risks entrenching existing disparities in media freedom and pluralism between Member States. Without strong oversight and political will of the EU institutions, particularly the Commission, the regulation's transformative potential could be weakened. Nonetheless, by establishing enforceable and directly applicable EU-level standards regarding media ecosystem, the EMFA holds the promise of improving prosperity and reinforcing the normative foundations of European democracy.

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Re-Reading Historic Articles in the ZaöRV: Anniversary Series

The Inter-American Commission on Human Rights: Past, Present, and Future

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Abstract

In 1968, Christian Tomuschat published the article titled 'Die Interamerikanische Menschenrechtskomission' (The Inter-American Commission on Human Rights) on the history, operations, and impact of the then-still-nascent institution.[1] Now, more than fifty years after Tomuschat's analysis, this essay critically revisits his core claims and offers an updated perspective on the challenges, threats, and opportunities facing the Inter-American Commission on Human Rights (hereinafter 'IACHR', 'the Commission', or 'the Inter-American Commission'). While Tomuschat understood the challenges faced by the system with far greater clarity than his contemporaries, his analysis and solutions are nonetheless tinged with a Euro-centric perspective that overemphasises written standards and the role of individual cases, implicitly stressing legalistic measures that seek to emulate the European system as the (only possible) solution. Tomuschat recognises the social and political factors at play in the Americas, but does not centre them in his analysis. We contend it is these factors, and the response to them by the Commission, more than the formal legal standards themselves (whether in treaties, statutes or rules of procedure), that have fundamentally determined the limits and achievements of the system. To his credit, Tomuschat does recognise the Inter-American capacity to adapt to local circumstances with local knowledge, but he does not anticipate (admittedly, a very high bar of expectation) the Commission's ability to develop a dynamic system moulded by and suited to the needs of the hemisphere despite the shortcomings in its formal, legal standards.

The essay proceeds in three parts, representing the three main themes that it covers. First, it explores Tomuschat's argument that a binding treaty would render the Commission more effective by assessing the impact of the American Convention in relation to other factors. We note in the first part that it was the practice of country visits and reports that raised the profile of the Commission in the hemisphere in the 1970s, and not the drafting and entry into force of the American Convention in that same period. Second, we note that Tomuschat rightly predicted that a binding treaty would strengthen the implementation of human rights standards in the Americas. Still, he does not afford adequate explanatory force to the system's ability to drive human rights change even without such a treaty and, later, its capacity to do so despite a treaty that still lacks important ratifications. We contend that Tomuschat mistakes treaty ratification – an important indicator of commit-

[1] Christian Tomuschat, 'Die Interamerikanische Menschenrechtskomission', HJIL 28 (1968), 531-560.

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ment to the rule of law and human rights – with actual commitment to the rule of law and human rights. Positive changes in state policy, implementation of measures needed to curtail abuses, and financial and other support for the system itself are more relevant indicators of commitment to human rights than treaty ratification. Still, he is correct that the creation and ratification of the American Convention would be an important advance in many countries in the Americas and for the Inter-American system as a whole. The Convention not only codified the functions and powers that the Commission had developed on its own, but also granted the Commission additional authority. The creation of a binding treaty, however, has not rendered the selection of commissioners a merit-based system, nor has it ensured the financial stability of the Commission and Court. As we explain, both of those essential elements in state commitment to human rights and thus system efficacy are driven by political forces not fully addressed by Tomuschat. Third, the essay argues that although Tomuschat predicted many challenges that the Commission would face, because his analysis implicitly accepts the European human rights system as *the* model, and because his analysis centres on critical review of texts rather than political and social forces and the responses of the Commission to those forces, he failed to foresee the depth of the challenges and the full potential of the Inter-American Commission. We emphasise in this section the role of the United States (US) and financial constraints in limiting the system's efficacy. We then turn to the unique aspects of the Commission's contemporary role and its transformative impact over the past five decades. Ironically, these aspects are today sorely needed in the European system, whose membership has expanded in ways that suggest the need for a further 'Inter-Americanisation' of the European system, rather than the reverse. The essay concludes by noting the continuing challenges to the effectiveness of the Inter-American Commission and international human rights oversight in general, while suggesting how these challenges might be addressed in the future.

Keywords

Inter-American Commission on Human Rights (IACHR)

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I. A Critical Summary of Tomuschat's 'Die Interamerikanische Menschenrechtskomission'

In his article 'Die Interamerikanische Menschenrechtskomission', Tomuschat made two core claims. First, he contended that the Inter-American Commission on Human Rights is 'one of the most original and most effective legal instruments' for the promotion and protection of human rights.[2] Second, Tomuschat argued that the work of the Commission would be significantly more effective if the Americas had 'a binding international treaty similar to the European Convention on Human Rights'.[3]

Acknowledging the importance of regional context when comparing legal systems, Tomuschat highlighted that in the Americas the threats to life, liberty, and security were commonplace. Meanwhile, in Western Europe such threats had been 'reduced to a peripheral exception'.[4] While accurate to significant extent at the time, at least with regard to the limited set of states in the European Court system, the implicit claim that certain abuses are to be expected in the Americas but not in Europe has failed to pass the test of time. Over the past five decades, Europe has experienced genocidal campaigns (e. g., Srebeniça), massacres (Russia), and forced disappearances (Turkey), among other grave violations of the rights to life, liberty, and security. At the same time, while grave violations of civil and political rights in the Americas have continued, the Inter-American system has addressed increasingly sophisticated issues related to these rights and has developed jurisprudence on economic, social and cultural rights far more than the European system.

Regarding the first proposition, Tomuschat found the work of the Inter-American Commission to be significant from the institution's start.[5] Although the Commission began with a mandate that was limited, and at times, unclear, it was bold and innovative in asserting authority.[6] For example, the Commission's 1960 Rules of Procedure did not give it express authority to receive communications from individuals, but the Commission determined that receiving these communications was necessary for conducting its work,

2 Tomuschat (n. 1), 532.

3 Tomuschat (n. 1), 549-550.

4 Tomuschat (n. 1), 549-550.

5 Tomuschat (n. 1), 532; see also Felipe González Morales, 'La Comisión Interamericana de Derechos Humanos: Antecedentes, funciones y otros aspectos', Anuario de Derechos Humanos (2009), 35-57 (56).

6 Alexandra Huneeus and Mikael Rask Madsen, 'Between Universalism and Regional Law and Politics: A Comparative History of the American, European, and African Human Rights Systems', I.CON 16 (2018), 136-160 (144).

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and that it must therefore have been granted the power implicitly.[7] In 1965, the Commission acquired the express authority to process individual complaints concerning human rights violations and to direct recommendations to individual States.[8] Although the Commission uses many methods for the promotion and protection of human rights, today it is best known for its adjudication of individual complaints, a power it first claimed for itself before its official or formal legal recognition.[9]

Tomuschat also observed that the Commission, both in the processing of individual complaints and in its other efforts, relied on and contributed to the development of human rights standards. The American Declaration on the Rights and Duties of Man was the primary foundation for the Commission's early work. The Commission provided advice and recommendations to the Organization of American States (hereinafter 'the OAS') Member States by interpreting and applying this Declaration. Tomuschat also noted that the Commission was able to rely on other Inter-American legal instruments, including binding conventions on the rights of women and asylum-seekers, as well as other sources of international law, including *jus cogens* and general principles of law, when considering the standards to which States in the Americas should be held.[10] The absence of a treaty that was the equivalent to the European Convention on Human Rights did not signify the absence of a legal framework as the Inter-American Commission could still provide recommendations, as well as rely on international law.[11]

Moreover, Tomuschat observed that the Commission prompted practical implementation of legal standards through the exertion of political and moral pressure.[12] This pressure sometimes resulted from the processing of individual complaints. Tomuschat claimed that 'the far-reaching political significance of the weighed opinion of a panel of respected experts who have formed their

7 Tomuschat (n. 1), 533.

8 Tomuschat (n. 1), 534. Inter-American Court of Human Rights, 'Basic Documents Pertaining to Human Rights in the Inter-American System: Updated to July 2003' (2003), <https://www.corteidh.or.cr/docs/libros/basingl01.pdf>, last access 3 December 2025.

9 Joel Hernandez García, 'Proposals for the Improvement of the Work of the Inter-American Commission on Human Rights' in: Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi (eds), *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (Oxford University Press 2024), 521-536 (523); Claudio Grossman, 'Protecting Human Rights in the Americas: The Continuous Role of the Inter-American Commission on Human Rights' in: Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi (eds), *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (Oxford University Press 2024), 34-48 (34, 62).

10 Tomuschat (n. 1), 538.

11 Tomuschat (n. 1), 538.

12 Tomuschat (n. 1), 547.

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opinion in full independence cannot be ignored'.[13] In this regard, Tomuschat makes an essential point about the efficacy of supranational oversight: Often, the most powerful effects flow from the prestige and credibility of the decisions or actions of a body like the Commission, together with popular, political, and media pressure. This dynamic is often of far greater consequence than the weight of binding legal obligations, which depending on a range of non-legal forces, may be disregarded. To this day, compliance still remains a concern, yet the Inter-American system continues to exert influence on states and other actors across the hemisphere.

Related to this observation, Tomuschat notes that political and moral pressure might also come in other forms.[14] For instance, the Commission has been conducting country visits on an ad hoc basis with the consent of States since 1961,[15] which has led to government action with an occasional backlash due to a given government's fear of a public airing of grievances by civil society and a fact-finding investigation by the Commission.[16] Tomuschat also noted that the Commission's country reports were an effective tool for increasing public knowledge of rights violations, and underscored the importance of annual reports that would further publicise the work of the Commission.[17]

Here, Tomuschat's observations are essential and prescient. The role of the Commission in visiting countries with serious human rights challenges and in

13 Tomuschat (n. 1), 544; See also Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi, 'Introduction' in: Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi (eds), *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (Oxford University Press 2024), 1-14 (5); Marcelo Torelly, 'From Compliance to Engagement: Assessing the Impact of the Inter-American Court of Human Rights on Constitutional Law in Latin America' in: Par Engstrom (ed.), *The Inter-American Human Rights System: Impact Beyond Compliance* (Palgrave Macmillan 2019), 115-141 (116-21).

14 Mayra Ortiz Ocaña and Aníbal Pérez Liñán, 'Transformative Impact: A Framework for Analysis' in: Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi (eds), *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (Oxford University Press 2024), 176-198 (181-84); García (n. 9), 525.

15 See Marisol Blanchard, 'Overview of Regional and Sub-regional Mechanisms: Access and Relationship between Courts and Commissions; Existing Cooperation with Other Mechanisms' (2015), <https://www.ohchr.org/sites/default/files/Documents/Countries/NHRI/StrasbourgPresentations/Marisol_Blanchard_IACHR.doc>, last access 3 December 2025.

16 Tomuschat (n. 1), 547.

17 Tomuschat (n. 1), 547, 549. As he noted: On several occasions, 'the CIDH has visited the Dominican Republic […] where there was serious unrest in 1961 after the assassination of the dictator Trujillo and in 1965 after the fall of the ruling military junta. On these occasions, the Commission has always taken the utmost care to obtain an accurate and unbiased picture of the situation by calling on all those involved in any way – official government bodies, all political groups, professional associations and unorganised individuals from the population – as well as by travelling around the country and making site visits.' Tomuschat (n. 1), 546.

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issuing and publishing country reports transformed the Commission from a marginal body to a central force in hemispheric relations. This change would not become evident until the later years of the following decade, when the Commission's visits to Nicaragua and Argentina (discussed below) were decisive in the transformations in both those countries. Other visits by the Commission in the late 1970s and early 1980s were nearly as important. Together, they raised the profile of the Commission, the system as a whole, and of human rights in general. All this was done with relatively little emphasis on individual cases or the American Convention on Human Rights.[18]

However, one of Tomuschat's greatest concerns was the lack of a binding treaty, which he referred to as '[a] serious weakness'.[19]

II. The American Convention, Country Visits, Selection of Commissioners, Financing and the Strengthening of the Inter-American Commission on Human Rights

1. The Impact Through Country Visits: Two Examples

The American Convention was adopted in 1969 and entered into force with the eleventh ratification in 1978. The Convention addressed many of the concerns that Tomuschat had raised back in 1968, such as the lack of the independence of the Commissioners[20] and 'the uncertain nature of the legal bases on which it is at present functioning'.[21] In the years immediately following the Convention's entering into force, the Commission intensified its practice of visiting countries and issuing reports on those visit. The increased profile and impact of the work of the Commission in those years, however, had little to do with the American Convention and everything to do with the political context in the region, the role of the hemisphere's superpower (the United States) and the remarkable courage demonstrated by the Commission. These factors – political context, the positions adopted by the United States, and the actions of the commissioners (and the commission as a body) in response, have continued to be the factors that define the

18 On the importance and impact of the on-site visits and country reports by the Commission in this period, see Tom Farer, 'The Rise of the Inter-American Human Rights System: No Longer a Unicorn, Not Yet an Ox', HRQ 19 (1997), 31-64.

19 Tomuschat (n. 1), 536.

20 Tomuschat (n. 1), 535.

21 Tomuschat (n. 1), 551.

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successes and failures of that institution and the inter-American human rights system in general.

In the late 1970s, Latin America was dominated by vicious, authoritarian regimes who coordinated their abusive policies through Operation Condor, with the support and training of the intelligence and military forces of the United States. This type of security coordination (to a lesser extent) and US intervention had been the practice since the onset of the Cold War and even before. At the same time, on the heels of the disastrous Vietnam war and the Watergate scandal, voters in the United States elected Jimmy Carter to the presidency. Among other changes initiated by Carter was a focus on human rights (and not *only* anti-communism) in the US foreign policy. Carter signed the American Convention and submitted it to the Senate (which, to date, has not advanced the treaty to ratification) and pressed states in the Americas to ratify the binding human rights treaty of the OAS. By mid-1978, with the ratification of eleventh state (Grenada on July 14 of that year), the American Convention entered into force.[22]

It was in this context that the Commission was operating in the late 1970s and in which two vitally important country visits took place: the 1978 visit to Nicaragua and the visit the following year to Argentina. Former Commissioner Tom Farer recounts the role of the Commission in several important country visits in that period. In particular, he relays the details of the visit to Nicaragua, whose date was moved up because of the deteriorating human rights situation in the country, and the final report on which was written in record time.[23] The report was extremely harsh, concluding that violations were endemic. Farer recounts that the 'truly extraordinary features of the report came at its very end'. The report, he notes, supported the call for a change in the regime. Farer observed that, 'the Commission for the first and only time in its history addressed no recommendations to the government'.[24]

Summarising the text of the report, Farer observed two decades later that '[t]hroughout Latin America, those words, written by a body six of whose seven members were conservative representatives of Latin American establishments, were read and were intended to be read as a statement of moral conviction that the entire political order, the whole system of public authority in Nicaragua, was root and branch rotten'. Farer notes the impact of the report in these terms, '[b]efore his death, Anastasio Somoza would cite the Commission report as one of the decisive forces driving him to resign and

22 See, Status of Ratifications of the American Convention on Human Rights, <https://www.cidh.org/Basicos/English/Basic4.Amer.Conv.Ratif.htm>, last access 3 December 2025.

23 Farer (n. 18).

24 Farer (n. 18), 538.

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flee the country even though the [National] Guard was still holding the line in most of the country'.

A second, transformative visit and country report involved Argentina, a country which had been submerged in horrendous rights abuses since the March 1976 coup that brought a vicious junta into power. Having witnessed the pushback to the abuses committed by Augusto Pinochet in neighbouring Chile, the Argentine junta opted to eliminate opponents by making them 'disappear'.[25] Estimates of those disappeared – activists, leftist guerrillas, student leaders, trade union members and many others against whom some vague suspicion had been cast – range from 9,000 to 30,000. Actors within the United States (most notably Assistant Secretary of State Patricia Derian) pressed Argentina to curb the most atrocious forms of rights abuse. Congress cut off military aid to Argentina. The administration then made much-needed multilateral financial support dependent on Argentina inviting the Inter-American Commission to visit.[26]

Margaret Keck and Kathryn Sikkink document the precipitous decline in forced disappearances that coincided with the visit of the Commission. From a high of 4,105 people disappeared in 1976 to 3,098 in 1977, the number dropped to 969 in 1978 and then to 181 in 1979, the year of the Commission's visit, and 83 in 1980.[27] The State Department reported on the press coverage of the Commission's visit in these terms:

> 'A media barrage – The Commission's visit was massively covered by the Argentine press, television and radio. There can hardly be an Argentine alive who is now unaware that human rights are an issue of significance. Everywhere the Commission went and everybody they met with – except for cases where the Commission sought and obtained more confidential meetings – was reported. The dramatic assembly of hundreds of people waiting outside […] to report disappearances drove home the point that many have complaints.'[28]

In Argentina today, it is not uncommon for rights activists and those who lived through the dictatorship to speak of Argentina before and Argentina after the visit of the Inter-American Commission. The Center for Legal and

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25 Margaret E. Keck and Kathryn Sikkink, *Activists Beyond Borders* (Cornell University Press 1998). See generally Chapter 3, 'Human Rights Networks in Latin America'; Keck and Sikkink (103 f.) write in this regard: 'Even before the military coup of March 1976, international human rights pressures had influenced the Argentine military's decision to cause political opponents to "disappear", rather than imprisoning them or executing them publicly'.

26 Keck and Sikkink (n. 25), 107.

27 Keck and Sikkink (n. 25), graph at 108.

28 U. S. Department of State, 'The IAHRC Visit: Not Much Changed?', 21 September 1979, Doc. 1979BUENOS07875, declassified version D063, paras 3-6, <http://www.cipol.org/colecciones.php#documentos>, last access 3 December 2025.

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Social Studies (CELS), Argentina's leading human rights organisation, refers to the visit of the Commission as 'an inflection point for the construction of the truth about the violations committed during the dictatorship and the struggle for human rights in our country'.[29]

Still, Tomuschat rightly predicted that a binding treaty would strengthen the ability of the Inter-American Commission to ensure the practical implementation of human rights standards. A binding treaty set mutual obligations and has served as a basis for individuals to assert claims against their governments in the inter-American system. As previously mentioned, although the Inter-American Commission had been able to claim implicit powers, explicit authority granted the Commission additional legitimacy among the international community and the States. The role of case-processing became more central to the work of the Commission (and Court) in the 1990s as states transitioned to civilian from authoritarian rule, as we outline below.

2. The Role of the Convention in Institutional Strengthening

The American Convention on Human Rights did strengthen the institutionality of the Inter-American Commission by codifying the functions and powers the Commission had claimed for itself and by granting the Commission additional authority. The American Convention turned the Commission from a charter body (one whose authority was derived from the Charter of the Organization of American States) into a hybrid charter and treaty body (one whose authority is derived from an inter-American treaty other than the OAS Charter). As per OAS Charter Article 106, 'There shall be an Inter-American Commission on Human Rights, whose principal function shall be to promote the observance and protection of human rights and to serve as a consultative organ of the Organization in these matters.'[30] The Article did not include additional details about the operations of the Commission. Instead, it stated, '[a]n inter-American convention on human rights shall determine the structure, competence, and procedure of this Commission'.[31] The American Convention on Human Rights was the treaty anticipated by the OAS Charter in this provision.

29 CELS: Memoria, Verdad y Justicia, 'cidh: 40 años de una visita histórica', <https://www.cels.org.ar/web/2019/09/a-40-anos-de-la-visita-de-la-cidh/>, last access 3 December 2025 (translation by authors).

30 Art. 106 Charter of the Organization of American.

31 Art. 106 Charter of the Organization of American.

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Article 41 of the American Convention officially affirmed the OAS Charter's general assertion of the Commission's purpose, stating that '[t]he main function of the Commission shall be to promote respect for and defense of human rights'.[32] Then, it detailed the functions and powers through which the Commission should achieve this purpose.[33] The Commission's role of informing the public about human rights, including the need to produce an annual report, became official under the Convention.[34] Article 41 also expanded the Commission's consultative role, which the OAS Charter had directed toward the OAS as whole, to be applicable also to individual Member States requesting the Commission's advice.[35] The same provision also affirmed the Commission's authority to, at its own discretion, conduct investigations, draft reports, request information from Member States, and make recommendations to Member States.[36] Relatedly, Article 38 of the American Convention left to the Commission's discretion the preparation of the Commission's Statute and the establishment of its Regulations.[37]

Article 41(f), by way of Articles 44 through 51, formally authorised the Commission to receive complaints from individuals or Non-Governmental Organisations (NGOs) alleging violations of the American Convention on Human Rights and explained the processing of these complaints.[38] The Convention authorised the Commission to assess the admissibility of a complaint, to request information concerning the complaint from all parties, including the State, to hold hearings regarding the complaint, reach friendly settlements or, if not, to produce a report with conclusions and recommendations.[39]

After communicating its report to the State and waiting three months, if the State has not taken adequate measures to comply with the Commission's recommendations, the Commission may publish its decision or, alternatively, the State or the Commission may submit the case to the Inter-American Court of Human Rights,[40] in case the State has accepted the jurisdiction of the Inter-American Court. The Commission also has authority under Article

32 Art. 41 American Convention on Human Rights (ACHR).
33 Art. 41 ACHR.
34 Art. 41 ACHR.
35 Art. 41(e) ACHR.
36 Art. 41(b)-(d) ACHR, Article 43 ACHR additionally provides that 'the State Parties undertake to provide the Commission with such information as it may request of them as to the manner in which their domestic law ensures the effective application of any provisions of this Convention'.
37 Art. 38 ACHR.
38 Arts 41(f), 44-51 ACHR.
39 Arts 46-50 ACHR.
40 Art. 51 ACHR. See also Art. 61 ACHR.

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63(2) of the American Convention to request provisional measures from the Court.[41]

Other provisions of the American Convention on Human Rights also strengthened the institutionality of the Inter-American Commission. For example, Article 71 of the American Convention codified the requirement that Commissioners be independent and impartial, which had been a concern of Tomuschat's.[42] Articles 35 and 36 additionally clarified that the Commissioners serve in their individual capacity and not as a representative of any one State.[43] Article 34 went further, specifying that the Commissioners 'shall be persons of high moral character and recognized competence in the field of human rights'.[44]

3. Limits of the Formal Legal Provisions: Political Appointments, Funding

Notwithstanding the requirements of independence and high moral character, the selection of commissioners (and judges) has been, and continues to be a political process. In the vast majority of countries, the process for selecting candidates to serve on the Commission is shrouded in secrecy. On many occasions, states have chosen candidates with suspect qualifications, likely due more to their alignment with the priorities of the particular administration than their commitment to human rights.

Once in office, Commissioners may be subject to pressures from their home governments, whatever the text of the Convention may assert regarding independence. The authors can attest to their colleagues routinely visiting the Embassy and or the Mission of their home countries on arrival in Washington for sessions. While it is possible that those visits might have pro forma, it is just as likely that discussions turned to state interests and positions regarding the work of the system.

Another vital issue that has plagued the Commission since its inception has been the instability and insufficiency of the budget allocated by the OAS. Tomuschat fails to address this issue. While one cannot expect any analysis to include all possible challenges to a given system, the financial challenges have been too central and crucial to be cast aside. Tomuschat's analysis, which is fundamentally legal and focuses on the texts rather than the practice entirely

41 Art. 63(2) ACHR.
42 Art. 71 ACHR.
43 Arts 35-36 ACHR.
44 Art. 34 ACHR.

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misses what might be termed the main event – the means that states have used to control and limit the impact of the Inter-American human rights system. Article 40 of the American Convention provided that the Secretariat, the specialised unit within the OAS that supports the work of the Commission, 'shall be provided with the resources required to accomplish the tasks assigned to it by the Commission'.[45] Again, while laudable, this statement simply does not comport with the reality of the functioning of the Secretariat, which has been underfunded for decades. As the docket of the system has grown, increases in the budget afforded the Secretariat have not kept pace with demand. Today, despite its broad mandate and expanding docket, the Commission receives from regular funds of the OAS only US $10.4 million.[46] By comparison, the Commission on Human Rights of the City of New York had an operating budget of more than $14 million in Fiscal Year 2025.[47] The European Court had a budget of 85 million euros in 2024,[48] roughly equivalent to US $100 million at this writing.

To understand the role of finances and budget in the Inter-American system, one must understand the political dynamics of the system. A few examples illustrate this principle. The 2015-2016 crisis, initially triggered by the loss of voluntary contributions from European states facing their own migration crisis intensified when Mexico withdrew funding and, some say, worked behind the scenes to ensure that other states not come to the rescue of the Commission. At the time, Mexico was upset by the independence of the expert group on Ayotzinapa (Grupo Interdisciplinario de Expertos Independientes, or GIEI) that it initially supported but whose robust, independent actions threatened the highest authorities in the country. The crisis dragged on for a year. Eventually, the Commission and Secretariat raised enough fundings to hold hearing that had to be cancelled and managed to save the jobs of some 40 staff who were to be released in mid-2016. At that

45 Art. 40 ACHR.

46 See, Inter-American Commission on Human Rights, Annual Report 2024, <https://www.oas.org/en/iachr/docs/annual/2024/IA2024_ENG.pdf>, last access 3 December 2025. The regular fund totalled $10,649,900. Other sources brought the total budget to more than $21 million.

47 New York City Council Hon. Adrienne Adams, Speaker of the Council Hon. Justin Brannan, Chair Finance Committee Hon. Nantasha Williams, Chair, Civil and Human Rights Committee Note on the Fiscal 2025 Executive Plan and the Fiscal 2025 Executive Capital Commitment Plan for the Commission on Human Rights, <https://council.nyc.gov/budget/wp-content/uploads/sites/54/2024/05/CHR.pdf#:~:text=%20of%20Human%20Rights%20%28CHR%20or%20the%20Commission%29.,and%20%2455%2C000%20greater%20than%20its%20Fiscal%202024%20budget>, last access 3 December 2025.

48 European Court of Human Rights website, <https://www.echr.coe.int/budget>, last access 3 December 2025.

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point (in effect, having lost the battle), the Mexican government worked to increase the OAS budget.[49]

The recent financial crisis provoked by the sudden and extreme decision of the United States to suspend funding to the OAS is another example of the politicised nature of the system.[50] While the Permanent Council of the OAS responded to avert the crisis by allowing funds to be reallocated to prevent widespread layoffs,[51] the threat of financial chaos continues. The dependence of the system on its largest donor – the United States – has always been a core, political weakness. None of this, however, can be gleaned from careful, lawyerly review of the legal instruments of the system.

III. The Commission's Contemporary Role and Impact

More than 50 years after 'Die Interamerikanische Menschenrechtskomission', the IACHR remains a significant institution in the protection of human rights in the region. Although Tomuschat anticipated many issues that were addressed at some level with the American Convention, he could not possibly predict, back in the 60's, the complete potential of the Inter-American Commission.[52]

While the adoption of the American Convention constituted a significant factor in strengthening the Inter-American Commission's mandate to protect human rights in the region, the Commission's institutional potential has transcended its legal foundations. This is due to three key factors: (a) addressing the sociopolitical context and institutional resilience; (b) developing innovative mechanisms and institutional incrementalism; and (c) expanding reparations and the victim-centric approach. Each of these three dimensions will be examined in the sub-sections that follow.

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49 This is typical of the transactional nature of the Mexican states' engagement with the Inter-American system. When it became clear that the stick was not beating the Commission into submission, Mexico pivoted to the carrot.

50 See, e. g., Redacción Judicial, 'EE.UU. canceló fondos para la CIDH que, entre otros, afecta programas indígenas', El Espectador on 31 January 2025, <https://www.elespectador.com/judicial/eeuu-cancelo-fondos-para-la-comision-y-corte-idh-afectando-programas-indigenas/#google_vignette>, last access 3 December 2025.

51 OEA, 'Res 1277' of 3 March 2025, CP/RES. 1277/25.

52 Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi (eds), *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (Oxford University Press 2024).

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1. Addressing the Sociopolitical Context and Institutional Resilience

As Christian Tomuschat stated in 'Die Interamerikanische Menschenrechtskomission', when analysing the work of the Commission, one must consider the unstable political context of the Americas, which he described as 'a sociological milieu […] in which the implementation of a human rights program faces far more obstacles than is the case in West Europe in particular […]'.[53] The Commission has been effective in large part because it has successfully adapted its methods to suit the ever-changing political situation.[54]

The concerns raised by Tomuschat regarding implementation are reflected in the response of the Commission over the past five decades: the development of robust toolbox. The different tools reflect the hybrid nature of its mandate, which combines political (such as *in loco* visits, investigations) and quasi-judicial functions (the petition and case system). Historically, the Commission has adapted its methodology to respond to context, choosing tools best suited to each situation. We contend that the Commission has been successful (or not) to the extent it has thoughtfully assessed the political and social context and developed approaches likely to succeed in the particular situation.

To understand the engagement of the Commission, we apply the analytical typology developed by Claudio Grossman who identified three historical phases. During the first phase, which ranged from the 1960s, when the Commission was created, to the early 1980s, the Commission focused on country visits and country reports based on fact-finding investigations. As we note above, these were the most effective tools to face the dictatorships of the time,[55] which had been hiding information from their citizens about gross human rights violations. States also refused to engage honestly and productively in dialogues with or proceedings before the Commission.[56] In this first phase, country visits and country reports informed and facilitated international pressure in the context of the Cold War to move authoritarian Latin American states to curb abuses.

53 Tomuschat (n. 1), 582.

54 Grossman (n. 9), 35; González Morales (n. 6), 35-57; Felipe González, Three Key Aspects of Strengthening the Inter-American Human Rights System (June 2012). Aportes DPLF No. 16, 15, available at: <https://corteidh.or.cr/tablas/r33168.pdf>, last access 3 December 2025.

55 Grossman (n. 9), 34-35.

56 Grossman (n. 9), 37; Huneeus and Madsen (n. 6), 145; Robert K. Goldman, 'History and Action: The Inter-American Human Rights System and the Role of the Inter-American Commission on Human Rights', HRQ 31 (2009), 856-887 (873 f.).

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The second phase ran from the late 1980s into the 1990s, as democratisation spread through the region. Even if democratic, governments inherited 'normative constraints', such as amnesty and contempt laws, as well as military jurisdiction over human rights violations.[57] During this time, the Commission began to rely more on its case system because civil society organisations had sufficient freedom and information to use it. In addition, elected governments were more willing to engage in individual proceedings than they were to cooperate with general investigations, which they argued were appropriate only for dictatorships.[58]

Lastly, the third and current historical phase involves a higher level of inclusion, as well as political participation.[59] During this phase, the Commission has worked to support the expansion of the scope of democracy, as well as to prevent democratic governments from backsliding into authoritarian regimes.[60] The current context is complex, with depleted trust in political institutions and populist authoritarian forces seeking to respond in their (abusive) ways to the challenges of the Americas.[61] In this most recent phase, the Commission has also created eleven Rapporteurships that operate under the Commission and two autonomous Rapporteurships, the Special Rapporteurship for Freedom of Expression and the Special Rapporteurship on Economic, Social, Cultural, and Environmental Rights.[62] The Rapporteurships seek to address the various structural, endemic challenges to the enjoyment of rights in the hemisphere that persist since the transitions to democratic rule. That is, they address primarily groups in situations of vulnerability even in countries in which states are unlikely to target political opponents or dissidents (as was the norm for authoritarian regimes in the 1970s and 1980s).

In this way, the breadth of challenges that the Americas are experiencing has required the Inter-American Commission to use a mix of the tools developed in its three historical phases.[63] Country visits and reports remain apt for combatting a new wave of authoritarianism in the region,[64] while

57 Grossman (n. 9), 37.

58 Grossman (n. 9), 37 f.; Huneeus and Madsen (n. 6), 152; Goldman (n. 56), 874 and 880; González Morales (n. 6), 39 f.

59 Grossman (n. 9), 39.

60 Grossman (n. 9), 39.

61 Grossman (n. 9), 40; See Moisés Naím and Brian Winter, 'Why Latin America Was Primed to Explode', Foreign Affairs on 29 October 2019, <https://www.foreignaffairs.com/articles/central-america-caribbean/2019-10-29/why-latin-america-was-primed-explode>, last access 10 April 2025.

62 Inter-American Commission on Human Rights, 'Thematic Rapporteurships and Units'. <https://www.oas.org/en/iachr/mandate/rapporteurships.asp>, last access 3 December 2025.

63 Grossman (n. 9), 39-44.

64 Grossman (n. 9), 41.

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thematic reports and individual petitions are key for addressing issues of exclusion and discrimination.[65]

2. Developing Innovative Mechanisms and Institutional Incrementalism

The IACHR, with its hybrid mandate,[66] has developed innovative mechanisms to address emerging human rights challenges in the region. Above and beyond the tools discussed in the previous section, this section emphasises the work of the following mechanisms, which may arguably be considered the most high profile and high impact developments of the past dozen years: the Interdisciplinary Group of Independent Experts (GIEI) Mexico; the Interdisciplinary Group of Independent Experts (GIEI) for Bolivia; the Special Monitoring Mechanism for Venezuela (MESEVE); the Special Monitoring Mechanism for Nicaragua (MESENI); the Interdisciplinary Group of Independent Experts (GIEI) for Nicaragua; and the SACROI COVID-19.

The Interdisciplinary Group of Independent Experts (GIEI) in Mexico was formalised on 28 November 2014 through an agreement between the IACHR, the State of Mexico and the representatives of the missing students of Ayotzinapa.[67] The agreement allowed the IACHR to appoint an Interdisciplinary Group of technical cooperation to address the disappearance of 43 students in Ayotzinapa, Mexico.[68] The aim was to address the structural issues underlying forced disappearances in general in Mexico.[69] The Commission developed this innovative mechanism in response to the demands of and in collaboration with civil society organisations that had a close relationship with local social movements.[70] The GIEI reviewed thousands of pages of

65 Grossman (n. 9), 42.

66 Art. 41 ACHR.

67 Inter-American Commission on Human Rights, 'Interdisciplinary Group of Independent Experts (GIEI)', <https://www.oas.org/en/iachr/jsForm/?File=/en/iachr/giei/ayotzinapa/default.asp>, last access 3 December 2025.

68 Inter-American Commission on Human Rights, 'Interdisciplinary Group of Independent Experts (GIEI)', <https://www.oas.org/en/iachr/jsForm/?File=/en/iachr/giei/ayotzinapa/default.asp>, last access 3 December 2025.

69 Inter-American Commission on Human Rights, 'Interdisciplinary Group of Independent Experts (GIEI)', <https://www.oas.org/en/iachr/jsForm/?File=/en/iachr/giei/ayotzinapa/default.asp>, last access 3 December 2025.

70 Gabriela Kletzel, 'Activism Strategies Involving the Inter-American System: Reflections for the Field of Action and Perspectives from National Human Rights Organizations' in: Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi (eds), *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (Oxford University Press 2024), 625-640 (633).

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documents in the official investigation of the case, interviewed scores of witnesses, survivors, and family members. It visited locales, examined evidence and demonstrated grave errors in the domestic proceedings, including systematic torture and a cover-up that led to the highest levels. Its work was covered intensely in Mexican and international media and its impact reverberated through Mexican society. The success of the GIEI depended on both the stakeholders who called for and supported the Commission's intervention and on the institutional resilience of the Commission.[71]

The Commission created another GIEI to address emerging challenges in Bolivia. The Interdisciplinary Group of Independent Experts in Bolivia was established through an agreement signed on 12 December 2019 between Bolivia and the IACHR[72] to assist in the investigations of violent acts, as well as human rights violations that took place in Bolivia between 1 September and 31 December 2019.[73] According to Thomas Becker, expert on Bolivia and co-author of the Coup: A Story of Violence and Resistance in Bolivia, 'The GIEI [for Bolivia] was probably the most important factor in shifting both the public perception of and political response to the egregious rights abuses in 2019 and 2020 in Bolivia. The GIEI was the catalyst for accountability measures and reparations.'[74]

Another example of the Commission's flexible approach is the creation of a special mechanism for Venezuela. The Special Monitoring Mechanism for Venezuela (MESEVE) was created on 21 October 2019 to strengthen the Commission's monitoring activities of the human right crisis in Venezuela.[75] The MESEVE provides support to several IACHR mechanisms, including review of requests for precautionary measures to supporting the litigation of cases before the Inter-American Court of Human Rights.[76] The MESEVE also works with victims and civil society and mechanisms from not only the

71 Kletzel (n. 70), 634 f.

72 Inter-American Commission on Human Rights, 'Acuerdo entre la Comision Interamericana de Derechos Humanos y el Gobierno del Estado Plurinacional de Bolivia para apoyar la Investigación de los actos de violencia y las violaciones a los derechos humanos occuridas en Bolivia entre el 1 de septiembre y el 31 de diciembre de 2019', <https://www.oas.org/es/cidh/giei/Bolivia/acuerdo/default.html>, last access 3 December 2025.

73 GIEI-BOLIVIA, 'Acuerdo de creación y mandato', <https://gieibolivia.org/sobre-giei/>, last access 3 December 2025.

74 Text message from Thomas Becker to James Cavallaro, 31 October 2025 (on file with the authors).

75 Inter-American Commission on Human Rights, 'Special Monitoring Mechanism for Venezuela', <https://www.oas.org/en/IACHR/jsForm/?File=/en/iachr/meseve/default.asp>, last access 3 December 2025.

76 Inter-American Commission on Human Rights, 'Special Monitoring Mechanism for Venezuela', <https://www.oas.org/en/IACHR/jsForm/?File=/en/iachr/meseve/default.asp>, last access 3 December 2025.

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OAS, but also from the United Nations to support the documentation of human rights violations.[77]

The systematic and widespread human rights violations in Nicaragua led the Commission to also establish two new mechanisms: the Special Monitoring Mechanism for Nicaragua (MESENI) and the Interdisciplinary Group of Independent Experts for Nicaragua (GIEI-Nicaragua).

The IACHR created the MESENI in 2018 to monitor the human rights situation in Nicaragua, provide technical assistance to the State, and follow up on recommendations made to Nicaragua after a country visit and in the 'Gross Human Rights Violations in the Context of Social Protests in Nicaragua' report.[78] Although the IACHR's presence in Nicaragua was suspended six months later, MESENI continued its work from IACHR headquarters in Washington, DC.[79] Lastly, the IACHR also created the Interdisciplinary Group of Independent Experts for Nicaragua (GIEI) to support investigations relating to violent acts in Nicaragua between 18 April and 30 May 2018 in the context of social protests.[80] While Ortega government has resisted oversight by these mechanisms, they have no doubt served to raise the visibility of rights abuse in Nicaragua and have served to increase pressures from other international actors.

Finally, in response to the COVID-19 pandemic, the Commission created the 'SACROI COVID-19', a Rapid and Integrated Response Coordination Unit, to provide guidance to States about their human rights obligations in the midst of sickness and uncertainty. The Commission issued statements, resolutions, and guidelines for States, and hosted webinars on the right to health. Many of the recommendations contained in these documents shaped States' decision-making process in response to the pandemic. With SACROI, the Commission demonstrated the capacity to respond quickly, creatively, and effectively in face of evolving challenges. This kind of rapid and integrated response coordination could be a model for the Commission as it

77 Inter-American Commission on Human Rights, 'Special Monitoring Mechanism for Venezuela', <https://www.oas.org/en/IACHR/jsForm/?File=/en/iachr/meseve/default.asp>, last access 3 December 2025.

78 Inter-American Commission on Human Rights, 'Special Monitoring Mechanism for Nicaragua (MESENI)', <https://www.oas.org/en/IACHR/jsForm/?File=/en/iachr/meseni/default.asp>, last access 3 December 2025.

79 Inter-American Commission on Human Rights, 'Special Monitoring Mechanism for Nicaragua (MESENI)', <https://www.oas.org/en/IACHR/jsForm/?File=/en/iachr/meseni/default.asp>, last access 3 December 2025.

80 Inter-American Commission on Human Rights, 'Interdisciplinary Group of Independent Experts for Nicaragua (GIEI)', <https://www.oas.org/en/IACHR/jsForm/?File=/en/iachr/meseni/default.asp>, last access 3 December 2025.

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addresses some of the most pressing challenges of the twenty-first century, including artificial intelligence and climate emergency.

3. Expanding Reparations and the Victim-Centred Approach

In addition to the Inter-American Commission's commendable capacity to adapt and respond to structural and contemporary human rights challenges, the Commission has a unique victim-centred approach and a comprehensive approach to reparations. The IACHR uses a victim-centred approach that places rights-holders as protagonists – 'institutions, standards, and procedures are oriented to recognizing victim's agency and to placing their claims front and center'.[81]

For the IACHR, the victims and their families, as well as civil society, are the oxygen and driving force of the entire system. By incorporating victims and their families in its processes, the Commission has sought to be more inclusive. A structural dimension of the inter-American system is the dialogue between the inter-American system and the victims in its different mechanisms, such as the case system, *in loco* visits,[82] as well as during the IACHR sessions.

When institutions of the Inter-American System determine there has been a human rights violation, they proceed to establish reparations, following a comprehensive approach. Reparations include six kinds of measures: 1) restitution (when it is possible to return to the status quo prior to the violation); 2) rehabilitation (for example, in cases of torture and sexual abuse – measures that require psychological support services); 3) economic reparation; 4) combat against impunity (emphasising the State's duty to adopt due diligence to investigate, prosecute, and punish in cases of serious violation); 5) symbolic measures (for instance, erecting a statute in the name of the victim, ceremonies in which the State recognises its international responsibility); and 6) guarantees of non-repetition (which should foster structural changes, such as legal reforms and new public policies).

81 Armin von Bogdandy, Flavia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi, 'Conclusion' in: Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi (eds), *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (Oxford University Press 2024), 641-648 (643).

82 Mariela Morales Antoniazzi, Flávia Piovesan and Júlia Cortez da Cunha Cruz, 'Inter-American Human Rights System: Sociopolitical, Institutional, and Cultural Dimensions of Its Transformative Impact' in: Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi (eds), *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (Oxford University Press 2024), 49-75 (63).

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Comprehensive reparations are also implemented in the Inter-American Commission's friendly settlements. These settlements have been employed by both the Commission and the Courts in a range of cases, with generally positive results. The reparations measures in friendly settlements are likely to have greater impact than those in final decisions, given the relatively high degree of compliance with settlements as compared to final reports from the Commission (and even sentences of the Court). Writing in 2011, Ariel Dulitzky observed that while 60 % of recommendations made by the Commission in merits reports are not carried out, approximately 85 % of friendly settlement agreements have been complied with at least partially.[83]

Thus, the Inter-American Commission has evolved and contributed to human rights in ways that 'Die Interamerikanische Menschenrechtskomission' article could not have fully foreseen.

Conclusion

This essay has noted that Tomuschat correctly assessed that the Commission was original and effective in the promotion of protection of human rights at the time of his writing in 1968. Tomuschat believed that a binding treaty would be the key to greater effectiveness. While the development and entry into force of that treaty – the American Convention on Human Rights – established important standards and mechanisms, it was not the essential instrument that catapulted the Commission to relevance in the hemisphere. Instead, it was the practice of country visits and release of reports, in conjunction with other forms of pressure, that made the Commission a dynamic and essential actor in the Western hemisphere in the late 1970s and beyond.

This is not to say that the Convention has not been important. As states in the hemisphere transitioned from authoritarian to more democratic rule, the system has placed greater emphasis on the case system. In this phase of the work of the Commission, the Convention has been more important. In the current phase of the Commission, creative mechanisms, such as the GIEI, have taken centre stage over the case-processing function of the Court. Throughout, the guiding thread in the success and failure of the Commission has been its capacity to respond to the social and political forces at work in the Americas. When the Commission has had the support of key actors (and even when it has not), and when it has leveraged that support or the support

83 Ariel Dulitzky, 'The Inter-American Human Rights System Fifty Years Later: Time for Changes', R. Q. D. I., Special Edition (2011), 127-164 (127, 138).

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of media, social justice activists and other forces, it has been able to produce meaningful advance in human rights. Tomuschat recognised the adaptability of the Commission but could not foresee this – rather than a binding treaty – as the engine that would lead the Commission to play a key role in limiting and challenging abuses in the Americas.

Moving forward, the Commission faces severe threats and challenges. First, the Commission has been and continues to be under-resourced and understaffed.[84] As a result, and in a context of increasing engagement with and interest in the inter-American system,[85] the Commission is facing slow processing and backlog of petitions.[86] Cases before the Commission are estimated to take around six and a half years from beginning (the admissibility of the petition) to end (the merits report).[87] The Commission must be furnished with adequate resources, including a higher budget and additional staff, to be able to work effectively and independently.[88] Additionally, to strengthen the Commission's independence and effectiveness, the process for nominating Commissioners must undergo reforms that include increased transparency and a higher involvement of civil society[89]. These changes would do a great deal to ensure that the system can adjudicate cases fairly

84 Human Rights Clinic of the University of Texas School of Law, 'Maximizando la justicia, minimizando la demora: acelerando los procedimientos de la Comisión Interamericana de Derechos Humanos' (December 2011), 4, <https://www.corteidh.or.cr/tablas/28253.pdf>, last access 3 December 2025; Françoise Hampson, Claudia Martin and Frans Viljoen, 'Inaccessible Apexes: Comparing Access to Regional Human Rights Courts and Commissions in Europe, the Americas, and Africa', I.CON 16 (2018), 161-186 (169); Goldman (n. 56), 882.

85 Par Engstrom, 'The Impact of the Inter-American Human Rights System Beyond Latin America' in: Armin von Bogdandy, Flávia Piovesan, Eduardo Ferrer Mac-Gregor and Mariela Morales Antoniazzi (eds), *The Impact of the Inter-American Human Rights System: Transformations on the Ground* (Oxford University Press 2024), 100-121 (119).

86 Human Rights Clinic of the University of Texas School of Law, 'Maximizando la justicia, minimizando la demora: acelerando los procedimientos de la Comisión Interamericana de Derechos Humanos' (December 2011), <https://www.corteidh.or.cr/tablas/28253.pdf>, last access 3 December 2025; Ariel E. Dulitzky, 'Muy poco, muy tarde: la morosidad procesal de la Comisión Interamericana de Derechos Humanos', JA (12) 2015, 21-75, <https://www.corteidh.or.cr/tablas/r33492.pdf>, last access 3 December 2025.

87 Grossman (n. 9), 45; Human Rights Clinic, University of Texas School of Law, 'Maximizing Justice, Minimizing Delay: Streamlining Procedures of the Inter-American Commission on Human Rights' (2011), <https://law.utexas.edu/wp-content/uploads/sites/11/2015/04/2012-HRC-IACHR-Maximizing-Justice-Report.pdf>, last access 3 December 2025.

88 Santiago A. Canton, 'To Strengthen Human Rights, Change the OAS (Not the Commission)', Human Rights Brief 20 (2013), 5-12 (8, 10-11); Felipe González, 'Three Key Aspects' (n. 54), 17; Dinah Shelton, 'The Rules and the Reality of the Petition Procedure in the Inter-American Human Rights System', Notre Dame J. Int'l. & Comp. L. 5 (2015), 2-28 (26-28).

89 See CEJIL, The Selection Process of the Inter-American Commission and Court of Human Rights: Reflections on Necessary Reforms (2014) Position Paper No. 10-2014, available at: <https://cejil.org/wp-content/uploads/pdfs/Position%20Paper%20No.%2010_3.pdf>, last access 3 December 2025.

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and efficiently. As with most of what makes the system thrive or fail, these measures depend on political will and financial support, rather than the existence or ratification of any treaty.

That said, incomplete ratification of the American Convention and of other inter-American human rights treaties, as well as the denunciation of the American Convention by a few members, such as Trinidad and Tobago and Venezuela pose real challenges to the system. The United States of America, Canada, and several Caribbean countries have also failed to ratify the Convention altogether.[90] Although the Commission is able to process individual complaints against OAS member States that are not party to the American Convention by interpreting and applying the American Declaration,[91] States' failure to ratify and withdrawals from the Convention affect the legitimacy of the inter-American human rights system as a whole, with severe implications to the Commission's effectiveness. Finally, the Commission continues to face low rates of State compliance with its recommendations,[92] and so does the Court.[93] Although it is important to consider the impact of the inter-American system beyond compliance, compliance itself is still a worthwhile aim. All these challenges stem from a greater problem that has afflicted the Americas in varying degrees over the past six decades: the lack of political will and commitment to human rights and the rule of law. Today, the hemisphere faces perhaps the greatest collective threat to human rights since the creation of the Commission in 1959, in no small measure because of the hostile attitude and actions of the United States, the hemispheric and global leader. This crisis will not be resolved by the existence of the system's main binding treaty nor even more complete ratification of the American Convention, although such ratification by powerful states might be a sign of greater hemispheric commitment to human rights. As Tomuschat himself observed in assessing the impact of the Inter-American Commission in its first decade, it would be 'inadequate' to engage in 'a mere legal comparison of systems […] without taking into account the results of practical legal implementation.[94] On this dimension, the system now faces its greatest challenges in decades.

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90 OAS Department of International Law, 'American Convention on Human Rights 'Pact of San José Costa Rica' (B-32): Signatories and Ratifications', <https://www.oas.org/dil/treaties_b-32_american_convention_on_human_rights_sign.htm>, last access 3 December 2025.

91 Thomas Buergenthal, Dinah Shelton, David P. Stewart and Carlos M. Vázquez, *International Human Rights in a Nutshell* (West Academic Publishing 2002), 277.

92 von Bogdandy, Piovesan, Ferrer Mac-Gregor and Morales Antoniazzi (n. 13), 5.

93 Shelom Velasco, *The Inter-American Court of Human Rights: Emerging Patterns in Judgment Compliance* (Indiana University Maurer School of Law J.S.D Dissertation, May 2016).

94 Tomuschat (n. 5), 583.

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While the hurdles before the Commission may seem insurmountable, the IACHR may well be able to face and overcome them if it can harness the support of civil society, friendly state actors, media, and the Commission's inherent creative capacity to adapt and to address an ever-changing world. The Inter-American system's institutional resilience, as seen historically in its innovative and responsive approaches to human rights abuses in the Americas, has not only ensured the Commission's effectiveness thus far, but is its best hope in the future. The Commission is well positioned to identify challenges, adapt its methods, and create mechanisms to address the current sociopolitical context. Whether it will be able to survive the grave threats that it and the entire project of human rights face today, and possibly even thrive, remains to be seen. Given the history of the hemisphere and the record of the Commission over the years, we remain cautiously optimistic.

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Abhandlungen

The European Health Union
Set Up, Challenges, and Global Outlook

A. Katarina Weilert, Pedro A. Villarreal, Laura Hering*

Introduction

The concept of a European Health Union emerged in November 2020 as a political response to the structural deficiencies within the European Union's system of preparedness and crisis management revealed by the COVID-19 pandemic. The pandemic exposed the limited capacity of the existing coordination mechanisms to ensure a timely and coherent response to cross-border health threats and brought renewed attention to the fragmented allocation of competences in the field of health under EU law.

Even after an acute crisis like COVID-19, health policy remains, in its core, a domain reserved for the Member States. The organisation and delivery of medical care fall within their exclusive responsibility, while Union competences are confined to specific aspects of public health and health security.[1] The most far-reaching legal basis is found in Article 168(4) Treaty on the Functioning of the European Union (TFEU), which forms part of the shared competences pursuant to Article 4 TFEU and allows the Union to adopt measures addressing common safety concerns. This competence underpins, inter alia, the establishment and functioning of the European Medicines Agency (EMA), which is additionally supported by internal market harmonisation under Article 114 TFEU. By contrast, the European Centre for Disease Prevention and Control (ECDC) operates primarily on the basis of

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1 Seminal works on this subject include: Tamara Hervey and Jean V. McHale, *European Union Health Law. Themes and Implications* (Cambridge University Press 2015); Anniek de Ruijter, *EU Health Law & Policy* (Oxford University Press 2019).

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Article 168(5) TFEU, which enables the Union to support, coordinate, and supplement Member State action through monitoring, early warning and risk assessment in relation to serious cross-border threats to health. These activities fall within the category of supporting competences as defined in Article 2(5) TFEU.

Against this constitutional background, the academic and policy debates on the European Health Union have been accompanied by calls for far-reaching institutional and legal reforms. Some commentators on European Union (EU) Law have advocated either an expansion of Union competences in the health sector through Treaty amendment, arguing that only a recalibration of primary law would enable the EU to respond effectively to future pandemics;[2] or, alternatively, not to 'expand' but rather to 'settle' the question of competences between the EU and Member States as the division in both shared and supporting competences in health makes it difficult to draw lines.[3] Even at the political level, the possibility of Treaty revision was not categorically excluded. Nonetheless, such proposals face considerable legal and political obstacles,[4] and are not currently being pursued. In the absence of primary law reform, the development of the European Health Union proceeds within the existing Treaty framework.

The European Commission has framed this process in programmatic terms, emphasising the objectives of strengthening the EU's health security framework, reinforcing the crisis preparedness and response role of key Union agencies, and enhancing the Union's capacity to address present and future health emergencies.[5] Yet, the notion of a 'European Health Union' itself remains legally indeterminate. It is a political concept and strategy designed to bring greater focus to the previously neglected area of health rather than a term of art, and its normative implications are far from clear. While Article 168(1) TFEU requires that a high level of human health protec-

2 Claudia Seitz, 'The European Health Union and the Protection of Public Health in the European Union: Is the European Union Prepared for Future Cross-Border Health Threats?', ERA Forum 23 (2023), 543 (565).

3 Vincent Delhomme and Carina van Os, 'Building the European Health Union (2019-2024): Successes, Limits and Future Perspectives', European Journal of Risk Regulation 16 (2025), 942-960 (958).

4 On the hurdles for Treaty reforms and how they were politically discussed at the European Parliament: Karolina Borońska-Hryniewiecka and Jan Kotýnek Krotký, 'Easier Said Than Done: the European Parliament's Entrepreneurs in the Treaty Change Discourse', West European Politics (September 2025), 1-27 (14), available at: <https://www.tandfonline.com/doi/full/10.1080/01402382.2025.2557032#abstract>.

5 European Commission, *The European Health Union: Acting Together for People's Health*, COM(2024) 206 final (22 May 2024), <https://commission.europa.eu/document/download/98c6e4dc-0fc3-4ec6-8ec2-bfcdcb2f018a_en?filename=policy_com-2024-206_en.pdf>, last access 22 December 2025.

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tion be ensured in the definition and implementation of all Union policies and activities, health does not constitute an overarching objective to which all other Union aims are subordinated. The terminology of a 'Health Union' therefore raises fundamental questions concerning the constitutional status of health within the EU legal order and the permissible depth of integration in this field.

In practice, the European Health Union seeks to enhance coordination among the Member States in addressing cross-border health threats and to strengthen the mandates of existing Union agencies. The revised secondary law framework significantly expands the tasks of both the ECDC and the EMA through the adoption of new regulations and reform of existing ones. The ECDC is now empowered[6] to, among other things, deploy an EU Health Task Force – which will provide technical assistance to Member States but may not override decisions made by national public health authorities – and develop a network of reference laboratories, much like the World Health Organization, albeit focusing on facilities within EU Member States. Moreover, in light of a new Regulation to strengthen its role in public health emergencies, the EMA is now tasked[7] with monitoring and mitigating the shortages of critical medicines and medical devices, particularly through a Medicines Shortages and Safety Steering Group composed of representatives of both EMA and EU Member States.[8] This will allow for joint decision-making on how to address shortages of medical products, even beyond pandemics.

Beyond the reinforcement of these agencies, the Commission has established a new body, the Health Emergency Preparedness and Response Authority (HERA).[9] HERA was founded in September 2021 to improve coordination before and during health crises, to bring together Member States, industry and other stakeholders, and to support the development, procurement, stockpiling and equitable distribution of medical countermeasures, while also contributing to the global health emergency response architecture. Given the urgency of the situation due to the COVID-19 pandemic,

6 Regulation 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control, PE/82/2021/REV/1, L314/1.

7 Regulation 123/2022/EU of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, L20/1.

8 Emer Cooke, 'Preparing Europe for Future Health Threats and Crises – the European Medicines Agency; Ensuring Safe and Effective Medicines and Medical Devices', Eurosurveillance 27 (2022), doi: 10.2807/1560-7917, 2200798.

9 Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02.

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HERA was first created as a Directorate by a European Commission Decision,[10] a fact that raised major questions about its degree of autonomy, competences, and relationship with EU Member States.[11] Subsequently, HERA was given a concrete mandate for monitoring and reviewing the implementation of the European Regulation on Cross-Border Threats to Health,[12] one of the key legal instruments underpinning the European Health Union.

It is against this evolving legal and institutional landscape that the present special issue situates its inquiry into the European Health Union. We, the guest editors, conceived this theme in response to the legal questions raised in the wake of the COVID-19 pandemic about the role of the EU – and, in particular, its institutions – in coordinating health emergency responses across its Member States.[13] The seven contributions in this issue address these questions from both legal and multidisciplinary perspectives. We believe that they offer new insights into the remaining challenges to make the European Health Union a legally sound and effective initiative that protects individuals and communities both within and beyond the EU against future pandemics. Meanwhile, since the inception of this issue, new legal fields within the European Health Union that warrant further analysis have emerged. First, a package known as the European Pharmaceutical Legislation has been proposed. Second, the so-called European Health Data Space was created, through which access to health data by both public and private actors is regulated in detail to strike a balance between allowing the use of such data for innovation, on the one hand, and safeguarding the privacy rights of individuals whose data are collected, on the other hand. The latter development, in particular, is examined more closely in one of the timely pieces of this special issue.

10 Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, 2021/C 393 I/02.

11 Olivier Wouters, Rebecca Forman, Michael Anderson, Elias Mossialos, Martin McKee, 'The Launch of the EU Health Emergency Response Authority (HERA): Improving Global Pandemic Preparedness?', Health Policy 133 (2023), doi:10.1016/j.healthpol.2023.104844.

12 Regulation 2371/2022/EU of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU, L 314/27.

13 For an in-depth legal examination of the EU's actions during the COVID-19 pandemic, see Tamara Hervey, Sabrina Roettger-Wirtz and Alexandra Fyfe, 'The European Union: Legal Response to Covid-19' in: Jeff King, Octavio Ferraz, Pedro Villarreal, Andrew Jones, Alan Bogg, Nicola Countouris, Eva Pils, Nico Steytler, Elena de Nictolis, Bryan Thomas, Michael Veale, Silvia Suteu, Colleen Flood, Cathryn Costello and Natalie Byrom (eds.) *The Oxford Compendium of National Legal Responses to Covid-19* (Oxford University Press online, 2024), available at: <https://oxcon.ouplaw.com/display/10.1093/law-occ19/law-occ19-e35>.

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The contributions assembled here examine the concept of a European Health Union from complementary perspectives, ranging from competence allocation and constitutional principles to emergency governance, global supply chains, and data governance. The resulting studies offer a critical assessment of whether and to what extent the European Health Union can deliver a coherent and sustainable framework for health governance within the limits of the existing Treaties. In his contribution, *Markus Frischhut* adopts a historical perspective by revisiting the plans for a European Health Community developed in the 1950s. He explores the lessons that can be drawn from these early integration projects for the present debate and examines whether human health should be elevated to the status of a Union value or even recognised as a fundamental right. This inquiry is situated against the background of the Court of Justice's judgment of December 2020, in which animal welfare was explicitly recognised as a value of the Union. *Christian Calliess*, in turn, addresses the scope and limits of the European Union's capacity to act in the field of pandemic prevention and response. Drawing on legal and economic evaluative criteria, he assesses the existing distribution of competences under the Treaties and exposes the structural deficiencies that constrain effective Union action. On this basis, he argues for a targeted amendment of Article 168(4) TFEU, designed to enhance the EU's regulatory capacity and to enable a more adequate and timely response to future cross-border health crises. *Giacomo Di Federico* investigates the most salient elements of the still ongoing reform of the EU's health emergency governance. His analysis assesses the efficiency and internal coherence of the emerging system of preparedness and crisis management in light of both the objectives of the European Health Union and the orientations set out in the new EU Global Health Strategy. The contribution offers a critical appraisal of whether the current reform trajectory is capable of delivering a genuinely integrated and effective emergency management framework. *Vincent Delhomme* turns to the regulation of non-communicable diseases and critically examines the reliance on Article 114 TFEU as a legal basis for Union measures concerning tobacco, food, and alcoholic beverages. He identifies a series of constitutional tensions, in particular with regard to the principles of conferral and subsidiarity, as well as the systematic use of minimum harmonisation. The contribution submits that these tensions reveal structural shortcomings in the current constitutional framework and proposes a Treaty amendment that could be integrated into the broader reforms required for the establishment of a coherent and balanced European Health Union. In their contribution, *Michael Bayerlein, Prachi Agarwal* and *Bettina Rudloff* analyse the legal and economic mechanisms for securing medical supply chains, focusing on the legal framework of the World Trade Organization

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(WTO). Identifying critical import dependencies within EU Member States, they highlight the potential repercussions of export restrictions on medical goods, stressing the importance of securing supply chains. They conclude with an analysis of how the EU may pursue a legally sound and economically sustainable strategy to strengthen the resilience of medical supply chains. *Julian Sellner, Giovani Francois Nantcha and Fruzsina Molnár-Gábor* address the creation of the European Health Data Space. They analyse its envisaged functioning and institutional structure, its relationship with the General Data Protection Regulation, and its legislative evolution. The contribution further assesses the initiative from the perspective of Union legislative competence in the fields of the internal market, data protection and public health, and critically examines its compatibility with the principle of proportionality. The special issue concludes with a practitioner's perspective by *Bartolomej Kurcz*, who draws on his experience as Deputy Head of Unit (Policy and Coordination), HERA, at the European Commission. His article examines the institutional, legal, and practical constraints on Union action in the field of health emergency preparedness and response. By analysing the limits of coordination, competence and implementation at EU level, the contribution provides an insider's account of the challenges faced in operationalising the European Health Union.

Taken together, the emergence of the European Health Union illustrates a broader transformation of Union governance under conditions of crisis. It exemplifies a mode of integration driven less by formal competence expansion rather than by institutional adaptation, reinterpretation of existing legal bases, and the strategic use of secondary legislation. Evidently, it is more of a political approach that works around the fact that the Member States are not yet willing to create a European Health Union with a broader legal basis in the Treaties. This development raises fundamental questions concerning the constitutional balance between the Union and its Member States, the limits of functional integration in the absence of Treaty change, and the role of agencies and executive coordination in areas traditionally characterised by national autonomy.

The European Health Union thus constitutes neither a fully-fledged policy field nor a clearly delineated legal regime. Rather, it represents a dynamic and contested process situated at the intersection of public health, internal market regulation, emergency governance, and fundamental constitutional principles. Whether this process will result in a stable and coherent framework for Union action, or remain a crisis-induced assemblage of sectoral measures, depends on its legal consolidation, democratic accountability, and judicial scrutiny.

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The present special issue seeks to contribute to this debate by subjecting the European Health Union to a systematic legal analysis. By examining its conceptual foundations, institutional architecture, and normative implications, the contributions aim to clarify the legal nature and constitutional significance of this evolving project. In doing so, the issue does not proceed from the assumption that 'more Europe' in health is necessarily desirable or legally unproblematic. Instead, it explores the conditions under which Union action in the field of health may be both effective and constitutionally legitimate within the existing framework of European integration.

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The Missing Keystone of the 'European Health Union'. Historic Development, *status quo* and Ideas *de lege ferenda*

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'There is another concern that we must not neglect, and that is concern for people. If there is one domain where great efforts must be made, it is the domain of health. If there is one domain that seems to lend itself to agreement, it is the fight against disease. Epidemics and social problems know no borders.' (Robert Schuman)[1]

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1 Maryse Cassan, *L'Europe Communautaire de la Santé: Préface de Louis Dubois* (Economica 1989), 229 (author's translation).

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Abstract

The concept of a 'European Health Union' (EHU) is in the spotlight, but has not been defined so far. It is no International Organization, as the failed 'European Health Community' in the 1950s would have been. The EHU can be seen as an amalgam of already existing projects (Beating Cancer, etc.) and a reaction to the crisis of the pandemic. Quite some progress has been made in strengthening existing agencies (European Centre for Disease Prevention and Control [ECDC], European Medicines Agency [EMA]), creating a new authority Health Emergency Preparedness and Response Authority (HERA), updating cross-border health threats to a European Union (EU) regulation, and anchoring the 'One health'-approach (humans, animals, environment). However, a step that was announced by von der Leyen is still missing, an amendment of EU primary law; the keystone so to say. Another idea *de lege ferenda* is based on the case-law of the European Court of Justice (ECJ) on 'animal welfare' and suggests to see human health as an EU value.

Keywords

European Health Union – European Health Community – One Health – EU Values

I. Setting the Agenda

Ideally, the vertical distribution of competences between the supra-national European Union on the one hand and its Member States on the other ought to be based on considerations such as the effectiveness of performance of tasks at each level. According to the 'principle of conferral', the EU can only act 'within the limits of the competences conferred upon it by the Member States in the Treaties', and competences not conferred upon the EU remain with the Member States (Article 5(2) Treaty on European Union [TEU]).[2] The principle of subsidiarity embodies the idea of determining the most appropriate level of authority for specific tasks. According to the latter principle, the question is whether tasks cannot be sufficiently achieved by the Member States (at central, regional, or local level), and whether they can be better achieved at the Union level. However, this principle applies only to

2 Treaty on European Union, Consolidated version OJ 2016 C 202/13.

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existing (non-exclusive) competences (Article 5(3) TEU). In other words, it is not a legally binding principle to decide on the allocation of competences, as according to the principle of conferral, Member States must take this decision. Nonetheless, it can be a source of inspiration, as ideally the competences should be legally[3] located where they generate added value, as also expressed by the initial quotation of *Robert Schuman*.

However, the field of health is an illustrative example of Member States' reluctance to transfer more competences to the EU level. In a nutshell, Member States have been willing to transfer additional competences to EU level if they recognise that they individually are not able to provide the necessary solutions for certain challenges. In this context, solutions can refer to the adoption of legal documents (hence, the question of legislation and the vertical distribution of competences), or simply to cooperation (working together) or coordination (align one's actions with each other). The latter field of collaboration (cooperation and coordination) on a voluntary level can be related to the 'Open Method of Coordination' (OMC)[4]. Although the OMC can make an important contribution in the field of public health, it is neither the main focus nor in the sole spotlight of this contribution.

Instead, this contribution seeks to address the question of how the EU has reacted to the SARS-COV-2 pandemic, considering the development of EU 'public health'[5] competences so far, the *status quo* (i. e., Article 168 Treaty on the

3 I. e. according to the principle of conferral.

4 In the field of quality standards and setting up 'European Reference Networks', the OMC has been described as 'acts of formalised informality' (author's translation); Stephan Rixen, 'Die Patientenrechte-Richtlinie als "Dienstleistungsrichtlinie des Gesundheitswesens"?', GPR 9 (2012), 45-50 (45, 48). Vassilis Hatzopoulos, *Regulating Services in the European Union* (Oxford University Press 2012), 311 has described the OMC as follows: 'The OMC can be analysed as a multi-level process of governance, comprising at least four stages. First, the European Council agrees on the general objectives to be achieved and offers general guidelines. Then, the Council of Ministers selects quantitative and/or qualitative indicators, for the evaluation of national practices. These indicators are following a proposal by the Commission or by other independent bodies or agencies. The third stage is the adoption of measures at the national or regional level (taking local particularities into consideration), aiming at the achievement of the set objectives, and in pursuit of the indicators chosen. These are usually referred to as the "National Action Plan" or NAPs. The process is complete by mutual evaluation and peer review between member states (occasionally alongside a system of naming and shaming/faming), at the Council level.'

5 'Public health' has more of a collective dimension, whereas 'access to healthcare' has an individual connotation. 'Public health' can be understood as 'the management of health risks and the prevention of disease', whereas 'healthcare' refers to the 'provision of health services and medical care'; Vincent Delhomme and Tamara K. Hervey, 'The European Union's Response to the Covid-19 Crisis and (the Legitimacy of) the Union's Legal Order', YBEL 41 (2022), 48-82. See also Anniek de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press 2019), 62.

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Functioning of the European Union [TFEU][6]), and the question of possible future changes. In response to the pandemic, the EU has presented the concept of a 'European Health Union'. In this context, two issues must be addressed. First, what is the substance of this concept? Is it further determined or even clearly defined, and second, if this concept is located at the level of EU secondary or even primary law. The latter level is particularly interesting, given that in the past, the EU has had to restrict itself to focus on EU secondary law adopted by the EU institutions, due to the political infeasibility of the necessary unanimity among Member States to change EU primary law.

This contribution will examine the past examples (Section II.), briefly depict the *status quo* of the EU's competences in the field of public health (Section III.), and then showcase the European Health Union, covering the definition of this concept and the parts realised so far (Section IV.). This also includes the question of the significance of calling this construct a 'Union'. After depicting what has been achieved thus far (*de lege lata*), Section V. presents some ideas of what could be realised in the future (*de lege ferenda*). This contribution will focus on EU health law and, for reasons of space, mainly exclude more general questions on public health policy and governance. Hence, let us first turn to the past, before turning to the *status quo* and a possible future scenario.

II. Development and Early Ideas for EU Health Competences

1. The 1950s and the European Health Community Plan

At the beginning of European integration, a mention of 'health' could only be found in the Treaty establishing the European Coal and Steel Community (ECSC)[7] as a 'reason of justification' (e. g. Article 69(1)) within the internal market (i. e. the free movement of workers in the coal and steel industry). Hence, there were no substantive rules, but they only allowed for possible deviations from the free movement rules.

Among other initiatives[8], in September 1952, French Health Minister *Paul François Ribeyre* proposed a European Health Community (EHC), also

6 Treaty on the Functioning of the European Union, Consolidated version OJ 2016 C 202/47.

7 *Vertrag über die Gründung der Europäischen Gemeinschaft für Kohle und Stahl* of 18 April 1951, BGBl. 1952 II, 447. The ECSC Treaty had expired in 2002.

8 For further details, see Craig Parsons, *A Certain Idea of Europe* (Cornell University Press 2003); Frischhut, 'Eine Europäische Gesundheitsunion' (n. *).

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referred to as the '*pool blanc*' (the 'white pool'[9]). Although this project has failed, it is worth examining what could have been possible. Following the 'Community-method',[10] this draft would have proposed a supra-national legal entity; hence, far more than simply a reason of justification. According to *Ribeyre*, the EHC should have been able to act and take decisions based on a delegation of part of the sovereignty of the participating states.[11] The objective of the EHC would have been to coordinate and improve health and social protection, as well as a *de facto* solidarity[12] to provide a foundation for that Community. Also noteworthy is the emphasis that was placed on a 'moral obligation to put people first'.[13]

The EHC would have created a 'common market' (for medicines and pharmaceutical products, dressing materials, medical-surgical equipment, climatic and thermal springs) and included both binding legal norms (e. g., anti-discrimination provisions) as well as fields of (mere) cooperation. Likewise, the EHC would have provided for the creation of an 'International Institute of Hygiene' and the possibility of mobile teams (composed of technicians and practitioners from the fields of medicine and epidemiology, respectively). These teams would have been able to conduct on-site surveys and strengthen local protection mechanisms in the event of a new epidemic outbreak. While epidemics and pandemics are not the only public health challenges, they have become the primary focus in light of the SARS-COV-2 pandemic.[14] A counterfactual discussion of 'what would have happened if' is inherently speculative and laden with uncertainty. However, the reality remains that this Community would have possessed more powers than the EU did at the time of the pandemic.

Title V (Health Measures) Chapter V (Combating Epidemics) of the proposal describes the following:[15] First, (1) the adaptation of common provisions relating to vaccination or notification, and (2) the early application of protective measures (this depending on the coordination of early detection measures). Furthermore, (3) the exchange of epidemiological information and

9 As opposed to the coal and steel 'black pool'.

10 See Walter Hallstein, *Die Europäische Gemeinschaft* (5th edn, Econ 1979).

11 Cassan (n. 1), 232 ff.

12 This idea is reminiscent of the speech of *Robert Schuman* (French Foreign Minister at the time) that led to the ECSC. On the question of solidarity, see also Section V. (at n. 215).

13 Cassan (n. 1), 222.

14 'An "epidemic" refers to a contagious, infectious, or viral illness that spreads to many people in a specific region, whereas a "pandemic" surpasses this region'; Wendy E. Parmet, Markus Frischhut, Amandine Garde and Brigit Toebes, 'Introduction to Public Health Law' in: Tamara K. Hervey and David Orentlicher (eds), *The Oxford Handbook of Comparative Health Law* (Oxford University Press 2021), 68-76 (69).

15 For these documents, see Cassan (n. 1).

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applied research centres within the framework of the Community, (4) the organisation of the production of antigens and their distribution through the creation of a common market, as well as the standardisation of the composition of vaccines, their labelling, their dosage and the formation of safety stocks, or (5) in this area, the abolition of border controls. The creation of an 'International Health Police' has been considered.

Moreover, quite insightful from a contemporary pandemic perspective, Title VIII (pooling of resources) is of particular relevance. This would have provided for the gradual pooling of resources, the standardisation of production, the creation of stockpiles in the Member States in the event of an epidemic or other disaster, as well as the standardisation of product standards and the creation of a European pharmacopoeia (*pharmacopée européenne*).

In conclusion, this supra-national 'white pool' would have included many provisions that we find today in EU law (common market, non-discrimination, recognition of diplomas), but at the same time, it would have provided suggestions that could be pioneering in the light of the SARS-COV-2 pandemic. The latter field includes mobile teams for on-site surveys, international health police, and support for a country affected by a pandemic by means of resources through the EHC, as well as the gradual pooling of resources, etc.

As these plans could not be realised,[16] both in the 1951 ECSC and in the 1957 European Economic Community[17] (e. g. Article 36), health was only considered as a reason of justification within the internal market. The mention of 'health protection at work' only occurred in the context of the Commission promoting close cooperation between Member States (Article 118).

2. Development of Health Competences Since the 1950s

While the Treaties did not provide for hard competences, some progress[18] was evident in the fact that from 1984 onwards, the Health Ministers at least

16 With the departure of the father (*Ribeyre*) and the godfather (*Schuman*), the '*pool blanc*' became an orphan; see Alban Davesne and Sébastien Guigner, 'La Communauté européenne de la santé (1952-1954): Une redécouverte intergouvernementaliste du projet fonctionnaliste de "pool blanc"', Politique Européenne 41 (2013), 40-63 (55).

17 Vertrag zur Gründung der Europäischen Wirtschaftsgemeinschaft of 25 March 1957, BGBl. 1957 II, No 23, 753.

18 See also, for additional details, Anja Katarina Weilert, Ressortforschung: Forschung zur Erfüllung öffentlicher Aufgaben unter besonderer Berücksichtigung des Bereichs staatlicher und unionsrechtlicher Gesundheitsverantwortung (Mohr Siebeck 2022), 401-404.

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had informal meetings.[19] This suggests that health issues were becoming increasingly important. Like the above-mentioned OMC, the influence of EU integration occurs not only through hard law but also through softer forms of coordination. The European Parliament (EP)'s 1984 '*Spinelli*-draft'[20] would have foreseen the Union's power to 'take action in the field of social and health policy' with regard to 'the coordination of mutual aid in the event of epidemics or disasters' (Article 56 'Social and health policy'). This idea did not become primary law and for reasons of space will not be explored further.

Against the background of Bovine Spongiform Encephalopathy (BSE) and Human Immunodeficiency Virus (HIV)/ Acquired Immune Deficiency Syndrome (AIDS), the 1992 Maastricht Treaty[21] then enshrined 'public health' as a separate sectoral policy (in Article 129), hence more than just a reason of justification. Even before this Treaty, we can find examples of hard law based on other competences[22] as well as various soft law documents on cancer prevention[23], AIDS[24], or drug abuse[25].

The European Parliament's 1994 '*Herman*-draft'[26] did not strive to advance the European integration process in terms of 'public health' as a sectoral policy, but made two remarkable suggestions in terms of human rights and values. It would have enshrined a human right 'to benefit from measures for the good of their health'[27] and would have based EU membership on the values of 'freedom, equality, solidarity, human dignity, democracy, respect for human rights and the rule of law'[28]. Similar to the *Spinelli*-draft, these ideas were not implemented.

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19 Brigitta Lurger, 'Art. 168 AEUV' in: Rudolf Streinz (ed.), *EUV/AEUV* (3rd edn, C.H. Beck 2018), 1671-1707 (1675), para. 7.

20 Draft Treaty Establishing the European Union of 14 February 1984, OJEC C77/33, 298-327.

21 Treaty on European Union, signed in Maastricht on 7 February 1992, OJEC C191/01, 1-110.

22 Lurger (n. 19), 1675, para. 7.

23 Commission, Proposal for a Council Resolution on a programme of action of the European Communities on cancer prevention, OJ 1985 C 336/11. For the EHU and cancer, see n. 52.

24 Resolution of the Representatives of the Governments of the Member States, meeting within the Council, of 29 May 1986 on AIDS, OJ 1986 OJ C 184/21.

25 Resolution of the Council and the Ministers for Health of the Member States meeting within the Council of 16 May 1989 concerning a European network of health data on drug abuse, OJ 1989 C 185/1.

26 Resolution on the Constitution of the European Union, OJ 1994 C 61/155.

27 Art. 13 of Title VIII: Human rights guaranteed by the Union, OJ 1994 C 61/155 (n. 26).

28 Recital 2 of the preamble, OJ 1994 C 61/155 (n. 26).

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The 1997 Amsterdam Treaty[29] brought a slight strengthening of the quality and safety standards concerning organs, blood, etc.,[30] but at the same time emphasised the competence of the Member States for the organisation of healthcare and medical care. The 2001 Nice Treaty[31] brought no changes.[32] Finally, the 2007 Lisbon Treaty[33] essentially brought some clarifications (different types of competences, etc.) and additional competences in medicines and medical devices. As in the case of the two EP drafts (*Spinelli* and *Herman*), sometimes more interesting ideas can be found in those documents that did not enter into force. The 2004 Constitutional Treaty,[34] as is well known, did not enter into force. This would have provided for a strengthening in the 'monitoring, early warning of and combating serious cross-border threats to health', hence, a shared competence allowing for harmonisation (Article III-278 para. 4 lit. d). This provision would have provided, at least in theory, an opportunity to address the challenges raised by the pandemic.

In conclusion, although we can observe some progress, various plans would have been more ambitious (*Spinelli*, *Herman*). Let us now consider the legal *status quo* that was acceptable for the Member States as 'Masters of the Treaties'.

III. *Status quo* of the EU's Public Health Competences

As aptly mentioned in the literature, 'public health' is probably the EU competence that is most difficult to distinguish from shared competence, as the reality of EU health law and policy go beyond the wording of EU Treaties.[35] According to Article 168(1) TFEU, a 'high level' of human

29 Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, signed at Amsterdam on 2 October 1997, OJ 1997 C 340/1.

30 See now Regulation 2024/1938/EU of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC, OJ L 2024/1938, as corrected by OJ L 2024/90463.

31 Treaty of Nice amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, signed at Nice on 26 February 2001, OJ 2001 C 80/1.

32 See also Lurger (n. 19), 1675.

33 Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon on 13 December 2007, OJ 2007 C 306/1.

34 Treaty establishing a Constitution for Europe, signed at Rome on 29 October 2004, OJ 2004 C 310/1.

35 See Vincent Delhomme, 'Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health', European Journal of Risk Regulation 11 (2020), 747-756 (750).

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health protection[36] is required to be ensured in the definition and implementation of all Union policies and activities, as is also the case with other fields.[37]

In general, the EU only has a supportive[38] competence for the protection and improvement of human health, striving to prevent physical and mental illness and diseases, and obviating sources of danger to physical and mental health (Article 168(1) subparagraphs (2) and (3) TFEU). In the same way, the EU can only 'encourage' cooperation between the Member States (Article 168(2) TFEU) and not make it obligatory. Cooperation with third countries and the competent international organisations, both by the Union and by Member States, is also only encouraged ('to foster'), according to Article 168(3) TFEU. According to Article 168(5) TFEU, 'incentive [!] measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health' can be taken. While these measures can be taken according to the ordinary 'legislative procedure', they can only include 'incentive measures', hence, 'excluding any harmonisation of the laws and regulations of the Member States'. In the same vein, according to Article 168(6) TFEU, the Council can adopt (non-binding) recommendations[39] and Article 168(7) TFEU emphasises the 'responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care'.

Article 168(4) TFEU, introduced by the Treaty of Amsterdam, constitutes a particularity in this context of health-related competences. In this context,

36 See also Art. 35 CFR. Consolidated version of the Charter of Fundamental Rights of the European Union, OJ 2016 C 202/389.

37 Art. 67 (3) TFEU (area of freedom, security and justice), Art. 147 TFEU and Art. 9 TEU (employment), Art. 169 (1) TFEU (consumer protection), Art. 191 (2) TFEU and Art. 3 (3) TEU (environment), respectively Art. 114 (3) TFEU (harmonisation of national law). Likewise, Art. 151 TFEU (social policy, respectively employment) refers to 'lasting high employment' and Art. 165 (1) TFEU (education) to 'quality education' (in German: '*qualitativ hoch stehenden Bildung*'); see also Art. 9 TFEU.

38 Art. 6 TFEU, competence to carry out actions to support, coordinate or supplement the actions of the Member States.

39 While they 'have no binding force' according to Art. 288 (5) TFEU, 'national courts are bound to take recommendations into consideration in order to decide disputes submitted to them, in particular where they cast light on the interpretation of national measures adopted in order to implement them or where they are designed to supplement binding Community provisions'; ECJ, *Grimaldi v. Fonds des maladies professionnelles*, judgment of 13 December 1989, case no. C-322/88, ECLI:EU:C:1989:646, para. 18.

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the Union has a shared[40] competence for common safety[41] concerns in public health concerning organs and substances of human origin, as well as for blood and blood derivatives (lit. a), in the veterinary and phytosanitary fields (lit. b), as well as in medicinal products and devices for medical use (lit. c). Just for the sake of completeness, it should be mentioned that the EU does not only exert influence in the health sector through this apparent competence of Article 168 TFEU.

Besides these competences that can be attributed to the field of positive integration,[42] the European Court of Justice allowed individual patients to remove national barriers in the field of cross-border healthcare[43] by relying on the passive freedom of services[44] (negative integration).[45] These individual rights developed by the ECJ in a bottom-up manner have subsequently been codified in an EU directive that has been based not only (as often previously in similar cases) on Article 114 TFEU[46] but also on Article 168 TFEU.[47] Besides Article 114 TFEU and the more health-related fields, the EU has also exerted substantial influence in the field of health via the European Semester.[48]

40 Art. 4 (2) (k) TFEU.

41 On quality and safety standards, see Markus Frischhut, 'Standards on Quality and Safety in Cross-Border Healthcare' in: André den Exter (ed.), *Cross-Border Health Care and European Union Law* (Erasmus University Press 2017). See also Regulation 2024/1938/EU and Directives 2002/98/EC and 2004/23/EC, OJ L 2024/1938, as corrected by OJ L 2024/90463.

42 According to Carl Baudenbacher and Frank Bremer, 'European State Aid and Merger Control in the Financial Crisis: From Negative to Positive Integration', Journal of European Competition Law & Practice 1 (2010), 267-285 (267), the distinction between positive and negative integration 'was first made by the Dutch economist Jan Tinbergen, who called measures aiming at abolishing trade impediments between national economies with the goal of securing the proper operation of an integrated economic area "negative integration"'. 'Positive integration' 'was defined by Tinbergen as the "creation of new institutions and their instruments or the modification of existing instruments"'.

43 Besides these rights related to the (passive) freedom of services, social security rights are related to the free movement of workers; see Regulation 883/2004/EC of 29 April 2004 on the coordination of social security systems, OJ 2004 L 166/1, as amended by OJ 2019 L 186/21. See also Anja Katarina Weilert, 'Gesundheitsdienstleistungen im Binnenmarkt: Grundstrukturen und neue Entwicklungen', EuR 57 (2022), 731-754.

44 Art. 56 TFEU.

45 See Markus Frischhut and Hans Stein, *Patientenmobilität: Aktuelle Richtlinie und EuGH-Rechtsprechung* (Facultas.wuv 2011).

46 See case ECJ, *Germany v. Parliament and Council*, judgment of 12 December 2006, case no. C-380/03, ECLI:EU:C:2006:772, paras 39, 95.

47 Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare OJ 2011 L 88/45, as amended by OJ 2025 L 2025/327 (Directive patient mobility).

48 See Natasha Azzopardi-Muscat, Timo Clemens, Deborah Stoner and Helmut Brand, 'EU Country Specific Recommendations for Health Systems in the European Semester Process: Trends, Discourse and Predictors', Health Policy 119 (2015), 375-383.

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Based on the historic development and the *status quo* of EU health law, we now turn to the concept of the European Health Union and examine how it fits to the aforementioned developments.

IV. The Concept of a 'European Health Union'

1. A (Missing) Definition and Building Blocks

The European Commission has introduced the concept of the European Health Union, making it essential to first examine how the Commission defines and interprets this term. The European Commission addresses seven 'key initiatives' of the EHU.[49] The first two, crisis preparedness and the European Health Emergency Preparedness and Response Authority, can be seen as reactions to the pandemic. Four of them, the pharmaceutical strategy,[50] the European Health Data Space (EHDS),[51] Europe's Beating Cancer plan,[52] and the comprehensive approach to mental health,[53] are pre-existing issues that are placed under this 'umbrella term' of an EHU. In addition to this internal dimension, in the external sphere, this concept of the EHU is reinforced by the 'Global Health Strategy',[54] which was presented in November 2022 (i. e., two years after the presentation of the EHU concept; see below). Since its first usage by the European Commission, the understanding of the term has changed, and further elements have been added to it. Hence, the EHU can be seen as a shifting concept.[55]

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49 European Commission, 'European Health Union: Protecting the Health of Europeans and Collectively Responding to Cross-Border Health Crises', <https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en>, last access 29 October 2025.

50 Commission, 'Pharmaceutical Strategy for Europe' COM/2020/761 final. See also, in terms as a follow-up to this, COM/2023/192 and COM/2023/193 final. See also The EAHL Interest Group on Supranational Biolaw, 'Joint Statement "Health as a Fundamental Value.": Towards an Inclusive and Equitable Pharmaceutical Strategy for the European Union' (2022), <https://eahl.eu/eahl-interest-group-supranational-biolaw>, last access 29 October 2025.

51 Regulation 2025/327/EU of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU (Directive patient mobility) and Regulation 2024/2847/EU (Cyber Resilience Act), OJ 2025 L 2025/327 (Regulation EHDS).

52 Commission, 'Europe's Beating Cancer Plan', COM/2021/44 final.

53 Commission, 'On a Comprehensive Approach to Mental Health', COM/2023/298 final.

54 Commission, 'EU Global Health Strategy. Better Health for All in a Changing World', COM/2022/675 final.

55 See also the topics addressed in Commission, 'The European Health Union: Acting Together for People's Health', COM/2024/206 final.

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The question arises as to the meaning of the term 'European Health Union', keeping in mind the ECJ's interpretation rules, as summarised in established case law.[56] A literal interpretation ('everyday language') of the EHU proves to be difficult, as there is no proper definition. At least these 'building blocks'[57] of the already existing initiatives and those adopted in the reaction to the crisis (see below) provide some clarification. Although the ECJ does not give strong weight to a historical interpretation,[58] the evolution of this concept should not be ignored. In our context, this approach refers to the Commission President's speech[59] (September 2020) and the Commission's key document (November 2020), presented shortly after the beginning of the pandemic (around January 2020).[60] This evolutionary background reveals the intention of the Commission to 'draw the lessons from the health crisis'.[61] Likewise, a teleological ('purposes of the rules') interpretation (i. e. the *effet utile*)[62], considering the purpose (*telos*) of the law, goes in a similar direction. This reveals the Commission's objective to 'strengthen [the] crisis preparedness and management of cross-border

56 According to 'settled case-law, the meaning and scope of terms for which EU law provides no definition must be determined by considering their usual meaning in everyday language, while also taking into account the context in which they occur and the purposes of the rules of which they are part'; ECJ, *Partena ASBL v. Les Tartes de Chaumont-Gistoux SA*, judgment of 27 September 2012, case no. C-137/11 ECLI:EU:C:2012:593, para. 56.

57 Commission, 'Building a European Health Union: Reinforcing the EU's Resilience for Cross-Border Health Threats' COM/2020/724 final 3.

58 ECJ, *CILFIT v. Ministero della Sanità*, judgment of 6 October 1982, case no. C-283/81, ECLI:EU:C:1982:335, para. 20.

59 Ursula von der Leyen, 'State of the Union Address by President von der Leyen at the European Parliament Plenary: SPEECH/20/1655' (16 September 2020), <https://ec.europa.eu/commission/presscorner/detail/ov/SPEECH_20_1655>, last access 29 October 2025.

60 Even before the pandemic, the term 'European healthcare union' could be found in the literature; Hans Vollaard and Dorte S. Martinsen, 'The Rise of a European Healthcare Union', Comparative European Politics 15 (2017), 337-351. In response to the pandemic, in May 2020, there was also a call by the European Socialists in the European Parliament to increase EU health competencies, as follows: on the one hand, to strengthen resilience in relation to the pandemic, and on the other hand, to address certain future issues in the health sector. Progressive Alliance of Socialists and Democrats, 'A European Health Union – Increasing EU Competence in Health – Coping with Covid-19 and Looking to the Future', 12 May 2020, <https://www.socialistsanddemocrats.eu/publications/european-health-union-increasing-eu-competence-health-coping-covid-19-and-looking>, last access 29 October 2025.

61 von der Leyen (n. 59), 3.

62 E. g. ECJ, *Andy Wightman and Others v. Secretary of State for Exitingthe European Union*, judgment of 10 December 2018, case no. C-621/18, ECLI:EU:C:2018:999, para. 40; *Poland v. Parliament and Council*, judgment of 16 February 2022, case no. C-157/21, ECLI:EU:C:2022:98, para. 92, 'useful effect' (EN), '*effet utile*' (FR).

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health threats'.[63] From a more holistic or systematic perspective ('context in which they occur'), the Commission's November 2020 document highlights certain underlying ideas. The EHU strives for a less unilateral approach (and a more active role for the EU), focusing on vulnerable population, being based on solidarity, as well as the obligation to ensure a 'high level'[64] of human health protection.[65]

However, a systematic interpretation would eventually have to take into account the whole *acquis* (*communautaire*)[66] of EU law in this health-related context.[67] Since the entry into force of the Lisbon Treaty, EU values (both general ones[68] as well as health-related ones[69]) have to be envisaged together with human rights, especially Article 35 Charter of Fundamental Rights of the European Union (CFR).[70] This *acquis* also includes the principles developed by the ECJ (e. g., patient mobility) in the field of negative integration, and even the indirect EU impact via the European Semester.[71] This also includes all documents of positive integration, whether adopted based on economic competences and/or via Article 168 TFEU. In its last report on the Directive on patients' rights in cross-border healthcare[72] (based on both Article 114 TFEU and Article 168 TFEU), the Commission mentioned that '[m]aximising the potential of the Directive and strengthening cooperation between Member States in cross-border healthcare will be a further [!] step in

63 von der Leyen (n. 59), 3. See also European Commission (n. 49): 'a strong European Health Union, in which all EU countries prepare and respond together to health crises, medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer', referring to the better protection of EU citizens, the goal to 'equip the EU and its Member States to better prevent and address future pandemics', as well as to the improvement of the 'resilience of Europe's health systems'.

64 See n. 36-37.

65 Commission (n. 57), 1 f.

66 Given the changes brought about by the Lisbon Treaty (n. 33), it should nowadays read '*acquis de l'Union*' more precisely.

67 As mentioned above at the end of Section III.

68 Art. 2 TEU. See Markus Frischhut, The Ethical Spirit of EU Values: Status Quo of the Union of Values and Future Direction of Travel (Springer 2022).

69 Council Conclusions on Common values and principles in European Union Health Systems OJ 2006 C 146/1.

70 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.'

71 I. e. a system of economic monitoring and governance impacting national health systems via Country Specific Recommendations (CSRs); see Azzopardi-Muscat, Clemens, Stoner and Brand (n. 48).

72 See Directive 2011/24/EU.

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building the European Health Union'[73]. This implies that there are more steps than just the three addressed by Commission president von der Leyen in her 2020 'State of the Union' speech.

In this speech, she had outlined her plan for an EHU consisting of three steps, as follows:[74] in the (1) first step, the EHU strives to 'reinforce and empower' two existing agencies (see below). The (2) second step attempts to 'build a European BARDA – an agency for biomedical advanced research and development'. While the first two steps are to be implemented at the level of EU secondary law, the (3) third step aims at amending EU primary law (see Section V.), referring to the necessity to 'discuss the question of health competences', also in the context of the 'Conference on the Future of Europe'.[75]

Meanwhile, the Commission's plans[76] (ad 1) have been implemented by the EU institutions. In January 2022, the EU strengthened the European Medicines Agency,[77] and in November 2022 the EU has upgraded Decision 1082[78] on serious cross-border health threats to an EU regulation[79] and strengthened the European Centre for Disease Prevention and Control.[80]

In addition to strengthening existing agencies as the first step mentioned by *von der Leyen*, she (ad 2) referred to a European 'Biomedical Advanced Research and Development Authority' (BARDA)[81] as a second step in her 2020 'State of the Union'-speech. With an acronym inspired by the wife of Zeus in Greek mythology, the Commission in mid-September 2021 proposed

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73 Commission, 'Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare', COM/2022/210 final, 16.

74 von der Leyen (n. 59), 3.

75 See, for instance, Peter-Christian Müller-Graff, 'The Conference on the Future of Europe. The Future of Legal Europe – Will We Trust in It?', Journal of the Academy of European Law 22 (2021), 465-473.

76 All three corresponding proposals (Commission COM/2020/725, COM/2020/726 and COM/2020/727) were adopted on 11 November 2020, i. e., the same day as Commission, COM/2020/724 (n. 57).

77 Regulation 2022/123/EU of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ 2022 L 20/1, as amended by OJ 2024 L 2024/568 (Regulation EMA).

78 Decision No. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health […] OJ 2013 L 293/1, as repealed by OJ 2022 L 314/26.

79 Regulation 2022/2371/EU of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU OJ 2022 L 314/26, as completed by OJ 2024 L 2024/1232 (Regulation Cross-Border Health Threats).

80 Regulation 2022/2370/EU of 23 November 2022 amending Regulation 851/2004/EC establishing a European centre for disease prevention and control OJ 2022 L 314/1 (Regulation ECDC).

81 See Michael B. Kraft and Edward Marks, *U. S. Government Counterterrorism: A Guide to Who Does What* (CRC Press 2021).

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the already-mentioned 'Health Emergency Preparedness and Response Authority' (HERA).[82] The title of this Commission document ('the next step towards completing the European Health Union') includes the idea that HERA can be seen as the second[83] step towards an EHU. HERA is not an agency[84] established by an EU regulation, but an 'authority' established by the Commission within its services,[85] to be supported by a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at the Union level.[86] The creation of another authority in the form of HERA alongside already existing (and even strengthened) agencies naturally brings with it the risk of overlap. The Commission apparently wanted to address this concern by providing an overview of the responsibilities of these three entities, which can be found in the annexe to one of the Commission's documents on HERA. In this annexe, the Commission generally distinguished between an initial 'preparedness phase' (marked in green in this annexe) and a possible subsequent 'crisis phase' (marked in red in this annexe).[87]

2. The Notion of a 'Union'

Since the EHU serves as a concept for responses to the pandemic on the one hand and already existing projects on the other, the question arises about the meaning of its designation as a 'union'. As the third step, changes to EU primary law, is still missing, the question of the institutional (or formal)

82 Commission, 'Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union', COM/2021/576 final. Commission, 'Decision establishing the Health Emergency Preparedness and Response Authority', C/2021/6712 final. In preparation for HERA, see also (from mid-February 2021): Commission, 'HERA Incubator: Anticipating together the threat of COVID-19 variants', COM/2021/78 final. See also the contribution of Bartłomiej Kurcz, 'Health Emergency Response at EU Level – Are There Legal Constraints, HJIL 85 (2025), 1195-1207.

83 The third step would be the discussion of an eventual changing of the existing vertical distribution of competencies (see Section V.).

84 See, for instance, Andreas Orator, *Möglichkeiten und Grenzen der Einrichtung von Unionsagenturen* (Mohr Siebeck 2017).

85 On 'DG Hera', including the four units 'policy and coordination', 'intelligence gathering, analysis and innovation', 'medical counter-measures' and the 'emergency office', see European Commission, 'HERA Organisational Chart', 16 February 2023, <https://health.ec.europa.eu/document/download/7cd9a972-de4a-467c-9c00-ca9671c2a73c_en?filename=organisational-chart_dg-hera_en.pdf>, last access 29 October 2025.

86 Council Regulation 2022/2372/EU of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level OJ 2022 L 314/64 (Regulation Medical Countermeasures).

87 Commission, COM/2021/576 final (n. 82).

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qualification of a 'union' arises, in addition to the already addressed substance of this 'concept' (Section IV. 1.).

Within the EU, there are several 'unions', e. g. the Political Union,[88] the Customs Union,[89] the Economic and Monetary Union (EMU),[90] the Energy Union,[91] the Banking Union,[92] the Capital Markets Union (CMU),[93] the Innovation Union,[94] a European Defence Union,[95] and so on.[96] None of these examples can be qualified as an international organisation, as it would have been the case in the context of the finally not realised European Health Community (see Section II.). Three of these unions are more based on primary law (Customs Union, Political Union, and EMU); the Energy Union and the Banking Union (BU), however, are also largely based on secondary law. Finally, the 'Innovation Union' is merely one of seven flagship initiatives

88 Although the term does not appear in the EU treaties, since Maastricht, it has been used to refer to the political component of the EU and the Common Foreign and Security Policy (CFSP) created at that time.

89 Art. 3 (1) (a) TEU, Arts 28-32 TFEU.

90 Art. 3 (4) TEU, Arts 119-144 TFEU.

91 Commission, 'A Framework Strategy for a Resilient Energy Union with a Forward-Looking Climate Change Policy', COM/2015/80 final.

92 Regulation 1022/2013/EU of 22 October 2013 amending Regulation 1093/2010/EU establishing a European Supervisory Authority (European Banking Authority) as regards the conferral of specific tasks on the European Central Bank pursuant to Council Regulation 1024/2013/EU, OJ 2013 L 287/5. Council Regulation 1024/2013/EU of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions, OJ 2013 L 287/63. Regulation 806/2014/EU of 15 July 2014 establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Resolution Fund and amending Regulation 1093/2010/EU, OJ 2014 L 225/1, as amended by OJ 2025 L 2025/1.

93 See European Commission, 'Capital Markets Union: New Proposals on Clearing, Corporate Insolvency and Company Listing to Make EU Capital Markets More Attractive: IP/22/7348', 7 December 2022, <https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7348>, last access 29 October 2025.

94 Commission, 'EUROPE 2020. A strategy for smart, sustainable and inclusive growth', COM/2010/2020 final 5, 12, 32.

95 See European Commission and High Representative of the Union for Foreing Affairs and Security Policy, 'JOINT WHITE PAPER for European Defence Readiness 2030: JOIN (2025) 120 final', 19 March 2025, 22, <https://defence-industry-space.ec.europa.eu/eu-defence-industry/white-paper-future-european-defence-rearming-europe_en>, last access 29 October 2025.

96 Some argue that there are even more unions; see Vollaard and Martinsen (n. 60), 337-338. Recent European Council conclusions have addressed various unions (Energy Union; Capital Markets Union; Banking Union; Savings and Investments Union; Union of Skills): European Council, 'Conclusions: EUCO 1/25', 20 March 2025, <https://www.consilium.europa.eu/media/viyhc2m4/20250320-european-council-conclusions-en.pdf>, last access 29 October 2025.

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in the context of 'Europe 2020',[97] and the notion of the Defence Union stems from the respective mission letter to Commissioner *Kubilius.*[98]

A parallel to the EHU can be found in the context of the Energy Union, where the Commission emphasises the fact of interdependence between the Member States, respectively a spill-over effect of a crisis,[99] resilience,[100] and sustainability, respectively, with the goal of putting the citizens[101] at the centre of the project.[102]

Likewise, the Banking Union and the EHU also have in common that both were conceived in response to a crisis,[103] and their objectives are comparable in this respect.[104] The similarity between the two crises (the sovereign debt crisis and the pandemic, respectively) is that in both cases, the inadequate response in one Member State can have a negative impact on other Member States.[105] As *Moloney* aptly pointed out, the Banking Union consists of several interrelated components. The heterogeneity of the legal sources is reflected in a mixture of international and Union law, in the latter a mixture of legally binding and soft law documents.[106] Some similarities also exist with

97 According to the Commission, 'the vision of Europe's social market economy for the 21st century'.

98 Ursula von der Leyen, 'Mission Letter to Andrius Kubilius, Commissioner-designate for Defence and Space', 17 September 2024, <https://commission.europa.eu/document/download/1f8ec030-d018-41a2-9759-c694d4d56d6c_en?filename=Mission%20letter%20-%20KUBILIUS.pdf>, last access 29 October 2025.

99 Also called a 'negative spill-over effect'. See Regulation 2021/241/EU of 12 February 2021 establishing the Recovery and Resilience Facility, OJ 2001 L 57/17, as amended by OJ 2024 L 2024/795 (Regulation Recovery and Resilience Facility), Recital 6: a 'lack of resilience can also lead to negative spill-over effects of shocks between Member States or within the Union as a whole'.

100 Emphasising resilience in the context of the EHU: Frank Vandenbroucke, 'A Health Union in Support of European and National Health Solidarity', The Lancet Regional Health – Europe 46 (2024), 101051.

101 Also emphasising the role of individuals in the context of the EHU, Clemens-Martin Auer, 'The Road Towards Developing a European Health Union: Milestones and the Debate of Common European Perspectives in Gastein', Eurohealth 28 (2022), 10-12 (12): 'A European Health Union that is formed in the interest of the citizen must guarantee the enforcement of the interests of the citizens as patients.'

102 Commission (n. 91), 2.

103 According to Delhomme and Hervey (n. 5), 2, a crisis can be defined as 'an unfolding circumstance which is generally understood as constituting an urgent and profound threat to core community values and the structures and institutions that support those values'.

104 Niamh Moloney, 'European Banking Union: Assessing Its Risks and Resilience', CML Rev 51 (2014), 1609-1670 (1629).

105 Oliver Bartlett, 'COVID-19, the European Health Union and the CJEU: Lessons from the Case Law on the Banking Union', European Journal of Risk Regulation 11 (2020), 781-789 (782).

106 Moloney (n. 104), 1625-1626. The EHU also comprises a mixture of EU secondary law, but not of international law.

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regard to the question of the concrete applicability of Article 114 TFEU as a legal basis with reference to the tobacco advertising judgments[107], etc.[108]. In both cases, the ECJ played an essential role in exploring the jurisdictional and other legal boundaries before the transition to the respective Union.[109] According to *Bartlett*, it can be assumed that the ECJ would also constructively support the development of the EHU.[110]

To put it bluntly, one can conclude that the term 'Union' serves as a compensation for the inability to respond to a crisis through an amendment of EU primary law.[111] Some of these crises concern a situation of mutual dependence between the Member States and require more resilience.[112] In this context, different secondary law measures (some of which were enacted at different times) are bundled together by the concept of 'Union'. Some measures such as the pharmaceutical strategy, the European Health Data Space and the 'Global Health Strategy' are more obviously linked to (post-pandemic) crisis preparedness, while Europe's Beating Cancer plan is a topic that is only indirectly[113] linked to the pandemic. However, unlike the drafted European Health Community, the EHU does not constitute a Union in the sense of a legal entity. In a formal sense, these changes still qualify as a sectoral policy (i. e., part III TFEU). In a substantive sense, both the Banking Union and the EHU can be described in some sense as examples of an upgraded 'sectoral policy'.[114] The notion of a strengthened sectoral 'Union' within the EU therefore remains an elastic concept, reminiscent to some extent of the *Hallstein*-formula concerning 'association agreements' (trade agreements plus 1, or full EU membership minus 1).[115]

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107 See ECJ, *Germany* (n. 46). On the Treaty establishing the European Stability Mechanism (ESM-Treaty), see ECJ, *Thomas Pringle v. Government of Ireland and Others*, judgment of 27 November 2012, case no. 370/12, ECLI:EU:C:2012:756.

108 Moloney (n. 104), 1653.

109 Concerning the Banking Union, see Moloney (n. 104), 1654.

110 Bartlett (n. 105), 784.

111 A preliminary question is obviously, if a change of EU Primary law is necessary (see also Section V.).

112 See now also Regulation 2024/2747/EU of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Council Regulation 2679/98/EC (Internal Market Emergency and Resilience Act), OJ 2024 L 2024/2747.

113 A pandemic can also result in delays or interruptions in treatment for cancer patients.

114 See Frischhut, 'Eine Europäische Gesundheitsunion' (n. *).

115 Michael Schweitzer, Waldemar Hummer and Walter Obwexer, *Europarecht: Das Recht der Europäischen Union* (Manz 2007), 286-287.

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3. A Selection of the Key Elements of the EHU

For reasons of space, only selected aspects of the key elements of the Union can be considered. This will include (1) some selected principles (such as, 'one health', a high-level of protection, solidarity, etc.), (2) stress tests, (3) joint procurement, (4) the EU Health Task Force, and (5) the situation of a 'public health emergency at Union level'.

The pandemic began because of a zoonotic disease. Against this background, climate change and the Commission's 'Green Deal'[116], it is not surprising that the EHU (ad 1) embraces[117] the 'one health'-approach.[118] According to Article 3(7) Regulation Cross-border Health Threats, '"One Health" means a multi-sectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions'. Besides this holistic approach (humans, animals, environment), the EHU also embraces[119] the well-known 'Health in All Policies'-approach,[120] and also repeats[121] the requirement to ensure a 'high level of human health protection'.[122] Another element of the underlying philosophy of the EHU, striving for more resilience and better preparedness, is (at least on paper[123]) solidarity[124]. Apart from the

116 Commission, 'The European Green Deal' COM/2019/640 final.

117 DG Santé section A is now entitled 'One Health'; see European Commission, 'DG Health and Food Safety – Organisation Chart', 12 March 2023, <https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-and-food-safety_en#leadership-and-organisation>, last access 29 October 2025.

118 See Jane Johnson and Chris Degeling, 'Does One Health Require a Novel Ethical Framework?', Journal of Medical Ethics 45 (2019), 239-243; Martin McKee, 'One Health Through the Lens of the Sustainable Development Goals', Eurohealth 28 (2022), 40-42.

119 Art. 1 (3) Regulation Cross-border Health Threats.

120 'Health *in* all policies' refers to considering health in other fields (that have to be willing to 'engage with health'), whereas 'health *for* all policies' strives to emphasise the 'mutual benefits of health and other sectors working together', hence, striving to create 'win-win solutions'. See Scott L. Greer et al., 'Making Health for All Policies: Harnessing the Co-Benefits of Health', POLICY BRIEF 50 (2023), 1-30 (5).

121 Art. 3 (1) Regulation Cross-border Health Threats; Art. 1 (3) and Art. 3 Regulation Medical Countermeasures, *et passim*.

122 See n. 36-37.

123 Criticising a lack of solidarity and risk-sharing between Member States, Anniek De Ruijter and Eleanor Brooks, 'The European Health Union: Strengthening the EU's Health Powers?', Eurohealth 28 (2022), 47-49 (48).

124 'The COVID-19 pandemic has revealed shortcomings in Union mechanisms for managing health threats, which call for a more structured Union-level approach, which is also built on the European value of solidarity, to future health crises'; Commission, 'Proposal for a Regulation Amending Regulation (EC) No 851/2004 Establishing a European Centre for Disease Prevention and Control', COM/2020/726 final 1. As aptly stated by Karin Henke, 'Der Aufbau der Europäischen Gesundheitsunion – Lernen aus der Corona-Krise', MedR 39 (2021), 890-896 (896), a EHU has to go beyond just the lessons learned out of the Covid-19 pandemic (see above n. 61).

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'one health'-approach, these elements (health in all policies, high level of health protection) are not new. Solidarity is an EU value enshrined in Article 2 TEU since the entry into force of the Lisbon Treaty (1 December 2009), as well as a principle[125]. However, the pandemic has particularly highlighted the necessity for solidarity in the field of health.

After the key principles, we proceed to (ad 2) stress tests. Resilience can be achieved by preparedness. Preparedness must be tested during normal periods, before a crisis occurs. Depending on which entity oversees the relevant field, such a 'stress test' can be mandatory or recommended. In a Council recommendation[126] on the resilience of critical infrastructure, the Council simply encouraged Member States to conduct stress tests in sectors of cross-border relevance, (such as energy, digital infrastructure, etc.).[127] In contrast, the new EMA regulation foresees 'targeted stress tests' to avoid the shortage of both medicinal products and medical devices to be performed by the Commission, EMA, Member States or other relevant actors.[128] Likewise, the ECDC is tasked to develop such stress tests in close collaboration with the Member States and the Commission.[129]

Stress tests were suggested in May 2020;[130] hence, before the Commission's EHU plan from November 2020. So far, stress tests have already been carried out by the EU in the energy or banking sector, and according to these plans, they could be carried out in the health sector by the Member States according to the parameters established by the Commission. This should help Member States to detect areas that must require approval and, accordingly would allow the Commission to propose a 'Directive on minimum standards for quality healthcare',[131] based on the findings of these tests.[132] While respecting Member States' competence (see Article 168(7) TFEU), this would have introduced European minimum standards for quality healthcare and patient

125 Frischhut, *The Ethical Spirit of EU Values* (n. 68), 83-92.

126 Hence, a soft law document.

127 Council Recommendation of 8 December 2022 on a Union-wide coordinated approach to strengthen the resilience of critical infrastructure OJ 2023 C 20/1.

128 'Such stress tests entail a simulation of a public health emergency or major event in which some or all [!] segments of the processes and procedures laid down in this Regulation are tested'; Regulation EMA Recital 15. See also Regulation EMA on reinforced monitoring and mitigating shortages of critical medicinal products (Chapter II) and medical devices (Chapter IV).

129 Regulation ECDC Art. 5b (2) (e). See also Regulation Cross-Border Health Threats Art. 5 (5), addressing the Commission in this context.

130 Progressive Alliance of Socialists and Democrats (n. 60), 2.

131 This can currently conflict with Art. 168 (7) TFEU. Currently, according to Art. 4 (1) (b) Directive patient mobility, the Member State of treatment is responsible for 'standards and guidelines on quality and safety'.

132 Progressive Alliance of Socialists and Democrats (n. 60), 2.

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safety.[133] Another possibility would be to amend EU primary law to provide for a shared competence in this field,[134] as then such stress tests could serve to monitor the correct implementation of EU law.

Although the Member States are responsible 'for the definition of their health policy and for the organisation and delivery of health services and medical care' (Article 168(7) TFEU), they can voluntarily cooperate, for instance, in the field of (ad 3) joint procurement, to achieve a better bargaining position. Joint procurement is not new and has already been an issue in the case of the 'swine flu' way back in 2009.[135] In this light, 'Regulation Cross-border Health Threats' strives to 'strengthen and extend' the current framework[136] for the joint procurement of medical countermeasures, and its Article 12 ('joint procurement of medical countermeasures') provides for the necessary details. An important question is whether a possible parallel procurement would be legal. According to Article 12(3)(c), it is only 'possible' to restrict parallel procurement and negotiation activities.[137]

In the context of 'support for international and field preparedness and response', ECDC shall establish (ad 4) an 'EU Health Task Force', i. e., outbreak assistance teams, with the aim to assist in local responses to outbreaks of communicable diseases and to collect field data, both in Member States and in third countries.[138] The EU Health Task Force shall have a permanent capacity as well as an enhanced emergency capacity and shall consist of ECDC staff and experts from Member States. Although the overall aim was to strengthen the ECDC's mandate, it is also emphasised that the new Regulation does 'not confer any regulatory powers on the Centre'.[139] Rather, the ECDC shall provide 'robust and independent scientific expertise'.[140]

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133 Progressive Alliance of Socialists and Democrats (n. 60), 2. This directive should have comprised criteria to be reported to the Commission (relating to the parameters, such as hospital beds per capita, numbers of doctors, etc.), allowing the progress of healthcare systems to be tracked and being linked to the European Semester.

134 See Section V.

135 Anniek de Ruijter, 'A Silent Revolution: The Expansion of EU Power in the Field of Human Health: A Rights-Based Analysis of EU Health Law & Policy', (PhD thesis, fully internal, University of Amsterdam 2015), 205-212.

136 Regulation Cross-border Health Threats Recital 18, referring to the Joint Procurement Agreement for medical countermeasures, approved by the Commission on 10 April 2014.

137 On this 'exclusivity clause', see also Regulation Cross-Border Health Threats Recital 19.

138 Art. 11a Regulation ECDC (see also Recitals 23 and 24). On the EHC (and the possibility of mobile teams), see Section II.

139 Recital 29 Regulation ECDC.

140 Recital 8 Regulation ECDC.

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A noteworthy innovation of the EHU is also the use of artificial intelligence (AI),[141] which shall be used for the digital platform for surveillance,[142] for updating the Early Warning and Response System (EWRS),[143] as well as by the EMA in the context of the 'European Health Data Space'[144] and the 'European shortages monitoring platform'.[145]

An important novelty for crisis preparedness is also the Commission's possibility to formally recognise (ad 5) a 'public health emergency at Union level', 'including pandemic situations where the serious cross-border threat to health in question endangers public health at Union level'.[146] So far, it has been up to the World Health Organisation (WHO) to declare a 'public health emergency of international concern' (PHEIC).[147] While the EU becomes more independent of the WHO, the Commission still has to 'liaise with the WHO in order to share [its] analysis of the situation of the outbreak'.[148] While this can be an advantage in terms of speedy reaction to a pandemic, this possibility may, of course, be challenging, as both the decision itself, as well as its timing, can certainly be the subject of heated political debate.[149] Following such a determination, the Council may, in accordance with 'Regulation Medical Countermeasures', activate an emergency framework. This framework allows for a variety of measures. These measures are 'medical countermeasures' (that is also why 'Regulation Cross-border Health Threats' has a broader scope) and shall ensure the supply of medical countermeasures

141 See Regulation 2024/1689/EU of 13 June 2024 laying down harmonised rules on artificial intelligence […] (Artificial Intelligence Act), OJ 2025 L 2024/1689.

142 Art. 14 (2) (a) Regulation Cross-Border Health Threats, 'for data validation, analysis and automated reporting, including statistical reporting'. See also Art. 3 (2) (a) and Recital 15 Regulation ECDC. This platform shall enable especially the automated collection and handling of surveillance and laboratory data.

143 Art. 18 (2) Regulation Cross-Border Health Threats. See also Art. 8 (4) and Recital 22 Regulation ECDC. The EWRS is a system 'enabling the notification at Union level of alerts related to serious cross-border threats to health', 'in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner', Recital 29.

144 Recital 45 Regulation EMA. On the EHDS, see n. 51.

145 Recital 58 Regulation EMA; i. e., an IT platform 'that is capable of processing information on the supply of and demand for critical medicinal products [especially] during public health emergencies or major events', Recital 20.

146 Art. 23 (1) Regulation Cross-Border Health Threats.

147 World Health Organization, *International Health Regulations (2005)* (2nd edn, World Health Organization 2008); Art. 1 defines a PHEIC, and Art. 12 provides for the procedure of determination of a PHEIC (see also Annexe 2); see also Art. 57 (3).

148 Art. 23 (3) Regulation Cross-Border Health Threats.

149 See also Eleanor Brooks, Anniek De Ruijter, Scott L. Greer and Sarah Rozenblum, 'EU Health Policy in the Aftermath of COVID-19: Neofunctionalism and Crisis-Driven Integration', Journal of European Public Policy 30 (2023), 721-739.

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that are crisis-relevant.[150] As this framework applies in the case of a 'public health emergency at Union level', this requires an activation through Council regulation, 'taking into account the need to ensure a high level of protection of human health'.[151] As this regulation is based on Article 122 TFEU (see below Section IV. 4.), the use of measures within the emergency framework is limited in time for a maximum period of six months (which can be prolonged).[152] Obviously, for reasons of time, HERA was set up as a Commission Directorate-General, and not as an agency. In the typical review-report of this regulation, the question of a possible upgrade of HERA to an agency shall also be addressed.[153]

4. Primary Law Dimension (*de lege lata*)

In the case of severe difficulties arising in the supply of certain products (notably in energy), Article 122(1) TFEU allows the Council to take appropriate measures 'in a spirit of solidarity between Member States'. The second paragraph refers to 'financial assistance' for a Member State experiencing difficulties or being seriously threatened with 'severe difficulties caused by natural disasters or exceptional occurrences beyond its control'. The European Parliament is side lined in this context and must only be informed according to the second (not in the case of the first) paragraph. So far,[154] sixteen documents[155] have been adopted based on Article 122 TFEU,[156]

150 These measures can include the following: a monitoring mechanisms (Art. 7); procurement, purchase and manufacturing of crisis-relevant medical countermeasures and raw materials (Art. 8); emergency research and innovation aspects of the preparedness and response plans, as well as the use of clinical trial networks and data-sharing platforms (Art. 9); an inventory of crisis-relevant medical countermeasure production (Art. 10) or raw materials (Art. 11); measures to ensure the availability and supply of crisis-relevant medical countermeasures (Art. 12); emergency funding (Art. 13).

151 Art. 3 Regulation Medical Countermeasures.

152 Art. 3 (4) Regulation Medical Countermeasures.

153 Art. 16 Regulation Medical Countermeasures. For a possible future development of HERA, see also Charlotte Godziewski and Simon Rushton, 'HERA-lding More Integration in Health? Examining the Discursive Legitimation of the European Commission's New Health Emergency Preparedness and Response Authority', Journal of Health Politics, Policy and Law 49 (2024), 831-854.

154 Valid as of mid-March 2025, all information retrieved from EUR-Lex. Four documents (in the field of energy and inflation) are no longer in force (see, for example, Regulation 2022/2578/EU of 22 December 2022 establishing a market correction mechanism to protect Union citizens and the economy against excessively high prices, OJ 2022 L 335/45, as amended by OJ 2023 L 2023/2920).

155 Mainly (twelve) Council regulations, two ECB decisions and two Council decisions.

156 Either the first (eight), the second (four) or both (four) paragraphs.

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mainly in the fields of energy (5), finance (5), and pandemic (4),[157] as well as in the fields of the environment (1) and inflation (1).[158] It clearly seems as if Article 122 TFEU has replaced Article 352 TFEU (the 'flexibility clause') to avoid the latter's requirement of the Council deciding by unanimity. In the context of the ESM-Treaty, in *Pringle*, the ECJ has emphasised the EU's power under Article 122 TFEU to grant *ad hoc* (financial) assistance (under paragraph 2). However, according to the ECJ, Article 122(2) TFEU does not constitute an appropriate legal basis for a 'mechanism envisaged […] to be permanent'.[159] Simply put, this legal basis can be used for a short-term reaction to a particular difficulty, but not for long-term reforms.

Next Generation EU (NGEU) is a huge package intended to help Member States recover from the pandemic. The 'European Union Recovery Instrument',[160] based on Article 122 TFEU (see above), 'acts as the container instrument'[161] for NGEU and comprises EUR 750 000 million in total. In addition to other components (including an updated Decision on Own Resources[162], based on Article 311 TFEU), the key instrument is the 'Recovery and Resilience Facility' (RRF)[163], based on Article 175 TFEU (see above). As mentioned above, the increasing use of Article 122 TFEU can be seen as an example of 'creative legal engineering'. The German Constitutional Court (BVerfG) had to decide on the approval act of the German parliament concerning the 'Decision Own Resources'.[164] Indirectly, this could also have endangered NGEU, as an impor-

157 Besides Regulation Medical Countermeasures, also the following: Regulation 2020/2094/EU of 14 December 2020 establishing a European Union Recovery Instrument to support the recovery in the aftermath of the COVID-19 crisis, OJ 2020 L 433/23 (Regulation EU Recovery Instrument). Regulation 2020/672/EU of 19 May 2020 on the establishment of a European instrument for temporary support to mitigate unemployment risks in an emergency (SURE) following the COVID-19 outbreak, OJ 2020 L 159/1. Regulation 2020/521/EU of 14 April 2020 activating the emergency support under Regulation 2016/369/EU, and amending its provisions taking into account the COVID-19 outbreak, OJ 2020 L 117/3.

158 See Regulation 2022/2578/EU of 22 December 2022 establishing a market correction mechanism to protect Union citizens and the economy against excessively high prices, OJ 2022 L 335/45, as amended by OJ 2023 L 2023/2920 (hence, no longer in force).

159 *Pringle* (n. 107), para. 65.

160 Regulation EU Recovery Instrument.

161 Bruno De Witte, 'The European Union's COVID-19 Recovery Plan: The Legal Engineering of an Economic Policy Shift', CML Rev 58 (2021), 635-682 (636).

162 Council Decision 2020/2053/EU, Euratom of 14 December 2020 on the system of own resources of the European Union and repealing Decision 2014/335/EU, Euratom, OJ 2020 L 424/1 (Decision Own Resources); see also European Commission, Next Generation of EU Own Resources, IP/21/7025 (2021).

163 Regulation Recovery and Resilience Facility (n. 99).

164 BVerfG, *Verfassungsbeschwerden gegen Eigenmittelbeschluss-Ratifizierungsgesetz (NGEU) erfolglos*, judgment of 6 December 2022, case no. 2 BvR 547/21, 2 BvR 798/21, ECLI:DE:BVerfG:2022:rs20221206.2bvr054721.

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tant 'financial dimension' of the European Health Union.[165] However, in the end, the two constitutional complaints were rejected. In particular, the statements with regard to Article 122 TFEU and its requirements[166] of a sufficient link between the pandemic and both the substance of the measures, as well as on a timeline (funds to be spent until 2026),[167] can make the 'creative legal engineering' (in terms of applying Article 122 TFEU) more challenging in the future.

In a sense, Article 122 TFEU can be seen to add up to the other legal bases that are complementing what has been called the 'web of health competence',[168] besides Article 168 TFEU. First and foremost, Article 114 TFEU (harmonisation of national law) should be mentioned here, which is often combined with Article 168 TFEU.[169] Further provisions to be mentioned are Article 153 TFEU (social policy),[170] Article 196 TFEU (civil protection),[171] Article 16 TFEU (data protection),[172] Article 173 TFEU (industry),[173] and Article 175 TFEU (economic, social and territorial cohesion).[174]

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165 For further details (on number of Member States that can be supported; a sufficient link between the pandemic and the measures financed, etc.), see Thu Nguyen and Martijn van den Brink, 'An Early Christmas Gift from Karlsruhe?: The Bundesverfassungsgericht's NextGenerationEU Ruling', Völkerrechtsblog, 9 December 2022, doi: 10.17176/20221210-001631-0; Rudolf Mögele, 'EU-Wiederaufbaufonds: Deutschlands Beteiligung am Corona-Aufbaufonds verfassungskonform', Anmerkung zu BVerfG, Urteil v. 6.12.2022 – 2 BvR 547/21, 2 BvR 798/21, EuZW 34 (2023), 113-139 (137).

166 As interpreted by the BVerfG.

167 See BVerfG, *NGEU* (n. 164).

168 Kai P. Purnhagen et al., 'More Competences than You Knew?: The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak', European Journal of Risk Regulation 11 (2020), 297-306. This concept refers to a web that is 'stronger than its individual threads' (p. 303), where health takes precedence over mere economic considerations (ibid.) and where solidarity plays an important role (p. 304). On the precedence of health over economic considerations, see also Vlad Constantinesco, 'The ECJ as a Law-Maker: Praeter aut Contra Legem?' in: David O'Keeffe and Antonio Bavasso (eds), Judicial Review in European Union Law: Liber Amicorum in Honour of Lord Slynn of Hadley (Kluwer Law International 2000), 73-79.

169 Directive patient mobility; Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU [i.e., Directive patient mobility] [2021] OJ L458/1.

170 E. g., Directive 2022/431/EU of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, OJ 2022 L 88/1.

171 Regulation 2021/836/EU of 20 May 2021 amending Decision No. 1313/2013/EU on a Union Civil Protection Mechanism, OJ 2021 L 185/1, also based on Art. 322 TFEU (budget).

172 E. g., Regulation EHDS (n. 51).

173 Regulation 2021/523/EU of 24 March 2021 establishing the InvestEU Programme and amending Regulation 2015/1017/EU, OJ 2021 L 107/30, as amended by OJ 2024 L 2024/795 (Regulation InvestEU).

174 Likewise, Regulation InvestEU (n. 173); Regulation Recovery and Resilience Facility (n. 99).

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In her 2020 'State of the Union'-speech, Commission president von der Leyen had referred to the third step of building an EHU, that is to say 'the question of health competences'.[175] This third step is still missing.[176] In the framework of the 'Conference on the Future of Europe',[177] the idea of making health and healthcare a competence shared between the EU and the EU Member States is mentioned,[178] however, without any concrete legal details concerning Article 168 TFEU.[179] In view of the obvious reluctance of the Member States to transfer further competences to the EU (not only in general, but also especially in the area of health), it will be interesting to see what lessons are actually drawn from the pandemic.[180] Nonetheless, the question remains about what needs to be done.

V. Suggestions (*de lege ferenda*): or the Missing 'Keystone'

1. Gradual Competence Creep?

The EU has often been accused of a 'competence creep', that is to say, a gradual extension of the powers of the EU to the disadvantage of the EU Member States and of national sovereignty.[181] The accusation of 'integration by stealth' goes in a similar direction; this refers to the fact of not following the aim 'to find the best feasible solution to a concrete problem', but to simply 'drive forward the integration process'.[182] Another accusation is 'crea-

175 von der Leyen (n. 59).

176 Valid as of mid-March 2025.

177 See Müller-Graff (n. 75).

178 Conference on the Future of Europe, 'Report on the Final Outcome', May 2022, 52, <https://www.europarl.europa.eu/news/en/press-room/20220509IPR29102/the-conference-on-the-future-of-europe-concludes-its-work>, last access 29 October 2025.

179 'Enhance the European Health Union Using the Full Potential of the Current Framework and Include Health and Healthcare Among the Shared Competencies Between the EU and the EU Member States by Amending Art. 4 TFEU'.

180 In view of new crises (war in Ukraine, inflation, etc.), the fear is justified that the 'window of opportunity' is already closed. On the window of opportunity and timing of health policy outputs, see Torben Fischer, Nicole Mauer and Florian Tille, 'A Framework for Studying EU Health Policy Through a Political Determinants of Health Lens: The Case of the European Health Union', Journal of Health Politics, Policy and Law 49 (2024), 691-720.

181 See, for instance, Sacha Garben, 'Competence Creep Revisited', JCMS 57 (2019), 205-222; Sacha Garben, 'From Sneaking to Striding: Combatting Competence Creep and Consolidating the EU Legislative Process', ELJ 26 (2020), 429-447; Stephen Weatherill, 'Competence Creep and Competence Control', YBEL 23 (2004), 1-55.

182 Giandomenico Majone, Dilemmas of European Integration: The Ambiguities and Pitfalls of Integration by Stealth (Oxford University Press 2005), 143-144.

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tive legal engineering',[183] which has both a vertical ('stretching of the EU's competences in Article 122 and Article 175 TFEU') and a horizontal (between EU institutions) dimension.[184] This criticism, however, addresses less the EU than the Member States, which are the 'Masters of the Treaties'. However, if they do not provide the necessary tools to solve a crisis, EU institutions have to find creative solutions to respond to a crisis.[185] Besides this gap in necessary tools and actual challenges, Calliess has also identified a gap between objectives (Article 3 TEU) and actual competences; amongst others, also in the field of Article 168 TFEU.[186] This challenge of not providing the necessary tools in EU primary law also has to be seen in the context of the phenomenon of 'failing forward'. This has been described as follows: 'in an initial phase, lowest common denominator intergovernmental bargains led to the creation of incomplete institutions, which in turn sowed the seeds of future crises, which then propelled deeper integration through reformed but still incomplete institutions – thus setting the stage for the process to move integration forward'.[187] The following section analyses how this can be prevented.[188]

2. Shifting Healthcare Competences to the EU Level

In architecture, the 'keystone' is the stone on top of an arch, placed at the end, and holding together the whole construction. While there have been various improvements to the existing legal framework (Section IV. 3.), it is advisable to also add this last piece to the architecture of a true European Health Union. This missing keystone is the amendment of Article 168 TFEU.

183 De Witte (n. 161), 681.

184 See also, more recently, Andreas Eriksen and Michelle Everson, 'Health Policy: A Cautionary Tale of Constitutional Slippage and Polity Building Between Crisis and Nation Building' in: Diane Fromage, Adrienne Héritier and Paul Weismann (eds), *EU Regulatory Responses to Crises* (Oxford University Press 2025), 63-91.

185 This creativity obviously has to respect the boundaries of EU primary law and is subject to the legal control of the ECJ.

186 Christian Calliess, 'Braucht die Europäische Union eine Kompetenz zur (Corona-) Pandemiebekämpfung?: Zugleich ein Beitrag zu Prüfkriterien in der europäischen Kompetenzdebatte', NVwZ 40 (2021), 505-511 (506, 510). See also the contribution of Christian Calliess, 'Filling the Gap in the Health Policy of the European Union (EU) – Lessons Learned from the Covid-19 Pandemic –', HJIL 85 (2025), 1045-1074.

187 Erik Jones, R. Daniel Kelemen and Sophie Meunier, 'Failing Forward? Crises and Patterns of European Integration', Journal of European Public Policy 28 (2021), 1519-1536 (1519 f.); see also Erik Jones, R. Daniel Kelemen and Sophie Meunier, 'Failing Forward?: The Euro Crisis and the Incomplete Nature of European Integration', Comparative Political Studies 49 (2016), 1010-1034.

188 See Calliess, 'Pandemiebekämpfung' (n. 186); Calliess, 'Filling the Gap' (n. 186).

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As the aim is an extension of the EU's competences to dispose of the necessary tools,[189] this would have to be implemented via the 'ordinary revision procedure' of Article 48(2)-(5) TEU, not according to the 'simplified procedure' of Article 48(6) TEU.[190] While there have been various proposals of how to amend Article 168 TFEU,[191] only a few are presented here.

The Constitutional Treaty[192] proposed upgrading 'measures concerning monitoring, early warning of and combating serious cross-border threats to health' to a shared[193] competence. Hence, allowing for harmonisation in this field in addition to other already existing safety concerns (blood, medical products, medical devices, etc.). While these existing shared competences of Article 168(4) TFEU are aimed at individual 'products', 'cross-border threats to health' target the preparedness of health systems, therefore, narrowing the scope of the Member States' competence of Article 168(7) TFEU with regard 'the definition of their health policy and for the organisation and delivery of health services and medical care'.

Based on Article 2(1) Regulation Cross-border Health Threats, 'communicable diseases'[194] are just one example of 'serious cross-border threats to health'. Hence, the proposal of Seitz to have a shared competence in the field of 'measures to prevent, control and combat communicable diseases with pandemic potential'[195] is narrower. This proposal is based on Calliess, who

189 Likewise, critical to refer to a EHU without changing EU primary law, Constanze Janda, 'Die Europäische Gesundheitsunion – Vorschläge der EU-Kommission' in: Indra Spiecker Döhmann (ed.), *Mehrebenensystem im Gesundheitswesen: Ein Jahr Corona: welche Lehren können wir ziehen?* (Peter Lang 2022), 9-39 (39).

190 See also, Calliess, 'Pandemiebekämpfung' (n. 186), 511; Andreas T. Müller, 'Europa und die Pandemie: Zuständigkeitsdefizite und Kooperationszwänge' in: Christian Walter (ed.), *Staat und Gesellschaft in der Pandemie: Berichte und Diskussionen auf der Sondertagung der Vereinigung der Deutschen Staatsrechtslehrer in Wien am 9. April 2021*, VVDStRl 80 (2021), 105-124 (114). Art. 46(7) TEU concerns another simplified procedure (qualified majority instead of unanimity).

191 See Frischhut, 'Eine Europäische Gesundheitsunion' (n. *).

192 Art. III-278(4)(d).

193 See also Art. 2(2) TFEU.

194 See Markus Frischhut and Scott L. Greer, 'EU Public Health Law and Policy – Communicable Diseases' in: Tamara K. Hervey, Calum Young and Louise E. Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar Publishing 2017); Markus Frischhut, 'Communicable and Other Infectious Diseases: The EU Perspective' in: Tamara K. Hervey and David Orentlicher (eds), *The Oxford Handbook of Comparative Health Law* (Oxford University Press 2021).

195 Claudia Seitz, 'The European Health Union and the Protection of Public Health in the European Union: Is the European Union Prepared for Future Crossborder Health Threats?', ERA Forum 24 (2023), 543-566 (562). See also, Claudia Seitz, 'Schutz der Gesundheit in der Europäischen Gesundheitsunion: Ist die Europäische Union auf zukünftige grenzüberschreitende Gesundheitsgefahren vorbereitet?', EuZ 24 (2022), L1-L33.

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has combined this upgrade with the possibility for Member States to 'maintain or adopt enhanced protection measures, where these are imperative'.[196] In the end, it will be a political question, if the broader (serious cross-border threats to health) or the more narrow (communicable diseases, especially pandemics) approach will be feasible.

In terms of the above-mentioned statement of *Schuman*,[197] (shared) competences for 'cross-border threats to health' (including a pandemic) should be located at the EU level, as the necessary tools have to be available where they actually make sense. This includes an integration of the already existing tool of stress tests, but not only concerning 'medicinal products' and 'medical devices' (EMA[198]), respectively only supporting or complementing Member States' measures (ECDC[199]). A shared competence including such stress tests in the context of preparedness for serious cross-border health threats[200] would provide the Union with the necessary tools, hence, taking the proposal of the Constitutional Treaty to the next level and avoiding a 'failing forward'.[201] While it could be seen as an additional step, ideally such a shared competence should also comprise minimum standards for quality healthcare in this context.[202]

Hence, the new *litera* (d) of Article 168(4), the (missing) keystone of the 'European Health Union', should be read as follows: 'measures concerning *preparedness (including stress tests)*, monitoring, early warning of and combating serious cross-border threats to health'.[203] On a parallel level,[204] this also requires an amendment to Article 35(2) CFR[205] and to extend the requirement

196 Calliess, 'Pandemiebekämpfung' (n. 186), 511 (translation), using not an identical, but a similar wording. The wording of *Calliess* is reminiscent of Art. III-278(4)(d). See also the contribution of Calliess, 'Filing the Gap' (n. 186).

197 See the quotation above Section I.

198 See Regulation EMA Recital 15 and Chapter II, IV (n. 128).

199 See Regulation ECDC Art. 5b(2)(e), Regulation Cross-Border Health Threats Art. 5(5) (n. 129).

200 Including, but not limited to, pandemics.

201 See Calliess, 'Pandemiebekämpfung' (n. 186); Calliess, 'Filling the Gap' (n. 186).

202 Progressive Alliance of Socialists and Democrats (n. 60), 2.

203 Emphasis indicating the new elements compared to Art. III-278(4)(d) Constitutional Treaty.

204 The parallelism of the amendment is required by Art. 51(2) GRC, as the 'Charter does not extend the field of application of Union law beyond the powers of the Union or establish any new power or task for the Union'.

205 Theoretically, one could also envisage the 'right of access to preventive health care and the right to benefit from medical treatment' of Art. 35(1) CFR. This has less practical impact and does not create an added value, as it refers to 'the conditions established by national laws and practices'. Deleting this latter part would be quite far reaching, as this would require a parallel amendment of Art. 168(7) TFEU itself, which is not realistic.

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of a 'high level of human health protection' not only to all 'Union's policies and activities' but also to all the activities of the Member States. However, this approach does not require an amendment of Article 4(2)(k) TFEU, as this proposal falls within the existing wording of 'common safety concerns in public health matters, for the aspects defined in this Treaty'.

However, besides Article 168 TFEU and Article 35 CFR, another dimension must also be considered. As mentioned above, the 'one health'-approach can be seen as 'a multi-sectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions'.[206] Since 1957,[207] the free movement of goods can be restricted for 'the protection of health and life of humans, animals or plants'. Hence, we can find the three dimensions of humans, animals, and the environment (or at least plants) as 'reasons of justification'. As we have seen in Section II., 'public health' has also developed from a mere 'reason of justification' (ECSC) to a distinct 'sectoral policy' (Maastricht). Likewise, the 'one health'-approach enshrined in Article 36 TFEU (free movement of goods) can be further developed as follows.

3. Health as an Additional Value

In a remarkable ruling of mid-December 2020, the ECJ qualified 'animal welfare' as 'an EU value' in the context of ritual slaughter with reference to an EU regulation[208] on the protection of animals at the time of killing.[209] This is remarkable insofar as it is the first value outside Article 2 TEU and the addressees are not humans but animals. This statement from 2020 is also noteworthy insofar as the ECJ had previously refused[210] to judge animal welfare as a 'general principle of law' about 20 years earlier.[211] Although both the values of Article 2 TEU and the 'general principles of EU law' formally qualify as EU primary law, the values are to be seen as 'more' in terms of content.

206 Art. 3(7) Regulation Cross-Border Health Threats.

207 Treaty establishing the European Economic Community, from 25 March 1957; nowadays identical in Art. 36 TFEU.

208 Regulation 1099/2009/EU of 24 September 2009 on the protection of animals at the time of killing, OJ 2009 L 303/1, as amended by OJ 2018 L 122/11.

209 ECJ, *Centraal Israëlitisch Consistorie van België and Others*, judgment of 17 December 2020, case no. C-336/19, ECLI:EU:C:2020:1031, para. 41.

210 ECJ, *Jippes and Others v. Minister van Landbouw, Natuurbeheer en Visserij*, judgment of 12 July 2001, case no. C-189/01, ECLI:EU:C:2001:420, para. 74.

211 Takis Tridimas, *The General Principles of EU Law* (2nd edn, Oxford University Press 2006), 27.

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Departing from animal welfare as a new value, one can argue (*argumentum a minori ad maius*) that human health is also a value in itself. This demand is of course formally[212] considered as a proposal *de lege ferenda* and would require either an EU primary law amendment by the 'Masters of the Treaties', or a corresponding further development of the law by the ECJ,[213] to be on the safe side. In the end, this approach could be seen as a complementary step in addition to the ECJ's case law[214] of giving precedence to health over mere economic considerations. However, no change of Article 2 TEU would be necessary by simply placing a stronger emphasis on the existing value of solidarity.[215]

In a holistic approach, the environment – as a human right[216] or value[217] – would also have to be considered. Both proposals, which show a certain connection against the background of the mention of human rights in Article 2 TEU, are, of course, also to be understood *de lege ferenda*. The connection of humans, animals, and the environment displayed in the 'one health'-approach would then also have a certain legal linking in the sense of three values, twice *de lege ferenda*, once already established by the ECJ. A certain parallelism would then also exist in the area of the vertical distribution of competences, if the EU would get more shared competences in health, as in the area of environment (Article 4(2)(e) TFEU). As is well known, environ-

212 This is to be understood as a cautious reading; in terms of content, the aforementioned conclusion '*argumentum a minori ad maius*' could already be sufficient at present to consider human health a value.

213 See for instance, Constantinesco (n. 168).

214 *Affish v. Rijksdienst voor de keuring van Vee en Vlees*, judgment of 17 July 1997, case no. C-183/, ECLI:EU:C:1997:373, para. 43; *P Artegodan v. Commission*, judgment of 19 April 2012, case no. C-221/10, ECLI:EU:C:2012:216, para. 99; *Swedish Match AB v. Secretary of State for* Health, judgment of 22 November 2008, case no. C-151/17, ECLI:EU:C:2018:938, para. 54.

215 In the past, for instance, patient mobility has been criticised of 'corroding solidarity'; Christopher Newdick, 'Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity', CML Rev 43 (2006), 1645-1668. An idea to be further developed within the 'Horizon Europe' project 'Flexible Approaches to Support Health Through Financing (FLASH)'. Also emphasising solidarity in the context of the EHU: Vandenbroucke (n. 100); Council of the EU, 'Council Conclusions on the Future of the European Health Union: A Europe that Cares, Prepares and Protects: 9900/24', 21 June 2024, 3, <https://www.consilium.europa.eu/en/meetings/epsco/2024/06/21/>, last access 29 October 2025.

216 Ferdinand von Schirach, *Jeder Mensch* (Luchterhand 2021) 18: 'Artikel 1 – Umwelt', 'Jeder Mensch hat das Recht, in einer gesunden und geschützten Umwelt zu leben'.

217 Frischhut, *The Ethical Spirit of EU Values* (n. 68), 227-229. Also referring to the 'value of health [as] the cultural backbone of our European civilisation', Vytenis Andriukaitis and Gediminas Cerniauskas, 'Scenarios for the EHU's Evolution: Legislative Process, Resources, Narrative, and Political Will' in: Vytenis Andriukaitis and Gediminas Cerniauskas (eds), *A European Health Union: A Blueprint for Generations* (FEPS 2023), 273-312 (307).

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mental and health policy are linked not least in that Article 191(1) TFEU also identifies 'protecting human health' as one of the objectives of environmental policy.

4. Conclusion: No 'Big Bang'

In conclusion, the EHU cannot thus be qualified as a 'big bang'.[218] To some extent, certain already existing legal possibilities for action have not been exhausted in the past.[219] Unlike in the context of previous crises, the response to the pandemic has taken place within EU law (and not outside, i. e., in international law).[220] It is intriguing that some elements of the EHU correspond to what had already been suggested in 1952, although not as a supra-national legal entity but as amendments to various documents of EU secondary law.

This contribution proposes the addition of the missing keystone (a new *litera* d for Article 168(4) TFEU) for the 'European Health Union'. At the moment, although consisting of valuable improvements, the EHU serves as an umbrella term[221] due to the lack of political will to change EU primary law. At the same time, it can be seen as a shifting concept that always incorporates current projects.

History consistently offers valuable lessons, and this holds true for the healthcare sector as well. It's fascinating to compare the idealistic vision behind the European Health Community – conceived freely on paper – with the more constrained, incremental development shaped subject to the limitations of the principle of conferral. While establishing a separate legal entity, such as a Health Community (in the sense of an international organisation), would neither add value nor align with the Lisbon Treaty,[222] the EU should

218 See also, Thibaud Deruelle, 'Covid-19 as a Catalyst for a European Health Union: Recent Developments in Health Threats Management' in: Bart Vanhercke and Slavina Spasova (eds), *Social Policy in the European Union: State of Play 2021: Re-Emerging Social Ambitions as the EU Recovers from the Pandemic* (ETUI Printshop 2022), 127-144; Müller (n. 190), 105, 129 and 131.

219 European Parliament Resolution of 10 July 2020 on the EU's public health strategy post-COVID-19 (2020/2691(RSP)), OJ 2021 C 371/102 Recital I, referring to European Parliamentary Research Service, 'Unlocking the Potential of the EU Treaties: An Article-by-Article Analysis of the Scope for Action', May 2020, 29-30. Purnhagen et al. (n. 168), 306.

220 Müller (n. 190) 125; Delhomme and Hervey (n. 5), 34.

221 Mentioning that the 'European Health Union is to be more than the sum of its parts', Martin McKee and Anniek de Ruijter, 'The Path to a European Health Union', The Lancet Regional Health – Europe 36 (2024), 100794.

222 In the sense of abolishing the temple or three pillars construction, established by the Maastricht Treaty.

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nonetheless be equipped with the necessary powers to address current and future health challenges. The original proposal for a European Health Community, which included ideas like mobile teams for on-site inspections and even an 'International Health Police', reflected a broader spirit of cooperation – such as resource pooling – that should continue to guide and inspire future reforms.

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Filling the Competence Gap in the Health Policy of the European Union (EU) by a New Article 168 (4) d) TFEU

– Lessons Learned from the Covid-19 Pandemic –

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Abstract

This article deals with the capabilities and limitations of the European Union in adopting measures in the fight against pandemics on the basis of legal and economic evaluative criteria. The Covid-19 pandemic has directed the spotlight on the EU's seemingly fumbling response in handling pandemics. The reason for this appearance of ineffectiveness lies in the lack of material competence of the EU in this area, which currently is limited to only a 'coordination competence' for health policy. The EU is thus dependent on the consensus and cooperation of all Member States in adopting measures such as the rules on vaccine procurement and on the vaccination passport. At the same time, given that pandemics do not stop at national borders, the European idea is dependent on a successful European response to pandemics, as only a common strategy can avoid border controls and ensure effective measures. Accordingly, the treaties include the goal of combating health hazards. However, the discrepancy between the European goal and the lack of necessary competences for its efficient accomplishment endangers the European idea as well as the Union's legitimacy. This must be resolved through an addition to the competence, while taking into account the criteria of the subsidiarity principle. This article proposes an amendment to add a subsection (subsection 'd)') to Article 168(4) of the Treaty on the Functioning of the European Union (TFEU) to supplement the EU's competence and to enable the EU to adequately react to future pandemics.

Keywords

European Health Union – European health competence – European public good – Corona pandemic – harmonisation and coordination of national health policies – European Medicines Agency

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I. Introduction

In some policy areas, the European Union (EU) suffers from a gap between promise and delivery: The political actors at the European level tend to promise ambitious policies to uphold the goals enshrined in the European Treaties, which the European institutions fail to 'deliver' due to insufficient competences. For example, the EU treaties envisage a stable euro area (Article 119(2) TFEU), but as evidenced by the events following the 2008 global financial crisis and the resultant sovereign debt crisis, the fulfilment of this promise cannot be guaranteed due to a lack of economic and fiscal policy competences (see Article 121 TFEU). Similarly, the EU treaties promise to EU citizens the freedom of movement without border controls in an 'area of freedom, security and justice' (Article 67 TFEU). However, with the temporary reappearance of border controls in the wake of the migration crisis and the security situation following the terrorist attacks in Paris, the institutions in Brussels and Berlin have made it clear that there are no practical guarantees in this regard.[1] A similar predicament exists in the field of health policy. 'The EU' promises a European health policy to its citizens (Article 168 TFEU with Article 35 Charter of Fundamental Rights of the EU), but in the throes of a pandemic with Europe-wide as well as global effects, the EU's role appears limited to that of mere coordination between the Member States. In all of these examples, the EU treaties include more ambitious goals than the EU can deliver on the basis of the competences assigned to it by the Member States.[2]

This problem was well-illustrated by the debate on the European Commission's handling of the joint procurement of vaccines for its twenty-seven Member States.[3] While the Commission appeared to be in charge, in reality, it could only *coordinate* the decision-making among Member States by consensus – a fact often overlooked by the public. A steering committee, comprising representatives from all twenty-seven Member States, as well as a joint negotiating team comprising representatives from the Commission, Germany, Spain, Poland, Italy, France, Sweden, and the Netherlands, seem-

1 For details on this and on the eurozone generally, see Christian Calliess, *Öffentliche Güter im Recht der EU*, (Bertelsmann Stiftung 2021), 19 et seq. and 45 et seq., doi: 10.11586/2020072.

2 Also using this at the outset and as a starting point of their analysis, Corina Andone and Florin Coman-Kund, 'Persuasive Rather than "Binding" EU Soft Law? An Argumentative Perspective on the European Commission's Soft Law Instruments in Times of Crisis', The Theory and Practice of Legislation 10 (2022), 22-47 (29-30).

3 Marie Gontariuk et al., 'The European Union and Public Health Emergencies: Expert Opinions on the Management of the First Wave of the COVID-19 Pandemic and Suggestions for Future Emergencies', in: Front. Public Health, 20 August 2021, doi: 10.3389/fpubh.2021.698995.

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ingly handled the negotiations with the vaccine manufacturers. However, according to publicly available information, the individual Member States had decided for themselves which manufacturer to pre-order from and how many vaccine doses to purchase. One might conjecture from this that the economically less prosperous Member States, also influencing the steering committee's decision, pushed for larger quotas of the cheaper vaccines to be ordered. Therefore, a costly spread of orders, as in the case of the US orders, was averted. Consequently, an insufficient amount of vaccines were ordered.

At the same time, due to the lack of a common European strategy, there were no coordinated controls on entry into the EU from third countries that were binding on all Member States. Among other consequences, this led to the (re-)introduction of national controls at the internal borders between Member States. In the first weeks of the pandemic, almost all borders in the Schengen area were subject to strict border controls, with some notable exceptions such as the German-Dutch border in the federal state of North Rhine-Westphalia.[4] This reaction to the pandemic impaired the free movement of persons within the internal market, infringing upon a core right of EU citizens (Article 21 TFEU) in the 'area of freedom, security and justice', the so-called Schengen area. In the wake of this fragmentation, there is a risk that the protective measures that make sense in and of themselves will be neither coherent, nor efficient, nor proportionate in light of the pandemic's cross-border dimension.[5]

Considering the difficulties experienced in the first months of the Covid-19 pandemic, the European Commission presented a proposal for the construction of a 'European Health Union' in November 2020. This proposal bundles various measures for more effective combating of cross-border health risks, including comprehensive precautionary strategies, institutional reforms, and binding obligations for Member States and compa-

4 Matthias Eckardt, Kalle Kappner and Nikolaus Wolf, 'Covid-19 Across European Regions. The Role of Border Controls', in: Charles Wyplosz (ed.), Covid Economics 42, 19 August 2020, 94-111 (97 et seq.).

5 In particular on the coherence requirement, see Matthias Ruffert, 'Article 7 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 2 et seq. as well as Christian Calliess, 'Article 13 TEU)' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), para. 2; with regard to the restriction of fundamental freedoms: ECJ, *Stoß et al. v. Wetteraukreis et al.*, judgment of 8 September 2010, ECLI:EU:C:2010:504; André Lippert, 'Das Kohärenzerfordernis des EuGH. Eine Darstellung am Beispiel der Rechtsprechung zum deutschen Glücksspielmonopol', Europarecht 47 (2012), 90-99; Bernd Hartmann, Kohärenz im Glücksspielrecht: vertikal – horizontal – intersektoral?, EuZW 25 (2014), 814-819.

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nies.[6] By 2025, the EU has transformed many of its proposals into legislation, pushing the European Health Union to the boundaries of what is possible in terms of competence in the area of health policy.

This article argues that this current framework is still insufficient to ensure the fulfilment of the objectives set out in the EU Ttreaties. It has become necessary to add a legislative competence regarding pandemic protection in the field of health policy. To this end, relying on legal and economic arguments, this article aims to develop criteria for transferring competences to the EU. In essence, the article argues that competences should be transferred when there is a gap between European public goods 'promised' in the objectives of the Treaties and the competences of the EU is entitled in this respect (II.). The analysis of the normative framework in the area of public health and the issues encountered by the EU during the Coronavirus pandemic show that these criteria are met (III.). Further, the internal market competences cannot remedy the lack of competence in the field of public health (IV.). Thus, to truly fulfil the objectives in the field of public health and safeguard the achievements of European integration, it is necessary to adapt the Treaties to include more expansive competences for health policy. Hence, this article closes with a plea to amend the treaties, in order to equip the EU with the necessary competence to combat any future pandemics (V.).

II. General Criteria for a Transfer of Competence to the EU

The transfer of competence to the EU is primarily a political, rather than a legal, decision. However, one can make a political argument for such a transfer on the basis of criteria developed in legal science and economics. Turning to the law, the legal standard governing the question of competences is the principle of subsidiarity. Directly, it applies only to the interpretation of existing competences, but it can – by analogy – also guide the question of the transfer of competences (1.). The same holds true for the criterion of 'European added value' provided by economic theory (2.). On this basis, in

6 European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Building a European Health Union, Strengthening the EU's resilience to cross-border health threats, COM/2020/724; European Commission, Proposal for a Regulation of the European Parliament and of the Council. On an enhanced role for the European Medicines Agency in crisis preparedness and management in relation to medicines and medical devices, COM/2020/725; European Commission, Proposal for a Regulation of the European Parliament and of the Council. Establishing a European Centre for Disease Prevention and Control, COM/2020/726 and European Commission, Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health, COM/2020/727.

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legal reasoning and economic theory, the political argument can be made that competences should be transferred from Member States to the EU, where the Treaties outline a common good that Member States cannot realise on their own due to its cross-border context (3.).

1. Objectives of the EU and the Principle of Subsidiarity

States are historically tasked with attaining goals pertaining to the realisation of common goods,[7] or public goods, as referred to in economics.[8] Article 3 of the Treaty on European Union (TEU) transfers some of these goals and tasks from the Member States to the EU under the premise that these are carried out adequately, and especially, to safeguard the public goods having a cross-border dimension: If the Member States are left to their own devices, they would be overburdened with solving the problems peculiar to the cross-border context.[9]

This overload can generally be substantiated based on the principle of subsidiarity. In this respect, the following two sets of questions must be distinguished:

On the one hand, there is the question of whether and how a competence transferred to the EU should be *exercised* to achieve a goal. This essentially means, whether the EU can and should *act at all*, and if so, to what extent. To answer these questions, the principles of subsidiarity and proportionality (Article 5 TEU) must be observed.[10] Article 5(3) TEU formulates, first, a 'negative criterion' according to which the EU may act in cases where an action by the Member States alone may not be sufficient to solve a problem. In addition to this according to a 'positive criterion', the EU must be able to

7 Christian Calliess, 'Gemeinwohl in der Europäischen Union – Über den Staaten- und Verfassungsverbund zum Gemeinwohlverbund', in: Winfried Brugger, Stephan Kirste and Michael Anderheiden (eds), *Gemeinwohl in Deutschland, Europa und der Welt* (Nomos 2002), 173-214.

8 For an overview, see Armin Steinbach and Anne van Aaken, *Ökonomische Analyse des Völker- und Europarechts* (Mohr Siebeck 2019), 49 et seq. with a general application of economic methods of analysis to European law reference areas on 147 et seq.

9 Thomas Dietz, Elinor Ostrom and Paul C. Stern, 'The Struggle to Govern the Commons', Science 302 (2003), 1907-1912; Inge Kaul, Donald Blondin and Neva Nahtigal, 'Introduction: Understanding Global Public Goods' in: Inge Kaul (ed.), *Global Public Goods* (Edward Elgar 2016), xiii-xcii; in addition, in overview Steinbach and van Aaken (n. 8), 49 et seq.

10 See European Commission, Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. The principles of subsidiarity and proportionality – strengthening their role in EU policy-making, COM/2018/703 final, 23 October 2018.

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act more adequately than the Member States, a fact to be evidenced by an evaluative comparison.[11]

On the other hand, the question as to whether the competence to attain an objective should be transferred to the EU in the first place is a *political decision* and legally carried out by way of a treaty amendment through the procedures specified under Article 48 TEU. Within this framework of competences conferred by such an amendment, the criteria of the principle of subsidiarity can only be applied by analogy. This means that a competence should be transferred where Member States alone cannot act sufficiently, and the EU is more suitably equipped to realise a goal specified in the treaties.

2. European Added Value in Economic Theory

Moreover, the criteria used within the framework of economic theory for the provision of the so-called '(European) public goods' confirms the above legal and political findings.[12] From this point of view, European action should be possible in those areas in which the Member States alone cannot act 'sufficiently' concerning the provision and realisation of a European public good due to 'policy spill overs', i. e. the States are overburdened, and in which the European level has more suitable and effective means at its disposal than the Member State level ('economies of scale'), i. e. the EU can act 'better' in comparison. Within this framework, it is important to identify those areas in which an action at the EU level brings 'European added value'[13] and thus (in the language of politics[14]) strengthens European sovereignty or autonomy. In other words, wherever the sum of all Member States makes a difference and thus, at the same time, an added value can be achieved in a global context through joint European action (the so-called 'Brussels effect'),[15] there is a European public good towards which the EU should be able to function and act. It is not by mere chance that these criteria, to a certain extent, coincide

11 Christian Calliess, *Subsidiaritäts- und Solidaritätsprinzip in der Europäischen Union* (2nd edn, Nomos 1999), 65 et seq. including a test grid on p. 271 et seq. with further references; most recently Calliess (n. 1), 22 et seq.

12 See Clemens Fuest and Jean Pisani-Ferry, 'A Primer on Developing European Public Goods', EconPol Policy Report 16 (2019), 1-42 (7 et seq.).

13 See Fuest and Pisani-Ferry (n. 12), 7 et seq.

14 See Press and Information Office of the Federal Government, 'Meseberg Declaration. Renewing Europe's Promise for Security and Prosperity', 19 June 2018, press release 214.

15 Anu Bradford, 'The Brussels Effect', Nw. U. L. Rev. 107 (2012), 1-68; Benjamin Hartmann and Sofia Lucas Areizaga, Kommission: Die Herausforderungen für die Zukunft der Europäischen Union, in: Gregor Kirchhof, Mario Keller and Reiner Schmidt (eds), Europa: In Vielfalt geeint!, Munich 2020, 101-116.

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with the criteria under the principle of subsidiarity, as outlined in Article 5 TEU.[16]

3. The Necessity of Competence Transfers Where European Tasks Exceed the EU's Capacity to Act

At this point, it is important to clarify that the objectives of the EU are not necessarily congruent with its competences, and therefore its capacity to act. Some objectives aim higher by specifying contents beyond the competences currently conferred upon the EU in the Treaties. This leads to the generally problematic discrepancy between the European promise and its delivery: The current European order of competences does not enable the EU to deliver on the promised European goals. Illustrative of such a deficit are the fields of European social policy (see Article 3 para. 3 TEU and Article 151 on the one hand, and Article 153 TFEU on the other), economic policy (see Article 119 on the one hand, and Article 121 TFEU on the other), and European health policy. This discrepancy between promise and potential delivery can prove detrimental to the EU's legitimacy and further lead to practical problems, as the tasks included in the treaties are usually aimed at addressing issues with a cross-border dimension. Thus, competence should be transferred where there is such a disparity between tasks and competences that undermines the Union's capacity to act.

III. The Covid-19 Pandemic and the Limits of EU Competence in the Field of Health Policy

A significant disparity between the specified tasks and assigned competences can be found in the field of public health policy, particularly in the response to the Covid pandemic (1.). While the EU has moved forward with the establishment of the European Health Union during the Covid-19 pandemic, a lack of legislative competence in this field has significantly constrained this development (2.).

1. Disparity Between Tasks and Competences in the Field of Health Policy

The challenges described above are exacerbated by the Covid-19 pandemic, which has made us aware of the fact that the competences conferred

16 In depth analysis Calliess (n. 1), 22 et seq.

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upon the EU in the area of public health, unlike those in environmental and consumer protection policy, are insufficient. While the European Court of Justice (ECJ) recognises a 'general principle' that health 'must undoubtedly be given priority',[17] particularly in relation to economic considerations, the Member States remain the 'masters of health policy'.[18] According to Article 168(1) TFEU, the EU's competence is generally restricted to activities that complement, promote, or coordinate the health policies of the Member States.[19] This limited competence of the EU remains unaltered by Article 35 of the Charter of Fundamental Rights of the EU, which postulates a 'right of access to preventive healthcare and the right to benefit from medical treatment'. Although arguments for a protective dimension of European fundamental rights ('duty to protect') have been advanced in case law and literature,[20] Article 51(1) sentence 2 and (2) of the Charter clarify that the rights listed therein may not lead to an expansion of the EU's competences.[21]

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17 ECJ, *Artegodan GmbH*, judgment of 19 april 2012, case no. C-221/10 P, ECLI:EU:2012:216, para. 99.

18 Markus Kotzur, 'Article 168 TFEU' in: Rudolf Geiger, Daniel-Erasmus Khan and Markus Kotzur (eds), *European Union Treaties* (C. H. Beck and Hart 2015), para. 7; Werner Berg and Steffen Augsberg, 'Article 168 TFEU' in: Ulrich Becker, Armin Hatje, Johann Schoo and Jürgen Schwarze (eds), *EU-Kommentar* (4th edn, Nomos / facultas / Helbing Lichtenhahn 2019), para. 16; Rudolf Mögele, 'Die EU und COVID-19: Befugnisse und Initiativen', EuZW 31 (2020), 297-344.

19 Thorsten Kingreen, 'Article 168 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 3 et seq. and 13 et seq.; Daniel Thym and Jonas Bornemann, 'Binnenmarktrechtliche Grundlagen des Infektions- und Gesundheitsschutzrechts', in: Stefan Huster and Thorsten Kingreen (eds), *Handbuch Infektionsschutzrecht* (2nd edn, C. H. Beck 2022), ch. 2, paras 49 et seq.; differentiating Astrid Wallrabenstein, 'Gesundheitspolitik' in: Bernhard W. Wegener, Armin Hatje, Peter-Christian Müller-Graff and Jörg Philipp Terhechte (eds), *Enzyklopädie Europarecht, Europäische Querschnittpolitiken*, vol. 8 (Nomos 2014), paras 65 et seq.; from a legal practitioner's point of view: Tobias Maass and Florian Schmidt, Die Entwicklung des EU-Gesundheitsrechts seit 2012, EuZW 26 (2015), 85-92.

20 Christian Calliess, 'Dimensions of Fundamental Rights – Duty to Respect versus Duty to Protect' in: Hermann Pünder and Christian Waldhoff (eds), *Debates in German Public Law* (Hart Publishing 2014), 27-42; also Gerald Sander, 'Europäischer Gesundheitsschutz als primärrechtliche Aufgabe und grundrechtliche Gewährleistung', ZEuS 8 (2005), 253-272; with a current overview and comparative analysis to positive obligations under the European Convention of Human Rights Niklas Täuber, 'Positive Obligations within the European Fundamental Rights Protection System: The Unleashing of a Beast or Realization of 21st Century Fundamental Rights Protection', Berliner Online-Beiträge no. 149, 19 September 2023, available at <https://www.jura.fu-berlin.de/forschung/europarecht/bob/berliner_online_beitraege/Paper149-Taeuber/BOB149_Positive-Obligations-within-the-European-Fundamental-Rights-Protection-System.pdf>, last access 12 November 2025.

21 'Article 52 CFREU' in: Rudolf Geiger, Daniel-Erasmus Khan and Markus Kotzur (eds), *European Union Treaties* (C. H. Beck and Hart 2015).

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According to Article 168(2) TFEU, the Commission may,

> 'in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation'.

In the exercise of such coordination by the EU, the competence of the Member States remains unaltered; that is, it is not – as in the case of binding legislation – *europeanised* or even limited (see Article 2 para. 2 TFEU). In this sense, within the paradigms of public health competence, the EU can merely facilitate coordination among Member States that make decisions themselves by unanimity. This shows that the real power remains in national hands (Article 2 para. 3 and 5 TFEU).[22] How this unfolds in practice is illustrated, for instance, by the recent attempt of the EU to address the Covid-19 pandemic by 'inviting'[23] manufacturers of masks and respirators to 'immediately increase production'. As such, pursuant to Article 168(2) TFEU, the Commission cannot bind or commit the Member States to any such joint procurement without their consent. It follows that this requires a voluntary agreement on the joint procurement of medical equipment via public tenders. Accordingly, it appeared on the outside that the Commission had carried out the procurement procedures; however, in fact, its acts were contingent on the consent of the Member States, which formally remained the purchasers of the products.[24] In this way – similar to the procurement of vaccines[25] – while ostensibly the EU appears to act, the real mandate remains with the Member States which decide by unanimity. Consequently, responsibility and competence diverge: The EU might be held responsible for all the failures that could occur during the procurement process, even though the European level never could or did act on its own accord due to its lack of competence.

This legal situation is underpinned by the exclusion of any European harmonisation of national laws of the Member States (Article 168(5) TFEU). This prohibition also covers measures

> '[…] designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health […]'.

22 Christian Calliess, 'Article 6 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 5 and 12 et seq. and Christian Calliess, 'Article 2 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 19 et seq.

23 Communication from the Commission COM/2020/112 final, 13 March 2020, 4.

24 Thym and Bornemann (n. 19), ch. 2, para. 16 with further references.

25 See Commission Communication, COM/2020/245 final, 7 June 2020.

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An exception to this prohibition on European harmonisation only applies in the case of narrowly defined areas explicitly listed in Article 168(4) TFEU, which are as follows:

> 'a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;
>
> (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
>
> (c) measures setting high standards of quality and safety for medicinal products and devices for medical use.'

Currently, only the above-listed measures can qualify as '*common safety concerns in public health matters*' as defined under Article 4(2)k) TFEU, where the EU may have full (shared) legislative competence. Not surprisingly, the list reflects competences transferred to the EU level in the course of past political experience with crises (such as HIV blood products, BSE, EHEC).[26] Consequently, Member States can only be bound by the European requirements within the scope of application of Article 168(4) TFEU.

2. EU Practice in the Covid-19 Pandemic: Moving Forward, but with the Handbrake on

In comparison to the European legal framework in the field of public health prior to the Covid-19 pandemic (a.), the EU has taken significant steps forward with the adoption of its Health Union framework. However, it has repeatedly come up against the restrictive boundaries of the coordination competence (b.).

a) EU Secondary Law and Administrative Framework Before the Covid-19 Pandemic

While the EU has widely exercised its competences under Article 168(4) TFEU,[27] the existing legislation to combat pandemics was very limited, given the prohibition on harmonisation under Article 168(5) TFEU. The frame-

26 Sander (n. 20), 253 et seq.; Kingreen (n. 19), paras 18 et seq.; Birgit Schmidt am Busch, *Die europäische Gesundheitssicherung im Mehrebenensystem* (Mohr Siebeck 2007).

27 With an overview Kotzur, 'Article 168 TFEU' (n. 18), paras 13 et seq.

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work essentially came down to Decision 1082/2013/EU on improving cooperation and coordination, which enabled epidemiological surveillance and monitoring, early detection and control of diseases, through close coordination between the Union and the Member States. Central to this coordination were the establishment and maintenance of an early warning and response system, as well as the work of a 'Health Security Committee' comprising representatives from national health authorities working in close coordination with the Commission.[28]

Other pre-existing parts of the framework are the two EU agencies: the well-known European Medicines Agency (EMA) and importantly, the Stockholm-based European Centre for Disease Prevention and Control (ECDC), which was established in 2004.[29] The independent agency collects information, identifies and assesses hazards on this basis, and can provide expert opinions. In 2013, the aforementioned Decision 1082/2013/EU entrusted the ECDC with the task of operating and coordinating a transnational network comprising the Agency, the Commission, and the Member States for the epidemiological surveillance of communicable diseases. Furthermore, the ECDC also operates an early warning and response system.[30]

b) Making Full Use of Limited Competences – More but Still Not Enough

As outlined above, the Covid-19 pandemic called on the European Union to take action, especially given the cross-border dimension combined with the specific goal of the Union to ensure a high level of health protection for its citizens. However, despite the limited competences in the area of health, the EU was able to strengthen the existing structures and expand them to form a network of measures, procedures and institutions, which also serve to protect human health in the event of an infectious risk.[31]

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28 See 1 and 8 et seq. of Decision 1082/2013/EU of 22 October 2013 of the European Parliament and of the Council on Serious Health Procedures, Official Journal of the EU, no. L 293 of 5 November 2013.

29 Regulation 726/2004/EC of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Official Journal of the EU, no. L 136 of 30 April 2004; on this Andreas Orator, *Möglichkeit und Grenzen der Einrichtung von Unionsagenturen* (Mohr Siebeck 2017), 142 et seq.

30 See Article 4 et seq. Regulation 51/2004/EC of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control, Official Journal of the EU, no. L 142 of 30 April 2004; Orator (n. 29), 131-132.

31 See the overview in Thym and Bornemann (n. 19), ch. 2, paras 44 et seq. and 68 et seq.

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aa) Limited Strengthening of the Existing Framework

Additionally, in the course of the Covid-19 pandemic, the EU relied on this existing framework and – in 2022 – decided to facilitate and expand this existing network to protect EU citizens' health against infectious risk.

(1) Substantial Rules

The above-mentioned Decision 1082/2013/EU was repealed by Regulation 2022/2371/EU dated 23 November 2022. The change in the nature of the legal strategy – issuing a Regulation instead of an updated decision – already indicates a more expansive approach of the Union in this regard. The Regulation aims to broaden the Union's powers to react to cross-border health threats. The framework is – due to Article 168(5) TFEU – scaled back to the coordinating functions of the Union. This includes *inter alia* more substantive rules for the Union's coordination of Member States' prevention, preparedness, and response-planning to such cross-border health threats and their review (Article 5 et seq.) as compared to the former framework under Decision 1082/2013. These efforts are still coordinated by the Health Security Committee, now set up under Article 4 of the Regulation.[32]

(2) Expanding Mandates of EMA and ECDC

Additionally, the EU further broadened the mandate of the pre-existing institutions, the EMA and ECDC, throughout the pandemic. On the basis of Article 168(4)(c) TFEU, the role of the EMA was strengthened through Regulation 2022/123/EU. Its mandate now includes the following under Article 1:

> '(a) preparing for, preventing, coordinating and managing the impact of public health emergencies on medicinal products and on medical devices and the impact of major events on medicinal products and on medical devices at Union level;
>
> (b) monitoring, preventing, and reporting on shortages of medicinal products and on shortages of medical devices;
>
> (c) setting up an interoperable information technology (IT) platform at Union level to monitor and report on shortages of medicinal products;
>
> (d) providing advice on medicinal products that have the potential to address public health emergencies
>
> (e) providing support for the expert panels provided for in Article 106(1) of Regulation (EU) 2017/745.'

32 Providing an analysis of the Regulation Daniel Alin Olimid and Anca Parmena Olimid, 'Accuracy of Information, Data and Health Resilience: An Analytical Study of the Regulation (EU) 2022/2371', Revue des Sciences Politiques 77 (2023), 49-61.

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As the competence basis for this is Article 168(4)(c), the competence limit of Article 168(5) TFEU does not apply. Hence, this has facilitated the possibility of more detailed substantive rules, which are now available in the restricted area of medicinal products.

Additionally, EMA is now involved in the Union's assessment of public health risks, as per Article 20 of Regulation 2022/2371/EU.

The role of ECDC in responding to the pandemic remains crucial: In the early days of the Covid-19 pandemic, it was able to provide conclusive data on the spread of the virus.[33] Subsequently, the ECDC was significantly strengthened through Regulations 2022/2370/EU and 2022/2371/EU. Regulation 2022/2370/EU extended its mandate to include protection from cross-border health-threats, still encompassing well-functioning procedures as the aforementioned early warning and response system (now in Article 8). The same applies for Regulation 2022/2371/EU, according to which the ECDC plays a central role in the coordination of the pandemic prevention efforts by the Member States. Its central task here is to assess risks for current and future pandemics, as well as to assess the prevention, preparedness, and response-planning by the Member States every three years as per Article 8 of Regulation 2022/2371/EU, which enables it to issue recommendations to the Member States to adapt their planning.[34]

(3) Vaccine Procurement

Deficits are also been identified with regard to attempts by the EU to increase the production of protective equipment such as masks and respirators. In this respect, the European Commission 'requests'[35] the suppliers to 'increase production without delay'. Only such a non-binding request is possible within the framework of Article 168(2) TFEU, so that nothing more (but also nothing less) than a voluntary agreement on the joint procurement

33 Providing a detailed overview of the involvement of ECDC in the first months of the pandemic Dionyssis G. Dimitrakopoulos and Georgette Lalis, 'The EU's Initial Response to the COVID-19 Pandemic. Disintegration or 'Failing Forward'?, Journal of European Public Policy 29 (2021), 1395-1413 (1399-1400).

34 Maria an der Heiden, Julia Schilling and Ute Rexroth, 'Pandemic Preparedness im Rahmen der Internationalen Gesundheitsvorschriften (IGV): Die Rolle des ÖGD', Public Health Forum 31 (2023), 332-335 (333); with a summary (while still referencing the proposal) Elenor Brooks, Anniek de Ruijter, Scott L. Greer and Sarah Rozenblum, 'EU Health Policy in the Aftermath of COVID-19: Neofunctionalism and Crisis-Driven Integration', Journal of European Public Policy 30 (2023), 721-739 (729).

35 European Commission, Communication from the Commission to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup. The coordinated economic response to the COVID 19 pandemic, COM/2020/112 final, 5.

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of medical equipment via public tenders was launched. In this context, although the Commission could take over the implementation of the procurement procedures, the EU acted on behalf of the Member States, which formally remained the purchasers of the products.[36] In this way, as in the case of vaccine procurement,[37] externally, it is the EU that appears to act, but internally, it is the Member States that decide by consensus, and retain control over the entire process. Once again, responsibility and competence diverge here. This means that from the outset there was a danger that the EU could be held responsible for all mistakes, although internally, it was fully dependent on the involvement and agreement of the Member States; i. e. it could not act independently.

bb) Adding a Financial Framework Through EU4Health

With Regulation 2021/522/EU, the Union has used its coordination competence under Article 168(5) TFEU to support Member States in order to improve human health. In this regulation, the initial tension between the Union's goals and competence becomes apparent in the regulation's preliminary considerations. The Regulation considers:

> '(1) According to Article 3(1) of the Treaty on European Union (TEU), among the aims of the Union is the promotion of the well-being of its peoples.
>
> (2) According to Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.'

Then, rather underwhelmingly, the Regulation is compelled to admit its limited possibilities:

> '(3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of Member States for the definition of their health policies and for the organisation, management and delivery of health services and medical care.'

However, the Regulation provides a framework for such coordination, and, more importantly, from its budget of 5.1 billion euros, provides Member States with significant funds.[38] Thus, while following a coordinative ap-

36 Thym and Bornemann (n. 19), ch. 2, para. 16 with further references.

37 See European Commission, Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank. EU Strategy for COVID-19 Vaccines, COM/2020/245.

38 Brooks, de Ruijter, Greer and Rozenblum (n. 34), 734.

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proach, the Union might have a significant impact on the quality of health of its citizens by the provision of these funds.[39]

cc) Installation of HERA

In addition, the European Health Emergency Preparedness and Response Authority (HERA) has been added to the network and has been fully operational since 2022, building on the experience of the Covid-19 pandemic. HERA is another 'indispensable centrepiece of a strong Health Union' and is intended to provide preparedness for cross-border crises – such as pandemics – in the future, and to take immediate action when such a crisis occurs. This includes, in particular, ensuring the production and supply of medical protective equipment and vaccines. HERA is also intended to ensure better coordination in the event of a crisis by acting as a joint resource control centre for the Member States and EU institutions.[40] Putting this into practice, the EU was able to secure the procurement of vaccines within a very limited timeframe after an Mpox outbreak in 2022.[41] However, as far as binding and harmonising measures are concerned, the proposals continue to be pitted against the competence limit of Article 168(5) TFEU.[42]

dd) Further Crisis Response in the Aftermath of the Covid-19 Pandemic Outside the Scope of Article 168 TFEU

However limited the Union's competences under Article 168(5) TFEU, the EU has put forward a variety of further responses to the Covid-19 pandemic. Considering the findings so far, it does not surprise that major legislation brought forward by the EU lies outside the strict limits of Article 168. The most prominent example of this, of course, is the EU's recovery plan NextGenerationEU based on Articles 162, 175 ff., and 136 TFEU, with the aim of combatting the economic impacts of the Covid-19 pandemic.[43]

39 Further on the economic response to the Covid-19 pandemic Vincent Delhomme and Tamara Hervey, 'The European Union's Response to the Covid-19 Crisis and (the Legitimacy of) the Union's Legal Order, YBEL 41 (2022), 48-82 (54 et seq.); Chih-Mei Luo, 'The COVID-19 Crisis: The EU Recovery Fund and Its Implications for European Integration – a Paradigm Shift', European Review 30 (2021), 374-392.

40 For more details, see Commission Communication, COM/2021/576 final.

41 European Commission, Achievements of the von der Leyen Commission. Overcoming the Covid-19 Pandemic Together and Building a Health Union, 8 March 2024, 2; on the installation of HERA Delhomme and Hervey (n. 39), 58 et seq.

42 As to the reluctance to add additional powers of the Member States Brooks, de Ruijter, Greer and Rozenblum (n. 34), 732.

43 See Christian Calliess, 'Erweiterung und Reform der Europäischen Union', EuZW 34 (2023), 781-788 (783).

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Another example of a yet-to-be-adopted measure tackles the issue of digitalisation and healthcare: The Commission has put forward a proposal for a Regulation on the 'European Health Data Space', aiming to simplify the circulation of health data between the Member States.[44] The Commission bases its proposal on the internal market competence in Article 114 TFEU.

For a full overview of the detailed measures, the Commission has recently published an overview as to the successes of the Health Union until this point.[45]

c) Interim Result

It is clear from the foregoing examples that both the network outlined in the area of European health protection and the proposal for its further development within the framework of the 'European Health Union', must build on the non-binding measures typical for a coordination competence.[46] A ban on harmonisation under Article 168(5), in turn, leaves the Union at the mercy of the voluntariness and consensus between the Member States. From a health policy perspective, the same applies to the proposal for a European vaccination passport. While overall, these developments demonstrate some progress, any further developments are blocked by the competence limit set by Article 168 (5) TFEU. The EU made the best out of the tools available – within the ambit of Article 168 TFEU and without.[47] More detailed and, most importantly, binding action by the EU will require a change in the EU treaties. Following this, a crucial lesson to be learnt from the Covid-19 pandemic is that the ECDC should be strengthened and developed into a 'real' EU health agency, possibly with executive powers, and entrusted by the Member States with the responsibility for crisis preparedness and response. As part of this, the ECDC will be equipped with the ability to provide practical support to Member States in situations such as the Covid-19 pandemic.[48]

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44 European Commission, Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM/2022/197 final.

45 European Commission, Achievements of the von der Leyen Commission. Overcoming the Covid-19 pandemic together and building a Health Union (November 2024, available online).

46 In this regard Christopher Schoenfleisch, *Integration durch Koordinierung?* (Mohr Siebeck 2018), 7 et seq. and 109 et seq.

47 With the same conclusion Martin Rhodes, '"Failing Forward": a Critique in Light of Covid-19', Journal of European Public Policy 28 (2021), 1537-1554 (1544 et seq.).

48 See European Commission, Building a European Health Union: Strengthening the EU's resilience to cross-border health threats, COM/2020/724 final, 5 and 17 et seq. and in detail European Commission, Establishing a European Centre for Disease Prevention and Control, COM/2020/726.

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IV. Health Policy on the Basis of the Internal Market Competence?

The lack of a genuine competence for health policy can also not sufficiently be compensated for through a more expansive use of the EU's internal market competence. The establishment of a common market or 'internal market'[49] has been a core objective of the European Economic Community since it was founded in 1957 and continues to be one of the central objectives of the EU today according to Article 3(3) TEU. Article 26(2) TFEU defines the internal market as 'an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty'. As such, the idea behind an internal market is about the merging of national markets into a single market in which goods and persons can circulate without border controls or other restrictions as freely as possible. The realisation of the internal market is based on two – ideally complementary – strategies, namely 'positive' and 'negative' integration.[50]

1. Positive Integration

Within the framework of positive integration, the European legislator realises the freedom of movement within the internal market through harmonisation. In this respect, the Article 114 TFEU provides the general competence basis for internal market measures. Additionally, there are also specific competences pertaining to free movement of persons (e. g. Article 21 para. 2, Articles 46, 50, 53 TFEU) which allow the EU to harmonise Member States' legislation which may affect the smooth functioning of the internal market.[51] Such legislation includes those aimed at the protection of health during pandemics. In particular Art. 114 TFEU might provide for a potential basis to supplement the limited competence of the EU under Article 168 TFEU. This is because there are respective provisions for the internal market, like

49 This was preceded by the Commission's White Paper on 'Completing the Single Market' of 14 June 1985 (COM/85/310); on this and on the conceptual delimitation Markus Kotzur, 'Article 26 TFEU' in: Rudolf Geiger, Daniel-Erasmus Khan and Markus Kotzur (eds), European Union Treaties (C. H. Beck and Hart 2015), paras 1 et seq.

50 See Fritz W. Scharpf, 'Negative and Positive Integration in the Political Economy of European Welfare States', in: Gary Marks, Fritz W. Scharpf, Philippe C. Schmitter and Wolfgang Streeck, *Governance in the European Union* (Sage 1996), 15-39; Stefan Korte, 'Article 26 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C. H. Beck 2022), paras 10 et seq. and 26 et seq.

51 For more details, see the study by Markus Ludwigs, *Rechtsangleichung nach Article 94, 95 EG-Vertrag* (Nomos 2004).

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Article 9 TFEU coupled with Article 168(1) TFEU, which provide for measures on protecting health, like Article 11 TFEU does concerning environmental policy,[52] Article 12 TFEU on consumer protection policy, and Article 147(2) TFEU on employment policy. These cross-cutting tasks must therefore always be considered for all EU measures in other areas, including in the context of internal market-related legal harmonisation pursuant to Article 114(1) TFEU. This is underlined not the least by Article 114(3) TFEU, which directs the Commission to assume a high level of protection in its proposals for legislative harmonisation with regard to some of these policy areas, such as health protection.

Article 114(1) TFEU in its wording appears to provide a *carte blanche* to the EU to enact 'measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market'. However, it is precisely this wording which leads to recurrent questions about understanding this seemingly no-holds-barred cross-sectional competence vis-a-vis other specific substantive competences conferred upon the EU by the Member States: This is necessary to ensure that alongside the smooth functioning of the internal market, public welfare too can be protected. This is to be done through policies in the areas such as environmental, consumer, and health protection. Also debated is the question of where the 'limitation' on EU competence of health protection under Article 168 TFEU stops, and where the general harmonisation power under Article 114 TFEU begins.

a) Leading Decision on the Tobacco Advertising Ban

The case law of the ECJ on the European tobacco advertising ban throws light on the question about which health related measures can be based on Article 114 TFEU.[53] While the regulation of tobacco and its advertising continues, to this day, to be the subject of inconsequential follow-up judg-

52 Christian Calliess, 'Die neue Querschnittsklausel des Article 6 ex 3 c EGV als Instrument zur Umsetzung des Grundsatzes der nachhaltigen Entwicklung', DVBl 1998, 559-568.

53 ECJ, *Germany v. Council and Parliament*, case no. C-376/98 [2000] ECR I-2247; see also the contributions in Doris König and Dirk Uwer (eds), *Grenzen europäischer Normgebung* (Bucerius Law School Press 2015), 13 et seq.; critically Devika Khana, 'The Defeat of the European Tobacco Advertising Directive: A Blow for Health', YBEL 20 (2001), 113-138; Walter Frenz and Christian Ehlenz, 'Rechtsangleichung über Art. 114 AEUV und Grenzen gem. Art. 5 EUV nach Lissabon', EuZW 22 (2011), 623-626; Sacha Prechal, Sybe de Vries and Hanneke van Eijken, 'The Principle of Attributed Powers and the "Scope of EU Law"' in: Leonard Besselink, Frans Pennings and Sacha Prechal (eds), *The Eclipse of the Legality Principle in the European Union* (Wolters Kluwer 2011), 213-248 (236 et seq., 245).

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ments by the ECJ[54] as well as numerous debates and disagreements in legal scholarship,[55] the first tobacco advertising ban ruling gives a clear and coherent answer to the question of delimitation between the internal market and health policy competence, and should thus be the basis of any further discussion. The decision provides in clear albeit terse terms that other ancillary articles of the TEU may not be used as a legal basis to circumvent the express exclusion of any harmonisation provided under Article 168(5) TFEU. At the same time, however, the ECJ points out that this is not to say that the harmonisation measures adopted on the basis of Article 114(1) TFEU may not incidentally impact the protection of human health. As such, under certain circumstances, health protection may even play a 'decisive role' in the context of the intended measure. The ECJ arrived at this conclusion based on a joint reading of Article 114(3) TEU and the corresponding cross-cutting health policy clause of Article 168(1) TFEU, which obliges the Union institutions to also strive to achieve a high level of health protection in the pursuit of other Treaty objectives. The latter, however, was only deemed to be a 'secondary objective', or incidental, to the main regulation.[56] Against this background, the ECJ then examined the following about the measure in question supposedly based on the internal market competence under Article 114 TFEU:

1. First, whether the measure actually serves to eliminate obstacles to the free movement of goods and the freedom to provide services;[57] and
2. Secondly, whether it actually contributes to the elimination of distortions of competition.[58] Within the framework of this objective of Article 114 TFEU, the ECJ specifically examines whether the distortions of competition which the act seeks to eliminate are justified. If this condition were not met, there would be practically no limits to the competence of the Community legislator.[59]

The ECJ considers this requirement of actually serving to eliminate trade barriers and noticeable distortions of competition in the internal market to be mandatory and therein clarifies that Article 114(1) TFEU contains a general, but not unrestricted, competence to enact harmonisation measures. Any measure that does not fulfil this requirement – as emphasised by the ECJ –

54 Latest addition ECJ, *Poland v. Parliament and Council*, case no. C-358/14, ECLI:EU:C:2016:323, para. 26, 32 et seq. (); also see ECJ, *Ireland v. Parliament and Council*, case no. C-301/06, ECLI:EU:C:2009:68.

55 Critical of recent case law Martin Nettesheim, 'Die Tabak-Urteile des EuGH: Lifestyle-Regulierung im Binnenmarkt', EuZW 27 (2016), 578-581 (580).

56 Werner Berg, *Gesundheitsschutz als Aufgabe der EU* (Nomos 1997), 463 et seq.

57 ECJ, *Germany v. Council and Parliament* (n. 53), paras 95-102.

58 ECJ, *Germany v. Council and Parliament* (n. 53), paras 106-114.

59 ECJ, *Germany v. Council and Parliament* (n. 53), paras 106 et seq.

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must be regarded as a circumvention of Article 168(5) TFEU, which prohibits harmonisation of areas outside the scope of those listed in Article 168(4) TFEU.[60] This leads to the conclusion that the measures intending to combat pandemics such as Coronavirus cannot be based on the internal market competence of Article 114(1) TFEU just because it allows the possibility of harmonisation to the European legislator.

The clear wording of Article 168(5) TFEU and the accompanying conclusions must also apply *mutatis mutandis* to the specific free movement competences under Article 21(2) as well as Articles 46, 50, 53 TFEU. This is illustrated by, for example, Recommendation (EU) 2020/1475 of 13 October 2020, which, pursuant to Article 288(5) TFEU, is non-binding and is explicitly 'only' intended to ensure a coordinated approach or enhanced coordination in case a Member State wishes to take measures to restrict freedom of movement on public health grounds. Concerning the risk of cross-border infection chains, this was in turn supplemented by another Recommendation (EU) 2021/119 dated 1 February 2021.[61]

Thus, with the law on the internal market and the free movement of persons, the EU at best only has an indirect regulatory access to the health and infection control law of its Member States. If, for example, it lays down secondary legislation for the authorisation and distribution of medicinal products or vaccines, it primarily regulates the free movement of goods in the internal market, but at the same time ensures uniform (minimum) standards for the European public good of health protection for the citizens of the Union. In this respect, the aforementioned European Medicines Agency (EMA)[62] is also a supranational regulatory agency that facilitates the EU-wide testing and authorisation of medicines and vaccines and thus establishes common standards.

b) European Vaccination Certificate

Contrary to what has been discussed above, the Commission has relied on Article 21(2) TFEU as legal basis in its proposal submitted on 17 March 2021 for a European vaccination passport (so-called 'digital green passport'). This proposal is likely to encounter a similar objection to the one which was the subject of the ECJ decision on the tobacco advertising ban. On the flip side,

60 Torsten Stein, 'Die Querschnittsklausel zwischen Maastricht und Karlsruhe, in: Ole Due, Marcus Lutter and Jürgen Schwarze (eds), *Festschrift für Ulrich Everling*, vol. II (Nomos 1995), 1439-1453 (1441 et seq.); Kotzur, 'Article 168 TFEU' (n. 18), para. 10.

61 OJ EU L 337, 14.10.2020, p. 3 and OJ EU L 36 I, 2.2.2021, p. 1 respectively.

62 Regulation 726/2004/EC of 31 March 2004 establishing a European Medicines Agency, Official Journal of the EU, no. L 136 of 30 April 2004; on this Orator (n. 29), 142 et seq.

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one could argue that this measure serves to advance the freedom of movement, as its focus is on safe travel during a pandemic, and that health protection is only incidentally affected. Indeed, the Regulation proposes that the results of receiving a COVID-19 vaccination, recovering from a COVID-19 illness, or testing negative should be recorded in a forgery-proof certificate based on uniform criteria. In concrete terms, this certificate can be converted into a QR code that can be presented on paper or a smartphone, just like a train ticket. Overall, it remains unclear whether Article 21(2) TFEU can hold up as competence basis for the vaccination passport.

As an alternative, the vaccination passport could have also been based on the EU's coordination competence under Article 168 TFEU. Indeed, the development of a technical platform that enables the vaccination card databases of the Member States to exchange information with one another, as well as to verify and mutually recognise the 'certificates', can be achieved in this manner. In this respect, the expectation is that Member States will set up national databases and require the testing and vaccination centres, as well as doctors, to upload all relevant data on vaccinations administered, negative test results, and recoveries from the illness. Above all, Member States should remain free to decide for themselves which concrete benefits they might wish to link to the green certificate. On the other hand, if they continue to require travellers holding these certificates to quarantine or undergo additional testing, they will have to notify the Commission, as well as all other Member States, and justify why such additional requirements are necessary.[63]

The fact remains that, despite proposing a Regulation on the legal basis of Article 21 TFEU, the Commission has willingly limited itself to the role of a coordinator/mediator, which is rather in accordance with the coordination competence of Article 168 TFEU. Having acted in this manner, the Commission has cautiously taken into account the potential limitations to its competence and skilfully avoided a potential rebuke by the ECJ similar to the first decision on the ban on tobacco advertising.

c) Interim Result

As a result, the EU's role in the area of health and infection control can at best be described as that of having indirect regulatory access over the health

63 See in detail the proposal for a Regulation on a framework for the issuance, verification and acceptance of interoperable certificates for vaccination, testing and recovery with the objective of facilitating free movement during the COVID 19 pandemic (digital green passport), see COM/2021/130 final.

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and infection control law of the Member States via its competences pertaining to the internal market and freedom of movement.

2. Negative Integration

Where positive integration through European harmonisation cannot take place, the EU may resort to negative integration, which is defined by the fundamental freedoms that characterise the internal market. Here, the role of health protection will be limited to that of a justification for national measures such as export restrictions or border controls.[64]

In its *Cassis de Dijon* ruling[65] on the fundamental freedom of free movement of goods, the ECJ established the principle of mutual recognition. According to this principle, any product lawfully manufactured and marketed in one Member State may also be imported into other Member States, where it must, as a rule, be freely marketable. In this way, it has in effect formulated a sort of presumption as to a country-of-origin principle for goods in the internal market, according to which the legal and technical regulations of one Member State are, in principle, to be considered equivalent to those of another. However, the country of destination can rebut this presumption by defending its national legislation on the basis of written and/or unwritten grounds of justification (e. g. according to Article 36 TFEU as well as beyond this, by way of so-called imperative requirements of public interest). If the justification is found valid, i. e. the country of destination justification outweighs the country of origin principle, the said presumption is deemed to be rebutted, with the consequence that there is no mutual recognition, i. e. the internal market remains fragmented.[66] In this matrix of internal market regulation, *national health protection* is one such possible justification in the public interest that can be legitimataly raised and must always be balanced against the European fundamental freedoms, namely, the free movement of goods, services, and persons, bearing in mind the principle of proportionality.[67] This means that the national border controls may be

64 Thym and Bornemann (n. 19), ch. 2, paras. 13 et seq. and 22 et seq. with further references.

65 ECJ, *Cassis de Dijon*, judgment of 20 February 1979, case no. C-120/78 (1979) ECR 649, ECLI:EU:C:1979:42, para. 14.

66 In detail Christian Calliess, 'Europäischer Binnenmarkt und europäische Demokratie: Von der Dienstleistungsfreiheit zur Dienstleistungsrichtlinie – und wieder Retour?', in: DVBl 2007, 336-346.

67 For further details, see Thorsten Kingreen, 'Article 34-36 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, Munich 2022), paras 89 et seq. and 198 et seq.; Markus Kotzur, 'Article 36 TFEU' in: Rudolf Geiger, Daniel-Erasmus Khan and Markus Kotzur (eds), *European Union Treaties* (C. H. Beck and Hart 2015), paras 1 et seq.

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rightfully justified as a measure to curtail the spread of a pandemic. Similarly, export bans imposed by a Member State with the aim of securing its own needs for medical products may also be legitimate, even though these bans interfere with the principle of the free movement of goods (Article 35 TFEU). In this respect, the ECJ has confirmed that '*the need to ensure the regular supply of the country for essential medical purposes may justify an obstacle to intra-Community trade*', provided that the specific measure is proportionate.[68] Within the framework of this balance, the national public good of health protection seen from the lens of the European internal market, mediated via the justification test, acquires the character of a European public good in certain aspects. At the same time however, the internal market remains fragmented as a uniform area without border controls. In the wake of the Covid-19 pandemic, the European Commission has emphasised that 'essential goods needed to contain health risks can reach all those in need'.[69] It could be the case that such an approach to ensuring the availability of protective equipment across Member States through a coordinated strategy, rather than through harmonisation, was done with a view to avoid political interference.[70] However, making the functioning of the internal market contingent upon solidarity or unanimity is neither legally necessary nor compelling.[71]

3. Interim Result

This analysis has demonstrated that the lack of competence for health policy cannot be remedied by the rules on the internal market to achieve proper pandemic protection at the EU level. From the perspective of positive integration, the use of the internal market competence through Article 114 TFEU is clearly limited and subject to the ban on harmonisation under Article 168(5). From the perspective of negative integration, the fundamental freedoms put the need of justification on Member States that impose border controls. However, many of these measures can be justified on the basis of a public health emergency. The overall possibilities of the EU to introduce countermeasures to pandemics are thus extremely limited.

68 ECJ, *The Queen v. Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd.*, judgment of 28 March 1995, case no. C-324/93, ECLI:EU:C:1995:84, para. 37.

69 Communication from the Commission COM/2020/112 final, 13 March 2020, 3.

70 See European Commission/European Council, Common European Roadmap for the Repeal of COVID-19 containment measures, 11.

71 Thym and Bornemann (n. 19), ch. 2 para. 14 with further references.

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V. Filling the Gap Between Promise and Delivery in the Field of Pandemic Protection

As outlined above, a treaty amendment is politically necessary if a discrepancy between treaty objectives and the competences conferred upon the EU is to be resolved. This is the case if there is a gap between European public goods 'promised' in the objectives of the Treaties (and thus recognised by all Member States when signing them) and the corresponding competences to which the EU is entitled, in the course of which the EU either cannot act at all, or cannot act sufficiently.

1. Pandemic Protection as a European Public Good

Considering the above-mentioned shortcomings in European health policy on the one hand, and the criteria applicable in the context of economic theory for the provision of (European) public goods[72] on the other, certain avenues of action at the EU level emerge: While keeping the criteria of subsidiarity in mind, it follows that in policy fields wherein Member States alone cannot act 'sufficiently' to provide for and realise a European public good because of 'policy spill overs', the EU is better equipped to act ('economies of scale').[73] When employed correctly, in these fields EU measures add value[74] and thus (in the language of politics[75]) strengthen European sovereignty or autonomy. Put simply, this advantage is achieved by strength in numbers (of Member States) as well as through joint European action (the so-called 'Brussels effect').[76]

Taking these criteria as a basis, it becomes clear that cross-border pandemic control is a European public good that cannot be sufficiently provided for by a purely coordinating competence alone. This is particularly evident in the lack of a cross-border strategy in the fight against the pandemic: In the course of this shortcoming, the introduction of national controls at the internal borders between the Member States may affect the free movement of persons in the internal market, and thus infringe upon a core right of the EU citizens

72 See Fuest and Pisani-Ferry (n. 12), 7 et seq.
73 Calliess, *Öffentliche Güter* (n. 11), 22 et seq.
74 See Fuest and Pisani-Ferry (n. 12), 7 et seq.
75 See Meseberg Declaration (n. 14).
76 On this, from a legal perspective, Christian Calliess, 'Finanzkrisen als Herausforderung der internationalen, europäischen und nationalen Rechtsetzung', VVDStRL 71 (2012), 113-182 (esp. 175 et seq.); in depth Bradford (n. 15); on this in context: Hartmann and Areizaga (n. 15), 101 et seq.

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(Article 21 TFEU) within the Schengen area. At the same time, however, there are no coordinated controls on entry into the EU from third countries. In light of this fragmentation, which is rooted in the lack of material competence of the Union, there is a real and significant risk of deploying protective measures that lack coherence, efficiency, or proportionality, given the cross-border dimension of the pandemic.[77]

2. Possible Gap Filling in the Field of Pandemic Protection

Based on the foregoing, according to the current allocation of competences in the Treaties, the EU is not sufficiently equipped to take on the fight against pandemics, primarily because the European legislative competences in the area of public health policy are limited under Article 168(4) TFEU. In this respect, there is an evident discrepancy between the goals and tasks of the EU on the one hand, and the actual competences of the EU on the other. While according to Article 168(5) TFEU, the EU should, on the one hand, be able to act to '*combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health*', on the other hand, it may only do so by way of coordinating support measures and not by way of enacting harmonising legislation. As shown above, such coordination competence falls short of ensuring effective cross-border pandemic control and avoiding the collateral damage to European citizens and the European idea as a whole caused by border controls mentioned above.

If one also looks (by way of a systematic interpretation) at the catalogue of EU competences, it becomes clear that the European strategies and measures to combat pandemics such as the Coronavirus can certainly be classified as '*common safety concerns in public health matters*' under Article 4(2)k) TFEU.

It should therefore be noted that to realise the European public good of health protection, there is an *evident discrepancy* between what has been promised in the Treaties versus the actual possibilities of achieving those promises. More specifically, the possibilities for action by the EU legislator are insufficient due to the limits on the form of competences. Based on the foregoing, in order to realise European public goods, Article 168(4) TFEU on its

77 In particular on the coherence requirement in the EU, see Matthias Ruffert, 'Article 7 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C.H. Beck 2022), paras 2 et seq. as well as Christian Calliess, 'Article 13 TEU' in: Christian Calliess and Matthias Ruffert (eds), *EUV/AEUV* (6th edn, C.H. Beck 2022), para. 2; with regard to the restriction of fundamental freedoms: ECJ, Stoß et al. (n. 5); Lippert (n. 5); Hartmann (n. 5).

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own would be insufficient, and therefore, would have to be supplemented by an additional European legislative competence for combating cross-border pandemics.[78]

The above definition of European public goods and the application of the standards of the principle of subsidiarity outlined above (here, in the context of an amendment of the Treaty, 'only' as a political guideline), support the argument in favour of a specific European competence in fighting pandemics. Since a pandemic does not stop at borders and spreads across Europe as it does globally, the fact that a common European response will provide added value with regard to prevention and control is decisive. At the same time, this would ensure that the reimposition of national border controls, which restricts the functioning of the internal market and the Schengen area, would no longer be necessary and could only be justified in extreme or exceptional cases, such as, in the face of complete inaction on the part of the EU or an obviously ineffective European strategy. However, in order not to prevent the Member States from doing 'more', in the sense of achieving the right balance between the principles of solidarity and subsidiarity,[79] and attaining cooperation based on the division of labour, the possibility of strengthening protection by way of national action would have to be granted in the Treaty. This would allow decentralised action above and beyond what can be achieved through European harmonisation.

Against this background, in April 2021, I had proposed an amendment to the European health competence of Article 168(4) TFEU by a new letter d), which ran as follows:[80]

> 'Measures for the early notification, monitoring and control of serious cross-border health threats, in particular in the event of pandemics. These measures shall not prevent Member States from maintaining or adopting reinforced protective measures where these are necessary.'

As already illustrated above, due to the systematic position of Article 168 (4), the prohibition of harmonisation for the field of pandemic protection in

78 Considering but disregarding the necessity of a treaty change Delhomme and Hervey (n. 39), 59; also promoting the necessity of a treaty change to add competences in the field of pandemic control Juuso Järviniemi, Robert Scholz and Kalojan Hoffmeister, 'From COVID-19 Towards a European Health Union: Proposals for Treaty Reform on Health', 2022, available at: <https://jef.eu/wp-content/uploads/2022/06/From-COVID-19-towards-a-European-Health-Union-Proposals-for-Treaty-reform-on-health.pdf>, last access 12 November 2025.

79 Calliess (n. 11), 'Subsidiaritäts- und Solidaritätsprinzip', 185 et seq. with further references.

80 First published in Christian Calliess, 'Braucht die Europäische Union eine Kompetenz zur (Corona-) Pandemiebekämpfung', NVwZ 40 (2021), 505-511 (511).

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Article 168 (5) would no longer apply so that the EU would gain a genuine legislative competence in the field of pandemic protection.

Very similar to this is the wording proposed in the draft report on proposals of the European Parliament for the amendment of the Treaties (2022/2051 (INL)) submitted by the Committee on Constitutional Affairs on 22 August 2023:

> 'Measures for the early notification, monitoring and management of serious cross-border threats to health, in particular in the event of pandemics. These measures shall not prevent Member States from maintaining or adopting reinforced protective measures where these are imperative.'

The draft report was adopted by a narrow majority on 22 November 2023. The European Council must now decide whether to open the Constitutional Convention according to Article 48 TEU. In its conclusions of 15 December 2023 (EUCO 20/23), the Council emphasised that it will address the issue of internal reforms at its next meetings, with a view to adopting conclusions in the summer of 2024.

Such an addition to the competences would – as has been shown above – not least also be necessary for the realisation of an effective 'European Health Union' as well as the accompanying legal, financial, and personnel strengthening of the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). This is because, according to the principle of conferral, agencies can only be established within the scope of the Treaties (Article 5(2) TEU) and, have clearly defined executive powers that are subject to the control of the ECJ.[81] Their work could, moreover, be complemented by the establishment of a new agency modelled on the US Agency for Advanced Biomedical Research and Development (BARDA).

3. Ways of Closing Gaps in the Area of Pandemic Protection

Under certain conditions, the simplified Treaty Amendment Procedure (Article 48(6) TEU) can be deployed to supplement competences. In the past, this is how a new paragraph 3 was added to Article 136 TFEU to legitimise the European Stability Mechanism (ESM) in the context of the rules of Economic and Monetary Union.[82] However, since the proposed amendment

81 ECJ, *United Kingdom v. European Parliament and Council*, case no. C-270/12, ECLI:EU:C:2014:18; in detail Orator (n. 29), 185 et seq. and 459 et seq.

82 On this, Christian Calliess, 'Perspektiven des Euro zwischen Solidarität und Recht – Eine rechtliche Analyse der Griechenlandhilfe und des Rettungsschirms, Zeitschrift für europarechtliche Studien, ZEuS 14 (2011), 213-282. ZEuS 2011, 213 (275 et seq.); Christian Calliess, *Die neue Europäische Union nach dem Vertrag von Lissabon*, 2010, 90 et seq.

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would extend the EU's competences, the ordinary Treaty Amendment Procedure pursuant to Article 48 (2) and (3) TEU without setting up a convention may have to be resorted to. Every Ttreaty amendment requires the consent of all Member States (see Article 48 para. 4 and para. 6 TEU).[83]

If such a consensus cannot be achieved, then the mechanism of enhanced cooperation (Article 20 TEU, 326 et seq. TFEU) – often referred to as 'coalition of the willing' – can be considered as a strategy to equip the EU with more expansive possibilities in the field of pandemic protection at least in the participating Member States.[84]

If neither of these mechanisms are successful, a specific treaty under international law between the willing Member States – as was done for example with the European Fiscal Treaty of 2012[85] – may be considered as the last resort.

VI. Conclusion

The Covid-19 pandemic made it painfully obvious that the EU only possesses a coordinating competence in the area of health policy and is therefore dependent on the consensus and cooperation of all Member States in deploying its measures. At the same time, only a common European strategy can avoid border controls and ensure effective measures in dealing with the pandemic. Against this background, there are important factual and legal arguments in favour of changing the wording of Article 168(4) TFEU, as proposed above, to include the combatting of pandemics, and thus introduce a genuine legislative competence of the EU. The systematic position of such an amendment in Article 168(4), in turn, would mean that the prohibition of harmonisation according to Article 168(5) TFEU would no longer apply. The wording proposed above in compliance with the ideal of subsidiarity attempts to find a balance between binding European measures and Member State flexibility: On the one hand, it can resolve the obvious discrepancy between European task and competence, as described above, by enabling a common European strategy through which the reimposition of national

83 Jean-Claude Piris, The Future of Europe (Cambridge University Press 2012), 106 et seq.

84 Matthias Ruffert, 'Article 20 EUV' in: Christian Calliess and Matthias Ruffert (eds): *EUV/AEUV* (6th edn, C. H. Beck 2022, paras 1 et seq.; in the context of a reform of the EU: Christian Calliess, 'Szenarien für die EU der Zukunft' in: Gregor Kirchhof, Mario Keller and Reiner Schmidt (eds), *Europa in Vielfalt geeint!, 30 Perspektiven zur Rettung Europas vor sich selbst* (C. H. Beck 2020), 263-296 (281 et seq.).

85 For further details see Christian Calliess, 'From Fiscal Compact to Fiscal Union? New Rules for the Eurozone' in: Cambridge Yearbook of European Legal Studies 14 (2012), 101-117.

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border controls may be avoided while ensuring effective measures for attaining the European public good of health during a pandemic. At the same time, such a strategy should be deployed – in accordance with the principles of subsidiarity and proportionality – in an open manner that leaves room for the necessary flexibility and gives leeway to the Member States, should they wish to go beyond the common European measures.

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Legal Preparedness and the European Health Union

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Abstract

The pandemic has made clear the absolute need to coordinate Member States' action on health matters and to create a supranational health governance capable of anticipating and responding to health crises. The attention towards legal preparedness in the context of public health emergencies is well reflected in the post-pandemic acts adopted by the European Union (EU) legislator. This contribution aims at singling out the most prominent aspects of the (still ongoing) reform process with a view to assess the efficiency and coherence of the overall system of emergency management in light of the objectives of the European Health Union and the new EU Global Health Strategy.

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Keywords

European Health Union – Public Health Emergency – Health Governance Legal Preparedness – Capacity Building – Cross Border Health Threats

I. Preliminary Remarks

The pandemic has made clear the absolute need to coordinate Member States' action on health matters, to create a supranational health governance capable of anticipating and responding to health crises, and to share skills, knowledge and expertise across the European Union and beyond. These objectives are at the heart of the European Health Union[1] but also pivotal elements of the new EU Global Health Strategy.[2] Indeed, notwithstanding the limited competences of the Union in the field of public health, the shortcomings in terms of preparedness and response capacity emerged during the sanitary crisis have been promptly addressed by the EU legislator in the immediate aftermath of the pandemic. As a consequence of man-made or natural disasters, the proliferation of health emergencies in the last decades has brought to the forefront – at least in democratic societies – the need to be legally prepared to prevent, respond and overcome the ensuing crises.

The attention towards legal preparedness as a 'crucial sub-category of public health emergency preparedness'[3] was already well-reflected in the EU legal order, but COVID-19 undoubtedly highlighted regulatory shortcomings that needed to be addressed. This paper aims to assess the scope and possible added value of the new post-pandemic framework. For present purposes, the following acts are particularly noteworthy (European Health Union Package): the Decision establishing the Health Emergency Preparedness and Response Authority (HERA),[4] Regulation 2022/123 on a reinforced role for the European Medicines Agency (EMA) in crisis prepared-

1 The need for a true European Health Union in which Member States work together to detect, prepare, and respond collectively was advocated by President of the Commission Ursula von der Leyen in her State of the Union Speech of 2020.

2 Communication from the Commission, 'EU Global Health Strategy – Better Health for All in a Changing World', COM/2022/675 final 2022.

3 Stefania Negri, Sandro Bonfigli, Emanuele Cesta and Giacomo Di Federico, Strengthening Legal Preparedness and Response Within the Global Health Emergency Framework: the Role of the GHSA Legal Preparedness Action Package, Journal of Global Health Law 1 (2024), 88-105 (90).

4 Commission Decision of 16 December 2021 establishing the Health Emergency Preparedness and Response Authority, OJ 2021, C 393I/3.

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ness,[5] Regulation 2022/2370 extending the mandate of the European Centre for Disease Prevention and Control (ECDC),[6] Regulation 2022/2371 revamping the legal framework on serious cross-border threats to health,[7] Regulation 2022/2372 on measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level,[8] and the amended Decision 1313/2013 on the Union Civil Protection Mechanism (EUCPM).[9]

After briefly recalling the role of law in combating cross-border threats in the European Union (Section II.), this contribution will focus on health governance and response capacity resulting from the European Health Union package (Section III.). Subsequently, the main features of the post-pandemic EU legislation will be singled out and assessed against the need for greater preparedness when the next pandemic strikes (Section IV.). Some final remarks on the effectiveness, *rebus sic stantibus*, of the post-pandemic EU legal framework and future perspectives will conclude (Section V.).

Before proceeding, however, a caveat is needed. This contribution will not tackle the need to regulate in compliance with the rule of law,[10] ensuring the protection of fundamental rights and the subsistence of adequate political

5 Regulation 2022/123/EU of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ 2022 L 20/1.

6 Regulation 2022/2370/EU of 23 November 2022 amending Regulation 851/2004/EC establishing a European centre for disease prevention and control, OJ 2022 L 314/1.

7 Regulation 2022/2371/EU of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU, OJ 2022 L 314/26.

8 Regulation 2022/2372/EU of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, OJ 2022 L 314/64.

9 Regulation 2021/836/EU of 20 May 2021 amending Decision No. 2013/1313/EU on a Union Civil Protection Mechanism, OJ 2021 L 185/1.

10 See, inter alia, International Development Law Organization, *Preventing Pandemics through the Rule of Law: Strengthening Countries' Legal Preparedness for Public Health* Emergencies (IDLO 2023); Global Health Law Consortium, *The Principles and Guidelines on Human Rights and Public Health Emergencies* (2023) and European Parliament, 'The Impact of Covid-19 Measures on Democracy, the Rule of Law and Fundamental Rights in the EU', PE 651.343, 23 April 2020, all accessible online. In legal literature, see also Filipe Brito Bastos and Anniek De Ruijter, 'Break or Bend in Case of Emergency?: Rule of Law and State of Emergency in European Public Health Administration', European Journal of Risk Regulation 10 (2020), 610-634 and Joelle Grogan, 'COVID-19, The Rule of Law and Democracy. Analysis of Legal Responses to a Global Health Crisis', Hague Journal on the Rule of Law 14 (2022), 349-369. On the admissibility under EU law of national restrictive measures issued during the sanitary crisis, see also ECJ, *Nordic Info BV v. Belgium*, judgment of 5 December 2023, case no. C-128/22, ECLI:EU:C:2023:951.

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debate during health emergencies[11]. These aspects are indispensable for the legitimacy of Union law,[12] and are addressed elsewhere in this special issue.[13]

II. The Role of Legal Preparedness in Public Health Emergencies

Legal preparedness facilitates prevention, detection, and rapid response to public health emergencies in accordance with international standards.[14] According to the Global Health Security Agenda (GHSA), 'In the context of public health emergencies, legal preparedness is the capability to map, develop, refine, and implement the use of legal instruments across sectors to help to prevent, detect, react, and respond to and recover from infectious disease threats'.[15] The GHSA effectively brings together many of the actors that operate on the international scene advocating multisectoral awareness, the development of technical tools, capacity building through training, as well as the adoption of legal benchmarks to support the process of preparedness and response to public health emergencies.[16]

Although health is eminently a state responsibility, there is a growing attention towards legal preparedness at the global[17] and regional level, includ-

11 See inter alia Annalisa Volpato, Mariolina Eliantonio and Kathryn Wright, 'Transparency and Participation in the Face of Scientific Uncertainty: Concluding Remarks', European Journal of Risk Regulation 14 (2023), 371-381. It is also worthwhile noting that the General Court has recently annulled the European Commission's decision to withhold text messages exchanged between Commission President Ursula von der Leyen and Pfizer CEO Albert Bourla (General Court, *Stevi and The New York Times v. Commission*, judgment of 14 May 2025, case no. T-36/23, ECLI:EU:T:2025:483). See further Pielpa Ollikainen, 'Inconsistent and Imprecise Explanations: NYT v. Commission, Transparency, and the Search for Lost Documents', European Papers 10 (2025), 451-462.

12 Vincent Delhomme and Tamara Hervey, 'The European Union's Response to the Covid-19 Crisis and (the Legitimacy of) the Union's Legal Order', YBEL 41 (2022), 48-82 (48).

13 See in this special issue Christian Calliess, 'Filling the Gap in the Health Policy of the European Union (EU) – Lessons Learned from the Corona Crisis (Covid-19 Pandemic) –, HJIL 85 (2025), 1045-1074.

14 On the origin, development and reach of the concept of legal preparedness, see further Georges C. Benjamin and Anthony D. Moulton, 'Public Health Legal Preparedness: A Framework for Action', Journal of Law, Medicine and Ethics 36(S1) (2008), 13-17.

15 Legal Preparedness Action Package, *Defining Legal Preparedness in the Context of Public Health Emergencies*, Official Website of the Global Health Security Agenda. On the importance of global health lawyers supporting the development of this young field of law, see also Roojin Habibi, '"Someone Call a Global Health Lawyer!": Global Health Law as an Emerging Community of Practice', Journal of Global Health Law 1 (2024), 71-87.

16 GHSA is an international group that brings together more than seventy countries and several international organisations. A full list of the members is available on the Official website of GHSA <https://globalhealthsecurityagenda.org/>, last access 12 November 2025.

17 In this regard, the reader is referred to Gian Luca Bussi, 'The COVID-19 Pandemic and the Development of Global Health Law: Managing Crises or Achieving Structural Changes?', Journal of Global Health Law 1 (2024), 8-25.

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ing the European Union and the African Union.[18] The health package presented by the Commission in November 2020 begins by stating that there should be 'a strengthened framework for cross-border cooperation against all health threats in order to better protect human lives and the internal market and to maintain the highest standards in terms of protection of human rights and civil liberties'.[19]

The lack of a sound legal framework is broadly acknowledged in the reform package,[20] and ultimately justifies the adoption of more stringent rules on surveillance, preparedness, early warning, and response during public health emergencies, as well as stronger powers for the main actors, namely EMA and the ECDC. COVID-19 brought to the forefront some central questions that needed to be tackled at the national level, but also at the EU level: is there an *ad hoc* regime for public health emergencies? Which subjects of the system are legitimised to proclaim a state of emergency? When can the applicable regime be activated? What kind of coordination is ensured between public agencies? Are surveillance and early warning mechanisms for shortages of medicinal products and medical devices in place? How is access to the protective equipment and medical supplies actually guaranteed?

As will be seen shortly hereafter, the post-pandemic legal framework under consideration addresses these concerns in the attempt to establish greater legal preparedness through a solid framework to prevent, detect, and respond to cross-border health threats.[21] Although the overall efficiency of the system could certainly be improved, it can hardly be doubted that the legal instruments developed in the immediate aftermath of the crisis offer the relevant institutional actors new and more effective ways of shaping the

18 In December 2020, a new platform was created to enable stakeholders from both continents to exchange ideas, best practices and make recommendations on major challenges affecting both Africa and Europe.

19 European Commission, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM/2020/724 final.

20 See Recital 3 Regulation 2022/123/EU, Recital 3 Regulation 851/2004/EU (as amended by Regulation 2022/2370/EU), and Recital 2 Regulation 2022/2371/EU.

21 An analysis of all the post-pandemic acts relevant during a sanitary crisis falls beyond the remit of this contribution. The plethora of measures is quite impressive for magnitude, including the Regulation 2022/2065/EU of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act), OJ 2022 L 277/1; the revised Schengen Borders Code (COM/2021/891 final); Regulation 2024/2747/EU of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Regulation 2679/98/EC, OJ 2024, 2747; Regulation 2024/1689/EU of 13 June 2024 laying down harmonised rules on artificial intelligence, OJ 2024 L 1689; Regulation 2025/327 of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation 2024/2847/EU, OJ 2025 L 327; and the new pharmaceutical framework to make the EU more resilient, fair and competitive and to ensure timely and equitable access to safe and effective medicines (COM/2023/193 final and COM/2023/192 final).

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Union's public health policy in case of emergencies. The strengthening of the overall capacity to respond to cross-border health threats is particularly important now, with "Russia's illegal war of aggression against Ukraine, rising geopolitical tensions, state-sponsored hybrid and cyberattacks, sabotage targeting critical assets, foreign information manipulation and interference, and electronic warfare".[22]

III. The Health Package Presented by the Commission

In the European Union, the need to respond to serious cross-border health threats (Bovine Spongiform Encephalopathy [BSE], Severe Acute Respiratory Syndrome [SARS], Ebola, Zika, COVID-19) has gradually led to the enhancement of the legal capacity to respond.[23] In that respect, the European Health Union currently rests on three pillars: 1) the new Regulation on the response to serious cross-border health threats, complemented by the decision to create an internal service within the Commission called HERA (Authority for Preparedness and Response) and by a strengthened and extended mandate for EMA and the ECDC; 2) the new Regulation reforming the decision on the Union Civil Protection Mechanism; 3) the Regulation on a framework of measures to be activated in the event of public health emergencies.

As anticipated, we shall now try to single out the distinctive features of the reform process concentrating on health governance and response capacity. Although the purely financial *volet* of preparedness falls outside the remit of this contribution, it is nevertheless worth underlining that in order to implement the health package, the Union and the Member States must find adequate resources: on the one hand, vital support was offered by the Next GenerationEU recovery plan to sustain recovery and favour resilience;[24] on

22 Joint Communication to the European Parliament, the European Council, the Council, the European economic and social Committee and the Committee of the Regions on the European Preparedness Union Strategy, JOIN(2025) 130 final, p. 1.

23 On the constitutional developments in the field of health at the EU level, see Anniek De Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford University Press 2017), 76-79; Markus Frischhut and Scott Greer, 'EU Public Health Law and Policy – Communicable Diseases' in: Tamara Hervey, Calum Young and Louise Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar 2017), 315-346 (318-325) and Tamara Hervey and Jean McHale, *European Union Health Law. Themes and Implications* (Oxford University Press 2015), 30-53.

24 Delhomme and Hervey (n. 12), 55. The Next Generation is based on Art. 122 TFUE, which allows the Council the power to grant financial assistance to a Member State struck by 'severe difficulties caused by natural disasters'. However, the authors correctly note that 'NGEU is not only an emergency instrument, it is here to support "recovery" and "resilience" and the funds allocated will be used for long term objectives that ostensibly have little to do with Covid-19, such as the green and digital transitions sought for the Union's economy'.

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the other hand, one cannot overstate the importance of the EU4Health Programme – 'a vision for a healthier European Union'. With a €5.3 billion budget during the 2021-2027 period, it provides an unprecedented support in health signalling that investment in this area represents a priority for the Union.[25]

1. Health Governance

As far as governance is concerned, the health package strengthens the role and powers of existing bodies, rationalises their internal organisation, creates a new Directorate-General within the Commission and sets up advisory bodies and networks. Proceeding in orderly fashion, the new Regulation on cross-border threats generalises the guidance power of the Health Security Committee (HSC) through the 'adoption of opinions and guidelines, including on specific response measures for Member States for the prevention and control of serious cross-border health threats'.[26] Indeed, the HSC, comprising a representative from each Member State (but with the meetings chaired by a representative of the Commission), is entrusted with a stronger control and supervision function on preparedness and response planning and implementation at the national level, monitoring, early warning and assessment capacity in relation to serious cross-border threats to health. In this respect, suffice it here to mention, on the one side, that the HSC has turned into a forum for regular coordination, as opposed to a 'simple' (occasional) consultation room,[27] and, on the other side, that Member States are now obliged to report to it 'any substantial revision of their national prevention, preparedness and response plan'.[28] Moreover, it should be noted that to secure

25 Regulation 2021/522/EU of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, OJ 2021, 107/1 (EU4Health). See also Decision No. 1786/2002/EC of 23 September 2002 adopting a Programme of Community action in the field of public health (2003-2008) – Commission Statements (budget: EUR 312 million), OJ 2002 L 271/1; Decision No. 1350/2007/EC of 23 October 2007 establishing a second Programme of Community action in the field of health (2008-2013) (budget: EUR 321.5 million), OJ 2007 L 301/3; Regulation 282/2014/EU of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) (budget: EUR 449.3 million), OJ 2014 L 86/1.

26 Regulation 2022/2371/EU (n. 7), Art. 4 para. 3 lit. d).

27 See Decision No. 1082/2013/EU of 22 October 2013 on serious cross-border threats to health and repealing Decision No. 2119/98/EC, OJ 2013 L 293/1, Art. 4 para. 1 and Regulation 2022/2371/EU (n. 7). In this sense, see also Dimitri Eerens, Rok Hrzic and Timo Clemens, 'The Architecture of the European Union's Pandemic Preparedness and Response Policy Framework', European Journal of Public Health 33 (2022), 42-48 (46).

28 Regulation 2022/2371/EU (n. 7), Art. 6 para. 3.

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legitimation, consistency, and coherence, as well as to increase transparency and accountability, the HSC works as a two-tier structure of senior and technical level, with the involvement of the pertinent Union agencies and bodies, as well as of the European Parliament, as observers.[29]

On the other hand, with a view to ensure a real capacity to monitor shortages of medicines and medical devices, the EMA revised mandate envisages two executive steering groups, the Medicine Shortages Steering Group (MSSG) and the Medical Device Shortages Steering Group (MDSSG), responsible for managing problems relating to the supply of medicines and medical devices, respectively.[30] Moreover, under the new mandate, a Single Point of Contact (SPOC) Working Party has been created to support timely and effective monitoring via information sharing between Member States, EMA and the European Commission during major events or public health emergencies.[31]

Similarly, to support the ECDC's epidemiological surveillance, preparedness and response tasks, Member States are called upon to designate a coordinating competent body, a national coordinator, national focal points and operational contact points for public health functions with reporting duties and advisory functions. But it is also worth mentioning the EU Health Task Force (HTF) set up under the reinforced mandate of the ECDC, comprising 'the Centre's staff and experts from Member States, fellowship programmes and international and non-profit organisations'[32] and offering science-based recommendations for prevention, preparedness and response planning.[33]

In addition, as is well known, HERA has been created as a Directorate General of the Commission with the objective to 'strengthen Europe's capa-

29 Regulation 2022/2371/EU (n. 7), Art. 4 para. 1. The HCB HSC is co-chaired by the Commission and the rotating presidency of the Council. The representatives of the Member States each have one vote and the Board deliberates by consensus or, in the lack thereof by a majority of two thirds (Regulation 2022/2371/EU (n. 7), Art. 4 para. 4).

30 To ensure the widest participation, these steering groups involve one observer member of the Patients' and Consumers' Working Party (PCWP) and one observer member from the Healthcare Professionals' Working Party (HCPWP). See Regulation 2022/123/EU (n. 5), Art. 3 para. 2 and Art. 25 para. 1.

31 The working party is based on the pilot SPOC network that the HMA / EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use set up in April 2019.

32 Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No. 851/2004 establishing a European centre for disease prevention and control, Art. 11a.

33 Regulation 851/2004/EC of 21 April 2004 establishing a European Centre for disease prevention and control, OJ 2004 L 142/1 (as amended by Regulation 2022/2370/EU (n. 6)), Art. 5.

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city to prevent and detect health emergencies of a cross-border nature and to respond rapidly to them, ensuring the development, production, acquisition and equitable distribution of key medical countermeasures'. The HERA Board brings together high-level representative from each Member State, as well as representatives from the ECDC and EMA as permanent observers, with a view, *inter alia*, to draw up opinions on threat assessment and monitoring the supply and demand of medical countermeasures.[34] The HERA Board is assisted by the HERA Forum, a group of experts providing scientific and technical expertise.[35] Leaving the more operational aspects to the next section, it is here useful to anticipate that HERA can operate in two different modes: a preparedness mode to steer investment and enhance prevention, and an emergency mode to react to public health emergencies.[36]

As indicated, advisory bodies have also been set up to offer assistance and guarantee evidence-based decisions. This is the case with the Advisory Committee on Public Health Emergencies (ACPHEs) created under Regulation 2022/2371, which includes independent experts in public health and representatives of the ECDC and EMA as permanent observers to offer multidisciplinary support to the HSC on topics ranging from the existence of an emergency at Union level to the formulation of response measures.[37] This is the case, moreover, with the Emergency Task Force (ETF) established in accordance with Regulation 2022/123, and composed of experts from the EMA committees and working parties and from the national clinical-trial authorities, which is entrusted with the task of providing scientific advice and supporting clinical trials.[38]

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34 Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, C(2021) 6712 final. It is interesting to note that the high-level representative from each Member State (with a two-year term, renewable once) is appointed by the Commission on the basis of nominations by the relevant national authorities (Art. 6 para. 1).

35 Two sub-groups assist the HERA Forum: on the one side, the Joint Industrial Cooperation Forum and, on the other side, the Civil Society Forum, Decision C(2021) 6712 final (n. 34), Art. 7.

36 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union, COM/2021/576 final, 1-15 (2).

37 Regulation 2022/2371/EU (n. 7), Art. 24 paras 1 and 2.

38 To ensure proper coordination with Regulation 536/2014/EU of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ 2014 L 158/1, the Clinical Trials Coordination and Advisory Group (CTAG) is also represented (Regulation 2022/123/EU (n. 5), Art. 15 para. 3 lit. e).

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Regulation 2022/2372 on medical countermeasures, on its part, provides for the creation of a Health Crisis Board (HCB) to ensure coordination in the supply of, and access to, crisis-relevant material during an emergency. It comprises a representative of the Commission and one representative from each Member State, with the participation of EMA, ECDC, and the HSC.[39] Its function is to advise and assist the Commission when the situation so requires, most notably on the drafting of a list of crisis-relevant medical countermeasures and raw materials,[40] as well as on the appropriate mechanism to purchase crisis-relevant gear.[41] Moreover, the Regulation on cross-border health threats creates a network of EU reference laboratories for public health and a network for substances of human origin, both operated and coordinated by the ECDC[42] to connect expertise throughout the Union on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.[43]

Likewise, the decision on the EUCPM has been amended to allow for the creation of an EU civil protection knowledge network, a supranational hub connecting first responders, disaster risk managers, centres of excellence, universities and researchers and decision-makers, and matching their needs for expertise and good practices with methodologies, tools, solutions, and resources.[44]

2. Response Capacity

Turning the attention towards response capacity, the updated legal framework enhances instruments and mechanisms designed to prevent, contain, manage, and overcome sanitary crisis. In particular, legal preparedness de-

39 Regulation 2022/2372/EU (n. 8), Art. 5 para. 4.

40 Regulation 2022/2372/EU (n. 8), Art. 7 para. 1. See also Communication from the Commission to the European Parliament, the Council, the European economic and social Committee and the Committee of the Regions - Preparing the EU for the next health crisis: a Medical Countermeasures Strategy, COM/2025/529 final.

41 Regulation 2022/2372/EU (n. 8), Art. 8 para. 1.

42 In the former case, reference laboratories with certain characteristics spelled out in the text of the regulation are designated by the Commission by means of implementing acts; in the latter case each Member State designates the competent authorities responsible for the use of substances of human origin, including transfusion and transplantation (Regulation 2022/2371/EU (n. 7), see Art. 15 para. 1 and Art. 16 para. 3). See also Commission implementing regulation 2024/892/EU of 22 March 2024 designating European Union reference laboratories for certain specific areas of public health, OJ 2024 L 892/1 and Commission Implementing Regulation 2024/2959/EU of 29 November 2024 designating European Union reference laboratories for public health on food- and water-borne bacteria; on food-, water- and vector-borne helminths and protozoa; and on food- and water-borne viruses, OJ 2024.

43 Regulation 2022/2371/EU (n. 7), Art. 15 para. 1.

44 Decision 2013/1313/EU (n. 32) (as amended by Regulation 2021/836/EU (n. 9)), Art. 13.

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mands that specific obligations, viable tools and appropriate procedures are in place, and fully operational.

Based on the pandemic experience, the new measures pursue a double objective.

First, they are intended to increase the ability to gather, share, and process health related data for monitoring, risk assessment, and training purposes. Concretely, this means dedicated services and IT tools. The European Health Union package builds upon the existing services for risk management, surveillance, and preparedness control, such as the Emergency Response Coordination Centre (ERCC), rapid alert mechanisms, like the Early Warning and Response System (EWRS) and the Common Emergency Communication and Information System (CECIS), and technical and communication web-based platforms, such as the European Surveillance System (TESSy) and the Epidemic Intelligence Information System (EPIS). At the same time, it fosters the creation of additional IT tools such as European shortages monitoring platform (ESMP), activated within EMA (with a dedicated Working group),[45] the new Vaccine Monitoring Platform (VMP),[46] governed by a steering group and supported by a joint EMA-ECDC secretariat, the Data analysis and real-world interrogation network (DARWIN EU) to allow and facilitate the collection by EMA and national authorities of reliable and timely real-world evidence from routinely collected electronic health data,[47] and the Advanced Technology for Health Intelligence and Action It System (ATHINA), developed by HERA in collaboration with the recently created European Health and Digital Executive Agency.[48] All these IT tools support monitoring and surveillance through a web of competences and authorities.

The capacity to acquire, exchange, and elaborate data also entails more control by EU institutions and agencies and more notification and reporting duties, not only for the Member States, but also for the industry. To exemplify, if in the preparedness mode HERA is committed, *inter alia*, to collect intelligence in order to assess threats, under EMA's new mandate marketing authorisation holders are bound to offer the Agency all relevant information on

45 Regulation 2022/123/EU (n. 5), Art. 13. The basic version of the European Shortages Monitoring Platform was launched on 28 November 2024. The platform is fully operative (with all functionalities) since 29 January 2025.

46 Regulation 2022/123/EU (n. 5), Art. 20.

47 Regulation 2022/123/EU (n. 5), Art. 20 lit. a).

48 Implementing Decision 2021/173/EU of 12 February 2021 establishing the European Climate, Infrastructure and Environment Executive Agency, the European Health and Digital Executive Agency, the European Research Executive Agency, the European Innovation Council and SMEs Executive Agency, the European Research Council Executive Agency, and the European Education and Culture Executive Agency and repealing Implementing Decisions 2013/801/EU, 2013/771/EU, 2013/778/EU, 2013/779/EU and 2013/779/EU, OJ 2021 L 50/9.

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critical medicinal products,[49] and pursuant to Regulation 2022/2372 economic operators must disclose in a timely manner (within 5 days) to the Commission information concerning their facilities, the actual total production capacity, the expected production output for the following three months and the possible existing stocks of the crisis-relevant medical countermeasures.[50]

Improving monitoring and risk assessment, however, also means standardising the kind and quality of the pertinent data provided to the competent supranational bodies. By means of implementing acts, the Commission is entrusted with the task of developing templates for monitoring supply and demand of crisis-relevant material, 'including production capacity, stockpiles, possible critical aspects or the risk of disruption in the supply chains and purchasing agreements'.[51] In line with the evidence-based approach, the ECDC is to report on communicable disease trends over time pursuant to agreed indicators, harmonised data collection specifications and epidemiological modelling with the use of Artificial Intelligence (AI).[52] More generally, it is among its (new and reinforced) goals to develop, together with the Member States and the Commission, 'preparedness, monitoring and evaluation frameworks', and to elaborate 'indicators for preparedness based on the IHR, in cooperation with the WHO'.[53] The introduction of a Union preparedness plan, elaborated by the Commission in accordance with the International Health Regulations (IHR), has also been accompanied by the desire to detail its structure and content.[54] Additionally, the Member States' reports on prevention, preparedness, and

49 Regulation 2022/123/EU (n. 5), Arts 9 and 10.

50 Regulation 2022/2372/EU (n. 8), Art. 10 para. 2.

51 Regulation 2022/2372/EU (n. 8), Art. 7 para. 1.

52 Regulation 851/2004/EC (n. 33) (as amended by Regulation 2022/2370/EU (n. 6)), Art. 3 para. 2 lit. b). In this respect, privileged access to health data for research and epidemiological aspects (secondary use) in the context of the European Health data space will augment exponentially its assessing ability.

53 Regulation 2022/2370/EU (n. 6), 5 b para. 2, lit. b). The provision also adds that these frameworks and indicators will be discussed within the HSC.

54 Regulation 2022/2371/EU (n. 7), Art. 5. See also the European Preparedness Union Strategy and the Communication from the Commission to the European Parliament, the Council, the European economic and social Committee and the Committee of the Regions – Introducing the Union prevention, preparedness and response plan for health crises, COM/2025/745 final. As is well known, the IHRs have been amended in 2024. For an overview of the relevant changes, see Roojin Habibi, Mark Eccleston-Turner and Gian Luca Burci, 'The 2024 Amendments to the International Health Regulations: A New Era for Global Health Law in Pandemic Preparedness and Response?', Journal of Law, Medicine and Ethics 53(S1) (2025), 47-50 and Ashley Bloomfield and Abdullah Assiri, 'The Updated International Health Regulations: Good News for Global Health Equity', The Lancet 403 (2024), 2761-2762. Concomitantly, a pandemic treaty is being discussed within the WHO and should be adopted in the near future. See further, Alexander Finch et al., 'The Promise and Compromise of the WHO Pandemic Agreement for Spillover Prevention and One Health', The Lancet 405 (2025), 1800-1802. A (still) provisional text of the Pandemic Agreement (12th April) can be found on the WHO website.

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response planning and implementation shall be based on agreed common indicators and include a set of data included in a dedicated template (possibly consistent with the IHR State Parties reporting framework).[55] Similarly, in the pillar dedicated to the EUCPM, the Commission has been empowered to set, in cooperation with the Member States, non-binding Union objectives for disaster resilience in the field of civil protection through recommendations.[56]

Second, the new measures are aimed at enhancing the capacity to acquire and allocate essential goods, raw materials, and human resources that are crucial during an emergency. The formal recognition of emergency situations is perhaps among the most prominent features of the reform. Pursuant to Regulation 2022/2371, the pertinent assessment is the responsibility of the Commission via implementing acts after consulting the ECDC (and other competent agencies) and the ACPHEs.[57] The decision is autonomous (but the Commission must liaise with the World Health Organization [WHO]) and implies the application of a specific legal regime that goes well beyond the variation of the terms of the marketing authorisation for medicinal products and influenza vaccines for human use previously provided for by Decision 1082/2013.[58] To begin with, the measures on medicinal products and medical devices covered by Regulation 2022/123 on the enhanced role of EMA may be activated. *In concreto*, this determines the involvement of the ETF and may lead the Agency to establish a list with the main therapeutic groups of medicinal products required to face the sanitary crisis.[59] Within EMA, the MSSG and the MDSSG are competent to adopt the relevant critical medicines and medical devices lists,[60] and the ETF will perform a systematic scientific assessment of evidence on medicines and issue recommendations on medicines that are not yet authorised.[61]

55 See Regulation 2022/2371/EU (n. 7), Art. 7 and Commission implementing Regulation 2023/1808/EU setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health, OJ 2024 L 234/105. According to the Union prevention, preparedness and response plan for health crises, 'To date, all 30 EU/EEA countries have national prevention, preparedness and response plans in place and reported on their capacities in the first self-reporting exercise in 2023' (p. 10).

56 This is intended to improve the ability of the Union and the Member States 'to withstand the effects of a disaster which causes or is capable of causing multi-country transboundary effects' (Decision 2013/1313/EU (n. 32) as amended by Regulation 2021/836/EU (n. 9), Art. 4).

57 Regulation 2022/2371/EU (n. 7), Arts 23 and 24.

58 Decision 1082/2013/EU (n. 27).

59 Regulation 2022/123/EU (n. 5), Art. 6.

60 Regulation 2022/123/EU (n. 5), Arts 7 and 22.

61 More precisely, the members of the ETF comprise representatives of the scientific committees, working parties and staff of the Agency, as well as representatives of the Clinical Trials Coordination and Advisory Group established in accordance with Regulation 536/2014/EU (n. 38) and clinical trial experts on behalf of the national authorities competent for medicinal products (Regulation 2022/123/EU (n. 5), Art. 15 para. 3).

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In addition, it is possible to have recourse to the mechanisms set out in the Medical Counter Measures Regulation, with the involvement of the HERA in crisis response mode.[62] Most notably, the Commission, after having sought the advice of the Health Crisis Board, can draw up (by means of implementing acts), a list of crisis-relevant medical countermeasures and raw materials,[63] and purchase crisis-relevant medical countermeasures and raw materials under one of the available instruments, namely the financial support foreseen in Regulation 2016/369, the joint procurement procedure established in Regulation 2022/2371 – with possible restrictions to parallel negotiation activities by the participating countries for the countermeasure in question – or a European Innovation Partnerships contemplated in Regulation 2021/695, but also following an autonomous procurement mode.[64] Moreover, the Commission can draw up and regularly update an inventory of crisis-relevant medical countermeasure production and production facilities; an inventory that can be extended to crisis-relevant consumables, medical devices, equipment and infrastructure.[65] When there is a risk of a shortage of such material, the Commission is entitled to adopt 'specific measures to ensure the efficient reorganisation of supply chains and production lines and utilise existing stocks to increase the availability and supply of crisis-relevant medical countermeasures'.[66] Furthermore, it should not be forgotten that in order to reserve manufacturing capacities and obtain a priority right for manufacturing of vaccines in case of a future public health emergency, the Commission and the European Health and Digital Executive Agency, using HERA's budget in accordance with the 2022 working programme, have established the EU FAB Programme, 'a network of manufacturing facilities reserving capabilities for the production of vaccines'.[67]

As mentioned, human resources are another crucial element of the overall system of prevention, preparedness, and response, and an essential component of the Union plan and the national plans. Hence, investing in capacity building through recruitment and training is of the essence. HERA, EMA,

62 See to this effect Regulation 2022/2372/EU (n. 8), Recital 4.

63 Regulation 2022/2372/EU (n. 8), Art. 7 para. 1.

64 Regulation 2022/2372/EU (n. 8), Art. 8. Very significant is the power granted to the Commission to conclude purchase contracts after having carried out on-site visits to the economic operators concerned (i. e. potential suppliers).

65 Regulation 2022/2372/EU (n. 8), Arts 10 and 11.

66 Regulation 2022/2372/EU (n. 8), Art. 12. The Commission will have to seek the agreement of the Member States and consult with the economic operators concerned.

67 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions State of Health Preparedness Report, COM/2022/669 final, 1-21 (17).

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ECDC, and HERA (and more generally the Commission[68]) are all involved in training activities, with a particular attention towards international standards (WHO), the One Health approach, digital literacy, multi-disciplinarity and inter-specialty (e. g. for cancer healthcare professionals), vulnerable groups and non-discrimination, but also towards making healthcare professions more appealing. These activities are funded with EU money and should promote a leadership, patient-centred, whole-of-government/whole-of-society approach.[69] In addition to traditional training activities, the exchange of health professionals and public health personnel and even the temporary secondment of personnel between Member States, candidate countries or Union agencies and bodies is envisaged, possibly in the framework of Union-supported programmes with the contribution of health professional organisations.[70]

Under the EUCPM, instead, the HTF will complement and integrate the capacities of the European Medical Corps and will also be able to contribute to the relevant mechanisms of the WHO. Furthermore, quite tellingly, in April 2023 the Commission allocated EUR 106.2 million to eight countries

68 According to Art. 11 para. 1 of Regulation 2022/2371/EU (n. 7): 'The Commission may organise training activities, in close cooperation with the relevant Union agencies and bodies and professional health organisations and patient organisations, for healthcare staff, social service staff and public health staff in the Member States, in particular interdisciplinary One Health training, including on preparedness capacities under the IHR.' In addition, the reformed Decision 2013/1313/EU (n. 32) entrusts the Commission with the task of developing and managing a training and exercise programme on disaster prevention, preparedness and response aimed at civil protection personnel as well as emergency management personnel, including health professionals. This programme, aimed at improving complementarity between the resources made available by the Member States upon request (Art. 9), the resources of the European Civil Protection Pool (Art. 11) and the resources deployed under rescEU (Art. 12), 'includes joint courses and a system for the exchange of expertise in the field of emergency management' (Art. 13 para. 1 lit. a)).

69 For reasons of cost-efficiency and sustainability, as well as to increase participation, training can also take place at a distance and the pertinent administrations are invited to promote the dissemination of the knowledge acquired by the participants in the national context (Regulation 2022/2371/EU (n. 7), Art. 11 paras 1, 2 and 4). More detailed rules concerning the organisation of training activities are left to an implementing decision of the Commission (Art. 11 para. 6). The training activities are organised in cooperation with the relevant Member States and the ECDC (Art. 11 para. 3).

70 See Regulation 2022/2371/EU (n. 7), Art. 11 para. 5 and Decision 2013/1313/EU (n. 32) (as amended by Regulation 2021/836/EU (n. 9)), Art. 13 para. 1, lit. a). The need for adequate training programmes has also been stressed in legal literature. See, for instance, Mariana Peyroteo et al., 'European Health Information Training Programme: a Sustainable Strategy for Strengthening Capacity in Health Information', European Journal of Public Health 34 (2024), 35-42 and Anu-Marja Kaihlanen et al., 'Continuing Education in Digital Skills for Healthcare Professionals – Mapping of the Current Situation in EU Member States', International Journal of Health Policy and Management 13 (2024), 1-7.

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to develop the new rescEU EMT (Emergency Medical Team) capacity,[71] and thereby enhance emergency medical support to populations affected by natural or man-made disasters.[72]

IV. Emergency Management, Response Capacity and Resources: the Main Features of the Post-Pandemic Reform Process

Especially following the entry into force of the Lisbon Treaty, it is possible to observe the emergence of an elaborate and complex network of bodies, mechanisms, and procedures aimed at facilitating risk identification, sharing of epidemiological data, threat assessment, coordination of response and cooperation in the implementation phase. However, it should be borne in mind that pursuant to Article 168(7) Treaty on the Functioning of the European Union (TFEU), the Union is bound to 'respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care', which deeply affects the reach and scope of the European Health Union.[73]

That being said, the distinctive features of the European Health Union package all revolve around the three main elements of the Union prevention,

71 More specifically, these are: Belgium, France, Germany, Italy, Luxembourg, Portugal, Romania, and Turkey. According to the consolidated version of Decision 2013/1313/EU (n. 32), it is up to the Commission to define, by means of implementing acts, the rescEU resources taking due account of the shortcomings at Union level in the area of emergency health response (Decision 2013/1313/EU (n. 32), Art. 12 para. 2, as amended by Regulation 2021/836/EU (n. 9)).

72 The new rescEU EMT will comprise three Emergency Medical Teams with seventeen specialised care teams: from intensive care to advanced diagnostics, from maternal and child support to mental health support, from orthopaedic care to oxygen supply. rescEU EMT is expected to become (gradually) operational in 2024, complementing the fifteen Emergency Medical Teams that make up the European Medical Corps of the European Civil Protection Pool.

73 Mary Guy, 'Towards a European Health Union: What Role for Member States?', European Journal of Risk Regulation 11 (2020), 757-765 (759). In this regard, one should bear in mind that there is no separate Council of Ministers health formation, which means that EU action in this field does not necessarily imply the involvement of the relevant ministerial departments (Anniek de Ruijter and Eleanor Brooks, 'The European Health Union: Strengthening the EU's Health Powers?', Eurohealth 28 (2022), 47-49 (49)). In turn, the European Parliament has (albeit only recently) created a Committee on Public Health <https://www.europarl.europa.eu/committees/en/sant/home/highlights>, last access 24 November 2025. Vincent Delhomme, 'Where Market and Health Collide: The Limits of Policy Experimentation in EU Prevention of Non-Communicable Diseases and Tobacco Control', HJIL 85 (2025), 1095-1117; Markus Frischhut, 'The Missing Keystone of the "European Health Union". Historic Development, *status quo* and Ideas *de lege ferenda*', HJIL 85 (2025), 1011-1043.

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preparedness, and response plan, i. e. governance, capacities, and resources. The enhancement of the Union's ability to react to a cross-border health threat strongly depends on standardisation, expertise, digitalisation, and international cooperation. These are the main priorities resulting from a more attentive reading of the measures under consideration. Credible risk assessment postulates the existence of comparable data, common indicators, and agreed benchmarks. An evidence-based approach to decision making, especially in emergency situations, demands the involvement of strategic economic operators, experts, patient and healthcare professions associations in the decision-making process. The secure, rapid, and reliable processing of large amounts of data requires the use of IT tools and AI. Finally, since the focus is on cross-border health threats, special attention needs to be paid to the international context and to the coordination with the WHO.

The analysis of the European Health Union package suggests that, in line with the concept of legal preparedness outlined above, the emerging institutional architecture designed to handle future pandemics is based on synergic multi-sectoral cooperation between political and technical bodies for intelligence gathering, on digital platforms, big data, and machine learning for performance evaluation and on decentralised networks for the collection of specific information. All this through a system of governance that, far from entailing a transfer of sovereignty to the centre, rests on the joint exercise of competences at the centre. This process of institutional centralisation has wittily been labelled 'expansive unification' and effectively allows the Member States to retain their responsibility in the field of public health.[74] Besides form being represented in the various agencies and bodies, they have a strict control over the application of the relevant measures. As a matter of law, sensitive matters such as the state of implementation of the national preparedness plans and their coherence with the Union plan or the list of 'the categories of personal data that may be exchanged for the purpose of the coordination of contact-tracing measures'[75] have been left to delegated acts, while implementing acts are adopted pursuant to the examination procedure.[76]

Given the plethora of EU acts dealing with prevention, preparedness, and response to public health emergencies, there is a risk of normative stratification

74 Maurizio Ferrera, Anna Kyriazi and Joan Miró, 'Integration Through Expansive Unification: The Birth of the European Health Union', Publius 54 (2024), 1-26 (2).

75 Regulation 2022/2371/EU (n. 7), Art. 28 para. 6, lit. b).

76 Regulation 2011/182/EU of 16 February 2011 on laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ 2011 L 55/13, Art. 5. Interestingly enough, the European Health Union package contemplates two ad hoc committees: the Committee on serious cross-border threats to health established (Regulation 2022/2371/EU (n. 7), Art. 29) and the Health Crisis Committee (Regulation 2022/2372/EU (n. 8), Art. 14).

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and inconsistency. These are perhaps the most evident *vulnera* of the current legal framework. Of course, this state of affairs is closely related to the principle of conferral, which forces the EU legislator to follow a silos-like regulatory approach where the scope and form of action, and the involvement of the Parliament, effectively depend on the applicable legal bases. To be sure, the cross-border health threats Regulation and the revised mandate of the ECDC are grounded on Article 168(5), the amended Decision on the EUCPM is founded on Article 196 TFEU, the reinforced mandate of EMA relies on Arts 114 and 168(4), lett. c, TFEU and the counter-measures Regulation on Article 122 TFEU. Whilst the latter entitles the Council to act single handedly, the other legal basis contemplate the ordinary legislative procedure. However, the fact remains that outside the exceptions concerning the safety of medicinal products and medical devices, the Union is prevented from harmonising national laws and regulations in the field of public health protection.[77]

In truth, 'the discrepancy between the European task and competence' gives rise to *ultra vires* concerns when it comes to prevention, preparedness, and response during pandemics.[78] Indeed, some provisions, like those on the elaboration of templates and evaluation methods could be questioned under (a strict reading of) the principle of conferral. In this sense, it should not go unnoticed that in its recent resolution on proposed amendments to the current treaties, the European Parliament advocates the conversion of public health into a shared competence and a modification of Article 168(4), lett. c).[79] This would (formally) allow the Union to set common indicators for healthcare systems and adopt (minimum) harmonised rules for 'early notification, monitoring and management of serious cross-border threats to health, in particular in the event of pandemics'.[80]

V. Final Remarks

Over the last two decades, the Union has equipped itself with an increasingly comprehensive framework of rules applicable in the event of health

77 See Art. 4 para. 2 lit. k), Art. 6 lit. a), Art. 168 para. 5 and Art. 196 para. 2 TFEU.

78 Claudia Seitz, 'The European Health Union and the Protection of Public Health in the European Union: Is the European Union Prepared for Future Cross-Border Health Threats?', ERA Forum 23 (2023), 543-566 (561-562). The author advocates the inclusion of a fourth 'exception' in the list of Art. 168 para. 4 lit. c), namely: 'measures to prevent, control and combat communicable diseases with pandemic potential'.

79 Proposals of the European Parliament for the amendment of Treaties, European Parliament Resolution of 22 November 2023 on proposals of the European Parliament for the amendment of the Treaties (2022/2051(INL)), C/2024/4216, pt. 14.

80 Proposals of the European Parliament (n. 79), Amendment No. 150.

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emergencies. After several health crises of a cross-border nature, three revisions of the treaties (Treaty of Amsterdam, Treaty of Nice, and Treaty of Lisbon) and the transfer of more competences to the Union in the field of public health in emergency contexts of a cross-border nature, it is now possible – more than 70 years after the failure of the European Health Community[81] – to finally imagine a 'strong' European Health Union.[82]

This contribution has tried to single out the most prominent aspects of the (still ongoing) reform process, taking into consideration the legal challenges posed by public health emergencies at the global level. In this respect, supranational action can be said to have succeeded in tackling all the main issues raised by the conceptual framework on legal preparedness. Limited competences notwithstanding, the EU institutions have consolidated health governance, advanced IT tools, designed procedures and mechanisms to detect and address shortages of crisis-relevant goods and resources.[83]

Although institutional coordination and the efficiency of working methods can certainly be improved, one has to bear in mind that health emergencies are complex phenomena that intercept various areas of EU competences, be it shared or supporting competences. Regardless of governance unification and independently of the extensive and pervasive 'normalisation' of numerous issues linked to the gathering, sharing, and processing of data, or more operational aspects such as procurement and stockpiling of crisis-relevant material, the European Health Union package can broadly be said to have remained within the limits of the principle of conferral. Member States retain important decision-making, normative, and implementing, powers –, and HERA could possibly turn into a fully-fledged EU agency.[84]

Independently of future (improbable) treaty amendments granting the EU more shared competences in areas pertaining to cross border health threats,

81 Maryse Cassan, *L'Europe communautaire de la santé* (Économica 1989).

82 It is worth recalling that above and beyond stronger crisis preparedness, the European Health Union also comprises a comprehensive action against cancer, antimicrobial resistance, and mental health, a far-reaching pharmaceutical strategy to ensure access to more affordable medicines, and a number of initiatives to promote and facilitate the digital transition in health. European Commission, *A Strong European Health Union for All – Stepping-Stones for Better Healthcare and More Resilient Health Systems*, 2024, accessible online at <https://ec.europa.eu/commission/presscorner/api/files/attachment/878547/Factsheet%20Strong%20Health%20Union_EN.pdf>, last access 26 November 2025.

83 Kai P. Purnhagen et al., 'More Competences Than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak', European Journal of Risk Regulation 11 (2020), 297-306.

84 The choice to opt for the creation of an internal service has indeed been criticised by some authors. See Olivier J. Wouters et al., 'The Launch of the EU Health Emergency Preparedness and Response Authority (HERA): Improving Global Pandemic Preparedness?', Health Policy 133 (2023), 1-6.

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the current legal framework is believed to have great potential and should be fully exploited.[85] Nonetheless, to push the pursuit of convergence beyond the current level of normative intervention would most probably imply an ultra vires action. *Rebus sic stantibus*, effectiveness seems to largely depend on the supervisory role of the HSC and the Commission. Unlike what happened during the pandemic, under Decision 1082/2013, the latter should exercise its prerogatives in accordance with Article 258 TFEU, most notably in relation to the elaboration, development and updating of national preparedness plans. The new legal framework must be taken seriously, regardless of whether the obligations imposed on Member States stem from acts adopted within the realm of supporting competences.

85 See further, Ilona Kickbusch and Anniek de Ruijter, 'How a European Health Union Can Strengthen Global Health', The Lancet Regional Health – Europe 1 (2021), 1-2.

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Where Market and Health Collide: The Limits of Policy Experimentation in EU Prevention of Non-Communicable Diseases and Tobacco Control

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Abstract

European Union (EU) policy on non-communicable diseases (NCDs) is primarily conducted through Article 114 Treaty on the Functioning of the European Union (TFEU). This contribution submits that the use of this provision to regulate unhealthy consumptions – tobacco, food, and alcoholic beverages – gives rise to a number of constitutional tensions and malfunctions, regarding in particular the principles of subsidiarity, conferral and the use of minimum harmonisation. This is due both to the economic nature of the EU's internal market powers and the characteristics of lifestyle-related health risks as a regulatory object. This affects, as a result, the clarity and legitimacy of EU action in the field, as well as undermines the quality of the legislation and the level of public health protection. To tackle these problems, a Treaty change would be the best way forward, which could be paired to the broader reforms necessary to the building of a strong and balanced EU Health Union.

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Keywords

Health – NCDs – Market – Harmonisation – Tobacco

I. Introduction

Smoking, drinking alcohol, eating salty or sugary foods: these habits constitute major behavioural risk factors for non-communicable diseases (NCDs), such as cancers, cardio-vascular diseases or diabetes. The prevalence of NCDs is rising globally, fuelled by a growing standardisation of consumption habits and a buoyant world market for unhealthy commodities. To address this mounting health burden,[1] the EU has developed a policy aimed at curbing the consumption of these products.[2] Strong measures have been adopted on tobacco, among which are the prohibition of products for oral use and those with a characterising flavour, rules on packaging and labelling,[3] and a ban on cross-border advertising and sponsorship.[4] As regards food, EU intervention is primarily concerned with the regulation of mandatory and voluntary health and nutrition information.[5] EU alcohol policy remains largely underdeveloped.[6] The 2021 Europe's Beating Cancer Plan provided a

1 Organisation for Economic Co-operation and Development (OECD) and European Commission, 'Health at a Glance: Europe 2024: State of Health in the EU Cycle', OECD Publishing, 18 November 2024.

2 For an overview, see Alberto Alemanno and Amandine Garde, 'The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets', CML Rev. 50 (2013), 1745-1786; Alberto Alemanno and Amandine Garde, *Regulating Lifestyle Risks: The EU, Alcohol, Tobacco and Unhealthy Diets* (Cambridge University Press 2015); Vincent Delhomme, 'Regulating Lifestyle Risks in EU Law: Promoting Health in a Diverse Market', PhD dissertation UCLouvain (2023), available at: <http://hdl.handle.net/2078.1/275547>, last access 14 November 2025.

3 Directive 2014/40/EU of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (Tobacco Products Directive), OJ 2014 L 127/1.

4 Directive 2003/33/EC Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products, OJ 2003 L 152/16.

5 See in particular Regulation 1169/2011/EU of 25 October 2011 on the provision of food information to consumers, OJ 2011 L 304/18; Regulation 1924/2006/EC of 20 December 2006 on nutrition and health claims made on foods OJ 2006 L 404/9.

6 See the specific rules contained in Regulation 1169/2011/EU and Regulation 1924/2006/EC. For an introduction to EU alcohol policy and its shortcomings, see Oliver Bartlett and Amandine Garde, 'EU Public Health Law and Policy – on the Rocks? A Few Sobering Thoughts on the Growing EU Alcohol Problem' in: Tamara K. Hervey, Calum Alasdair Young and Louise E. Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar Publishing 2017), 369-397.

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new impetus for EU action, with the objective of achieving a 'tobacco-free' generation by 2040.[7] Possible reforms of the EU legal framework include the introduction of plain tobacco packaging and front-of-pack nutrition labelling, changes to the excise duties regime and stricter regulation of commercial communications for food and alcohol. Despite good intentions, the Plan remains yet to be implemented.[8]

EU intervention in the field of NCDs comes in spite of a limited legal competence in public health matters. Health falls predominantly within the category of supporting competences,[9] which implies that Union action in that field is limited to measures that 'support, coordinate or supplement' those adopted by national governments, excluding any harmonisation of Member States' laws or regulations.[10] Article 114 TFEU, however, the internal market legal basis, offers a strong support for EU prevention and control of NCDs. Tobacco, food, and alcohol are, after all, consumer products traded across borders. Building a market for unhealthy commodities requires regulation at the EU level, to eliminate the barriers to trade resulting from Member State action and limit, to a certain extent, the harmfulness of the products put on the market.

While acknowledging the positive contribution that internal market powers have made to EU health policy, this article investigates the conceptual problems and regulatory malfunctions that arise from pursuing a health policy through the market, especially where that policy aims at reducing the consumption of a given product or eliminating it outright, like it is the case for tobacco. The contribution does so by looking at two specific policies: the prohibition of tobacco for oral use and the use of plain packaging for tobacco products. These two cases studies highlight the contradictions existing between the demands of the internal market – the removal of barriers to trade and a certain degree of regulatory uniformity – and the needs for flexibility and experimentation in NCDs prevention and control, a field characterised by behavioural diversity and a degree of scientific uncertainty. These contradictions can be expressed through the EU law vocabulary of conferral and

7 Communication from the Commission, 'Europe's Beating Cancer Plan', COM/2021/44 final, 8-11.

8 Amandine Garde et al., 'Lobbying, Transparency and Trust: Power Imbalances and the Failure to Implement Europe's Beating Cancer Plan', The Lancet Regional Health – Europe 51 (2025).

9 Health has a mixed competence structure under the TFEU. Art. 6(a) TFEU grants a competence to the Union to carry out actions to support, coordinate or supplement the actions of the Member States as regards the 'protection and improvement of human health'. Under Art. 4(2)(k), the Union also shares competence with the Member States in the area of 'common safety concerns in public health matters'.

10 Art. 2(5) TFEU.

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subsidiarity. These, ultimately, affect the clarity and legitimacy of EU action, the quality of the legislation and the level of public health protection. The article is divided as follows. Section II introduces the reader to some basic features of NCDs prevention and control and clarifies the power attributed to the EU in that regard. Sections III and IV contain the two case studies. Section V offers conclusive remarks on EU prevention and control of NCDs, and EU health law and policy more generally. The need is not for the EU to gain more formal powers, but for a Treaty change that better reflects current legislative developments. Such a change would allow the Union to pursue public health policies openly and legitimately, rather than framing them as internal market measures.

II. Prevention and Control of NCDs in the EU: Between Unity and Diversity

The EU has made positive contributions to the global fight against NCDs. Action at the supranational level nonetheless gives rise to challenges, linked to scientific uncertainty and the diversity of lifestyle practices (1). These challenges are further compounded by the limited nature of the EU's powers in the field of health, which has led to the adoption of control measures through the EU's internal market competence (2).

1. EU and the Diversity of Lifestyles

In high-income countries, sanitation policies and the development of public healthcare systems have led to a steady decrease in the burden of infectious diseases and other causes of ill-health, progressively replaced by NCDs. Fuelled by this 'epidemiologic transition',[11] a 'new' public health has come of age, less preoccupied with hygiene, filth, and contagion, but focusing on health and the self, how people live and what they eat, drink, or smoke.[12] Lifestyles are an essential determinant of health and a key priority for the

11 Abdel R. Omran, 'The Epidemiologic Transition: A Theory of the Epidemiology of Population Change', The Milbank Quarterly 83 (2005), 731-757; Robert E. McKeown, 'The Epidemiologic Transition: Changing Patterns of Mortality and Population Dynamics', American Journal of Lifestyle Medicine 3 (2009), 19S-26S.

12 Alan Petersen and Deborah Lupton, *The New Public Health: Health and Self in the Age of Risk* (SAGE Publications Ltd 2000).

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prevention of NCDs.[13] Tobacco consumption is the largest avoidable behavioural risk factor to health and the most significant cause of premature death in the EU.[14] In 2021, almost 210 000 deaths and 6.8 million disability-adjusted life years were attributable to alcohol consumption in the EU.[15] The rate of people who are overweight or obese has recently increased to over 60 % of the adult population.[16]

The paradox is that, unlike many dangerous or potentially deadly objects, tobacco, alcohol, and unhealthy foods are ubiquitous in our societies. They are lawfully accessible to consumers and may be purchased with limited constraints. Regulators tend to follow what William Bogart describes as a 'permit but discourage' logic,[17] adopting taxes, labels, and warnings to discourage consumption, but refraining from banning unhealthy practices altogether. Part of the explanation for such an approach is that unhealthy products represent a big segment of our economy, with billions in profits and millions of jobs dependent on it. Their consumption, while it is frowned upon by some, is considered acceptable and experienced as pleasurable by many. Eating, drinking, and smoking are entangled in a complex set of moral values, ethical norms, and cultural practices. Lifestyles are not 'the uncoordinated behaviours of disconnected individuals, but are personal routines that merge into an aggregate form representative of specific groups and classes'.[18] They are profoundly influenced by structural factors, such as age, wealth, gender, and ethnicity,[19] and are therefore marked by diversity. These differences between groups highlight the power of social norms, i. e. social attitudes of approval and disapproval.[20] While laws that are buttressed by social norms are more likely to be

13 WHO, 'Global Noncommunicable Diseases (NCD) Compact 2020-2030', <https://cdn.who.int/media/docs/default-source/ncds/final_ncd-compact-(1).pdf?sfvrsn=d8895106_1>, last access 15 April 2025. For the EU, see most recently Regulation 2021/522/EU of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, OJ 2021 L 107/1, Art. 3(a).

14 OECD and European Commission (n. 1).

15 Michael Brauer et al., 'Global Burden and Strength of Evidence for 88 Risk Factors in 204 Countries and 811 Subnational Locations, 1990-2021: A Systematic Analysis for the Global Burden of Disease Study 2021', The Lancet 403 (2024), 2162-2203.

16 WHO Regional Office for Europe, 'WHO European Regional Obesity Report 2022' (2022), <https://apps.who.int/iris/handle/10665/353747>, last access 01 August 2023.

17 William A. Bogart, *Permit But Discourage: Regulating Excessive Consumption* (Oxford University Press 2010).

18 William C. Cockerham, 'Health Lifestyle Theory and the Convergence of Agency and Structure', Journal of Health and Social Behavior 46 (2005), 51-67 (56).

19 Cockerham (n. 18).

20 Cass R. Sunstein, 'Social Norms and Social Roles', Colum. L. Rev. 96 (1996), 903-968 (914); Shaon Lahiri et al., 'Understanding the Mechanisms of Change in Social Norms Around Tobacco Use: A Systematic Review and Meta-Analysis of Interventions', Addiction 120 (2025), 215-235.

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respected, a law that goes against an entrenched social norm, something widely held to be an acceptable behaviour, is likely to fail.[21]

The prevention and control of NCDs is an area where scientific uncertainty persists regarding certain risks and where the effects of regulatory instruments are not always well-known. There is, for instance, still a considerable debate on the risks associated with the electronic cigarettes and the role that this product may play in tobacco control.[22] How effective a policy or instrument will be is affected by social norms and the aetiology of behaviour in a given social group. The multifactorial nature of the underlying causes of NCDs renders the measurement of the effectiveness of different regulatory options as well as the identification of the individual contribution of each of them difficult.[23] Uncertainty and diversity plead for a flexible use of EU powers, which, when necessary, would allow to conduct policy experimentation at the national level and/or allow Member States to deviate from the chosen EU standard. Minimum harmonisation represents therefore an appealing regulatory option in this field. It allows Member States to reach different levels of protection, in accordance with the severity of the public health problem faced in each country and the preferences and habits of the population. It is also a cautionary tool, in an area where a degree of uncertainty remains as to the effectiveness of different regulatory instruments and where policy experimentation may therefore appear desirable. The argument could even be made that, from a health point of view, minimum harmonisation always represents the best option, 'as it would be counterproductive to set a ceiling to the level of protection that can be applied across the EU'.[24] In the same vein, the principle of subsidiarity may warrant to let the upper hand to Member States, in cases where a health problem or the solution to that problem are country-specific.[25]

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21 Benjamin van Rooij and Adam Fine, *The Behavioral Code: The Hidden Ways the Law Makes us Better or Worse* (Beacon Press 2021), 122-135.

22 Susan Feeney, Victoria Rossetti and Jill Terrien, 'E-Cigarettes – a Review of the Evidence – Harm versus Harm Reduction', Tobacco Use Insights 15 (2022), doi: 10.1177/1179173X221087524.

23 See Alberto Alemanno and Amandine Garde, 'The Emergence of EU Lifestyle Risk Regulation: New Trends in Evidence, Proportionality and Judicial Review' in: Hans-W. Micklitz and Takis Tridimas (eds), *Risk and EU Law* (Edward Elgar Publishing 2015).

24 Sacha Garben, 'Article 169 TFEU' in: Manuel Kellerbauer, Marcus Klamert and Jonathan Tomkin (eds), *The EU Treaties and the Charter of Fundamental Rights: A Commentary* (Oxford University Press 2019), 1456-1466 (1460). The argument is made regarding consumer protection but equally applies to public health.

25 According to Art. 5(3) TEU: '[u]nder the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level'.

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As we shall see with the two case studies, due to the limits of its competence to address NCDs risks, the EU is ill-equipped to make space for such regulatory diversity.

2. The Push Towards Market Uniformity

To regulate unhealthy lifestyles and fight NCDs, the EU cannot rely on its limited direct legislative competence in the field of health. It is clear from Article 168 TFEU that the prevention of health damages associated with hazardous lifestyles is one of the EU's main health priorities. The importance of NCDs for EU health policy appears most clearly from Article 168(5), which grants the power to the Union to adopt 'measures which have as their direct objective the protection of public health regarding *tobacco and the abuse of alcohol*'.[26] As previously mentioned, however, health falls predominantly within the category of supporting competences, which implies that Union action in that field is limited to measures that 'support, coordinate or supplement' those adopted by the Member States and that Union action may not supersede their competence. According to Article 2(5) TFEU, '[l]egally binding acts of the Union adopted on the basis of [supporting competences] *shall not entail harmonisation* of Member States' laws or regulations',[27] a prohibition reiterated as regards health at Article 168(5) TFEU, which '*exclud[es] any harmonisation* of the laws and regulations of the Member States'.[28] The EU may therefore only adopt incentive measures or recommendations.[29]

Considering the limitations of Article 168 TFEU, the EU has used another route to legislate in the area, this one related to the market aspect of unhealthy products, Article 114 TFEU. It has allowed the EU to adopt a wide range of NCDs control measures. In its landmark *Tobacco Advertising I* ruling, the Court of Justice, while declaring the Directive at issue invalid, also

26 Art. 168(5) TFEU, emphasis added.

27 Emphasis added.

28 Emphasis added. A derogation exists for the 'common safety concerns in public health matters' referred to at Art. 4(2)(k) TFEU, in relation to which the Union may adopt harmonisation measures, see Art. 168(4). On the matter, see the contribution by Christian Calliess, 'The Corona Crisis (Covid-19 Pandemic) and the European Union (EU) – Health Policy as a Topic for the Conference on the Future of Europe –', Berlin e-Working Papers on European Law (No. 131), 7 May 2021. In this special issue: Christian Calliess, 'Filling the Competence Gap in the Health Policy of the European Union (EU) by a New Article 168 (4) d) TFEU – Lessons Learned from the Covid-19 Pandemic', HJIL 85 (2025), 1045-1074.

29 Art. 168(6) TFEU.

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permitted the Union legislator to use its internal market powers to adopt measures in the field of health:

> '[P]rovided that the conditions for recourse to Articles [114 53(1) and 62] as a legal basis are fulfilled, the [EU] legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made.'[30]

This aspect of the judgment, often overlooked, is arguably the most important one. It paved the way for the adoption of various NCDs control measures, making up for the EU's lack of direct harmonisation powers in the field of health.

Yet, while being broad in scope, Article 114 TFEU does not provide the EU with an unlimited competence. As ruled by the Court in *Tobacco Advertising I* case, Article 114 TFEU does not grant the EU with a 'general power to regulate the internal market'.[31] To be lawfully adopted under that provision, measures 'must *genuinely* have as [their] object the improvement of the conditions for the establishment and functioning of the internal market'.[32] For a measure to be considered a genuine contribution to the internal market, two conditions must be fulfilled. First, there needs to be actual divergences between the laws of the Member States which create obstacles to free movement or distortions of competition[33] or future divergences likely to give rise to such obstacles or distortions.[34] Second, the adopted measure must remove these obstacles or distortions.[35] Merely identifying obstacles to free movement or distortions of competition resulting from differences in national legislation is not enough to justify the harmonisation of these national provisions. The proposed EU measure must eliminate these obstacles or distor-

30 ECJ, *Germany v. European Parliament and Council (Tobacco Advertising I)*, case no. C-376/98, ECLI:EU:C:2000:544, para. 88; ECJ, *Philip Morris Brands*, case no. C-547/14, ECLI:EU:C:2016:325, para. 60.

31 ECJ, *Tobacco Advertising I* (n. 30), para. 83.

32 ECJ, *Tobacco Advertising I* (n. 30), para. 84, emphasis added.

33 ECJ, *Vodafone e. a.*, case no. C-58/08, ECLI:EU:C:2010:321, para. 32. The most recent cases do not explicitly refer to these two concepts of 'obstacles to free movement' and 'distortions of competition' but tend to refer to those under the common term of 'obstacles to trade'. Yet, through a direct reference to paragraph 32 of the *Vodafone* case, these cases can be considered as upholding the difference between 'obstacles' and 'distortions': see ECJ, *Philip Morris* (n. 30), paras 58-59; ECJ, *Poland v. European Parliament and Council*, case no. C-358/14, EU:C:2016:323, paras. 32-33. See also ECJ, *Czech Republic v. Parliament and Council*, case no. C-482/17, EU:C:2019:321, Opinion of Advocate General Sharpston, para. 44, referring to the elimination of 'obstacles to free movement' and 'distortions in competition'.

34 ECJ, *Philip Morris* (n. 30), para. 59; ECJ, *Poland v. Parliament and Council* (n. 33), para. 33.

35 ECJ, *Tobacco Advertising I* (n. 30), paras 84, 95.

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tions. This essential requirement gives rise to conceptual and practical difficulties illustrated by the two case studies selected.

III. Tobacco for Oral Use and Harm Reduction

Various forms of tobacco are regulated under EU law, beyond cigarettes and other products for smoking. The Tobacco Products Directive (TPD) also applies to smokeless tobacco products (STPs), i. e. tobacco products that do not involve any inhalation. STPs include tobacco for oral use, chewing tobacco, and nasal tobacco.[36] These are only niche products, consumed by a very small fraction of the EU population.[37] The most commonly known STP is a product called *snus*, a 'moist oral tobacco product which is placed behind the upper lip, either loose or in portioned sachets, which resemble miniature tea bags'.[38] Consuming snus is not risk-free – it is especially associated with a risk of oral cancer – but it is substantially less hazardous than smoking and lowers the risk to which smokers are exposed if used as a substitute.[39] The smoke from cigarettes contains over 4000 chemicals and at least 70 known carcinogens and is responsible for most of the harm associated with tobacco.[40] On the other hand, no smoke is emitted an inhaled during the consumption of snus. Nicotine, the highly addictive stimulant contained in all tobacco products, including snus, is of limited harm per se.[41]

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36 Under the Art. 2(8) TPD, tobacco for oral use means 'all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets'.

37 See European Commission, 'Attitudes of Europeans Towards Tobacco and Electronic Cigarettes', Special Eurobarometer 506 (2021).

38 Elizabeth Clarke et al., 'Snus: A Compelling Harm Reduction Alternative to Cigarettes', Harm Reduction Journal 16 (2019), 1-17 (1).

39 Clarke et al. (n. 38); Konstantinos Farsalinos, 'Snus: Swedish Snus Is Different', British Dental Journal 226 (2019), 85; Lars M. Ramström, 'Much Safer with Snus', British Dental Journal 226 (2019), 85; Ellen Meier et al., 'A Randomized Clinical Trial of Snus Examining the Effect of Complete Versus Partial Cigarette Substitution on Smoking-Related Behaviors, and Biomarkers of Exposure', Nicotine & Tobacco Research 22 (2020), 473-481 (478).

40 Shannon Gravely et al., 'European Adult Smokers' Perceptions of the Harmfulness of E-Cigarettes Relative to Combustible Cigarettes: Cohort Findings from the 2016 and 2018 EUREST-PLUS ITC Europe Surveys', European Journal of Public Health 30 (2020), iii38-iii45 (iii38).

41 Jacques Le Houezec, Ann McNeill and John Britton, 'Tobacco, Nicotine and Harm Reduction', Drug and Alcohol Review 30 (2011), 119-123 (120).

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The EU prohibits the placing on the market of tobacco for oral use since 1992,[42] on grounds of the specific health risks associated with it and of its potential role as a gateway to the consumption of other, riskier forms of tobacco products.[43] Consumption of tobacco for oral use was negligible in the EU at that time, to the exception of Sweden, which secured an opt-out from the ban upon its accession to the EU in 1995.[44] The opt-out is still currently in force.[45] The wide consumption of snus in Sweden, as a substitute for cigarettes,[46] is one of the factors behind the lower tobacco-related mortality registered in the country if compared to the rest of the EU Member States.[47] Norway, a country outside the EU, has also seen a gradual shift towards the consumption of snus in recent years.[48]

A number of public health experts call for a removal of the ban on snus, arguing that the product could be used and recommended as a cessation aid, taking the Swedish case as an example.[49] These advocates of 'harm reduction'– a term that refers 'to strategies designed to reduce the health risks associated with tobacco smoking but which may involve the continued use of

42 Tobacco Products Directive, Arts 1(c) and 17. The ban was first introduced by Council Directive 92/41/EEC of 15 May 1992 amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products, OJ 1992 L 158/30, Art. 1.

43 Council Directive 92/41/EEC, recitals.

44 Act concerning the conditions of accession of the Kingdom of Norway, the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded, OJ 1994 C 241/09, Art. 151.

45 Pursuant to Art. 17 of the TPD, 'Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden'.

46 Kirsimarja Raitasalo et al., 'Single, Dual, and Triple Use of Cigarettes, E-Cigarettes, and Snus Among Adolescents in the Nordic Countries', International Journal of Environmental Research and Public Health 19 (2022), 683-694.

47 Lars Ramström and Tom Wikmans, 'Mortality Attributable to Tobacco Among Men in Sweden and Other European Countries: An Analysis of Data in a WHO Report', Tobacco Induced Diseases 12 (2014), 1-4 (3); Lars Ramström, Ron Borland and Tom Wikmans, 'Patterns of Smoking and Snus Use in Sweden: Implications for Public Health', International Journal of Environmental Research and Public Health 13 (2016), 1110-1124 (1110); Clarke et al. (n. 38); Farsalinos (n. 39); Lars M. Ramström, 'If There Had Been No Snus in Sweden: The Impact of Snus on Mortality Attributable to Smoking', Harm Reduction Journal 21 (2024), 1-5 (4).

48 Tord Finne Vedøy and Karl Erik Lund, 'How Do Smokers in a Snus-Prevalent Society Consider E-Cigarettes, Snus, and Nicotine Replacement Therapy Products as Relevant Replacements for Cigarettes in the Event They Should Stop Smoking?', Nicotine & Tobacco Research 25 (2023), 1753-1761 (1754).

49 Clarke et al. (n. 38), 13; Farsalinos (n. 39); Ramström, 'Much Safer with Snus' (n. 39); Ramström, 'Mortality Attributable to Tobacco among Men in Sweden and Other European Countries' (n. 47), 3.

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nicotine'[50] – point to the difficulty that smokers have to quit nicotine altogether, suggesting an approach based on the transition from cigarettes to other lower-risk products, such as tobacco for oral use. Hence, from this perspective, snus should not be banned but regulated in a more nuanced way than cigarettes, so that it remains as little attractive as possible to non-users of tobacco while constituting a suitable alternative to smokers. There is however no consensus on this question in the public health community. If snus were to be reintroduced and led to dual use with cigarettes for current smokers, a documented phenomenon,[51] or, indeed, served as a gateway for non-smokers towards the consumption of cigarettes, the effect on public health would be negative. As observed by the Court in its *Swedish Match II* judgment,[52] uncertainty thus remains about the effectiveness of this form of tobacco, when used as a cessation aid, and its role in reducing exposure in the population to health risks, following a harm reduction strategy.

The prohibition of snus raises two important questions from the perspective of competence and the balance between health, diversity, and market uniformity. If taking a rigorous approach to the use of the EU's internal market powers under Article 114 TFEU, the very existence of the ban is questionable. Its legality was first contested in the *Swedish Match* and *Arnold André* judgments, for breach of the principle of conferral.[53] The Court upheld the ban in both cases, laying down the general principle according to which, under Article 114 TFEU, a measure 'may consist in […] provisionally or definitively prohibiting the marketing of a product or products'.[54] Thus doing, the Court failed to explain, however, how such a ban fulfils the necessary conditions for the use of that legal basis. The Court rightfully observed that prohibitions affecting tobacco for oral use enacted at the national level constitute obstacles to the free movement of goods,[55] but fully disregarded the condition that these obstacles be removed by the EU harmonisation measure. The Court's approach was recently confirmed in the *Swedish Match II* case.[56]

50 Sharon Cox and Lynne Dawkins, 'Global and Local Perspectives on Tobacco Harm Reduction: What Are the Issues and Where Do We Go from Here?', Harm Reduction Journal 15 (2018), 1-2 (1).

51 Raitasalo et al. (n. 46).

52 ECJ, *Swedish Match AB v. Secretary of State for Health (Swedish Match II)*, case no. C-151/17, ECLI:EU:C:2018:938, paras 41-45.

53 ECJ, *Arnold André*, case no. 434/02, ECLI:EU:C:2004:800, para. 35; ECJ, *Swedish Match*, case no. C-210/03, ECLI:EU:C:2004:802, para. 34.

54 ECJ, *Arnold André* (n. 53), para. 35; ECJ, *Swedish Match* (n. 52), para. 34.

55 ECJ, *Arnold André* (n. 53), paras 38-40; ECJ, *Swedish Match* (n. 52), paras 37-39.

56 ECJ, *Swedish Match II* (n. 52), paras 55-58.

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In *Swedish Match* and *Arnold André*, Advocate General Geelhoed offered a more detailed, albeit unconvincing, defence of the ban. Acknowledging that the 'prohibition on selling a product cannot itself improve the conditions for the marketing of that product' – '[i]n fact, the product is excluded from the market' –[57] he nonetheless considered that the ban on the marketing of tobacco for oral use improves trading conditions for 'related products', insofar as it helps reducing the enforcement costs of the legislation concerning these latter products.[58] 'In short, if snus is not on the market of the European Union, the effort to control the marketing of other smokeless tobacco products can be reduced.'[59] This may very well be the case. Yet, Advocate General Geelhoed does not explain how a reduction in enforcement costs benefits legally marketed products, by removing obstacles to trade from the point of view of the manufacturers or distributors of these products. It is hard not to see in the Advocate General's position an attempt to defend a rule which may be justified on grounds of public health, but does not fulfil the criteria set for the use of the Union internal market competence. The EU legislator may very well consider that uniformity alone, rather than the removal of barriers to trade, is a desirable goal for the internal market, but such are not the criteria set in *Tobacco Advertising I* and confirmed ever since, which the Court decided to disregard.

The push towards market uniformity raises a second problem, this time linked to compliance with the principle of subsidiarity in a harm reduction context. In *Swedish Match II*, the plaintiff argued for a breach of subsidiarity, sustaining that 'the general and absolute prohibition on the placing on the market of tobacco products for oral use deprives Member States of any discretion in their legislation and imposes a uniform body of rules, with no consideration of the *individual circumstances* of the Member States'.[60] Although that plea was not further substantiated, it could be argued that the effect of the ban on snus on public health is dependent on local circumstances, and that the decision would be better left to the national level. The report of the scientific committee that had informed the adoption of the ban invites to this conclusion, where it states that 'the association between patterns of smokeless tobacco use and smoking cessation differs between populations and is likely to be affected by cultural, societal and other factors', therefore concluding that 'it is not possible to extrapolate the trends in prevalence of smoking and use of oral tobacco if it were made available in an

57 Cases C-434/02 *Arnold André* and C-210/03 *Swedish Match*, ECLI:EU:C:2004:487, Joined Opinion of Advocate General Geelhoed, 7 September 2004, para. 78.

58 ECJ, *Swedish Match*, Opinion of the Advocate General (n. 57), para. 79.

59 ECJ, *Swedish Match*, Opinion of the Advocate General (n. 57), para. 79.

60 ECJ, *Swedish Match II* (n. 52), para. 64, emphasis added.

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EU country where it is now unavailable'.[61] The decision to use snus or not as a cessation aid recommended by public health authorities should depend on whether we can expect the harm resulting from people taking up snus – in single or dual use with cigarette – not to offset the reduction in harm coming from people who substitute snus for cigarette.[62] This is likely to be influenced by social norms. In countries neighbouring Sweden, such as Finland, where consumers are familiar with the product and use it to an extent,[63] the effect of authorising snus and publicly endorsing it are likely to be different than in countries where the product is virtually unknown. In sum, uncertainty pleads for regulatory diversity and, at the very least, a discussion on the legality of the ban under the principle of subsidiarity.

This discussion, unfortunately, did not take place in *Swedish Match II*. In its judgment, at no point did the Court address the question of subsidiarity from a health and harm reduction perspective,[64] and focused instead on the impossibility for Member States alone to contribute to the internal market objective, ruling that:

> *'Even if the second of those objectives [health] might be better achieved at the level of Member States*, the fact remains that pursuing it at that level would be liable to entrench, if not create, situations in which some Member States permit the placing on the market of tobacco products for oral use, whilst others prohibit it, thus *running completely counter to the first objective* of Directive 2014/40, namely the improvement of the functioning of the internal market for tobacco and related products.
>
> The *interdependence of the two objectives* pursued by the directive means that the EU legislature could legitimately take the view that it had to establish a set of rules for the placing on the EU market of tobacco products for oral use and that, because of that interdependence, *those two objectives could best be achieved at EU level*.'[65]

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61 Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 'Health Effects of Smokeless Tobacco Products' 12 (2008), <https://ec.europa.eu/health/other-pages/health-sc-basic-page/scientific-committee-emerging-and-newly-identified-health-risks-0_en>, last access 5 November 2025.

62 Karl Erik Lund and Tord Finne Vedøy, 'A Conceptual Framework for Assessing the Public Health Effects from Snus and Novel Non-Combustible Nicotine Products', Nordic Studies on Alcohol and Drugs 38 (2021), 586-604.

63 Marjut Salokannel and Eeva Ollila, 'Snus and Snus-Like Nicotine Products Moving Across Nordic Borders: Can Laws Protect Young People?', Nordic Studies on Alcohol and Drugs 38 (2021), 540-554; Raitasalo et al. (n. 46).

64 ECJ, *Swedish Match II* (n. 52), paras 68 f. The Advocate General did not address subsidiarity in his opinion.

65 ECJ, *Swedish Match II* (n. 52), paras 68 f.

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The Court, by analysing both objectives together, severely limits the possibility for Member States or other claimants to contest the validity of an EU measure based on the arguments developed above. The EU will always be comparatively better placed than Member States to act for internal market purposes. Indeed, '[t]he removal of obstacles to cross-border trade in the European internal market, which is the focus of interest in Article 114 TFEU, is a prime example of action which cannot, *as a rule*, be sufficiently realised at national level'.[66] Member States alone cannot, by definition, take action to remove obstacles to trade or distortions of competition trough harmonisation.[67] Hence, the internal market nature of legislative acts in the field of NCDs prevents health-based subsidiarity claims from being made. Useful policy experimentation is therefore barred. The absence of any discussion on this point is even more ironic since, as already established, the prohibition of tobacco for oral use does not serve to remove any obstacles to trade in the internal market.

This problem may have repercussions in other areas of EU tobacco control. E-cigarettes are another category of 'tobacco' products with harm reduction potential, because they emit vapour rather than combustion smoke. Evidence is mounting that for some long-term users of traditional cigarettes, e-cigarettes may be helpful for smoking cessation.[68] In England, the use of e-cigarettes has been officially endorsed as a cessation aid.[69] The controversy in this area is similar to the one present for tobacco for oral use, with opponents of harm reduction pointing at the risk of gateway effect and dual use. While the EU does not ban e-cigarettes, it has subjected these products to a drastic advertising and sponsorship ban, similar to the one applicable to other tobacco products. All cross-border advertising and sponsorship for e-cigarettes, on television, radio, or printed media is prohibited.[70] The EU legislator's decision is grounded in the fact that 'electronic cigarettes can develop into a gateway to nicotine addiction and ultimately

66 ECJ, *Poland v. Parliament and Council*, opinion of the Advocate General of 23 December 2015, case no. C-358/14, ECLI:EU:C:2015:848, para. 154, emphasis added.

67 It seems therefore 'plausible to conclude', with Davies, 'that subsidiarity has no relevance to those functional competences whose aim is to create the uniformity necessary for an internal market': Gareth T. Davies, 'Subsidiarity: The Wrong Idea, in the Wrong Place, at the Wrong Time', CML Rev. 43 (2006), 63-84 (75).

68 Feeney, Rossetti and Terrien (n. 22).

69 Virginia Berridge et al., 'E-Cigarettes: A Framework for Comparative History and Policy', Addiction 119 (2024), 1864-1870.

70 Art. 9(1)(d) Directive 2010/13/EU of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive), OJ 2010 L 95/1; Art. 20(5) TPD.

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traditional tobacco consumption, as they mimic and *normalise* the action of smoking'.[71] Proponents of harm reduction strategies are usually critical of total bans on e-cigarette advertising, considering that an equilibrium should be found between avoiding exposure of youth to such advertising, so as to prevent the take-up of any tobacco-related product, and ensuring that current smokers have an accurate perception of e-cigarettes, which remain less harmful than traditional tobacco.[72] Here as well, that equilibrium is likely to be influenced by social norms,[73] and it is not impossible that some countries might benefit differently from calibrated advertising. Any subsidiarity claim made in that regard is, however, for the reasons outlined above, unlikely to succeed.

IV. Tobacco Plain Packaging and Minimum Harmonisation

Plain packaging, or standardised packaging, is the most stringent form of regulation affecting the labelling and packaging of tobacco products. It consists in removing from unit packets all visual elements, such as branding, colours, or logos. These elements contribute to the attractiveness of tobacco products, affecting perceptions of harm, and influencing the experience of the taste and strength of tobacco.[74] The packaging area that is not covered by health warnings and other mandated elements must be in plain, standardised colour, usually brown or grey, with the brand name displayed in small font. A number of countries, mostly in Europe, have now adopted plain packaging, with evidence showing that it is an effective means to increase intentions to quit, induce negative attitudes towards smoking, as well as to reduce brand awareness and appeal of tobacco products.[75]

The TPD lays down a number of obligations regarding the packaging and labelling of tobacco products, including the obligation to carry textual and

71 Recital 43 TPD, emphasis added.

72 See Kristin Voigt, 'Smoking Norms and the Regulation of E-Cigarettes', American Journal of Public Health 105 (2015), 1967-1972.

73 Voigt (n. 72); Máirtín S. McDermott et al., 'Social Norms for E-Cigarettes and Smoking: Associations with Initiation of E-Cigarette Use, Intentions to Quit Smoking and Quit Attempts: Findings from the EUREST-PLUS ITC Europe Surveys', European Journal of Public Health 30 (2020), 46-54.

74 David Hammond and Carla Parkinson, 'The Impact of Cigarette Package Design on Perceptions of Risk', Journal of Public Health 31 (2009), 345-353; Lauren K. Lempert and Stanton Glantz, 'Packaging Colour Research by Tobacco Companies: The Pack as a Product Characteristic', Tobacco Control 26 (2017), 307-315.

75 Crawford Moodie et al., 'Plain Tobacco Packaging: Progress, Challenges, Learning and Opportunities', Tobacco Control 31 (2022), 263-271.

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pictorial health warnings.[76] The introduction of an EU plain packaging requirement was contemplated upon revision of Directive 2001/37,[77] the previous directive on tobacco products, but was finally not included in the proposal for the current TPD. Plain packaging was still a new measure when the TPD was adopted in 2014, and the impact assessment had observed in this regard that it was 'appropriate to wait for real life experience'.[78] A specific provision in the form of Article 24(2), was inserted in the TPD to formally permit Member States to introduce plain packaging rules at the national level. The idea was that local experimentation would help in building an evidence-base that would inform a potential future adoption by the EU.[79] Eight EU countries have introduced plain packaging to date.[80] Evidence from France, Ireland, and the United Kingdom, which have had the measure in place for a number of years, shows that it has brought a range of benefits: a reduction in the perceived attractiveness of tobacco, an increase in the perception of the harmfulness of smoking and a decrease in smoking prevalence.[81] As part of its new Beating Cancer Plan, presented in 2021, the Commission announced that it would be working towards a generalisation of plain packaging at the EU level.[82]

76 Arts 8-12 TPD in particular.

77 Directive 2001/37/EC of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, OJ 2001 L 194/26.

78 European Commission, 'Impact Assessment Accompanying the Document: Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products' (TPD impact assessment), Staff Working Document SWD (2012) 452 final, part. 1, 118.

79 See European Commission, 'Impact Assessment' (n. 78).

80 In the order in which the measure was adopted: France, Ireland, Belgium, Slovenia, the Netherlands, Denmark, Hungary, and Finland. See European Commission, 'Support Study to the Report on the Application of Directive 2014/40/EU', Final Report, Publications Office (2021), 157-158.

81 European Commission, 'Support Study' (n. 80). Regarding France, see Fabienne El-Khoury, Camille Bolze and Maria Melchior, 'Perceptions of Plain Tobacco Packaging: DePICT, a French National Survey', European Journal of Public Health 27 (2017), 420-421; Fabienne El-Khoury Lesueur, Camille Bolze, Ramchandar Gomajee, Vicki White and Maria Melchior, 'Plain Tobacco Packaging, Increased Graphic Health Warnings and Adolescents' Perceptions and Initiation of Smoking: DePICT, a French Nationwide Study', Tobacco Control 28 (2019), 31-36; Anne Pasquereau, Raphael Andler, Romain Guignard, Richard Jean-Baptiste and Viêt Nguyen Tanh, 'Smokers' Perception of Cigarette Packaging in France Before and After the Plain Packaging', European Journal of Public Health 30 (2020), v636-v637; Anne Pasquereau, Romain Guignard, Raphaël Andler, Karine Gallopel-Morvan and Viêt Nguyen-Thanh, 'Plain Packaging on Tobacco Products in France: Effectiveness on Smokers' Attitudes One Year after Implementation', Tobacco Induced Diseases 20 (2022), 1-11.

82 European Commission, 'Europe's Beating Cancer Plan' (n. 7), 9.

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Plain packaging seems to be a pertinent and successful use of minimum harmonisation. The EU could adopt other measures on the labelling and packaging of tobacco products – harmonising the size and shape of packets, introducing health warnings – without restraining those of the Member States that wished to go further in terms of public health protection. Local experimentation allowed the EU to gain more certainty over the effectiveness of this regulatory solution and to present a more solid evidence-base for its adoption. Yet, as much as minimum harmonisation may be politically desirable, it still raises thorny legal questions regarding its contribution to market uniformity. An EU act allowing for future divergences in national law seems to make a rather tenuous contribution to the removal of barriers to trade, as required under Article 114 TFEU. As rightly put by Nina Boeger, 'as minimum harmonisation introduces more political diversity into the internal market, the key question remains to what extent such diversity continues to be accepted even if it impinges on the economic objective to harmonise regulatory standards in the internal market'.[83]

To answer this question, it is useful to look in greater details at Article 24 TPD and its interpretation by the Court of Justice. Before doing so, an important conceptual and terminological distinction must first be drawn between *minimum* harmonisation and *partial* harmonisation, the former term being often improperly used to refer to the latter. These two concepts apply to two separate dimensions of an EU legislative act, its scope and its intensity,[84] dimensions which are sometimes conflated by the Court itself.[85] The *scope* of a legislative act, on the one hand, determines what this act covers and what it leaves unregulated. It is an issue of *partial* harmonisation: certain aspects of a policy area or of a given product are not subject to harmonisation.[86] Matters found to lie outside the legislative field of a harmonisation measure remain within the residual powers of the Member States.[87] The Union is not required to fully harmonise every product or service that it

83 Nina Boeger, 'Minimum Harmonisation, Free Movement and Proportionality' in: Philip Syrpis (ed.), *The Judiciary, the Legislature and the EU Internal Market* (Cambridge University Press 2012), 62-91.

84 Piet Jan Slot, 'Harmonisation', ELRev 21 (1996), 378-397 (388-389); Stephen Weatherill, 'Pre-Emption, Harmonisation and the Distribution of Competence to Regulate the Internal Market' in: Catherine Barnard and Joanne Scott (eds), *The Law of the Single European Market: Unpacking the Premises* (Hart Publishing 2002), 41-74 (52-63); Robert Schütze, *From Dual to Cooperative Federalism: The Changing Structure of European Law* (Oxford University Press 2009), 194-196.

85 See Slot (n. 84), 389.

86 For some elements on partial harmonisation and its different meanings: see Schütze (n. 84), 195. See also ECJ, *Mikrokasa v. XO*, opinion of the Advocate General of 19 December 2019, case no. C-779/18, ECLI:EU:C:2019:1146, paras 48-50.

87 Schütze (n. 84), 194 f.

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regulates, even less every policy area in which a measure is adopted. The *intensity* of an EU act, on the other hand, concerns the possibility granted to Member States to adopt a requirement that differs from the one prescribed in that act, usually to reach a higher standard of protection. Two main options exist.[88] Either the EU measure is of *total* harmonisation, in which case Member States are deprived of any possibility to act within its scope, or it is of *minimum* harmonisation, in which case Member States are allowed to adopt a standard stricter than the one set at EU level. A number of TFEU provisions contain a 'constitutional' minimum harmonisation clause, such as Article 168(4)(a) on the safety of organs and substances of human origin, Article 169(4) on consumer protection, and Article 193 on the environment – these routinely provide that EU measures adopted pursuant to these provisions 'shall not prevent any Member State from maintaining or introducing more stringent protective measures'. Article 114 TFEU does not contain such constitutional minimum harmonisation clause,[89] which means that the choice is left to the EU legislature and may vary from one instrument to the other.

With this distinction in mind, it is possible to make a careful reading and interpretation of Article 24 TPD. This provision states the following:

> '1. Member States may not, *for considerations relating to aspects regulated by this Directive*, *and subject to paragraphs* 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.
>
> 2. This Directive shall not affect the right of a Member State *to maintain or introduce further requirements*, applicable to all products placed on its market, in relation to the *standardisation of the packaging of tobacco products*, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. […]'

Judging from Article 24(1), the TPD appears to be a measure of *partial* and *maximum* harmonisation. Member States are prevented from enacting further measures that would restrict or prohibit the marketing of products complying with the TPD, *but only* for considerations relating to aspects

88 Leaving aside optional harmonisation: see Schütze (n. 84), 197 f.

89 See ECJ, *Commission v. France*, judgment of 25 April 2002, case no. C-52/00, ECLI:EU:C:2002:252, para. 15; ECJ, *Octapharma v. ANSM*, judgment of 13 March 2014, case no. C-512/12, ECLI:EU:C:2014:149, para. 43 f. One could make the argument that recourse to minimum harmonisation is required by the various health mainstreaming clauses contained in the TFEU and the Charter, which all refer to a 'high level of protection'. See in the area of consumer protection: Stephen Weatherill, 'Maximum versus Minimum Harmonization: Choosing Between Unity and Diversity in the Search for the Soul of the Internal Market' in: Niamh Nic Shuibhne and Laurence W. Gormley (eds), *From Single Market to Economic Union – Essays in Memory of John A Usher* (Oxford University Press 2012), 175-200 (186 f. and 199).

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regulated by the Directive, which implies that some of these aspects are not covered by it. Article 24(2) seems to bring a derogation to the principle contained in the first paragraph, allowing a Member State to maintain or introduce further requirements in relation specifically to the standardisation of the packaging of tobacco products, bringing an element of *minimum* harmonisation to the TPD. How should such a clause be interpreted under Article 114 TFEU?

The Court of Justice provided the answer in the *Philip Morris* judgment. Regarding Article 24(2), a provision that it deemed 'not devoid of ambiguity',[90] the Court considered that two interpretations could be made. That provision could be interpreted as permitting 'Member States to maintain or introduce further requirements *in relation to all aspects* of the packaging of tobacco products, including those which have been harmonised by the directive'.[91] This, however, 'would amount, in essence, to *undermining the harmonisation* effected by the directive' since 'the consequence of such an interpretation would be to permit Member States to replace the requirements relating to packaging which have been harmonised by the directive with other requirements, introduced at national level'.[92] 'Such an interpretation', the Court adds, '*would render Article 24(2) of Directive 2014/40 incompatible with Article 114 TFEU*'.[93] In a striking statement, the Court seemed to reject the use of minimum harmonisation under Article 114 TFEU.[94]

The other possible interpretation, the one favoured by the Court, was to make of Article 24(2) a clause of partial harmonisation: 'Article 24(2) of Directive 2014/40 may also be interpreted as meaning that it permits Member States to maintain or introduce further requirements *only in relation to aspects* of the standardisation of the packaging of tobacco products *which have not been harmonised* by the directive'.[95] Understood in this way, Article 24(2) still fails to guarantee the free circulation of products that comply with the Directive.[96] Yet, such 'partial harmonisation', whilst not eliminating 'all obstacles to trade, […] does eliminate some', which, for the Court, renders it

90 See ECJ, *Philip Morris* (n. 30), para. 69.

91 ECJ, *Philip Morris* (n. 30), para. 71, emphasis added.

92 ECJ, *Philip Morris* (n. 30), para. 71, emphasis added.

93 ECJ, *Philip Morris* (n. 30), para. 72, emphasis added.

94 The Court of Justice had already expressed its hostility towards the use of minimum harmonisation in internal market legislation in previous judgments, although never as clearly: see ECJ, *Tobacco Advertising I* (n. 30); ECJ, *Germany v. European Parliament and Council (Tobacco Advertising II)*, judgment of 12 December 2006, case no. C-380/03, ECLI:EU:C:2006:772.

95 ECJ, *Philip Morris I* (n. 30), para. 73, emphasis added.

96 ECJ, *Philip Morris I* (n. 30), para. 79.

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compatible with Article 114 TFEU.[97] Indeed, 'manufacturers of tobacco products throughout the internal market are able to use cigarette packets which have a uniform basic design and are required to adapt that design to the specificities of their respective national laws, regulations and administrative provisions only in certain details (colours, for example), but no longer in every respect'.[98]

The Court's interpretation of Article 24(2) appears formally correct from a free movement point of view, although one may doubt that this was truly what the legislator had in mind, considering that it renders Article 24(2) redundant with Article 24(1).[99] By ensuring that standards do not diverge in relation to at least some aspects of the product concerned, partial harmonisation, unlike minimum harmonisation, does contribute to removing obstacles to free movement. With partial harmonisation, Member States do not *replace* the EU requirement with a national requirement, they act *alongside* the EU requirement. In practice though, such a 'piecemeal' approach may still raise questions.[100] If the harmonisation of a product was so limited in scope that marketing it in several member States required separate production lines for the manufacturer, the removal of obstacles to trade or appreciable distortions of competition would be quite hypothetical.[101] *Philip Morris* provides a textbook example of the difficulty to reconcile provisions that have primarily, if not only, a public health purpose – ensuring that Member States retain the capacity to adopt more stringent tobacco control measures – with their stated and required objective to contribute to the smooth functioning of the internal market by removing obstacles to free movement or distortions of competition. In order to uphold provisions such as Article 24(2) TPD, without openly renouncing its case law regarding the conditions for the use of Article 114 TFEU, the Court is led to an interpretation that fails to fully convince. Similar difficulties regarding the space for national action under EU internal market

97 ECJ, *Philip Morris I* (n. 30), para. 81.

98 *ECJ, Philip Morris Brands SARL and Others v. Secretary of State for Health*, opinion of Advocate General Kokott of 23 December 2015, case no. C-547/14, ECLI:EU:C:2015:853, para. 119.

99 Indeed, if Art. 24(2) covers aspects of the standardisation of the packaging of tobacco products which have not been harmonised by the directive, then Art. 24(1) alone is sufficient for allowing Member States to act.

100 Gareth Davies, 'The Competence to Create an Internal Market: Conceptual Poverty an Unbalanced Interests' in: Sacha Garben and Inge Govaere (eds), *The Division of Competences Between the EU and the Member States: Reflections on the Past, the Present and the Future* (Hart Publishing 2017), 74-89 (79).

101 Contrary to what was argued by the Court in ECJ, *Philip Morris* (n. 30), para. 103. See also ECJ, *Philip Morris*, Opinion of the Advocate General (n. 98), para. 98.

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measures can also be seen in the field of food and nutrition, front-of-pack nutritional labelling more specifically.[102]

If taken at face value, the *Philip Morris* ruling has far-reaching application for the legislative acquis adopted under Article 114 TFEU which pursues health, environmental or consumer protection objectives. The finding that letting a Member State derogate from a standard set in the TPD would undermine the internal market objective of the Directive amounts to a general rejection of minimum harmonisation under Article 114 TFEU. Nothing from the judgment indicates that the solution found was particularly contextual. Yet, that pronunciation has not been repeated to date and recent case law does not indicate 'that the Court finds anything constitutionally troubling in a measure of harmonisation which leaves room for stricter rules to be selected by Member States which will lead to obstacles to trade even where the terms of the Directive have been met'.[103] Uncertainty on the issue is thus likely to persist.

V. Concluding Remarks

These two case studies illustrate the limits to the EU practice of pursuing a health policy with internal market means. The reason is twofold. First, because many public health interventions cannot reasonably be considered as contributing to the removal of obstacles to trade. The prohibition of tobacco for oral use is a clear example thereof. Second, because the push for market uniformity – an expression of the same requirement to remove obstacles to trade – is at odds with the needs for flexibility and experimentation, particularly present in the field of NCDs and lifestyle-related risks. The radical approach to minimum harmonisation and the internal market that *Philip Morris* invites us to take may not be satisfactory if viewing the internal market in an embedded way, where non-market values and interests have to be taken into account, and Member State autonomy somewhat accommodated. Full homogeneity is probably not an ideal perspective, if only a

102 Nikhil Gokani, 'Front-of-Pack Nutrition Labelling: A Tussle Between EU Food Law and National Measures' ELRev 47 (2022), 153-174 (154); Vincent Delhomme, 'Minimum Harmonization, Experimentation and the Internal Market' in: Ton Van Den Brink and Virginia Passalacqua (eds), *Balancing Unity and Diversity in EU Legislation* (Edward Elgar Publishing 2024), 194-210.

103 Stephen Weatherill, 'The Fundamental Question of Minimum or Maximum Harmonisation' in: Sacha Garben and Inge Govaere (eds), *The Internal Market 2.0* (Hart Publishing 2021), 261-284 (275-276). See e. g. ECJ, *Buhagiar v. Minister for Justice*, case no. C-267/16, ECLI:EU:C:2018:26, para. 49.

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feasible one, for the Union internal market.[104] It belongs nonetheless to the Court to properly discharge its duty and to clearly explain under which circumstances a measure that does not ensure the free movement of goods can be validly adopted under Article 114 TFEU, or to change its interpretation of the criteria for the use of that provision, going beyond the mere removal of obstacles to trade.

Ideally, the EU legislature should be able to adopt the measures that appear politically desirable to prevent the spread of NCDs, without the legal constraints originating from the internal market and its commitment to free movement. Promoting health, whether in the form of an outright prohibition of a given product on the entire EU market, or, on the opposite of the regulatory spectrum, in the form of a minimum harmonisation measure, should remain the core concern. Such policies should not falsely be based on internal market considerations, where it is clear they do not seek to create greater trading opportunities, but, rather, to diminish those. To tackle these problems, a Treaty change would be the best way forward,[105] which could be paired to the broader reforms necessary to the building of a strong and balanced EU Health Union.[106] This would not only strengthen the EU's NCDs policy but would also provide a solid foundation to any further expansion of EU action in the field of health. The protection of human health should become an area of shared competence, with direct harmonisation powers granted to the EU. A Treaty minimum harmonisation clause, of the kind used in Article 193 TFEU for the environment, should be added, to ensure that Member States can always go beyond the level of protection prescribed by EU law. In concrete terms, the area of 'protection and improvement of human health' would be moved from Article 6 to Article 4 TFEU. Article 4(2)(k) TFEU would hence no longer be needed and the prohibition of harmonisation contained in Article 2(5) TFEU would cease to apply to health. Article 168 TFEU would be amended to reflect these changes

104 See Stephen Weatherill, 'Supply of and Demand for Internal Market Regulations: Strategies, Preferences and Interpretation' in: Niamh Nic Shuibhne (ed.), *Regulating the Internal Market* (Edward Elgar Publishing 2006), 29-60 (47-49); Michael Dougan, 'Minimum Harmonisation after *Tobacco Advertising* and *Laval Un Partneri*' in: Mielle Bulterman, Leigh Hancher, Alison McDonnell and Hanna G. Sevenster (eds), *Views of European Law from the Mountain: Liber Amicorum for Piet Jan Slot* (Kluwer Law International 2009), 3-18 (17 f.).

105 See in this special issue, the contributions by Christian Calliess, 'Filling the Competence Gap in the Health Policy of the European Union (EU) by a New Article 168(4)(d) TFEU – Lessons Learned from the Covid-19 Pandemic', HJIL 85 (2025), 1045-1074 and Markus Frischhut, 'The Missing Keystone of the "European Health Union": Historic Development, *status quo* and Ideas *de lege ferenda*', HJIL 85 (2025), 1011-1043.

106 See Martin McKee and Anniek de Ruijter, 'The Path to a European Health Union', The Lancet Regional Health – Europe 36 (2024), 100794.

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and to provide the Union with general harmonisation powers in the field, excluding healthcare.[107]

Finally, a general remark regarding the status of health in the EU framework of competence is in order. In general, Union health powers are underestimated.[108] Such an observation suggests caution, rather than the usual response to call for more Union powers and a Treaty change to respond to every crisis, like it has often been the case with the Covid-19 pandemic and the EU Health Union. One needs to ask *why* more powers for the Union might be needed in the field. Should the Union directly order public health measures or take care of healthcare planning? There are good reasons for a division of tasks whereby the Union takes a leading role in public health and product regulation, while Member States retain primary responsibility for the organisation and delivery of healthcare, as well as the management of health crises.[109] Healthcare systems are at the core of modern welfare states and express sensitive socio-fiscal choices. National or sub-national governments are better placed than the Union to respond to their population's needs and to build a crisis response that panders to different ethos and relationships to risk. In any case, in health as in other matters, action from the EU and the Member States is increasingly intertwined.[110] Hence, what is needed is perhaps not a Treaty change allowing the EU to do more than it already does, but one that would better align what the EU does with the formal division of competence. As this article has hopefully shown, this would lead to better and more legitimate regulation.

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107 For an example of how Art. 168 TFEU could be redrafted, see Vincent Delhomme, 'Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health', European Journal of Risk Regulation 11 (2020), 747-756.

108 See Oliver Bartlett, 'COVID-19, the European Health Union and the CJEU: Lessons from the Case Law on the Banking Union', European Journal of Risk Regulation 11 (2020), 781-789; Tamara Hervey and Anniek De Ruijter, 'The Dynamic Potential of European Union Health Law', European Journal of Risk Regulation 11 (2020), 726-735; Kai P. Purnhagen, Anniek De Ruijter, Mark L. Flear, Tamara K. Hervey and Alexia Herwig, 'More Competences Than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak', European Journal of Risk Regulation 11 (2020), 297-306.

109 Vincent Delhomme and Carina van Os, 'Building the European Health Union (2019-2024): Successes, Limits and Future Perspectives', European Journal of Risk Regulation 16 (2025), 942-960.

110 See, in relation to the Covid-19 pandemic: Vincent Delhomme and Tamara Hervey, 'The European Union's Response to the Covid-19 Crisis and (the Legitimacy of) the Union's Legal Order', YBEL 41 (2022), 48-82.

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Securing the EU's Medical Supply Chains: Setting the Legal and Economic Scene for Achieving Import Diversification

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Abstract

Amid the COVID-19 pandemic, the European Union (EU) initiated the European Health Union (EHU) to fortify medical supply chains, aligning

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with broader economic security goals. Geopolitical tensions prompted the EU to adopt a package of initiatives centred on 'open strategic autonomy'. This paper explores the legal and economic mechanisms for securing medical supply chains, focusing on the World Trade Organization (WTO) framework and identifying critical import dependencies. Findings reveal a need for an economic approach to supplement WTO rules. A methodology for identifying vulnerable medical commodities is presented, emphasising risk assessment and import diversification. The study highlights the potential repercussions of export restrictions on medical goods, stressing the importance of securing supply chains. The paper concludes with recommendations for the EU to navigate legal and economic strategies for robust medical supply chains.

Keywords

Medical Goods – International Trade – Strategic Autonomy – European Union – Geopolitics

I. The Growing Issue of Medical Supply Chain Risks

In the wake of the COVID-19 pandemic, the EU Commission announced the creation of a European Health Union (EHU),[1] which aims to establish robust medical and pharmaceutical supply chains[2] and secure the availability of medical goods to citizens and health systems.[3] This objective is aligned with the EU's general attempt to increase its economic security. Respective approaches have been initiated responding to past and recent geo-economic and political tensions like the trade disputes initiated by the United States (US) and the Russian invasion of Ukraine, both contributing to the perception of supply chain fragility. The EU initiated a whole package of initiatives[4] around the

1 European Commission, 'Building a European Health Union: Stronger Crisis Preparedness and Response for Europe', Press Release, 11 November 2020, available at <https://commission.europa.eu/>, last access 21 November 2025.

2 The EU identified medical and pharmaceutical supplies to be severely disrupted during the pandemic due to an enormous sure in demand compared to supply that was worsened due to imposition of export restrictions by some countries. See more here: OECD, 'Global Value Chains: Efficiency and Risks in the Context of COVID-19, 2020', 11 February 2021, available at <https://www.oecd.org/>, last access 21 November 2025; European Commission, 'Updating the 2020 New Industrial Strategy: Building a Stronger Single Market for Europe's Recovery', COM/2021/350 final, 5 May 2021.

3 European Commission, 'Commission Steps up Actions to Address Critical Shortages of Medicines and Strengthen Security of Supply in the EU', Press Release, 24 October 2023, available at <https://commission.europa.eu/>, last access 21 November 2025.

4 Arthur Leichthammer, 'Navigating the Geoeconomic Tide: The Commission's Quest for a Policy Compass', Policy Brief, Hertie School Jacques Delors Centre, 16 April 2024, available at: <https://www.delorscentre.eu>, last access 21 November 2025.

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principle of 'open strategic autonomy', first mentioned in the trade strategy of 2021: The new general strategy on 'Economic Security' of 2023 and the 'Industrial Strategy' of 2020 are accompanied by sector-specific approaches like the 'Raw Material Act' of 2024, the 'Pharmaceutical Strategy' of 2020, the 'Food Contingency Plan' of 2021 as well as the 'Critical Medicines Acts' announced in early 2025. One of the youngest strategies is the European Compass of Competitiveness based on prior Draghi-, Letta- and Niinistö-reports – all considering a balance of strengthening European independence.

All these new initiatives by the EU are aimed at securing resilience of supply chains and avoiding risks associated with a strategic (ab)use of economic dependencies by trade partners, for which in principle a range of different and partially ambivalent tools are available. These are split between a domestic focus on raising self-sufficiency by increasing domestic production (on- or re-shoring) and establishing stockpiles, and a trade-focus that aims at reducing import dependencies.[5]

Although early EU initiatives heavily focused on securing access to critical raw materials[6] and semi-conductors,[7] the EU is now expanding its approach to include medical goods due to its goal of creating a robust EHU, the imposition of export restrictions during the COVID-19 pandemic, and rising geopolitical tensions having spillover effects on trade in medical goods.[8] The term 'medical goods' hereby describes a wide array of commodities used for medical purposes, in particular pharmaceuticals (e. g. vaccines and insulin), supplies (e. g. disinfectants and gloves), and equipment (e. g. x-ray generators and face masks). Differentiating between these goods is crucial in analysing and overcoming export restrictions as they greatly vary in terms of existing dependencies, cost structure, and the ability to near- or reshore in response to supply shocks.

Access to these medical commodities may be politically pursued by both, the domestic and the 'trade approach' to ensure EU's economic security. This

5 The Pharma Strategy specifically repeats access to and affordability of medicines and therapies, well-functioning supply chain, at the same time competitiveness and crisis preparedness. These aims remind of the 70-year-old aims of the food policy in the EU that laid down the Treaty on the Functioning of the European Union (TFEU) (Art. 39 TFEU) addressing availability of supplies, reasonable prices for consumers, ensure a fair living for farmers while at the same time envisage stable markets, and increase in productivity. European Commission, 'Pharmaceutical Strategy for Europe', COM/2020/761 final, 25 November 2020; Art. 39 TFEU.

6 European Commission, 'Critical Raw Materials: Ensuring Secure and Sustainable Supply chains for EU's Green and Digital Future', Press Release, 16 March 2023, available at <https://commission.europa.eu>, last access 21 November 2025.

7 European Chips Act, available at <https://commission.europa.eu>, last access 21 November 2021.

8 Michael Bayerlein and Pedro A. Villarreal, 'Global Health Governance and Geopolitics: How Germany Can Contribute to a New Global Health Architecture After Covid-19 Amid Growing Geopolitical Tensions', SWP Comment 2023/C57, 12 December 2023, doi: 10.18449/2023C57.

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is because while re-shoring and stockpiling can be economically feasible in a few cases, the basis of securing EU's supply of medical commodities should be to strengthen supply chains via diversified and open trade, i. e. the trade approach.[9] This is because re-shoring and stockpiling are costly, slow, and viable only for a narrow set of products, whereas diversifying imports across multiple reliable partners reduces concentration risks, cushions the impact of export restrictions and shocks, and secures access more efficiently in line with the EU's 'open strategic autonomy'.

The principle of open trade was violated during the COVID-19 pandemic when export restrictions were widely applied by countries.[10] The lack of diversification of supply-chains aggravated the situation further, eventually worsening the access to vital medical equipment and supplies by increasing prices, market volatility, and distorting investment decisions. Ultimately, the scope for the EU's access to medical goods was limited.[11] In addition to securing domestic supply by restricting exports, the resulting price effects may have supported a strategic use of export restrictions. This strategy was aimed at benefiting the exporting country by improving their terms of trade.[12]

As of the writing of this paper, the EU has yet to address its dependencies on medical commodity inputs provided by non-EU countries. The recently proposed Critical Medicines Act (CMA)[13] is a step towards reaching this goal. The CMA, however, has two major shortcomings. First, it

9 Michael Bayerlein, 'Medicine Shortages: Diversification of Supply Chains as the Primary Goal', Point of View, SWP, 17 May 2023, available at <https://www.swp-berlin.org/>, last access 21 November 2025; World Bank Group and World Trade Organization, 'Trade Therapy, Deepening Cooperation to Strengthen Pandemic Defenses', 2022.

10 Michael Bayerlein, 'The EU's Open Strategic Autonomy in the Field of Pharmaceuticals', SWP Comment 2023/C 02, 11 January 2023, available at: http://hdl.handle.net/10986/37494; Anirudh Shingal and Prachi Agarwal, 'COVID-Era Trade Policy Passthrough to Trade Flows: Idiosyncratic or Not?', Covid Economics 78 (2021), 159-191.

11 Will Martin and Kym Anderson, 'Export Restrictions and Price Insulation During Commodity Price Booms', American Journal of Agricultural Economics 94 (2012), 275-609; OECD, 'The Economic Impact of Export Restrictions on Raw Materials', in: OECD Trade Policy Studies Paris (OECD Publishing 2010); Mark Wu, 'Export Restrictions' in: Aaditya Mattoo, Nadia Rocha and Michele Ruta (eds), *Handbook of Deep Trade Agreements* (World Bank Group 2020), 87-110; Shingal and Agarwal (n. 10); Matteo Fiorini, Bernard Hoekman and Aydin Yildirim, 'COVID-19: Expanding Access to Essential Supplies in a Value Chain World' in: Richard Baldwin and Simon Evenett (eds), *COVID-19 and Trade Policy: Why Turning Inward Won't Work* (CEPR Press 2020), 63-76.

12 Shingal and Agarwal (n. 10).

13 European Commission, 'Laying a Framework for Strengthening the Availability and Security of Supply of Critical Medicinal Products as well as the Availability of, and Accessibility of, Medicinal Products of Common Interest, and Amending Regulation (EU) 2025/102', COM/2025/102 final, 11 March 2025.

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only focuses on pharmaceutical goods, neglecting the dependencies on medical goods, like face masks and equipment, in general. Second, re-shoring and stockpiling are still regarded as viable options for reducing the EU's critical dependencies while the diversification of supply-chains remains largely neglected, although the effects of and remedies against trade restrictions are well studied.

Research in economics and trade, which delves into the allocation of production and the resulting trade patterns and dependencies, frequently centres on the availability, accessibility, and trade of raw materials,[14] and commodities including food,[15] while political research on international relations and dependencies in the past often emphasised the flows of development aid[16] or sovereign debt.[17] The effects of trade-restricting measures and specifically of export restrictions is analysed intensively by economic modelling. Often the focus lies on food, a sector in which such restrictions are regularly and extensively applied – and at the same time criticised by affected countries.[18] Similarly, a growing number of publications extended the focus on trade restrictions of critical raw materials.[19]

14 Katrin Kamin, Michael Bayerlein and Jacqueline Dombrowski, 'Zeitenwende für die Außenwirtschaftspolitik', Wirtschaftsdienst 103 (2023), 23-26; Elena Vyboldina, Alexey Cherepovitsyn, Sergey Fedoseey and Pavel Tsvetkov, 'Analysis of Export Restrictions and Their Impact on Metals World Markets', Indian Journal of Science and Technology 9 (2016), doi: 10.17485/ijst/2016/v9i5/87633.

15 Siddhartha Mitra and Tim Josling, 'Agricultural Export Restrictions: Welfare Implications and Trade Disciplines', IPC Position Paper, January 2009, International Food & Agricultural Trade Policy Council; Robert Howse and Tim Josling, 'Agricultural Export Restrictions and International Trade Law: A Way Forward', IPC Position Paper, 2012, International Food & Agricultural Trade Policy Council; Will Martin and Joseph Glauber, 'Trade Policy and Food Security' in: Richard E. Baldwin and Simon J. Evenett (eds), *COVID-19 and Trade Policy: Why Turning Inward Won't Work* (CEPR 2020), 89-101.

16 Marcus Power and Giles Mohan, 'Towards a Critical Geopolitics of China's Engagement with African Development', Geopolitics 15 (2010), 462-495.

17 Sebastian Horn, Carmen Reinhart and Christoph Trebesch, 'China's Overseas Lending', Journal of International Economics 133 (2021), 103539.

18 OECD, 'The Economic Impact of Export Restrictions' (n. 11); Bettina Rudloff, *Trade Rules and Food Security, Scope for Domestic Support and Food Stocks* (Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ). 2015).

19 Frank van Tongeren, 'The Impact of Export Restrictions on Raw Materials on Trade and Global Supply', in: OECD, *Globalisation, Comparative Advantage and the Changing Dynamics of Trade* (OECD Publishing 2011), 317; Jeonghoi Kim, 'Recent Trends in Export Restrictions on Raw Materials' in: OECD, *The Economic Impact of Export Restrictions on Raw Materials* (OECD Publishing 2010), 13-57; Przemyslaw Kowalski and Clarisse Legendre, Raw Materials Critical for the Green Transition: Production, International Trade and Export Restrictions, OECD Trade Policy Paper No. 269, 11 April 2023, doi: 10.1787/c6bb598b-en.

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In contrast, economic research that specifically focuses on trade in medical commodities and critical dependencies is still scarce. Notable exceptions provide comprehensive deep dives into drivers of drug shortages[20] and dependencies when it comes to starting materials and active pharmaceutical ingredients (API)[21] as well as the risks associated with offshoring biosimilars.[22] We build on these important contributions by extending the research to still understudied commodities: Medical goods in general and finished pharmaceutical products. Further, we add to the literature by developing a methodology on how to identify critical dependencies and how to overcome them. The limited research is surprising as the political goal of securing access to raw materials is accompanied by a plethora of analyses with medical commodities receiving less attention.[23] Additionally, while legal analyses at least focus on medical goods by addressing the regulatory framework for countries to impose trade restrictions,[24] they lack an interdisciplinary approach that combines the legal assessment with economic assessments.

In addressing this research gap, and against the background of the EU's aim of securing medical supply chains, this paper focuses on the WTO rules as the key multilateral framework governing international trade, including restrictions that directly affect the supply of essential goods. In doing so, we ask two research questions: How do legal rules under the WTO regime secure access to medical goods? How can economic strategies to assess dependencies secure access? And how can legal shortcomings be compensated through economic action? Our core argument is that WTO rules, even when compared to the relatively more elaborated framework for food products, leave wide discretion to exporting states and are therefore insufficient to secuire access to medical goods. We therefore explore how insights from food-related trade rules can inform the discussion, while showing why an economic de-risking approach is necessary to supplement the legal framework.

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20 David Francas and Stephan Mohr, 'On the Drivers of Drug Shortages: Empirical Evidence from Germany', International Journal of Operations & Production Management 43 (2023), 1520-1538; Joost Pauwelyn, 'Export Restrictions in Times of Pandemic: Options and Limits Under International Trade Agreements', J. W. T. 54 (2020), 727-747.

21 David Francas, Manuel Fritsch and Jasmin Kirchhoff, Resilienz pharmazeutischer Lieferketten, Study for the Association of Research-Based Pharmaceutical Companies (vfa) of 31 March 2022.

22 David, Francas and Jasmin Kirchhoff, Wer Reshoring möchte, muss Offshoring vermeiden, Study on Behalf of Pro Generika e. V., 2023, Köln.

23 Lisandra Flach, Feodora Teti, Isabella Gourevich, Lisa Scheckenhofer and Leif Grandum, *Wie abhängig ist Deutschland von Rohstoffimporten? Eine Analyse für die Produktion von Schlüsseltechnologien*, (ifo Institut 2022); Andreas Baur, Florian Dorn, Lisandra Flach and Clemens Fuest, 'Rethinking Geoeconomics: Trade Policy Scenarios for Europe's Economy, EconPol Policy Report 44 (2023), available at <https://www.ifo.de/en/econpol/publications/2023/working-paper/rethinking-geoeconomics-trade-policy-scenarios-europes-economy>, last access 21 November 2025.

24 Pauwelyn (n. 20).

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We answer these research questions by examining the legal framework governing the implementation of export restrictions, with a specific focus on the food sector as a possible blueprint for medical commodities as they are both considered essential goods and therefore display several similarities. Despite of differences in the characteristics of food and medical supply chain we focus on the different policy experiences with restrictions and different regulatory scopes to react. Drawing upon provisions primarily and since long established in the food sector, our analysis reveals that countries possess a significant level of discretion when implementing trade-restrictive measures. Additionally, we contend that even within the comparatively more regulated food sector, countries are afforded various exceptions to the overarching framework of liberalised trade, posing an additional challenge in enforcing rules. Consequently, we assert that establishing EU's supply chain security necessitates an approach grounded in economics.

The economic aspect of our analysis presents a methodology for identifying medical commodities with crucial dependencies and suggests economic strategies based on individual risk assessments. Initially, we identify a subset of 36 vulnerable medical commodities by considering EU's relative import volume and the concentration of trade partners. Subsequently, we juxtapose the current sources of EU's imports for these vulnerable medical products with major global exporters of similar goods, thereby offering insights into potential import diversification tactics. Additionally, we pinpoint products characterised by high unit values, which may signify superior quality or advanced technology integration.[25] To this end, the EU's reliance on imported medical products, particularly those with high unit prices, can expose it to supply chain disruptions, especially in the absence of domestic production or substitutes. Therefore, import diversification becomes imperative in such scenarios.[26] We further assess whether the EU's primary trading partners have previously imposed

25 Alf Maizels, 'The Manufactures Terms of Trade of Developing and Developed Countries with Japan, 1981-2000', Queen Elizabeth House Working Paper Series – QEHWPS36, 2003; Sanjaya Lall, 'The Technological Structure and Performance of Developing Country Manufactured Exports, 1985-98', Oxford Development Studies 28 (2000), 337-369.

26 Moreover, higher import prices can indicate a higher quality of traded goods that tend to be concentrated in technologically sophisticated countries as opposed to those that remain stuck in low innovation intensity. Hence, import diversification towards technologically advanced economies could help secure reliant supply chains. Russell Hillberry and Christine McDaniel, 'A Decomposition of North American Trade Growth Since NAFTA, Office of Economics, Working Paper No. 2002-12-A, December 2002, doi: 10.22004/ag.econ.15866; Peter Schott, 'Do Rich Countries and Poor Countries Specialize in a Different Mix of Goods? Evidence from Product Level U.S. Trade Data', National Bureau of Economic Research, Working Paper No. 8492, September 2001, doi: 10.3386/w8492; Lall (n. 25); Raphael Kaplinsky and Amelia Santos Paulino, 'Innovation and Competitiveness: Trends in Unit Prices in Global Trade', Oxford Development Studies 33 (2005), 333-355.

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restrictions on medical commodity trade, which we identify as an increased risk of potential future trade limitations by these partners. Furthermore, we estimate the extent of supply chain exposure through the EU's internal trade in medical goods and its domestic demand.

The remainder of this paper is structured as follows: Section II delves into an examination of the multilateral legal framework governing international trade, with a specific emphasis on rules governing food products as a possible blueprint for medical commodities. Following this, in Section III, we introduce a comprehensive methodology for identifying 'critical import dependencies'. This encompasses several key steps: identification of at-risk commodities, mapping of current import dependencies and diversification potential, assessment of product complexity, identification of trade-restricting partners, calculating the exposure of the EU's supply chains, and the EU's demand for pharmaceuticals. Section IV discusses the necessary limitations of the findings. In Section V, we synthesise our findings to draw conclusions regarding the strategies available to the EU for establishing reliable supply chains of medical goods and mitigating potential import disruptions. The last section outlines policy recommendations.

II. Multilateral Framework on Trade and Export Restrictions

Since 1947, the General Agreement on Tariffs and Trade (GATT) and its successor, the World Trade Organization (WTO) (established in 1995), have championed the cause of unrestricted international trade of imports and exports. Their regulations tackle various trade mechanisms, both those directly impacting border controls such as tariffs, standards, and quantitative restrictions, and those influencing international competitiveness, like domestic and export subsidies. Quantitative restrictions are viewed as the most obstructive to trade and are therefore expressly prohibited.[27]

While the goal remains to facilitate unrestricted trade, various exceptions are delineated based on specific justifications. For instance, criteria are established for the imposition of quantitative restrictions under certain conditions such as domestic shortages (GATT XI). Moreover, general exceptions permit countries to pursue environmental objectives or safeguard public morals (GATT XX), or for reasons pertaining to national security (GATT XXI). Additionally, regulations govern adherence to import requirements, addressing sanitary and phytosanitary concerns (SPS Agreement) or technical speci-

27 Alan Sykes, The Laws and Economics of International Trade Agreements (Edward Elgar 2023), 155.

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fications (TBT Agreement) across multiple criteria.[28] In addition to trade in goods, specific rules are in place to address regulatory matters concerning services (General Agreement on Trade in Services [GATS]). Furthermore, a separate framework of rules enables countries to respond to the trade practices of other nations through the utilisation of anti-dumping and countervailing measures (GATT VI and corresponding Agreements), as well as safeguards (GATT XIX and relevant Agreements).[29]

Of particular significance to the trade of medical goods and associated regulatory considerations is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which guarantees the protection of intellectual property rights while outlining exceptions and criteria for licensing. Additionally, the Pharmaceutical Agreement, a plurilateral pact with EU as a member eliminates tariffs on medical goods and advocates for duty-free access not only among its signatories but also ensures the application of these regulations on a most-favoured-nation (MFN) basis for all WTO members. This agreement aligns with the EU's objective to boost medical imports.[30]

1. General Framework on Disciplining Export Restrictions

The WTO and its precursor GATT know several rules for divergent measures to limit trade, as exceptions from unhindered trade.[31] Restrictive trade barriers can be linked to products and can cover quantitative barriers, monetary fees or administrative ones like licenses.[32] Under GATT Article XI, there is a general aim to eliminate quantitative restrictions on imports and exports; however, certain exceptions are also provided.[33] Paragraph 2(a) focuses on export restrictions and outlines criteria for their temporary application, aiming to alleviate critical shortages of foodstuffs or other products deemed 'essential'

28 See for example in Bernard Hoekman and Charles Sabel, 'Open Plurilateral Agreements, International Regulatory Cooperation and the WTO', Global Policy 10 (2019), 297-312; Keith E. Maskus, 'Regulatory Standards in the WTO: Comparing Intellectual Property Rights with Competition Policy, Environmental Protection, and Core Labour Standard', World Trade Review 1 (2002), 135-152.

29 An overview of different nature of measures, see Table 1 of Bettina Rudloff, 'Yes, He Can: Trump Provokes a Trade War', SWP Comment 2018/C 29, 19 July 2018, available at <https://www.swp-berlin.org/publikation/yes-he-can-trump-provokes-a-trade-war>, last access 21 November 2025.

30 Deborah Gleeson et al., 'Analyzing the Impact of Trade and Investment Agreements on Pharmaceutical Policy: Provisions, Pathways and Potential Impacts', Globalization and Health 15 (2019), 1-17; Hoekman and Sabel (n. 28).

31 World Bank Group and World Trade Organization (n. 9), 70 ff.

32 World Bank Group and World Trade Organization (n. 9), 72, fig. 2.4.

33 Ryan Cardwell and William Kerr, 'Can Export Restrictions Be Disciplined Through the World Trade Organisation?', The World Economy 37 (2014), 1186-1196.

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to the exporting party. While no further definitions are provided for these criteria, they are extensively discussed in academic circles and have been subject to scrutiny in WTO disputes, offering insights for interpretation.[34] For instance, empirical observations suggest that once applied, export restrictions tend to persist.[35] Disputes such as those involving China and Indonesia have shed light on the potential extension of the definition of 'essential' products to include raw materials or natural resources.[36] Moreover, the determination of the criticality of shortages is examined within the context of a crisis deemed of paramount importance.[37] In addition to the general framework, specific regimes are established for certain products, such as food products. Recognising the essential nature of food products, we argue that the regulations governing trade in these goods are quite analogous to the trade in medical goods. This similarity offers an opportunity to explore whether the regulatory approaches to trade in food products can serve as a model to develop strategies aimed at securing medical commodity supply chains.

2. Specific Framework for the Essential Product 'Food'

Aside from the general rules under the GATT and WTO that are relevant for trade in all products, specific regulations are dedicated to trade in food products. These regulations are governed by the Agreement on Agriculture (AoA), ratified in 1994, which encompasses a wide range of policies aimed at ensuring supply security. These policies encompass various aspects, including the design and value of subsidies, as well as the reduction and establishment of maximum levels for tariffs.[38] GATT Article XI explicitly addresses quantitative restrictions on imports and exports, particularly focusing on food and agricultural products. Paragraph 2(1) specifies food as well as 'essential goods' for which exceptions are permitted to impose quantitative restrictions on exports.

Further, Paragraph 2(c) of the GATT includes agricultural and fisheries products among those subject to import restrictions. The Agreement on Agriculture (AoA) further elaborates on these criteria in Article 12, which

34 Ahan Gadkari, 'Legality of Export Restrictions Imposed During COVID-19 in International Economic Law', Journal of International Trade Law and Policy 22 (2023), 33-50.

35 Report Shows Many G20 Export Restrictions Remain in Place, Including on Food and Fertilizers, 4 July 2023, <https://www.wto.org/>.

36 World Trade Organization, 'WTO Analytical Index: GATT 1994 – Article XI (DS Reports)', available at <https://www.wto.org/english/res_e/publications_e/ai17_e/gatt1994_art11_jur.pdf>, last access 12 November 2025.

37 World Trade Organization (n. 36).

38 Rudloff, *Trade Rules* (n. 18).

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outlines disciplines on export prohibitions and restrictions. These include considering the effects on importing countries' food security (Paragraph 1 a) and providing a timely advance notice (Paragraph 1 b). However, these criteria do not apply to any developing country, unless it is a net-exporter of the specific food product concerned (Paragraph 2). Consequently, numerous countries frequently employ export restrictions on food without the obligation to notify the WTO, as the classification of developing countries relies on self-declaration. Countries such as India, (so far) China, and Argentina fall into this category and commonly implement export restrictions.

During the food price crisis triggered by the Russian invasion of Ukraine, additional measures were devised to alleviate the escalating global prices of numerous agricultural and fertilizer products, along with the increasing imposition of export restrictions, which had the potential to further exacerbate prices.[39] At the WTO 12th Ministerial Conference in 2022, members adopted several pertinent decisions encapsulated within the 'Geneva-package' addressing food-related issues.[40] The 'Ministerial Decision on World Food Programme (WFP) Food Purchases Exemptions from Export Prohibitions or Restrictions', stipulated that members agreed not to impose export bans or restrictions on foodstuffs purchased for humanitarian purposes by the World Food Programme. Nonetheless, this resolution does not inhibit any member from implementing measures aimed at ensuring its domestic food security. Moreover, the guiding principle for the WFP was rooted in procurement decisions based on the principle of 'do no harm' to the food-supplying members.

Another pivotal resolution, the 'Ministerial Declaration on the Emergency Response to Food Insecurity',[41] acknowledged the array of diverse approaches to achieving food security through trade and reiterated the significance of refraining from imposing export bans or restrictions in a manner contradictory to WTO provisions. It also emphasised the importance of information exchange and monitoring. Collectively, these initiatives highlight the delicate balance between addressing domestic food security – often a pertinent political concern – and simultaneously fostering open trade.

In conclusion, even in an area as regulated as food trade, the leeway on export restrictions remains high,[42] and despite existing rules and the new initiatives on raising awareness, agricultural trade remains the most affected by export restrictions – with some exceptions due to the COVID-19 pan-

39 See Table 1 in Bettina Rudloff, 'Politischer Umgang mit Nahrungsrisiken: Herausforderungen, Optionen und Verbesserungsansätze', Wirtschaftsdienst 103 (2023), 50-56.

40 Cosimo Avesani, Twelfth WTO Ministerial Conference (MC12) – Outcomes for Agriculture and Fisheries, Trade Policy Briefs 49, July 2022, doi: 10.4060/cc1235en.

41 World Trade Organization, MC12 Outcome Document of 22 June 2022, WT/MIN(22)/24.

42 Pauwelyn (n. 20).

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demic pertaining to restrictions on medical goods. Because of legal loopholes and existing exemptions legal frameworks – although contributing to trade liberalisation – are not wholly capable of serving as a blueprint for securing medical supply chains. Hence, rather than only improving the rules governing the trade in medical goods, de-risking of supply chains must be based primarily on an economic approach. Building on this conclusion, we turn to the economic dimension: the EU must adopt economic strategies that identify critical dependencies, assess diversification potential, and develop tools to reduce exposure to trade disruptions.

III. An Economic Approach to Securing Supply Chains

The outlined WTO rules provide only limited constraints on export restrictions. Economic strategies therefore play a crucial role in complementing the legal framework, particularly by addressing vulnerabilities that law leaves unresolved. When dealing with goods, the EU has already established some approaches to assess whether a commodity is 'critical'. This is most pronounced for raw materials. Here, the EU currently defines a raw material as critical based on its economic importance and supply risk.[43] The supply risk is determined based on the global export and EU import concentration, import reliance, and end-of-life recycling. Economic importance is calculated with the share of end-use applications, domestic value added, and the substitutability of a commodity. Research concerned with supply-chain risk assessments and the identification of critical import dependencies often applies a similar approach with certain modifications. Flach et al. propose a three-pronged assessment strategy to identify critical import dependencies via commodity relevance, import concentration, and substitutability through internal production.[44] Other contributions move beyond the import concentration and estimate diversification potential through global production and export shares of other countries.[45]

We develop a risk-assessment framework (RFA) that builds on the previous approaches, but introduces several modifications to account for particularities of medical commodities and allows for a granular and direct deduction of actionable recommendations. With our RFA methodology we can identify critical medical goods in six steps: 1) At-risk commodity identifica-

43 European Commission, Directorate-General Joint Research Centre: Gian Andrea Blengin et al., *Methodology for Establishing the EU List of Critical Raw Materials* (European Commission Publications Office 2017).

44 Flach, Teti, Gourevich, Scheckenhofer and Grandum (n. 23).

45 Lukas Mankhoff and Marius Zeevaert, 'Deutschland kann seine Versorgungssicherheit bei mineralischen Rohstoffimporten erhöhen', DIW-Wochenbericht 50 (2022), 667-675.

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tion, 2) import diversification potential analysis, 3) product complexity assessment, 4) export restriction evaluation, 5) extra-regional supply-chain exposure assessment, and 6) domestic demand analysis.

In detail, we first identify medical commodities 'at-risk', i. e., goods deserving particular attention, based on the EU's import volume and concentration. Second, for these at-risk commodities, we the EU's import partners to the top global exporters of these commodities to identify import diversification potential. Third, we calculate the unit price of commodities to gauge their complexity and substitutability, providing insights into supply disruption risks. Fourth, we analyse previous and current trade restrictions by high volume trade partners. Fifth, we estimate exposure to global supply chains through reliance on intra-EU trade. Lastly, we examine the foreign value added in domestic final demand. By applying this methodology, we identify 36 at-risk commodities with different levels of criticality. The results of our analysis are summarised in Figure 1.[46] The next sections provide a step-by-step application of our approach.

1. Commodity At-Risk Identification

The identification of commodities at-risk is based on the World Trade Organization's (WTO) list of medical goods from 2020, with which the WTO proposes a comprehensive identification of medical commodities beyond the goods that are essential for countering the COVID-19 pandemic.[47]

46 The figure indicates the degrees of criticality with values from 1 to 4 and different shades of grey from low criticality (1, light grey) to high criticality (4, dark grey). Additionally, we also calculate an unweighted composite score for each commodity and the commodity group. The composite scores are colour code from light grey (score below 2), mid-light grey (score between 2 and <2.5), mid-dark (2.5 to <3), and dark grey (score >3). The summary does not include the analysis of the foreign value added as data is only available for pharmaceutical commodities. Based on the summary figure, we can already discern that criticality is highest in the group of medical equipment and supplies, followed by medicaments and Personal Protective Equipment (PPE).

47 The list is a combination of three previously developed collections of medical commodities. These collections are the Information Technology Agreement (ITA) Expansion, the 1994 Agreement on Trade in Pharmaceutical Products, and the World Customs Organization's (WCO) HS Classification reference for COVID-19 medical supplies. Although being comprehensive, additional lists by WHO, WTO, as well as the World Bank (WB) do exist, which sometime provide slight changes. For further discussion of the different lists see Pierre Cotterlaz, Guillaume Gaulier, Aude Sztulman and Deniz Ünal, 'Pioneering a New Classification: a Comprehensive Study of Healthcare Products in Global Trade, Centre d'Etudes Prospectives et d'Informations Internationales (CEPII) Working Paper No. 2024-02, January 2024, available at <https://cepii.fr/PDF_PUB/wp/2024/wp2024-02.pdf>, last access 12 November 2012; World Trade Organization, 'Trade in Medical Goods in the Context of Tackling COVID-19, World Trade Organization Information Note No. 2020/01, 3 April 2020, doi: 10.30875/5a1af59c-en.

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The list identifies 92 medical commodities on the Harmonized System (HS) 6-digit level and groups the commodities into medicaments, medical supplies, medical equipment, and PPE.[48] Notably, the list does not include starting materials and Application Programming Interfaces (APIs) used in the production of finished pharmaceutical products. This fits well with the research gap addressed by our analysis.[49]

Using United Nations (UN) Comtrade,[50] we compiled a granular dataset of export flows from 165 countries to the world and to the EU. We exclusively focused on export flows to keep the reporters, i. e., the individual countries, constant and avoid mixing export and import data, which often shows discrepancies that stem from differences in the quality of the trade data reporting.[51] Hence, the 'EU imports' are determined by the exports of other countries to the EU.

Using this approach, we calculated the total weight of EU imports between 2018 and 2022 for the 92 commodities identified by the WTO. We extended the data to cover the years prior to the pandemic in order to account for any biases in the data that might arise due to focusing on a single year or the altered trade patterns during the COVID-19 pandemic.[52] Additionally, we followed previous contributions and used trade volume in terms of trade weights to mask quantitative dependencies on cheap products, e. g., generic antibiotics.[53]

48 The full list of commodities including their descriptions and HS codes is displayed in Table A.1.

49 For a detailed analysis on starting materials and APIs see Francas, Fritsch and Kirchhoff, Resilienz (n. 21).

50 UN Comtrade Database, <https://comtradeplus.un.org/>.

51 Imports, Exports and Mirror Data with UN COMTRADE, <https://wits.worldbank.org/wits/wits/witshelp/content/data_retrieval/T/Intro/B2.Imports_Exports_and_Mirror.htm>, last access 12 November 2025.

52 Guglielmo Caporale, Anamaria Sova and Robert Sova, 'The COVID-19 Pandemic and European Trade Patterns: A Sectoral Analysis', International Journal of Finance & Economics 30 (2024), 729-749

53 Bayerlein, 'EU's Open Strategic Autonomy' (n. 10).

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Figure 1: Critical Medical Goods Summary

Category	HS Code	Product	Diversification Potential	Production Complexity	Export Restrictions	External Dependency	Commodity Criticality Score	Unweighted Category Score
	300215	Immunological products (for retail)	4	4	1	3	3	
	300220	Vaccines for human medicine	2	4	2	1	2,25	
	300320	Antibiotics (not for retail)	4	1	3	3	2,75	
	300410	Penicillins (for retail)	3	1	4	1	2,25	
Medicaments	300431	Insulin (for retail)	2	2	3	1	2	2,28
	300432	Corticosteroid hormones (for retail)	1	2	2	1	1,5	
	300439	Hormones or steroids (for retail)	2	3	2	2	2,25	
	300441	Ephedrine (for retail)	3	4	2	1	2,5	
	300460	Antimalarial active principles (for retail)	2	3	4	1	2,5	
	300490	Medicaments n.e.s. (for retail)	2	1	2	2	1,75	
	284700	Hydrogen peroxide	1	1	3	1	1,5	
	300212	Antisera and other blood fractions	3	4	1	3	2,75	
	300510	Adhesive dressings and other articles	1	3	2	2	2	
	300590	Wadding, gauze, bandages and the like	3	2	3	2	2,5	
	350400	Peptones and their derivatives	2	2	1	2	1,75	
	350790	Enzymes and prepared enzymes, n.e.s.	3	3	2	2	2,5	
Supplies	380894	Disinfectants	2	1	2	1	1,5	2,52
	382200	Diagnostic or laboratory reagents	3	4	2	3	3	
	392620	Apparel and clothing of plastic sheeting	4	1	2	4	2,75	
	401511	Surgical gloves	3	2	4	4	3,25	
	401519	Gloves, mittens and mitts	4	1	4	4	3,25	
	901831	Syringes, with or without needles	2	3	3	3	2,75	
	901839	Needles, catheters, cannulae and the like	2	4	4	3	3,25	
	841920	Medical, surgical or laboratory sterilisers	2	1	1	2	1,5	
	901812	Ultrasonic scanning apparatus	3	4	1	4	3	
	901813	Magnetic resonance imaging apparatus	4	4	2	4	3,5	
	901819	Other electro-diagnostic apparatus	2	4	2	3	2,75	
Equipment	901920	Therapeutic respiration apparatus	2	2	2	4	2,5	2,6
	902212	Computer tomography apparatus	2	3	2	4	2,75	
	902214	Apparatus based on the use of X-rays	2	2	2	4	2,5	
	902290	X-ray generators	3	3	3	3	3	
	902519	Thermometers and pyrometers	3	1	2	3	2,25	
	940290	Medical furniture	4	1	2	2	2,25	
	340220	Other cleaning products	2	1	2	1	1,5	
PPE	392690	Plastic face masks	2	2	2	2	2	2,25
	630790	Textile face masks	3	4	2	4	3,25	

Our at-risk definition is based on the total weight of country's exports to the EU, i. e., EU imports and the import concentration measured by the Herfindahl-Hirschman Index (HHI). The HHI measures trade concentration by estimating the market share of different providers, i. e., countries. It runs from 0 to 1, with 1 indicating absolute market concentration with only one

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provider, i. e., a monopoly.[54] As a rule of thumb, values below 0.15 are categorised as unconcentrated markets, while values above 0.25 indicate highly concentrated markets.[55] For our at-risk classification we use an HHI of 0.2 as the cut-off point as the commodities with values of 0.2 and above already indicate moderately concentrated markets that merit a closer look.[56]

Since it is not only a question of trade concentration but also demand, we introduce a second cut-off based on the total weight of the EU imports. This cut-off is determined by calculating the median import weight for each commodity group (medicaments, supplies, equipment, and PPE). We consider a commodity at-risk if the import weight is above the median of the respective commodity group, i. e., if a large amount of the good is imported by the EU. We use the median instead of the mean, as the median is robust against outliers while at the same time captures the commodities with large trade quantities. The results of applying both cut-offs are displayed in Figure 2.

The figure shows several at-risk goods within each commodity group. While several goods show a high import volume, most fall slightly above the median, underscoring that the import volumes of most medical commodities within the four groups are similar. Contrary to that, HHI values display a considerable variance with many goods greatly exceeding the 0.2 and even the 0.25 mark. This indicated a very high import concentration for most commodities in the WTO list. In total, we identified 36 at-risk commodities based on the import concentration and the total import weights between 2018 and 2022. For these 36 at-risk commodities we further analysed existing trade patterns and developed import diversification scenarios.

2. Import Patterns and Diversification Potential

In the next step of our identification strategy, we analysed existing trade patterns and developed diversification scenarios. For this purpose, we first calculated the EU's import shares for each of the 36 commodities and listed the top ten import partners, i. e., the top ten exporters to the EU. In a second step, we calculated the global export shares of our sample countries and again listed the top ten exporters to the world for each commodity. Based on this, we compared the top EU partners to the list of major global exports and identified new potential partners.

54 Depending on whether market shares are expressed in percent or decimals values can also range from 0 to 10,000.

55 U. S. Department of Justice and the Federal Trade Commission, 'Horizontal Merger Guidelines', 19 August 2010, available at <https://www.justice.gov/atr/horizontal-merger-guidelines-08192010>, (accessed 12 November 2025).

56 Ivan Brezina, Juraj Pekár, Zuzana Čičková and Marian Reiff, 'Herfindahl–Hirschman Index Level of Concentration Values Modification and Analysis of Their Change', Central European Journal of Operations Research 24 (2016), 49-72.

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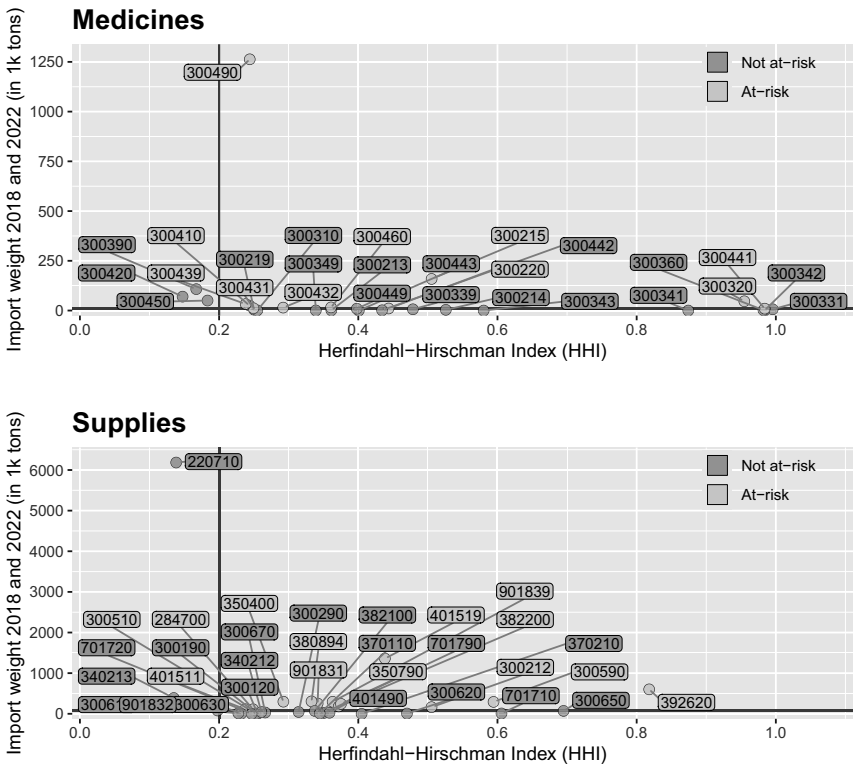
To move beyond the mere identification of such partners, we also derived scenarios of potential import diversification. For these scenarios we first calculated the average export shares to the EU for each commodity to identify common trade volumes. Second, we increased the EU import shares with these new partners up to the average trade share, while reducing the import shares of the largest and sometimes second largest EU import partner by the same amount.[57] Based on this new configuration of import partners we calculated the simulated HHI. Figure 3 provides on overview over the simulated HHI reduction (red) and the current HHI (blue) for each of the 36 at-risk commodities. The detailed list of the top EU partners and global exporters as well as the diversification scenarios are displayed in Table A.2 to A.5 in the appendix.

Figure 2: At-Risk Commodity Identification



57 This approach assumes a constant trade volume with partner countries as well as a constant EU demand for the respective commodities. Additionally, we assume substitutability of commodities between different countries. See Section 'Limitations and Further Research' for a more in-depth discussion of these assumptions and resulting limitations.

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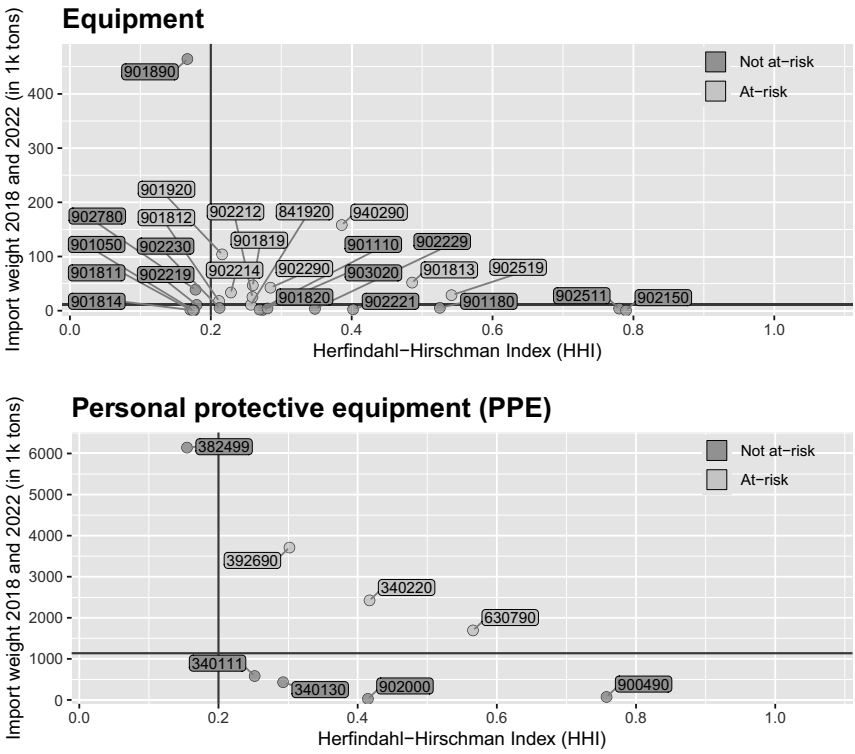

The figure shows considerable variance in the EU's import diversification potential. For some commodities like medicaments containing alkaloids (HS 300441), the HHI can almost be reduced by 50 % through import diversification, while other goods like antibiotics (HS 300320) show no import diversification potential. Although the import diversification not always results in the HHI falling below the critical value of 0.25, for a large share of the commodities analysed, we developed diversification scenarios that reduced the import concentration to levels below 0.25 (33 %) and even below 0.15 (8 %). Based on the HHI reduction, we grouped the commodities by four categories that indicated the diversification and criticality reduction potential: None, low, moderate, and high. The 'none' category is defined by the EU's import partners being identical with the top global exporters and the HHI lying above 0.25. The category 'low' indicates the absence of export potential below the values of 0.25 and the existence of export potential that falls short of reducing the HHI below 0.25. Commodities are classified as 'moderate' if the simulated reduction brings the HHI below the 0.25 mark or further reduces a HHI already below 0.25. Commodities falling below a simulated HHI of 0.15 are categorised as having a 'high' criticality reduction potential.

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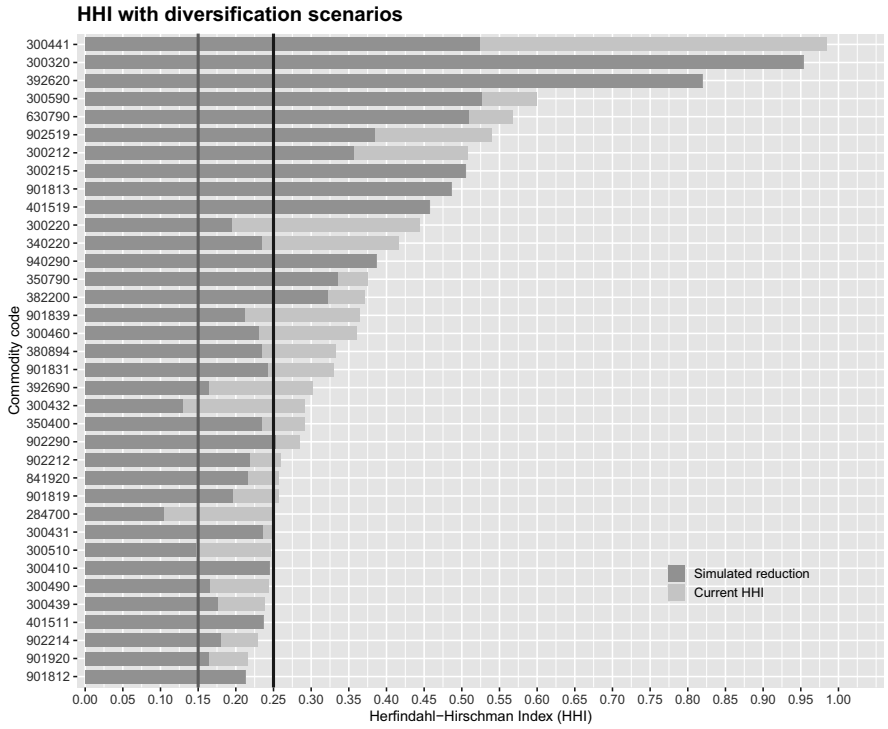
Figure 3: Current and Simulated HHI



3. Production Complexity

Moving beyond the current and potential import diversification, we analysed the production complexity of the at-risk commodities based on the level of sophisticated technology required to produce them. Previous research already focuses on the complexity of products to estimate supply chain resilience for the individual commodities.[58] The reasoning behind this is that highly complex products are dependent on a multitude of production steps and suppliers, which make the supply chain vulnerable to shocks. Additionally, countries can arguably not respond to disruptions in the supply-chain of these highly complex products due to various supply-side factors: a lack of close substitutes,[59] the highly sophisticated technology or

58 Robert Inman and Dennis Blumenfeld, 'Product Complexity and Supply Chain Design', International Journal of Production Research 52 (2014), 1956-1969.

59 Lawrence Edwards and Robert Z. Lawrence, 'Do Developed and Developing Countries Compete Head to Head in High-Tech?, National Bureau of Economic Research, Working Paper No. 16105, June 2010, doi: 10.3386/w16105.

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tools required for their production, and the time taken to establish production capabilities in exporting country.[60]

Even on the demand side, the price or unit value of a product can indicate the quality of the product[61] as capital and skill-rich countries tend to specialise in superior varieties that need more sophisticated technologies for production.[62] Therefore, to determine the complexity of products that can also be viewed as higher quality[63] or a measure for the technology embodied in the product,[64] we calculated the average unit value in current US$ for each at-risk commodity. It is important to note that while unit values are correlated with quality, quality increases beyond a certain threshold do not tend to drive prices as high production efficiency would keep prices stable.[65] Hence, although it is not a perfect measure of quality or embodied technology, it can be used as a general measure of complexity of final medical products imported by the EU.[66]

Since the quality of imported products is conditional on its price[67], the unit value (price) was calculated by dividing the value of the imports by the import quantity (for example, in tons, or number of pieces, or weight). For each of the four commodity categories we determined the relative complexity based on the distribution of the unit price values. For the lowest quartile, we assumed a low complexity of products. Commodities falling between the lowest quartile and the median were categorised as moderately complex. Goods with an average unit price between the median and the

60 Robert C. Feenstra and John Romalis, 'International Prices and Endogenous Quality', The Quarterly Journal of Economics 129 (2014), 477-527.

61 Peter K. Schott, 'Across-Product Versus Within-Product Specialization in International Trade', The Quarterly Journal of Economics 119 (2004), 647-678.

62 Alexandra Bykova, Mahdi Ghodsi and Robert Stehrer, 'The Evolution of Trade Unit Values: a Measurement on Quality', UNIDO Inclusive and Sustainable Industrial Development Working Paper Series WP 1/2018, available at <https://downloads.unido.org/ot/10/16/10166456/WP_1.pdf>, last access 12 November 2025.

63 Juan Carlos Hallak, 'Product Quality and the Direction of Trade', Journal of International Economics 68 (2006), 238-265.

64 Bykova, Ghodsi and Stehrer (n. 62).

65 Christian Henn, Chris Papageorgiou and Nikola Spatafora, Export Quality in Developing Countries, IMF Working Paper WP/13/108, 15 May 2013, doi: 10.5089/9781484351635.001.

66 Our study does not capture the trade in medical intermediate products, especially APIs that have low unit values usually due to optimised production (scale). Moreover, unit values of patented medicines depend on the remaining period of a patent held by a firm and distort average values. Further research can be conducted to determine the impact of patents on prices of medication. Patented-high-value medicines also tend to be traded through small B2C orders that are not usually captured in country-level trade data. Therefore, they have been excluded from this analysis.

67 Amit Khandelwal, 'The Long and Short (of) Quality Ladders', The Review of Economic Studies 77 (2010), 1450-1476.

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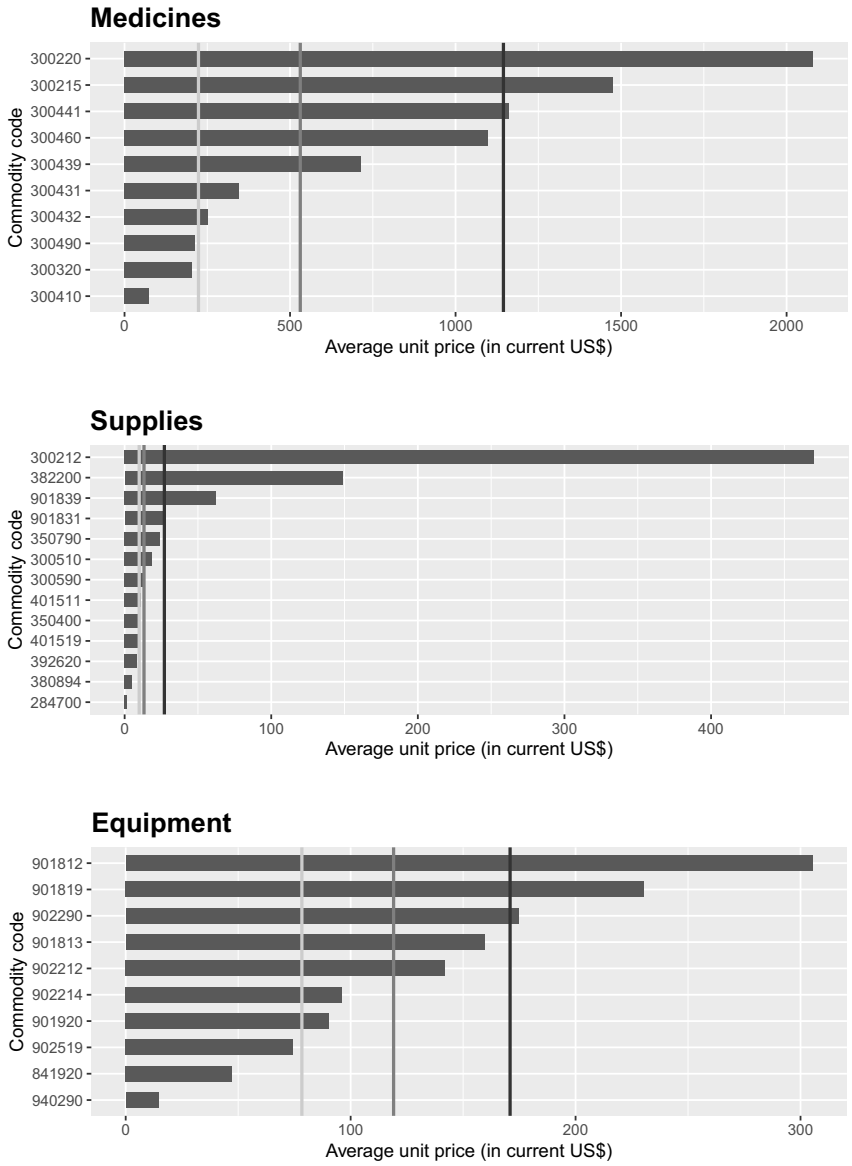
upper quartile resembled rather complex products, and commodities above the upper quartile were the most expensive and, in our reasoning, the most complex products. Using these cut-offs, Figure 4 shows the average unit price for the 36 commodities.

Figure 4: Product Complexity Assessment



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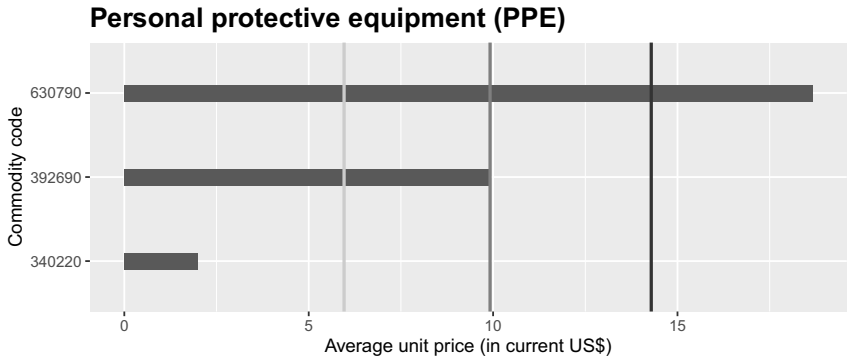

Focusing on medical goods, two commodities display particularly high average unit prices. These commodities are vaccines (HS 300220) and blood antisera for retail sale (HS 300215). Since vaccines are highly complex products, the identified products support our approach of measuring product complexity via the average unit price. Conversely, medical supplies like hydrogen peroxide (HS 284700) as well as disinfectants (HS 380894) are rather cheap products with a low production complexity.[68]

The interpretation of high and low complexity is dependent on the time horizon and intention. While higher product complexity correlates with higher supply-chain disruption risks and lower short-term compensation through re-shoring, re-shoring might nonetheless, be an option in the long run due to higher revenues associated with the commodity and the development of local production capabilities over time. At the same time, low product complexity can enable countries to re-shore production in the short-term but may not be economically feasible for some countries in the long run as high labour costs could drastically increase the price of commodities. For our analysis, we put greater weight on complexity being a short-term threat to securing medical supplies as we are interested in supply-chain security and overcoming immediate disruptions.

68 Note that antibiotics (HS code 300320) and penicillin (HS code 300410) also show a very low unit price. While the production of both medicaments is somewhat less complex than manufacturing for example vaccines, it is important to point out that economies of scale and expired patent protection reduce unit prices. Further, although the EU might have the necessary infrastructure to manufacture antibiotics, if necessary, this does not go for other countries. Thus, the evaluation of the complexity is highly context specific and does not permit us to derive that a low unit price means that all countries can produce the product.

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4. Patterns of Export Restrictions Across Trade Partners

To determine the level of exposure of the EU's medical supply chains due to export restrictions introduced by partner countries, we drew on data from the Global Trade Alert (GTA) database.[69] This dataset provides information on trade-affecting policies implemented by partner countries in our sample between 2008 and 2022. Due to our research interest, we exclusively focused on export restricting measures. The export measures included in the analysis are the following: ban, licensing requirement, quota, tariff quota, tax, related non-tariff measure, and other export inventive. We also only considered an intervention as relevant if the intervention according to GTA 'likely involves discrimination against foreign commercial interests' (amber GTA evaluation) or 'almost certainly discriminates against foreign commercial interests' (red GTA evaluation). Additionally, only measures on the national and supranational level were included.

We matched the 36 identified at-risk commodities with those affected by the respective export restrictions at the HS 6-digit level and by the implementing authority, as indicated in the GTA database. In total, we find 281 export restrictions imposed by countries on the 36 at-risk commodities.[70] Next, we matched the EU's top import partners with the countries with a recent history of applying export-restricting measures. Utilising our import flow database, we determined the number of the EU's import partners that have introduced export-restricting measures for each of the 36 commodities, i. e., the number of restriction-imposing countries on whom the EU is dependent for the respective commodity. Figure 5 shows the number of export-restricting partners for the commodities (at HS 6-digit) among the top five import partners.

The figure shows that all of the EU's imports of medical commodities are dependent on at least one country with a history of restricting export of medical goods. For five of the 36 at-risk commodities, we uncover that four of the top five trade partners have previously introduced measures limiting the export of medical goods. Six of the commodities have three top trading partners that implemented one or more export restrictions since 2008. Further, for an astonishing 20 out of the 36 commodities we find two trade partners with a history of export restricting measures. Lastly, only five commodities are primarily imported from partners where only one of the

69 Independent Monitoring of Policies that Affect World Commerce, <https Khandelwal:// www.globaltradealert.org/>, last access 12 November 2025.

70 The total is distributed across the types of export restrictions as follows: bans (137), licensing requirements (105), quotas (12), tariff quotas (0), taxes (7), related non-tariff measures (20), and other export inventives (0).

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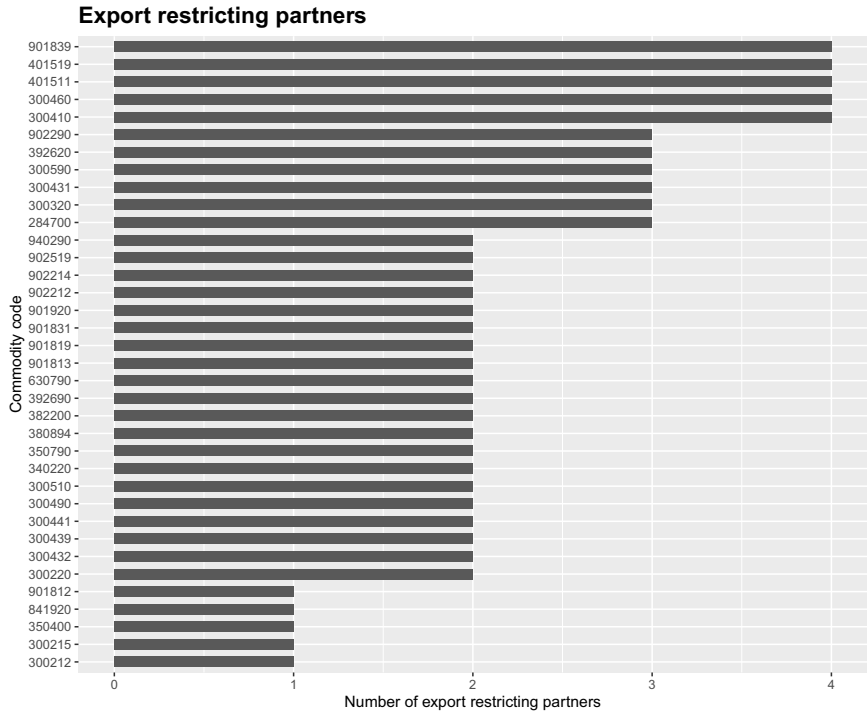
countries restricted the export of medical commodities.[71] Based on this, we again classify the commodities into four tiers of criticality depending on the number of export-restricting partners from very high (four+) to high (three) and moderate (3) as well as low (1 or less).

Figure 5: Export Restrictions by Import Partners



5. The EU's Extra-Regional Supply-Chain Exposure

The EU imports medical goods from several non-EU countries outlined in Tables A.2 to A.5 as well as from within the twenty-seven EU member states. A case can be made that if the EU does import most medical goods from inside the bloc, it would be more insulated from geopolitical supply shocks. To identify

71 It is important to note that our analysis includes the years 2020 to 2022 and therefore also captures export restrictions introduced during the COVID-19 pandemic. Although countries applied these measures prior to the pandemic, the GTA data shows an increase of these measures during the pandemic. We nonetheless include the behaviour of countries between 2020 and 2022 as the introduction of export restrictions during the pandemic is a testimony of how countries behave in crises. The criticality of the EU's import dependencies must include especially these circumstances.

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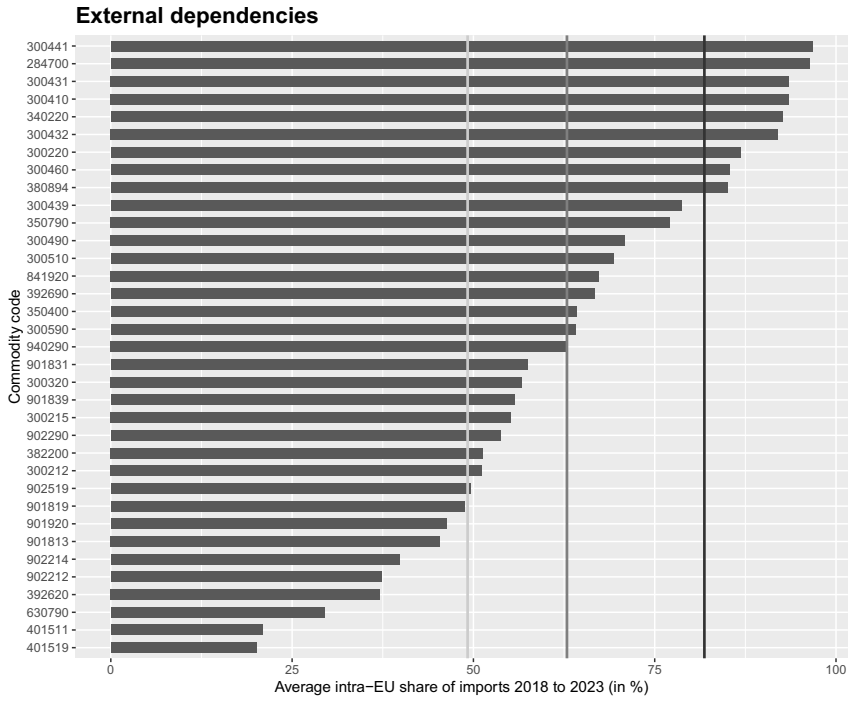
the commodities with a higher self-reliance we used data from UN Comtrade but this time the import data as it is reported by the EU was used.[72] With this data, we calculated the share of intra-EU imports in each of the 36 products that were branded to be at-risk. The data was again divided in quartiles using the median instead of the mean, as it is robust against outliers. The results are displayed in Figure 6 with vertical lines indicating the cut-off points.

Using this approach, we find nine products with the lowest intra-EU import shares, or the highest dependence on non-EU imports belonging to the lowest quartile, and therefore more exposed to global supply constraints and shocks. The identified commodities include several appliances (x-ray machines, therapeutic respiration apparatus, surgical instruments) and medical supplies made of rubber, plastic, and textiles. For these products, the intra-EU import share in total imports by the EU was below 48.2 percent, i. e., over fifty percent of such imports originated outside the EU bloc, exposing them to global export restrictions and shocks.

Figure 6: External Dependencies



72 We can focus on the import data reported by the EU countries since we do not compare this data with the export shares by other countries to the world. The methodological issues described above therefore do not apply.

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Among the rest of the twenty-seven at-risk products, thirteen were sourced mainly from other EU countries (intra-regional imports) with intra-EU imports comprising a share of seventy percent or more. This indicates that at most 30 percent of imports of these thirteen products are sourced from outside the EU. This group of products, including hydrogen peroxide, disinfectants, dressings, and a range of antibiotics, insulin, alkaloids, vitamins, and anti-malaria medicaments are therefore the least exposed to global shocks or export restrictions as they continue to be sourced from inside the single market and customs union of the EU.[73]

6. Connectedness of EU's Extra-Regional Demand

The last measure to determine the risk associated with supply chains is the import partner shares in foreign value added embodied in domestic final demand (DFD_FVApSH) from the OECD Trade in Value Added (TiVA) database.[74] This indicator provides a value-added perspective of the EU's relative connectedness to production in other countries and regions. A high value indicates a higher dependence on foreign industries to meet domestic demand. Due to the paucity of data, this section of the analysis only focuses on the pharmaceutical industry and is therefore not displayed in the summary table. The pharmaceutical products analysed include vitamins, antibiotics, hormone derivatives, vaccines, and other medicaments[75] that are usually highly complex and sophisticated products. Any external shock would disrupt supplies to the EU in the short run as these products require imported specialised equipment and raw materials to be produced; however, in the long run, the EU could develop production capabilities to reduce external supply chain risk. The FVA in DFD is plotted against the import shares of the commodities in Figure 7.

73 European Commission, *Trade: Towards Open and Fair World-Wide Trade*, available at <https://european-union.europa.eu/priorities-and-actions/actions-topic/trade_en>, last access 12 November 2025.

74 The complete guide to the database and the methodologies used by OECD can be found here: <https://web-archive.oecd.org/2023-11-24/644737-TiVA_2023_Indicators_Guide.pdf>, last access 12 November 2025.

75 This is based on the ISIC Rev 4 classification of products based on industrial activity. For this analysis, chapter Division 21 was chosen for the time-period 2017-2020. UN Department of Economic and Social Affairs, 'International Standard Industrial Classification of All Economic Activities Revision 4', Series M No. 4/Rev.4 Statistics Division, <https://unstats.un.org/unsd/publication/seriesm/seriesm_4rev4e.pdf>, last access 12 November 2025.

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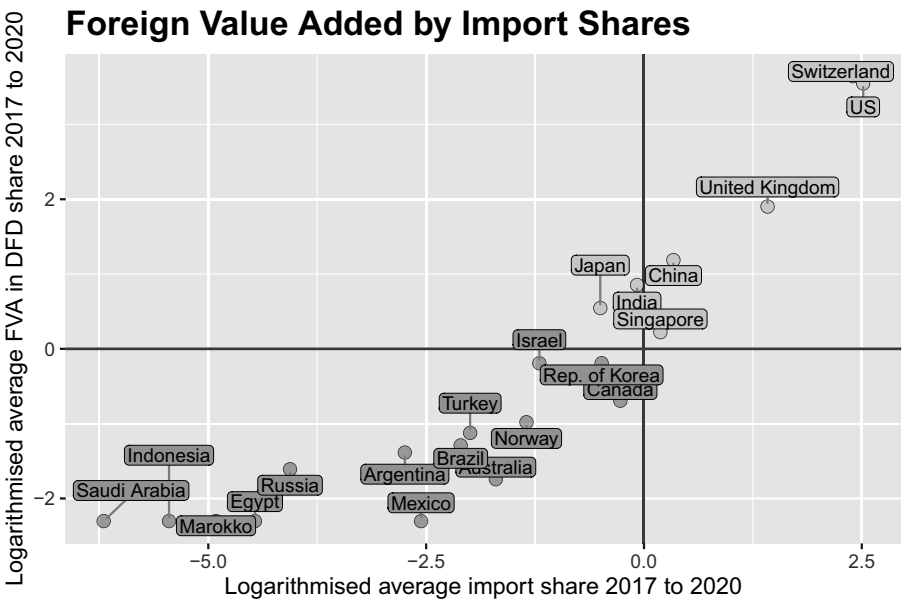
Figure 7: Supply-Chain Connectedness



When the FVA in DFD share is plotted against the average import share of the same products[76] over the same period of 2017-2020, we find highly concentrated dependence on foreign value added through imports from Japan, Singapore, India, China, the United Kingdom, the United States, and Switzerland to meet EU's final consumer demand of pharmaceutical products. This dependence can be interpreted as high-risk in the event of a supply-side shock originating in these countries.

IV. Limitations and Further Research

Our analysis is based on several assumptions that introduce limitations to the results. First, we assume a constant trade volume with partner countries, as well as a stable EU demand for the respective commodities across years. This assumption restricts the model's ability to account for variations arising from changes in demand. It may be violated in the event of demand surges within the EU or external supply shocks. Therefore, the empirical findings

76 The concordance between ISIC Rev 4 and HS2017 was developed by the OECD STAN Databases Team. HS to ISIC to End-Use Conversion Key, <https://www.oecd.org/sti/ind/ConversionKeyBTDIxE4PUB.xlsx>, last access 12 November 2025.

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derived from our RFA would need to be revisited and updated in response to significant shifts in demand or supply structures, as these may alter the list of identified at-risk commodities.

Second, we assume perfect substitutability of commodities across different countries. For example, we do not distinguish between vaccines imported from the US and those from the UK. While the available data does not permit a more detailed analysis of substitutability, this assumption imposes notable limitations. In practice, a measles vaccine cannot be substituted for a whooping cough vaccine – particularly where intellectual property rights are involved. Moreover, a trading partner capable of manufacturing a specific commodity, such as measles vaccine doses, is likely also capable of producing other generic vaccines, even if they are not doing so currently.

Third, the UN Comtrade trade data used in this analysis may obscure real economic dependencies when goods are imported indirectly through intermediary countries rather than directly from their country of origin. For instance, a product manufactured in China might first be imported into the UK and then re-exported to the EU. In trade statistics, this could appear as an import from the UK, thereby masking the EU's actual reliance on Chinese manufacturing. Such re-routing complicates efforts to trace supply chains and accurately assess strategic dependencies. Addressing this issue requires more granular trade data (not available through UN Comtrade) that can track whether specific commodities, such as measles vaccines, were first imported by a country before being re-exported to the EU.

The limitations discussed above also translate into constraints when drawing political conclusions. Nevertheless, the analysis still offers valuable insights into how critical dependencies can be evaluated, as well as which key parameters and indicators may support such assessments. In other sectors, there are often well-established approaches for defining criticality.[77] For example, in the context of food security, criticality is traditionally linked to achieving a high degree of self-sufficiency. In contrast, the EU defines the criticality of raw materials based on supply risks and recyclability.[78] Each of these approaches has its own limitations, and while different sectors exhibit unique production patterns, comparing various methodologies for assessing criticality can provide a richer foundation for future analyses.

77 Jennifer Clapp, 'Food Self-Sufficiency: Making Sense of It, and When It Makes Sense', Food Policy 66 (2017), 88-96.

78 Joint Research Center: EU Science Hub, Study on the Critical Raw Materials for the EU 2023, <https://publications.jrc.ec.europa.eu/repository/handle/JRC136041>, last access 12 November 2025.

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V. Results

Following the onset of the COVID-19 pandemic, the EU Commission unveiled plans for an EHU. The creation of this EHU also demanded the fortification of medical and pharmaceutical supply chains to ensure the availability of medical goods for European citizens and healthcare systems. This makes it even more surprising that the EU has thus far only developed strategies to other sectors outside the medical sector like to secure its supply for raw materials and semi-conductors, while mostly neglecting medical commodities. Further, previous research has also rarely addressed the sector-specific resilience of the EU's medical supply chains. Against this background we raised the following questions: What are the existing WTO rules to secure supplies and access to medical goods? How can economic strategies to assess dependencies secure access?

The WTO legal framework allows for a broad application of export restrictions, which – as illustrated by their extensive use in the food sector – demonstrates how even in a heavily traded essential sector countries retain wide discretion; by analogy, similar risks arise for medical supplies with potentially severe implications for global availability and prices. However, such measures may be counterproductive on a global scale, posing significant risks for countries that rely heavily on imports – particularly when exporting countries frequently impose these restrictions. Thus, the EU must assess and overcome critical dependencies in its import of medical goods. To this end, we designed a risk-assessment framework (RFA) to identify commodities and suppliers that may reduce critical dependencies. This RFA was based on six steps, including 1) At-risk commodity identification, 2) import diversification potential analysis, 3) production complexity assessment, 4) export restriction evaluation, 5) domestic demand analysis, and 6) extra-regional supply-chain exposure assessment.

Although developing tailored strategies for more resilient supply chains was not the primary aim of this study, the application of our RFA provides some initial insights into potential strategic approaches for different commodity groups. Using our RFA, we found that medical equipment showed particularly high level of criticality. This criticality is based on systematically higher levels of product complexity as well as external dependencies. On a positive note, however, apart from MRI scanners, our trade flow analysis showed great diversification potential for the EU, which could be further explored to reduce the risk imposed by the complexity and external dependency. Among the medicaments, immunological products and antibiotics showed the highest import concentration for the EU on one to three coun-

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tries. The high production complexity involved in developing immunological products further increase the risk associated with this commodity.

Antibiotics excluding penicillin are another critical medical commodity, as import diversification is essentially not possible now. For these products, a strategic political approach would be to ensure stable trade relations, as many countries may compete for a highly concentrated supply. Further, domestic production could be supported to enhance security. However, the situation for medicaments is very nuanced: while certain criticalities were identified, the combined scores suggest that other medical commodities may be equally or even more important. This is especially true for specific PPE supplies – such as gloves, syringes, catheters, and cannulas — which show particularly high levels of criticality. These commodities are often overlooked in other analyses, which limits the development of sound policy recommendations. Our findings highlight the need for trade diversification, especially for these products. Other items, such as face masks, also show high overall criticality. However, we found limited potential for import diversification in this case. Therefore, a trade strategy for such products should focus on maintaining stable import relationships and agreements, while also considering domestic production and strategic stockpiling.

VI. Policy Recommendations and Conclusion

Although the supply chains of medical and agricultural products differ in key characteristics – such as the role of research and development, territorial production dependencies, and perishability – valuable lessons can be drawn from the longstanding experience in regulating and responding to trade restrictions in the agricultural sector. A monitoring system (Agricultural Market Information System AMIS) has been initiated in one of the younger so-called global food price crises in 2011 by the G20. It informs on actual global supply and price of major products including inputs and stocks. This approach helps identify actual and potential shortage risks and may support efforts to avoid export restrictions – which are often counterproductive at the global level – when no global shortages are evident. Other monitoring systems focus specifically on export restrictions, such as the IFPRI-tracker.[79] A similar tracking system could be designed to measure global supply, prices, and stocks of medical products and inform of any shortages so that import-

79 Food and Fertilizer Export Restrictions Tracker, Food Security Portal IFPRI, <https://www.foodsecurityportal.org/tools/COVID-19-food-trade-policy-tracker>, last access 12 November 2025.

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dependent countries could find short-term solutions through diversification or stockpiling to meet domestic demand.

Another possible solution could be linked to awareness-raising activities or programmes on the risks of export restrictions. These have already been pursued increasingly since the pandemic. To this end, the WTO and IMF jointly called for refraining from applying export restrictions to avoid price peaks and reduced supply.[80] During the Russian invasion of Ukraine and the induced price rises, various WTO decisions of 2022 stressed on refraining from export restrictions in food products to ensure smooth functioning of humanitarian food programmes.[81] Such awareness-raising programmes could be replicated for medical goods.

Although the WTO system is currently weakened with a limited settlement procedure and global trade protectionism is on the rise, economically, pursuing open trade through international cooperation remains the first-best option. Therefore, convincing trade partners to refrain from applying restrictions on medical products is still relevant. Another approach may be to sign bilateral cooperation agreements or future-proof new free trade agreements to dis-incentivise the application of new trade-restricting measures.[82] According to our analysis relevant new partners might be the Republic of Korea for hydrogen peroxide, India for vaccines, or Uganda for alkaloids.

Current political discussion also heavily centre around dependencies on Asian countries, especially China. The dominant role of China identified by us for certain commodities (e. g., Antibiotics and blood antisera, see Table A.2.1) underscores the merit of this focus. However, our proposed framework treats by design all countries alike. This is because it is – as with other critical commodities – not only about China but critical dependencies in general. The import tariffs raised by the second Trump administration underscore that any market concentration be it with a country perceived as an 'ally' or a 'strategic rival' potentially threatens the EU's open strategic autonomy. Therefore, we also recommend that an evaluation of existing strategic dependencies as proposed by us should move beyond a mere focus on singular countries (be it China or Russia).

Regardless of the legal framework that allows for export restrictions, economic strategies play a crucial role in securing supply chains for medical products. The decision for strategies would depend on the time frame being considered. In the short run, any disruption in supply chains could be met

80 International Monetary Fund, WTO and IMF heads call for lifting trade restrictions on medical supplies and food, 24 April 2020, Press Release No. 20/287, <https://www.imf.org>, last access 12 November 2025.

81 WTO, WT/MIN(22)/29, WT/L/1140 of 22 June 2022.

82 World Bank Group and World Trade Organization (n. 9).

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with import diversification options that can be identified in advance using a risk-assessment framework such as proposed in this paper. Simultaneous stockpiling often is targeted to meet domestic demand for import-dependent countries in commodities that are most at-risk, however, as seen during the pandemic, stockpiling by net exporters of medical goods led to further shortages and price hikes that impacted many import-dependent countries across the world. Here again, experiences from the food sector can help highlight potential trade-offs. Existing WTO rules on subsidies – as well as those related to stockholding – aim to prevent international market disruptions both when building up reserves and when releasing them.[83] Import diversification in the long run is a recommended option for increased security of supplies. This would require negotiating new and sustainable supplier contracts.

The EU has also thus far refrained from establishing plurilateral agreements (so-called 'clubs')[84] to address medical supply-chain bottlenecks, albeit embracing this approach for critical raw materials.[85] The EU's reluctance to pursue plurilateral agreements in the medical goods sector may stem from sensitivities around national health sovereignty and regulatory divergence, further undermined by the erosion of trust during the pandemic due to vaccine nationalism and export restrictions, which made deeper cooperation politically and practically more difficult. But an important real difference to CRM alliances is that the EU can – in theory – produce medical commodities with less foreign inputs. Therefore, own production could be increased – eventually by financial incentives. Due to the economic downsides of these approaches, the EU should also explore the possibility of plurilateral agreements in the medical sector[86] Such a trade-link is relevant as well to the issue of re-shoring of supply chains in the aftermath of the pandemic, was also based on the need to secure supply of essential goods. However, re-shoring is only advised when it aligns in an economically sound manner with domestic production capabilities. In the long-run countries can move to domestic production of certain at-risk commodities that have few substitutes or only limited options for import diversification, however, this will require high value investments, supportive economic policies embedded in general strategies, and human capital to develop production capacity and capability.

83 Rudloff, *Trade Rules* (n. 18).

84 Bernard Hoekman, 'COVID-19 Trade Policy Measures, G20 Declarations and WTO Reform' in: Simon Evenett and Richard Baldwin (eds), *Revitalising Multilateralism Pragmatic Ideas for the New WTO Director-General* (CEPR Press 2020), 63-69.

85 Bayerlein, 'EU's Open Strategic Autonomy' (n. 10).

86 Bernard Hoekman, Matteo Fiorini and Aydin Yildirim, 'COVID-19: Export Controls and International Cooperation' in: Richard Baldwin and Simon Evenett (eds), *COVID-19 and Trade Policy: Why Turning Inward Won't Work* (CEPR Press 2020), 77-87.

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Appendix

Table A.1: At-Risk Medical Commodities Description

Category	HS Code	WTO Description
Medicaments	300215	Immunological products, … for retail sale
	300220	Vaccines for human medicine
	300320	Medicaments containing antibiotics, … not for retail sale
	300410	Medicaments containing penicillin or derivatives thereof … for retail sale
	300431	Medicaments containing insulin but not antibiotics, … for retail sale
	300432	Medicaments containing corticosteroid hormones, … for retail sale
	300439	Medicaments containing hormones or steroids … for retail sale
	300441	Medicaments containing ephedrine or its salts, … for retail sale
	300460	Medicaments containing any of the following antimalarial active principles … for retail sale
	300490	Medicaments consisting of mixed or unmixed products … for retail sale
Supplies	284700	Hydrogen peroxide, whether or not solidified with urea
	300212	Antisera and other blood fractions
	300510	Adhesive dressings and other articles … put up for retail sale for medical, surgical, dental or veterinary purposes
	300590	Wadding, gauze, bandages and the like put up for retail sale for medical, surgical, dental or veterinary purposes
	350400	Peptones and their derivatives; other protein substances and their derivatives, n. e. s.; …
	350790	Enzymes and prepared enzymes, n. e. s.
	380894	Disinfectants, put up in forms or packings for retail sale
	382200	Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents and certified reference materials
	392620	Articles of apparel and clothing accessories produced by the stitching or sticking together of plastic sheeting
	401511	Surgical gloves, of vulcanised rubber
	401519	Gloves, mittens and mitts, of vulcanised rubber
	901831	Syringes, with or without needles, used in medical, surgical, dental or veterinary sciences
	901839	Needles, catheters, cannulas and the like, used in medical, surgical, dental or veterinary sciences
Equipment	841920	Medical, surgical or laboratory sterilizers
	901812	Ultrasonic scanning apparatus
	901813	Magnetic resonance imaging apparatus
	901819	Other electro-diagnostic apparatus
	901920	Ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus
	902212	Computer tomography apparatus
	902214	Apparatus based on the use of X-rays, for medical, surgical or veterinary uses
	902290	X-ray generators, high tension generators, control panels and desks, screens, …
	902519	Thermometers and pyrometers, not combined with other instruments
	940290	Operating tables, examination tables, and other medical, dental, surgical or veterinary furniture
PPE	340220	Other cleaning products
	392690	Plastic face masks
	630790	Textile face masks

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Table A.2.1: Trade in Medicament Commodities (Weight)

			Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
Rank	HS Code	Product	Country	%	HHI	Country	%	Country	%	HHI
1			China	68,51		China	61,75			
2			Rep. of Korea	16,02		Rep. of Korea	13,92			
3			USA	9,67		USA	13,84			
4			Switzerland	3,42		Switzerland	5,35			
5	300215	Blood Antisera (packed)	United Kingdom	1,17	0,51	United Kingdom	1,23	None	None	None
6			Japan	0,43		Japan	1,14			
7			Türkiye	0,18		Türkiye	0,68			
8			Russian Federation	0,17		India	0,37			
9			India	0,15		Costa Rica	0,22			
10			Singapore	0,13		Mexico	0,21			
1			USA	63,54		USA	35,26	USA	28,54	
2			United Kingdom	18,37		India	21,60	India	25,00	
3			South Africa	5,42		China	10,73	United Kingdom	18,37	
4			Switzerland	4,33		United Kingdom	7,84	China	11,24	
5	300220	Vaccines	Singapore	2,48	0,44	Rep. of Korea	3,94	South Africa	5,42	0,20
6			Canada	1,52		United Arab Emirates	3,13	Switzerland	4,33	
7			China	1,24		Canada	2,53	Singapore	2,48	
8			Rep. of Korea	1,06		Russian Federation	2,34	Canada	1,52	
9			Australia	0,97		Uganda	2,06	Rep. of Korea	1,06	
10			India	0,42		Indonesia	1,99	Australia	0,97	
1			China	97,63		China	91,48			
2			USA	0,86		Canada	1,77			
3			United Kingdom	0,65		USA	1,60			
4			Canada	0,25		Thailand	1,01			
5	300320	Antibiotics	India	0,21	0,95	Saudi Arabia	0,86	None	None	None
6			Switzerland	0,15		United Kingdom	0,68			
7			Saudi Arabia	0,09		Switzerland	0,50			
8			Japan	0,05		Rwanda	0,38			
9			United Arab Emirates	0,04		India	0,25			
10			Morocco	0,02		China, Hong Kong SAR	0,23			
1			India	37,63		China	36,01			
2			United Kingdom	24,61		India	27,60			
3			China	19,64		United Kingdom	5,94			
4			Canada	4,77		Canada	5,65			
5	300410	Penicillin	Morocco	3,08	0,25	USA	3,27	None	None	None
6			Pakistan	2,21		Türkiye	2,29			
7			USA	2,09		Indonesia	1,96			
8			Türkiye	1,29		Russian Federation	1,71			
9			United Arab Emirates	0,97		China, Hong Kong SAR	1,60			
10			Russian Federation	0,95		Pakistan	1,42			

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Table A.2.2: Trade in Medicament Commodities (Weight) Continued

Rank	HS Code	Product	Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
			Country	%	HHI	Country	%	Country	%	HHI
1			China	35,70		USA	29,52	USA	27,48	
2			USA	22,48		India	27,89	China	25,70	
3			India	20,18		Brazil	13,96	India	25,18	
4			Brazil	17,40		China	12,62	Brazil	17,40	
5	300431	Insulin	United Kingdom	1,41	0,25	Malaysia	4,38	United Kingdom	1,41	0,24
6			Russian Federation	0,99		United Arab Emirates	2,59	Russian Federation	0,99	
7			Malaysia	0,69		Ukraine	2,45	Malaysia	0,69	
8			Indonesia	0,31		South Africa	1,74	Indonesia	0,31	
9			Türkiye	0,20		United Kingdom	1,35	Türkiye	0,20	
10			United Arab Emirates	0,19		Jordan	0,58	United Arab Emirates	0,19	
1			United Kingdom	51,01		India	22,62	United Kingdom	21,01	
2			USA	9,72		United Kingdom	18,18	India	18,05	
3			Switzerland	8,87		China	17,18	China	15,00	
4			Canada	7,94		USA	10,14	USA	9,72	
5	300432	Corticosteroids	Australia	5,35	0,29	Canada	6,45	Switzerland	8,87	0,13
6			Brazil	5,24		Switzerland	3,18	Canada	7,94	
7			Singapore	3,64		Australia	3,16	Australia	5,35	
8			India	3,05		Brazil	1,95	Brazil	5,24	
9			Russian Federation	1,08		Singapore	1,60	Singapore	3,64	
10			Serbia	1,07		China, Hong Kong SAR	1,56	Russian Federation	1,08	
1			Brazil	31,44		Pakistan	21,57	Brazil	23,44	
2			Switzerland	25,66		Brazil	13,14	Switzerland	21,66	
3			United Kingdom	25,31		Switzerland	10,63	United Kingdom	21,31	
4			USA	8,86		United Kingdom	9,53	Pakistan	13,30	
5	300439	Hormones	China	2,57	0,24	USA	9,07	USA	8,86	0,18
6			Tunisia	2,48		India	7,94	India	4,33	
7			India	1,33		Indonesia	3,16	China	2,57	
8			Japan	0,58		China	2,85	Tunisia	2,48	
9			Pakistan	0,30		Argentina	2,84	Japan	0,58	
10			United Arab Emirates	0,29		Türkiye	2,55	United Arab Emirates	0,29	
1			Malaysia	99,19		Malaysia	90,10	Malaysia	62,19	
2			United Kingdom	0,64		Uganda	8,10	Uganda	37,00	
3			United Arab Emirates	0,12		United Arab Emirates	0,62	United Kingdom	0,64	
4			Chile	0,03		Indonesia	0,38	United Arab Emirates	0,12	
5	300441	Alkaloids	Kenya	0,01	0,98	USA	0,19	Chile	0,03	0,52
6			Switzerland	0,01		Oman	0,15	Kenya	0,01	
7			South Africa	0,00		Chile	0,11	Switzerland	0,01	
8			New Zealand	0,00		United Kingdom	0,10	South Africa	0,00	
9			Australia	0,00		Kazakhstan	0,07	New Zealand	0,00	
10			Ukraine	0,00		Japan	0,04	Australia	0,00	

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Table A.2.3: Trade in Medicament Commodities (Weight) Continued

Rank	HS Code	Product	Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
			Country	%	HHI	Country	%	Country	%	HHI
1			United Kingdom	55,28		China	29,18	United Kingdom	30,28	
2			India	16,94		India	28,71	India	25,94	
3			China	13,39		Ukraine	26,71	China	21,39	
4			Ukraine	7,50		United Kingdom	12,58	Ukraine	15,50	
5	300460	Antimalarial	Switzerland	5,41	0,36	Switzerland	1,77	Switzerland	5,41	0,23
6			Morocco	1,28		Morocco	0,30	Morocco	1,28	
7			Canada	0,11		South Africa	0,14	Canada	0,11	
8			Malaysia	0,04		USA	0,14	Malaysia	0,04	
9			Ghana	0,02		Malaysia	0,08	Ghana	0,02	
10			USA	0,02		Canada	0,06	USA	0,02	
1			United Kingdom	43,53		India	19,17	United Kingdom	29,53	
2			Switzerland	18,93		China	13,60	Switzerland	18,93	
3			India	11,01		United Kingdom	10,23	India	16,01	
4			USA	5,18		USA	6,41	USA	5,18	
5	300490	Medicaments, n. e. c.	Serbia	3,38	0,24	Switzerland	4,77	Serbia	3,38	0,17
6			Singapore	3,14		China, Hong Kong SAR	3,29	Singapore	3,14	
7			Türkiye	2,35		Colombia	3,12	Türkiye	2,35	
8			China	2,25		Singapore	2,91	China	11,25	
9			Morocco	1,46		Malaysia	2,69	Morocco	1,46	
10			North Macedonia	1,40		Canada	2,67	North Macedonia	1,40	

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Table A.3.1: Trade in Medical Supplies Commodities (Weight)

			Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
Rank	HS Code	Product	Country	%	HHI	Country	%	Country	%	HHI
1			Norway	35,95		Thailand	16,77	Norway	15,95	
2			United Kingdom	30,69		Rep. of Korea	16,42	USA	13,44	
3			USA	13,44		Brazil	16,12	Thailand	10,00	
4			Israel	8,65		Canada	11,09	Rep. of Korea	10,00	
5	284700	Hydrogen peroxide	Japan	3,00	0,25	USA	10,13	Brazil	10,00	0,10
6			Brazil	2,09		Kazakhstan	7,21	Canada	10,00	
7			Switzerland	1,92		Japan	4,29	United Kingdom	10,69	
8			Türkiye	1,60		China	3,14	Israel	8,65	
9			Canada	0,67		Indonesia	2,47	Japan	3,00	
10			China	0,38		Kuwait	1,58	Brazil	2,09	
1			USA	67,75		USA	45,13	USA	54,75	
2			United Kingdom	21,15		United Kingdom	13,67	United Kingdom	21,15	
3			Switzerland	5,29		Argentina	10,77	Argentina	7,00	
4			Türkiye	2,63		Canada	8,25	Canada	6,00	
5	300212	Blood Antisera	Iran	1,00	0,51	Türkiye	4,57	Switzerland	5,29	0,36
6			Canada	0,65		Switzerland	2,56	Türkiye	2,63	
7			Brazil	0,28		Brazil	2,54	Iran	1,00	
8			Australia	0,25		Chile	2,29	Canada	0,65	
9			Rep. of Korea	0,22		Uruguay	2,17	Brazil	0,28	
10			Japan	0,15		Paraguay	1,99	Australia	0,25	
1			China	43,42		China	36,82	Malaysia	21,49	
2			United Kingdom	15,25		Malaysia	24,45	China	18,42	
3			USA	14,26		USA	9,60	United Kingdom	15,25	
4			Japan	9,08		Japan	8,75	USA	14,26	
5	300510	Dressings and adhesive	Thailand	4,27	0,25	United Kingdom	4,30	Japan	14,08	0,15
6			Egypt	4,17		Brazil	1,92	Thailand	4,27	
7			Switzerland	2,49		Thailand	1,75	Egypt	4,17	
8			Rep. of Korea	1,94		Rep. of Korea	1,48	Switzerland	2,49	
9			Türkiye	1,55		Mexico	1,45	Rep. of Korea	1,94	
10			South Africa	1,49		Türkiye	1,16	Türkiye	1,55	
1			China	76,78		China	71,06	China	71,78	
2			United Kingdom	7,46		Malaysia	6,96	United Kingdom	7,46	
3			Thailand	3,74		USA	4,72	Malaysia	5,00	
4			USA	3,42		United Kingdom	2,92	Thailand	3,74	
5	300590	Wadding, gauze, and bandages	India	3,09	0,60	India	2,60	USA	3,42	0,53
6			Türkiye	1,61		Mexico	1,36	India	3,09	
7			Switzerland	1,17		Rep. of Korea	1,27	Türkiye	1,61	
8			Morocco	0,92		Thailand	1,25	Switzerland	1,17	
9			Rep. of Korea	0,29		Türkiye	1,22	Morocco	0,92	
10			Bosnia Herzegovina	0,21		Singapore	0,73	Rep. of Korea	0,29	

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Table A.3.2: Trade in Medical Supplies Commodities (Weight) Continued

			Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
Rank	HS Code	Product	Country	%	HHI	Country	%	Country	%	HHI
1			China	47,48		China	59,16	China	40,62	
2			USA	22,41		USA	18,92	USA	22,41	
3			Switzerland	10,18		Brazil	5,65	Switzerland	10,18	
4			Australia	4,16		Canada	3,15	Brazil	6,86	
5	350400	Peptones and derivatives	Brazil	3,65	0,29	Australia	2,95	Australia	4,16	0,24
6			Canada	3,56		Switzerland	2,01	Brazil	3,65	
7			United Kingdom	3,36		India	1,15	Canada	3,56	
8			Norway	0,98		Chile	0,99	United Kingdom	3,36	
9			India	0,97		New Zealand	0,69	Norway	0,98	
10			New Zealand	0,76		Rep. of Korea	0,65	India	0,97	
1			USA	43,19		China	42,39	USA	43,19	
2			China	43,04		USA	29,83	China	38,04	
3			United Kingdom	3,78		Singapore	6,17	Singapore	5,00	
4			Japan	3,49		Türkiye	3,03	United Kingdom	3,78	
5	350790	Enzymes	India	1,61	0,38	Brazil	2,73	Japan	3,49	0,34
6			Canada	1,01		Japan	2,01	India	1,61	
7			Brazil	0,76		Malaysia	1,70	Canada	1,01	
8			Mexico	0,74		United Kingdom	1,66	Brazil	0,76	
9			Türkiye	0,62		Canada	1,59	Mexico	0,74	
10			Malaysia	0,47		India	1,41	Türkiye	0,62	
1			United Kingdom	52,39		China	36,84	United Kingdom	33,39	
2			China	19,61		USA	14,18	USA	24,58	
3			Türkiye	9,37		United Kingdom	6,87	China	21,61	
4			USA	7,58		Canada	4,88	Türkiye	9,37	
5	380894	Disinfectants	Switzerland	7,28	0,33	Mexico	4,34	Switzerland	7,28	0,23
6			Norway	1,18		Guatemala	3,96	Norway	1,18	
7			Canada	0,79		India	3,65	Canada	0,79	
8			China, Hong Kong SAR	0,40		Costa Rica	3,26	China, Hong Kong SAR	0,40	
9			Morocco	0,16		Türkiye	3,08	Morocco	0,16	
10			Tunisia	0,13		Argentina	2,90	Tunisia	0,13	
1			USA	57,98		USA	36,72	USA	53,46	
2			United Kingdom	15,56		China	19,90	United Kingdom	15,56	
3			China	8,99		Japan	7,20	China	8,99	
4			Switzerland	3,00		Singapore	6,75	Japan	3,82	
5	382200	Reagents	Japan	2,92	0,37	China, Hong Kong SAR	6,40	Singapore	3,62	0,32
6			Rep. of Korea	2,50		United Kingdom	4,90	Switzerland	3,00	
7			China, Hong Kong SAR	2,14		Rep. of Korea	3,23	Rep. of Korea	2,50	
8			Canada	1,46		Canada	2,89	China, Hong Kong SAR	2,14	
9			Türkiye	1,15		Brazil	2,50	Canada	1,46	
10			South Africa	1,00		Malaysia	1,36	Türkiye	1,15	

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Table A.3.3: Trade in Medical Supplies Commodities (Weight) Continued

			Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
Rank	HS Code	Product	Country	%	HHI	Country	%	Country	%	HHI
1			China	90,43		China	90,83			
2			Viet Nam	2,95		Viet Nam	1,67			
3			United Kingdom	2,76		Canada	1,54			
4			Türkiye	0,82		Thailand	0,88			
5	392620	Plastics	Thailand	0,79	0,82	USA	0,63	None	None	None
6			Indonesia	0,31		Malaysia	0,59			
7			USA	0,29		United Kingdom	0,46			
8			India	0,27		Türkiye	0,43			
9			Tunisia	0,25		China, Hong Kong SAR	0,26			
10			Malaysia	0,20		Indonesia	0,20			
1			Malaysia	36,78		Malaysia	34,59			
2			China	23,47		China	29,81			
3			Thailand	19,46		Thailand	17,84			
4			Sri Lanka	6,00		Sri Lanka	4,61			
5	401511	Surgical gloves	Türkiye	5,27	0,24	India	3,60	None	None	None
6			India	3,82		Türkiye	2,27			
7			United Kingdom	2,32		Oman	1,33			
8			Indonesia	0,98		Indonesia	1,31			
9			Viet Nam	0,65		USA	1,10			
10			USA	0,19		United Kingdom	0,61			
1			Thailand	61,05		Thailand	69,35			
2			Malaysia	28,73		Malaysia	22,22			
3			China	4,44		China	4,23			
4			Indonesia	2,03		Indonesia	1,61			
5	401519	Other gloves	Sri Lanka	1,68	0,46	Sri Lanka	0,74	None	None	None
6			Viet Nam	0,96		Viet Nam	0,66			
7			United Kingdom	0,75		USA	0,47			
8			Pakistan	0,06		United Kingdom	0,12			
9			USA	0,06		Canada	0,10			
10			Singapore	0,05		India	0,05			
1			Rep. of Korea	33,08		China	32,89			
2			China	25,38		Rep. of Korea	24,50			
3			USA	16,65		USA	19,51			
4			Japan	7,83		Japan	7,03			
5	901831	Syringes	Norway	4,71	0,21	China, Hong Kong SAR	4,35	None	None	None
6			China, Hong Kong SAR	3,78		Norway	3,07			
7			United Kingdom	2,83		Malaysia	1,42			
8			Malaysia	1,86		Singapore	1,39			
9			Switzerland	1,19		United Arab Emirates	1,12			
10			Singapore	0,69		United Kingdom	0,90			

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Table A.3.3: Trade in Medical Supplies Commodities (Weight) Continued

Rank	HS Code	Product	Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
			Country	%	HHI	Country	%	Country	%	HHI
1			China	50,30		China	55,19	United Kingdom	26,91	
2			United Kingdom	32,91		Mexico	19,01	Mexico	25,78	
3			Thailand	3,33		United Kingdom	7,50	China	25,30	
4			Belarus	2,71		Costa Rica	6,23	Costa Rica	8,37	
5	901839	Catheters and cannulas	Türkiye	2,63	0,37	Thailand	5,06	Thailand	3,33	0,21
6			Japan	2,42		Japan	2,14	Belarus	2,71	
7			Costa Rica	2,37		Türkiye	1,46	Türkiye	2,63	
8			Morocco	0,89		Rep. of Korea	0,69	Japan	2,42	
9			Mexico	0,78		Belarus	0,61	Morocco	0,89	
10			Switzerland	0,46		Dominican Rep.	0,32	Switzerland	0,46	

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Table A.4.1: Trade in Medical Equipment Commodities (Weight)

			Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
Rank	HS Code	Product	Country	%	HHI	Country	%	Country	%	HHI
1			China	42,03		China	48,93	China	36,03	
2			USA	25,24		USA	15,79	USA	25,24	
3			Switzerland	8,05		Canada	5,12	Canada	8,44	
4			Türkiye	5,88		Mexico	4,88	Switzerland	8,05	
5	841920	Sterilizers	United Kingdom	5,79	0,26	Türkiye	4,44	Türkiye	5,88	0,22
6			Israel	4,80		Japan	3,50	United Kingdom	5,79	
7			Canada	2,44		Rep. of Korea	2,78	Israel	4,80	
8			Rep. of Korea	1,77		Australia	2,49	Rep. of Korea	1,77	
9			Japan	0,76		United Kingdom	2,37	Japan	0,76	
10			Norway	0,74		Switzerland	2,32	Norway	0,74	
1			Rep. of Korea	33,08		China	32,89			
2			China	25,38		Rep. of Korea	24,50			
3			USA	16,65		USA	19,51			
4			Japan	7,83		Japan	7,03			
5	901812	Ultrasonic scanning apparatus	Norway	4,71	0,21	China, Hong Kong SAR	4,35	None	None	None
6			China, Hong Kong SAR	3,78		Norway	3,07			
7			United Kingdom	2,83		Malaysia	1,42			
8			Malaysia	1,86		Singapore	1,39			
9			Switzerland	1,19		United Arab Emirates	1,12			
10			Singapore	0,69		United Kingdom	0,90			
1			United Kingdom	64,08		China	51,32			
2			China	27,21		United Kingdom	34,17			
3			USA	3,79		USA	4,21			
4			Switzerland	1,52		United Arab Emirates	1,84			
5	901813	MRI apparatus	India	0,69	0,49	Rep. of Korea	1,27	None	None	None
6			Japan	0,47		Japan	1,12			
7			Türkiye	0,43		Türkiye	1,09			
8			Rep. of Korea	0,26		China, Hong Kong SAR	1,05			
9			Norway	0,25		Switzerland	0,96			
10			China, Hong Kong SAR	0,22		India	0,80			
1			USA	46,19		USA	27,52	USA	26,24	
2			China	14,46		China	17,80	China	14,46	
3			United Kingdom	12,61		Japan	9,33	United Kingdom	12,61	
4			Japan	5,29		Dominican Rep.	6,77	Japan	10,29	
5	901819	Electro-diagnostic apparatus	Tunisia	2,82	0,26	Thailand	5,86	Dominican Rep.	8,02	0,20
6			Israel	2,78		Mexico	5,25	Thailand	6,94	
7			China, Hong Kong SAR	2,30		United Kingdom	3,79	Tunisia	2,82	
8			Costa Rica	2,17		Israel	3,51	Israel	2,78	
9			Malaysia	1,77		Costa Rica	2,66	China, Hong Kong SAR	2,30	
10			Rep. of Korea	1,66		Indonesia	2,51	Costa Rica	2,17	

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Table A.4.2: Trade in Medical Equipment Commodities (Weight) Continued

			Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
Rank	HS Code	Product	Country	%	HHI	Country	%	Country	%	HHI
1			China	38,91		China	47,87	China	23,70	
2			United Kingdom	17,28		Mexico	12,15	United Kingdom	17,28	
3			USA	13,41		USA	9,43	Mexico	15,21	
4			Singapore	8,43		Singapore	8,29	USA	13,41	
5	901920	Therapeutic respiration apparatus	Malaysia	7,19	0,22	United Kingdom	4,62	Singapore	8,43	0,16
6			Australia	4,57		Malaysia	4,11	Malaysia	7,19	
7			New Zealand	3,50		Australia	3,12	Australia	4,57	
8			Switzerland	3,09		New Zealand	2,48	New Zealand	3,50	
9			Türkiye	1,57		Türkiye	1,50	Switzerland	3,09	
10			Canada	0,60		Dominican Rep.	1,03	Türkiye	1,57	
1			China	39,57		China	34,17	Japan	32,46	
2			USA	26,37		USA	25,64	USA	21,37	
3			Japan	13,46		Japan	19,23	China	20,57	
4			United Kingdom	9,18		Israel	7,57	Israel	12,85	
5	902212	X-rays (all use, incl. CT)	Israel	7,85	0,26	United Kingdom	4,58	United Kingdom	9,18	0,22
6			Switzerland	1,47		United Arab Emirates	2,68	Switzerland	1,47	
7			Rep. of Korea	0,37		Rep. of Korea	1,46	Rep. of Korea	0,37	
8			Norway	0,36		Mexico	0,98	Norway	0,36	
9			United Arab Emirates	0,18		Singapore	0,56	United Arab Emirates	0,18	
10			India	0,17		Switzerland	0,50	India	0,17	
1			USA	29,27		USA	32,40	United Kingdom	25,15	
2			United Kingdom	29,15		China	20,57	China	21,88	
3			China	21,88		United Kingdom	13,00	USA	20,27	
4			Japan	8,14		Rep. of Korea	12,84	Rep. of Korea	14,59	
5	902214	X-rays (medical, excl. CT)	Rep. of Korea	5,59	0,23	Japan	10,74	Japan	8,14	0,18
6			India	1,75		India	2,23	India	1,75	
7			Switzerland	1,35		United Arab Emirates	2,10	Switzerland	1,35	
8			Norway	0,54		Mexico	1,34	Norway	0,54	
9			Serbia	0,33		Türkiye	0,61	Serbia	0,33	
10			Malaysia	0,32		China, Hong Kong SAR	0,55	Malaysia	0,32	
1			China	48,87		China	54,81	China	45,37	
2			United Kingdom	15,18		USA	8,74	United Kingdom	15,18	
3			USA	11,87		United Kingdom	8,22	USA	11,87	
4			India	6,50		Japan	5,14	Japan	6,80	
5	902290	X-ray parts and accessories	Switzerland	4,75	0,28	India	4,90	India	6,50	0,25
6			Japan	3,30		Rep. of Korea	4,21	Switzerland	4,75	
7			Rep. of Korea	2,24		Singapore	2,50	Rep. of Korea	2,24	
8			Canada	1,53		Switzerland	2,44	Canada	1,53	
9			Israel	1,53		Malaysia	1,87	Israel	1,53	
10			Singapore	1,02		Israel	1,70	Singapore	1,02	

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Table A.4.3: Trade in Medical Equipment Commodities (Weight) Continued

			Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
Rank	HS Code	Product	Country	%	HHI	Country	%	Country	%	HHI
1			China	72,64		China	61,75	China	59,76	
2			United Kingdom	7,27		Thailand	14,20	Thailand	12,88	
3			USA	6,36		USA	6,15	United Kingdom	7,27	
4			China, Hong Kong SAR	3,55		Rep. of Korea	3,61	USA	6,36	
5	902519	Thermometers and pyrometers	Rep. of Korea	2,70	0,54	China, Hong Kong SAR	2,69	China, Hong Kong SAR	3,55	0,39
6			Switzerland	2,37		Mexico	1,76	Rep. of Korea	2,70	
7			Türkiye	1,07		United Kingdom	1,12	Switzerland	2,37	
8			Serbia	0,84		Singapore	0,94	Türkiye	1,07	
9			Canada	0,53		Viet Nam	0,89	Serbia	0,84	
10			Norway	0,49		Japan	0,80	Canada	0,53	
1			China	58,12		China	64,61			
2			USA	17,51		USA	12,84			
3			Türkiye	10,73		Türkiye	5,24			
4			United Kingdom	7,99		Mexico	3,10			
5	940290	Medicial furniture	Switzerland	0,97	0,39	Canada	3,06	None	None	None
6			Australia	0,67		United Kingdom	2,60			
7			Viet Nam	0,57		Indonesia	1,45			
8			Israel	0,46		Viet Nam	1,33			
9			North Macedonia	0,35		Japan	0,60			
10			Thailand	0,33		Thailand	0,54			

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Table A.5: Trade in Medical PPE Commodities (Weight)

Rank	HS Code	Product	Current EU Import Partners			Top World Exporters		Scenarios: EU Import Partners		
			Country	%	HHI	Country	%	Country	%	HHI
1			United Kingdom	62,19		China	15,76	United Kingdom	42,19	
2			Türkiye	12,07		USA	12,98	Türkiye	12,07	
3			Serbia	11,36		Türkiye	8,55	USA	11,99	
4			Switzerland	4,16		United Kingdom	7,53	China	11,46	
5	340220	Washing and cleaning preparations	USA	1,99	0,42	Mexico	6,58	Serbia	11,36	0,24
6			Norway	1,86		Russian Federation	6,12	Switzerland	4,16	
7			China	1,46		Saudi Arabia	4,46	Norway	1,86	
8			Russian Federation	1,38		Indonesia	4,06	Russian Federation	1,38	
9			Mauritius	0,68		Thailand	3,03	Mauritius	0,68	
10			Israel	0,62		Canada	2,32	Israel	0,62	
1			China	52,58		Mexico	62,85	Mexico	30,00	
2			United Kingdom	11,46		China	21,22	China	22,58	
3			USA	8,04		USA	3,77	United Kingdom	11,46	
4			Türkiye	4,20		India	1,85	USA	8,04	
5	392690	Plastics, n. e. c.	Switzerland	3,78	0,30	Malaysia	1,49	Türkiye	4,20	0,17
6			India	3,56		Rep. of Korea	0,81	Switzerland	3,78	
7			Tunisia	1,97		China, Hong Kong SAR	0,79	India	3,56	
8			Malaysia	1,66		United Kingdom	0,71	Tunisia	1,97	
9			Rep. of Korea	1,44		Thailand	0,69	Malaysia	1,66	
10			Japan	1,17		Japan	0,63	Rep. of Korea	1,44	
1			China	74,89		China	76,66	China	70,89	
2			Türkiye	5,37		USA	5,03	USA	5,84	
3			United Kingdom	3,00		Viet Nam	2,35	Türkiye	5,37	
4			Viet Nam	2,69		India	2,18	United Kingdom	3,00	
5	630790	Textiles, n. e. c.	Tunisia	2,62	0,57	Mexico	2,06	Viet Nam	2,69	0,51
6			Morocco	2,17		Türkiye	1,95	Tunisia	2,62	
7			USA	1,84		Chile	1,54	Morocco	2,17	
8			India	1,27		China, Hong Kong SAR	0,71	India	1,27	
9			Thailand	0,95		United Kingdom	0,65	Thailand	0,95	
10			China, Hong Kong SAR	0,80		Rep. of Korea	0,60	China, Hong Kong SAR	0,80	

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Processing Electronic Health Data in the European Health Data Space

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Abstract

The widespread use and exchange of health data is central to modern digital medical care and research as well as the development of a European market for healthcare services and products. With the Regulation on the European Health Data Space (2025/327, hereinafter 'EHDS'), the European Union is pursuing a landmark data infrastructure project that aims at improving the use of health data for healthcare, health research, health innovation, and health policy-making throughout the European Union (EU). This paper examines the EHDS' functioning, structure, and relation to the General Data Protection Regulation (GDPR), also including its legislative development, and assesses it from the perspective of legislative competence in the areas of the internal market, data protection, public health, and the principle of proportionality.

Keywords

European Health Data Space – healthcare – secondary data processing – administrative infrastructure – legal competences

I. Introduction

The widespread availability of health data and genetic data[1] provides the basis for the development of future digital healthcare and biomedical research. Person-centric medicine is transitioning to also become a data-driven healthcare system that brings together a large amount of sensitive data and

1 On Terminology: The GDPR defines the two terms separately (Art. 4 Nos. 13, 15 GDPR, Art. 9(1)(4) GDPR). In the EHDS, however, both categories of data fall under the generic term of *personal electronic health data*, if processed in electronic form (Art. 2(1)(a), (2)(a) EHDS). For further a wider discussion on *health data* as a term in the EHDS context see Franziska Sprecher, 'Regulierung von Gesundheitsdaten und Gesundheitsdatenräumen', MedR 40 (2022), 829-838 (830-832).

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increasingly stratifies treatments. This requires the digitalisation of healthcare systems, for example, in the form of the collection and storage of patient data within an e-health system that allows health data to be accessed in a secure and rapid way. The electronic patient file plays a central role in this shift, already used in several EU countries and recently introduced in Germany.[2]

The rapid and widespread availability of health data enables the improvement of existing care concepts, the development of new ones, and the testing and introduction of innovations, such as Artificial Intelligence (AI)-driven diagnostics. At the same time, this data is particularly sensitive and confidential and needs the highest possible level of protection.

As part of the European Data Strategy to create a single European market for data,[3] the Commission proposed the European Health Data Space in May 2022.[4] Following extensive negotiations and discussions,[5] it entered into force on 26 March 2025, will apply from 26 March 2027, with key provisions effective from 26 March 2029.[6] It aims to enable the use of electronic health data for healthcare and for the promotion of research, innovation and policy-making, in compliance with the GDPR.[7]

Currently, health data is fragmented across various types of data systems in all Member States.[8] There are divergent administrative models for data

2 German Federal Ministry of Health, Die ePA für alle, <https://www.bundesgesundheitsministerium.de/themen/digitalisierung/elektronische-patientenakte/epa-fuer-alle.html>, last access 19 November 2025.

3 European Commission, *A European Strategy for Data*, Communication of 19 February 2020, COM/2020/66 final, 5; see also Behrang Raji, 'Datenräume in der Europäischen Datenstrategie', Zeitschrift für Datenschutz 2023, 3-8 (5 f.).

4 European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space', Communication of 3 May 2022, COM/2022 hereafter: 'draft EHDS Regulation'.

5 Among others by EDPB-EDPS, *Joint Opinion 3/2022 on the Proposal for a Regulation on the European Health Data Space of 12 July 2022*, <https://edpb.europa.eu/our-work-tools/our-documents/edpbedps-joint-opinion/edpb-edps-joint-opinion-032022-proposal_en>, last access 19 November 2025.

6 Regulation 2025/327/EU of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation 2024/2847/EU, OJ L 2025/327.

7 Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

8 European Commission, *A European Strategy for Data* (n. 3), 34; DG SANTÉ, 'Combined Evaluation Roadmap/Impact Assessment European Health Data Space', Ares(2020) 7907993, 2, available at <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space>, last access 19 Nobember 2025; European Commission, 'Study Supporting the Impact Assessment of Policy Options for an EU Initiative on a European Health Data Space', April 2022, 7, <https://health.ec.europa.eu/publications/study-supporting-impact-assessment-policy-options-eu-initiative-european-health-data-space_en>, last access 19 November 2025.

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access[9] as well as national rules governing the processing of health data. The latter were also not harmonised by the GDPR, due to its broad opening clauses, particularly for the processing of health data (in particular Articles 9 (2)(h)(i)(j) and 9(4) GDPR).[10]

During its legislative process, the draft EHDS Regulation has been the subject of controversial debate, especially concerning its relationship to the provisions of the GDPR and the question of GDPR conformity.[11] Our aim is to present the EHDS in detail, giving due consideration to the final structure and its relation to the GDPR (II.), and to add an additional aspect to the discussion, namely an assessment from the perspective of legislative competences (III. 2.-4.). To this end, the competences relevant to the processing of health data (public health, internal market, and data protection) will be examined in greater detail (III. 1.), concluding with an outlook (IV.).

II. The European Health Data Space (EHDS)

1. Objective and Subject Matter of the EHDS Regulation

The EHDS Regulation establishes a European Health Data Space providing for common rules, standards and infrastructures and a governance framework, for both the primary and secondary use of electronic health data[12] (Article 1(1) EHDS). As it fosters EU-wide electronic health data access for better provision of healthcare (*primary use*), and research, innovation, and policy-making (*secondary use*) on the one hand,[13] natural persons are to be

9 European Commission, *A European Strategy for Data* (n. 3), 34; Nadina Iacob and Felice Simonelli, 'Towards a European Health Data Ecosystem', European Journal of Risk Regulation 11 2020, 884-893.

10 See Jürgen Kühling, 'Datenschutz im Gesundheitswesen', MedR 37 (2019), 611-622 (613); Christina Kühnl, Kerstin Rohrer and Nick Kai Schneider, 'Ein europäischer Gesundheitsdatenschutz', DuD 42 (2018), 735-740; see also Raji (n. 3), 6; Thomas Petri, ‚Die primäre und sekundäre Nutzung elektronischer Gesundheitsdaten', DuD 46 (2022), 413-418 (414).

11 See EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), Michael Denga, 'Die Nutzungsgovernance im European Health Data Space als Problem eines Immaterialgütermarkts', EuZW 34 (2023), 25-32 (29); Luca Marelli et al., 'The European Health Data Space: Too Big To Succeed?', Health Policy 135 (2023), 104861; Robin van Kessel et al., 'The European Health Data Space Fails to Bridge Digital Divides', British Medical Journal 378 (2022), 378.

12 Art. 2(2)(a), 1(2)(b), (f) EHDS.

13 See <https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en>, last access 19 November 2025. Although the EHDS may still be insufficient for research cases described in: Regina Becker, Davit Chokoshvili and Edward S. Dove, 'Legal Bases for Effective Secondary Use of Health and Genetic Data in the EU: Time for New Legislative Solutions to Better Harmonize Data for Cross-Border Sharing?', International Data Privacy Law 14 (2024), 223-246.

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given better control over their health data,[14] on the other. To this end, the EHDS Regulation establishes two new cross-border infrastructures: *MyHealth@EU* for primary use and *HealthData@EU* for secondary use.[15] In addition, the Regulation creates a harmonised legal framework for the development, marketing, and use of *electronic health record systems*.[16]

2. Legal Basis and Structure of the EHDS Regulation

The Commission bases the EHDS Regulation on Articles 114 and 16 TFEU. It is embedded within a comprehensive system of other data-related legal acts of the Union, including the GDPR, the Data Governance Act, the Data Act, and the AI Act, to which it refers in several places. According to Article 1(3)-(7) EHDS, these legal acts are not affected by the EHDS Regulation.[17]

The Regulation is divided into nine chapters, of which Chapters I, II, IV and VI are the focus of this paper. Chapter I presents the subject matter and scope of the Regulation, while Chapters II and IV set out rules on primary and secondary use of electronic health data. Chapter VI establishes a governance structure, including an EHDS Board and Steering groups for MyHealth@EU and HealthData@EU.

3. The Primary Use of Electronic Health Data in the EHDS

Chapter II EHDS regulates the primary use of electronic health data, which refers to data processed for the purpose of providing healthcare to the individual, including associated services.[18] The EHDS Regulation also aims to 'improve natural persons' access to and control over their personal electronic health data in the context of healthcare'[19] and explicitly provides data protection rights in Articles 3-10 EHDS (see II. 3. b).

a) Systematic Storage of Health Data in EHR Systems at the National Level for the Purpose of Healthcare Provision

To improve the availability of electronic health data across the EU, Member States ensure that health professionals register 'priority categories of

14 Primarily through Chapter II EHDS, in addition to GDPR rights (Art. 1(2)(a) EHDS).

15 See Art. 1(2)(d), (e) EHDS, Art. 23 EHDS, Art. 75 EHDS.

16 Art. 2(2)(k), 1(2)(b), Chapter III EHDS.

17 However, the AI Act (Regulation 2024/1689/EU) and also the Medical Device Regulation 2017/745/EU only to a limited extent, Art. 1(5) EHDS. Still, this does not mean that the relationship between the EU's legislative acts concerning data does not raise any questions.

18 Art. 2(2)(d) EHDS.

19 See Recital 1 EHDS.

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personal electronic health data' into an Electronic Health Record System (EHR system),[20] as per Article 13(1) EHDS.[21] The specific categories include patient summaries, electronic prescriptions and dispensations, medical images, test results, and discharge reports.[22]

Once registered, healthcare professionals shall have access to these categories of health data of persons under their treatment and update them with regard to healthcare services provided.[23] This access is to be provided securely via 'health professional access services',[24] who may be provided and maintained either by public or private entities, depending on the decision of each Member State.[25]

These EHDS provisions raise questions related to data protection law, especially with regard to the applicable legal basis under the GDPR, some of which, however, are left to be answered by Member State laws. As for the registration of health data in EHR systems, the EHDS Regulation as such does not require consent within the meaning of Article 6(1)(a) GDPR.[26] Instead, national legislation, as required by Article 13(1) EHDS, will presumably introduce a legal obligation for healthcare professionals to register health data in EHR systems, thereby constituting a legal basis in accordance with Article 6(1)(c), (3) GDPR. Recital 11 EHDS suggests, that Member States may introduce further conditions such as a consent requirement under national legislation based on Article 9(4) GDPR.

With regard to health professional access services, Recital 19 EHDS clarifies that their provision is a task in the public interest, establishing a legal basis under Article 6(1)(e), (3) GDPR for its providers. It also states that the EHDS Regulation provides for 'conditions and safeguards' necessary to process under Article 9(2)(h) GDPR, which is to be ensured in particular through the technical requirements for EHR systems.[27]

From a data protection perspective, it is also crucial to define the scope of healthcare providers' access to health data. However, this task falls to the Member States,[28] who must ensure compliance with Article 5 GDPR and

20 Defined in Art. 2(2)(j) EHDS.

21 Art. 13(1) EHDS reads like a regulatory mandate to the Member States to adopt corresponding legislation.

22 Art. 14(1) EHDS. The Commission is empowered to further define data quality requirements via implementing acts, Art. 13(4) EHDS.

23 Art. 12, 13(2) EHDS.

24 Service supported by an EHR system that enables healthcare professionals to access the data of natural persons under their care (Art. 2(2)(i) EHDS).

25 Art. 12, Recital 19 EHDS.

26 Denga (n. 11), 2).

27 See Chapter III EHDS, Annex II EHDS.

28 Art. 11(3) EHDS.

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data minimisation, without unduly restricting access to data essential for healthcare provision.

b) Rights of Natural Persons with Regard to Electronic Health Data

Against the backdrop of the fundamental right to the protection of personal data under Article 8 Charter of Fundamental Rights of the European Union, making electronic health data available must be matched by a corresponding control of natural persons over their data. To this end, Articles 3-10 EHDS provide for rights that are partly based on the rights of data subjects under GDPR and are specifically tailored to personal electronic health data.

Building on Article 15 GDPR, Article 3(1) EHDS grants natural persons the right to access their own personal electronic health data *immediately,*[29] free of charge and in an easily readable, consolidated and accessible form, via an 'electronic health data access service'[30] set up by Member States.[31] Beyond access, individuals may enter information into their EHR (e. g. through wellness applications)[32] and have the right to rectification in line with Article 16 GDPR.[33] This is supplemented by a right to obtain information on data access, including who accessed data, when, and for what purpose, under Article 9 EHDS. Article 7 EHDS further introduces a right to give access to, and transmit their data to another healthcare provider (right to data portability), this includes derived data and applies irrespective of the legal basis, therefore going beyond Article 20 GDPR.[34]

Article 8 EHDS allows individuals to partially or fully restrict access of health professionals and healthcare providers to their electronic health data. In addition, Article 10 EHDS allows Member States to introduce an absolute right for individuals to opt out from access to their personal electronic health data by anyone other than the healthcare provider that initially entered the

29 Thus, going beyond Art. 15 GDPR, Recital 9 EHDS.

30 Defined in Art. 2(2)(h) EHDS as 'online service, such as a portal or an application for mobile devices, that enables natural persons not acting in a professional capacity to access their own electronic health data or the electronic health data of those natural persons whose electronic health data they are legally authorised to access'.

31 Art. 4(1) EHDS.

32 Art. 5 EHDS.

33 Art. 6 EHDS.

34 Art. 20 GDPR 'is limited to data which the data subject has provided', Alexander Dix, 'Art. 20' in: Indra Spiecker gen. Döhmann, Vagelis Papakonstantinou, Gerrit Hornung and Paul De Hert (eds), *General Data Protection Regulation* (C. H. Beck 2023), para. 6; European Commission, *Frequently Asked Questions on the European Health Data Space*, v1.0 of 05 March 2025, 12, <https://health.ec.europa.eu/document/download/4dd47ec2-71dd-49fc-b036-ad7c14f6ed68_en?filename=ehealth_ehds_qa_en.pdf>, last access 19 November 2025.

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data. This includes individual's access to their own data via electronic health data access services and thus goes beyond Article 8 EHDS.[35] However, the registration and availability of health data in local systems are not affected.[36] The introduction of Article 10 EHDS during the legislative process marks a clear improvement in terms of data control.[37] While leaving its implementation optional for Member States may lead to unequal protection across the EU and may appear to stand in contrast to the Regulation's aims of improving individuals' control over their health data alongside data availability,[38] this regulatory approach may better reflect the respective competences of the EU and the Member States competences in the context of healthcare provision. As we will show in Section III. 3., the EHDS will have a significant impact on Member States' healthcare systems whose responsibilities for the organisation and management of those systems, as well as for the provision of healthcare must be respected (Article 168(7) Treaty on the Functioning of the European Union [TFEU]). Introducing a uniform right to opt-out of data access services that Member States have yet to create or have already established, could interfere with their competences.

Given the potential overlap with GDPR subject rights, the European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS) had criticised the unclear relationship between EHDS and GDPR in earlier EHDS drafts for the creation of legal uncertainty.[39] As Recital 9 EHDS now emphasises, the EHDS rights are to complement the GDPR subject rights and improve their effectiveness (e. g. with shorter delays and full digitalisation), with the latter continuing to apply. If implemented in an easily accessible and comprehensible way, it could improve individuals' effective control and transparency over their data. If not, individuals run the risk of further confusing their EHDS and GDPR rights.

35 See Recital 18 EHDS; The opt-out may also apply to specific data categories like genetic data.

36 European Commission, *EHDS FAQ* (n. 34), 14.

37 The Commission's original EHDS proposal (2022) did not include an opt-out mechanism. Which was rightly criticised Ulrich M. Gassner, 'Forschung und Innovation im europäischen Gesundheitsdatenraum', DuD 46 (2022), 739-746 (744 f.) and Centrum für Europäische Politik (cep), 'EU-Gesundheitsdatenraum' (EU Health Data Space), 18 f., <https://www.cep.eu/fileadmin/user_upload/cep.eu/Analysen/COM_2022_197_EU-Gesundheitsdatenraum/cepAnalyse_Langfassung_EU-Gesundheitsdatenraum_COM_2022__197.pdf>, last access 19 November 2025.

38 Recital 1 EHDS.

39 EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 47. In addition, Art. 3 of the draft EHDS Regulation allowed for the assertion of some rights via access services for electronic health data, potentially threatening a de facto exclusion of persons with only limited access to digital services, van Kessel et al. (n. 11), 378.

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c) Implementation of a National Digital Health Authority

On the national level, Member States designate, fund, and staff one or more digital health authorities responsible for implementing and enforcing the EHDS provisions on primary use at the national level.[40] Responsibilities of these digital health authorities include implementing rights and obligations under Chapters II and III EHDS, supervising the national contact point for digital health,[41] and other technical and coordinative tasks to support the MyHealth@EU infrastructure.[42] It must also ensure compliance with interoperability and security standards, cooperate with data protection and cybersecurity authorities, and contribute to Union-level specification work.[43] Natural persons can lodge a complaint with this authority.[44]

EDPB and EDPS had criticised the unclear relationship between the national digital health authorities and the data protection supervisory authorities in earlier EHDS drafts.[45] The EHDS now includes a more structured relationship. While national digital health authorities remain competent to enforce the EHDS provision for primary use,[46] data protection authorities retain exclusive competence to monitor and enforce Articles 3 and 5-10 EHDS, and may exert their powers under Articles 58 and 83 GDPR, including imposing administrative fines.[47] To this end, national digital health authorities can only receive complaints under Articles 3 and 5-10 EHDS and transmit them to the data protection authorities.

d) MyHealth@EU Cross-Border Infrastructure

'MyHealth@EU' is the central interoperability[48] platform for digital health and a further development of the existing infrastructure of the same name.[49] Unlike the latter, connecting to MyHealth@EU will become mandatory for the Member States, which must each designate a national contact point for digital health.[50] Internationally, these national contact points are

40 Art. 19(1), (3) EHDS.
41 See II. 3. d).
42 Art. 19(2) EHDS.
43 Art. 19(2) EHDS.
44 Art. 21 EHDS.
45 EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 67.
46 Art. 19(1) EHDS.
47 Arts 21 and 22 EHDS.
48 Definition: Art. 2(2)(f) EHDS.
49 Art. 23(1) EHDS; European Commission, *EHDS FAQ* (n. 34), 15.
50 See Art. 23(2) EHDS.

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connected to all other national contact points of the Member States to facilitate the cross-border exchange of priority health data for primary use through MyHealth@EU.[51] Nationally, the contact points are connected to healthcare providers and professionals, pharmacies[52] so that they can exchange data.[53] While MyHealth@EU does not include a central repository for health data,[54] it shall provide services to support and facilitate the cross-border exchange of personal electronic health data.[55] It is set up by the Commission, which is empowered to set the technical requirements and standards, including detailed rules concerning the security, confidentiality, and protection of health data, to join the platform.[56] The EHDS thus leaves it largely to the Commission's implementing acts to ensure GDPR-compliance in terms of data security for cross-border data exchange. However, it assumes to provide a sufficient legal basis for data exchange via MyHealth@EU in the sense of Article 6(1)(e), (3), 9(2)(h) GDPR, including adequate safeguards.[57]

With regard to data governance, Article 23(7) EHDS specifies that national contact points act as joint controllers for the processing operations in which they are involved, while the Commission merely acts as a processor. As a result, they may be subject to measures taken not only by the digital health authority but also by data protection supervisory authorities and may be liable for GDPR infringements.

At Union level, a MyHealth@EU Steering group composed of all national contact points decides on the development and operation and is supported by the EHDS Board.[58] The governance structure mirrors that of HealthData@EU also addressed in Section II. 4. f). Member States may introduce supplementary services through MyHealth@EU such as telemedicine, mobile health, vaccination cards, or connections to Client-Patient Management Systems.[59]

Third countries and international organisations may be connected to MyHealth@EU, provided that the requirements of Article 23 EHDS as well as those of Chapter V GDPR are met.[60] However, as Member States may

51 Art. 23(2), (3) EHDS.
52 Enabling EU-wide dispensation of prescriptions.
53 Art. 23(5), (6) EHDS.
54 European Commission, *EHDS FAQ* (n. 34), 15.
55 As in Art. 14(1) EHDS.
56 Art. 23(1), (4) EHDS.
57 See Recital 34 EHDS. Member States may still exert influence on these implementing acts according to Art. 98(2) EHDS, Art. 5 Regulation 182/2011/EU.
58 See Art. 95(1), Art. 94 EHDS, e. g. exchange of best practices and information.
59 Art. 24 EHDS.
60 Art. 24(3) EHDS.

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introduce further conditions under Article 9(4) GDPR on international access to and transfer of personal electronic health data,[61] cross-border data sharing to third countries for primary use will likely continue to vary between EU countries, leading to a regulatory fragmentation in the context of third country data transfers.

4. The Secondary Use of Electronic Health Data in the EHDS

Chapter IV EHDS regulates the secondary use of electronic health data, such as for scientific research, innovation, policy-making, and public health (Article 53(1) EHDS), whereby it assumes compliance with the GDPR and intends to reinforce individual data control.[62] Essentially, Chapter IV creates a sector-specific data access mechanism whereby access to health data held by various health data holders is granted and intermediated by public authorities at the request of health data users via secure processing environments (SPEs)[63], while the health data remains stored in a decentralised manner with the health data holders. Through a single application, users can request access to data from multiple holders and its linked provision within an SPE. For these reasons, the EHDS has the potential to significantly improve the availability of health data for secondary processing and to meet important data needs.

a) Obligation of Health Data Holders to Provide Electronic Health Data

Articles 60(1) and 51(1) EHDS obliges health data holders to make a broad variety of electronic health data, such as patient records, administrative data, genetic and genomic data, and data from biobanks or medical devices, available for the purposes listed in Article 53(1) EHDS. This includes data processed for primary use[64], among other categories of health data, even if protected by intellectual property or trade secrets.[65] The term *health data*

61 Art. 90 EHDS.

62 Art. 1(3), (2)(a), (c) EHDS; see also Christian Dierks, 'European Health Data Space – Anforderungen und Chancen für die pharmazeutische Industrie', PharmR 45 (2023), 369-374 (370 f.).

63 See Art. 2(1)(c) EHDS refers to the definition laid down in Regulation 2022/868/EU (Data Governance Act).

64 Art. 51(1)(a) EHDS and Art. 60(1) EHDS.

65 However, HDABs take measures to protect business secrets and intellectual property (Art. 52(1), (3) EHDS).

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holder covers a wide range of public and private actors in the health sector, such as health insurance companies, pharmacy data centres, public authorities, research data infrastructures, or private companies developing products or services intended for the health, healthcare or care sector.[66]

'(M)aking available' within Article 51(1) EHDS means making the electronic health data available to a *health data access body* (HDAB) at its request[67], which in turn grants access to the data users via a SPE[68] it operates.[69] Further duties of health data holders are listed in Article 60 EHDS.[70] National law may provide that the duties of certain categories of health data holders are to be fulfilled by health data intermediation entities.[71]

In line with the Regulation's objective to improve individuals' control,[72] an opt-out mechanism was introduced in the legislative process under Article 71 EHDS, marking a significant shift from the Commission's proposal. Compared to primary use, this opt-out is mandatory,[73] its design, however, is largely left to Member State law. In Germany, such an opt-out mechanism has yet to be created.

b) Health Data Access Bodies (HDABs) as Intermediaries of Electronic Health Data for Secondary Use

Under Article 55(1) EHDS, Member States designate one or more national HDABs. HDABs receive, assess, and decide on applications, process, collect and compile the electronic health data, and make that data available via a SPE.[74] In Germany, a central data access and coordination body for health data was established at the Federal Institute for Drugs and Medical Devices

66 See Art. 2(2)(t) EHDS; natural persons and microenterprises are exempted (Art. 50(1) EHDS). Although *data holder* is now clearer defined than in earlier drafts, the definition of the EHDS *data holder* partly diverges from the wider DGA *data holder* definition (Art. 2(8) DGA), which could lead to confusion among the actors concerned.

67 Art. 60(4) EHDS.

68 It is subject to technical and organisational measures within the meaning of Art. 32 GDPR (Art. 73(1) EHDS), which the Commission determines via implementing act, (Art. 73 (5) EHDS). HDABs stay in control of the data at all times (Recital 77 EHDS).

69 See Art. 68(7) EHDS and Art. 73(1), (2) EHDS.

70 For example, providing a general description of the datasets available to them, creating open access to non-personal data via open databases, providing an updated dataset after a dataset has been augmented following the receipt of a data permit.

71 Art. 50(3) EHDS.

72 Recitals 1 and 54 EHDS.

73 See 'shall' (Art. 71(1) EHDS) versus 'may' (Art. 10(1) EHDS).

74 Art. 57(1)(a), (b) EHDS, Art. 68 EHDS and Art. 73 EHDS.

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(BfArM)[75] which is likely to become the coordinating HDAB within the meaning of EHDS.[76]

In their supervisory function, HDABs also supervise compliance by data users and holders, and impose penalties in case of infringement.[77] For transparency towards the public, HDABs publish biannual activity reports.[78] As for informing natural persons, Article 58 EHDS introduces a public information approach, departing from Article 14 GDPR's individual notice requirement.[79] The restriction of the information obligations of the HDABs vis-à-vis natural persons under Article 14 GDPR in the draft version of the Regulation has been heavily criticised, as it was seen as undermining the effective control of data subjects over their data,[80] and has been amended by Article 58 EHDS. Further HDAB tasks are listed in Article 57 EHDS.

c) Health Data Access Application Process

Potential data users[81] may submit health data access applications. HDABs assess those applications, essentially taking into consideration whether the data requested serves (a) a permitted purpose of processing, (b) is necessary, adequate, and proportionate for the requested purposes, the requestor (c) has a legal basis under Article 6(1) GDPR, (d) has the required expertise (e) and sufficient measures against misuse, and (f) has an ethical assessment, if mandated by national law (Article 68(1) EHDS).

The permitted purposes in Article 53(1) EHDS reflect a broad understanding of secondary use,[82] and include scientific research related to the health or care sector, training and testing of algorithms, including in medical devices, AI systems and health applications, as well as support for public authorities or Union bodies to perform their statutory tasks. Conversely, Article 54 EHDS lists prohibited purposes (e. g. discriminatory processing and advertising) and prohibits reidentification by data users.

In the standard procedure, HDABs assess the legality, necessity, and risk of the application and issue data permits that are valid for up to ten years.[83] They

75 Section 3 of the Health Data Utilisation Act (GDNG).

76 See German Federal Institute for Drugs and Medical Devices, <https://www.bfarm.de/DE/Das-BfArM/Aufgaben/Datenzugangs-und-Koordinierungsstelle/Aktuelles/News/01_Newsletter-01-25.html>, last access 19 November 2025.

77 Art. 63 EHDS.

78 Art. 59 EHDS.

79 Also, Recital 66 EHDS.

80 EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 23; see also Marelli et al. (n. 11).

81 Natural and legal persons and Union entities Art. 67(1), 2(2)(u) EHDS.

82 EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 33.

83 Art. 68(1), (2), (12) EHDS.

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may charge fees for the provision of health data, which may include compensation for the costs incurred by the health data holder in compiling and preparing the data. This portion of the fees shall ultimately be paid to the health data holders by the HDAB.[84] HDABs are held to limit the data permit's scope to what is necessary for the processing's purpose.[85] Also, HDABs are held to only grant anonymised data access, unless data users can prove that pseudonymised access is necessary. Once issued, HDABs request the data from the relevant data holders.[86] Health data users can then access the health data via the HDABs SPE,[87] while HDABs ensure that users are only able to download non-personal electronic health data from the SPEs.[88] However, since this includes anonymised data,[89] HDABs may soon face the well-known question of when personal data can be considered truly anonymised.

By contrast, Article 72 EHDS allows a simplified procedure in which *trusted health data holders*, designated by Member States, provide their data directly via their own secure environment, without the HDAB as intermediary.[90] While the HDAB still issues the data permit, trusted holders may assess applications and propose a decision, provided the applications meet the EHDS requirements.[91] Member States must provide an accelerated procedure for national public sector bodies and Union institutions with a public health legal mandate.[92] In addition, data users also have the possibility to submit a data request with the aim of obtaining a response in an anonymised statistical format (Article 69 EHDS).

d) Legal Bases and Data Protection Roles for the Secondary Use of Electronic Health Data

Given that health data is sensitive data under Article 9 GDPR, each separate processing must be based on Articles 6 and 9 GDPR.[93] According to

84 Art. 62(1), (2) EHDS.
85 Art. 66(1) EHDS.
86 Art. 68(7) EHDS.
87 Art. 57(1)(a)(i) EHDS.
88 Including health data in an anonymised statistical format, see Art. 73(2) EHDS.
89 See Art. 2(2)(b) EHDS.
90 Art. 68(7) EHDS and Art. 72(2) EHDS.
91 Art. 72(2)-(5) EHDS
92 Art. 68(6) EHDS.
93 The ECJ has ruled that processing based on Art. 9(2) GDPR must also fulfil Art. 6 (1) GDPR. For instance ECJ, *ZQ v. Medizinischer Dienst der Krankenversicherung Nordrhein, Körperschaft des öffentlichen Rechts*, judgment of 21 December 2023, case no. C-667/21, ECLI:EU:C:2023:1022, para. 79, on Art. 9(2)(h) and Art. 6(1) GDPR; See András Jóri, 'Art. 9' in: Indra Spiecker gen. Döhmann, Vagelis Papakonstantinou, Gerrit Hornung, and Paul De Hert (eds), *General Data Protection Regulation* (C. H. Beck 2023), paras 12-17.

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Recital 52 EHDS, the EHDS builds upon the GDPR's option to create a Union-law legal basis, including the safeguards necessary under Article 9(2)(g)-(j) GDPR, for the secondary use of personal electronic health data. As adequate safeguards in the sense of Article 9(2) GDPR, the legislator views the EHDS provisions on access governance through HDABs, processing of pseudonymised data in SPEs[94] and on the further arrangements for data processing, set out individually in the data permits for data users.

Articles 6 and 9 GDPR apply without modification through EHDS provisions to the initial processing of data processed by *data holders*. For *data holders* making data available, Article 51 EHDS constitutes a legal obligation within the meaning of Article 6(1)(c) and Article 9(2)(i), (j) GDPR. *HDABs* are, according to Recital 52, performing a public interest task and can thus process data under Articles 6(1)(e) and Article 9(2)(g)-(j) GDPR. *Data users* have to provide an independent legal basis. Recital 52 clarifies that for data users choosing Article 6(1)(e)(f) GDPR as legal basis, the EHDS provides the necessary Article 9(2) GDPR safeguards.

Member States may not maintain or introduce under Article 9(4) GDPR further conditions, such as consent, for secondary use under the EHDS, except for specific categories of data as listed in Article 51(4) EHDS, such as genomic data.[95]

The EHDS thus not only harmonises access and processing rules for secondary use but also establishes uniform safeguards regardless of the data user's processing purpose (Article 9(2)(g)-(j) GDPR). However, HDABs retain a degree of discretion in assessing the legal basis of individual data users.[96] Consequently, their future decision-making will be crucial in determining whether the EHDS achieves equal access to health data and a consistent level of data protection across the EU.

As for data protection roles, in the regular procedure, data holders are controllers for the making available of personal data while HDABs are controllers when fulfilling their tasks; when providing through a secure processing environment, HDABs are processors on behalf of data users, who are deemed controllers.[97] Conversely, in the simplified procedure, trusted data holders act as controllers for their own processing, and as processors for

94 Technical and safety requirements for SPEs will be determined by the Commission via implementing acts, Art. 73(5) EHDS.

95 Recital 52 EHDS. EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 89, criticised the previous drafts for omitting to clarify the extent of national discretion under Art. 9(4) GDPR.

96 E. g. if a requested processing is necessary for a substantial public interest or for legitimate interests that outweigh those of data subject (see Art. 6(1)(e), (f) GDPR and Art. 9(2)(g) GDPR).

97 Art. 74(1) EHDS.

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the data they provide through the secure processing environment on behalf of data users (Article 74(2) EHDS).

e) Relationship Between HDABs and Data Protection Supervisory Authorities

In their supervisory functions, HDABs closely cooperate with data protection supervisory authorities and inform them of 'any penalties imposed' where personal data is affected. Data protection supervisory authorities remain exclusively competent to enforce the GDPR. Therefore, HDABs may impose fines for EHDS-specific infringements (e. g. Articles 63 and 64 EHDS), while only data protection supervisory authorities can enforce GDPR-specific measures and are also exclusively competent for supervising the right to opt-out (Articles 65 and 71 EHDS). Given this approach, the health data access bodies and the data protection supervisory authorities complement each other in their supervisory functions.

f) HealthData@EU Cross-Border Infrastructure

To enable cross-border access to health data for secondary use, Article 75 EHDS establishes HealthData@EU as a cross-border infrastructure comprising a central platform run by the Commission, national contact points for secondary use[98] designated by each Member State, the Union health data access service,[99] and other authorised participants, including research infrastructures and, under certain conditions, third countries or international organisations.[100] Member State participation is mandatory. An EU dataset catalogue connecting the national dataset catalogues set up by HDABs, allows users to find and access data sets for secondary use across all Member States.[101]

98 The national contact point for secondary use may be the coordinator health data access body referred to in Article 55(1). It is not necessarily the entity as national contact points for primary use.

99 Art. 56 EHDS.

100 See Art. 74(5) EHDS: third countries or international organisations must comply with the rules of Chapter IV EHDS and provide access to health data users located in the Union, on equivalent terms and conditions, to the electronic health data available to their health data access bodies, subject to compliance with Chapter V of Regulation 2016/679/EU. The prior compliance check, executed by the Commission, is a prerequisite for connecting these actors to HealthData@EU, Art. 75(5), (13).

101 Art. 79 EHDS.

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Cross-border access via HealthData@EU follows the single-application principle: a data user may submit one application to any HDAB under Article 67(3) EHDS. The application is then automatically forwarded to all relevant HDABs, which decide on access within their competence pursuant to Article 68 EHDS and request the necessary data from data holders.[102] Access may be granted either through each HDAB's SPE[103] or, at the request of at least two national contact points, via a central SPE hosted by the Commission, in which HDABs put their data.[104] Depending on the processing purpose, use of the central SPE may be advantageous for the data user, as analyses involving pseudonymised data are likely limited to within a single SPE and not across multiple SPEs.[105]

In parallel to MyHealth@EU, national contact points for secondary use act as joint controllers for processing within HealthData@EU, while the Commission acts as processor.[106] Operational decisions on the HealthData@EU infrastructure itself are taken by the HealthData@EU Steering Group, while the EHDS Board has a coordination and advisory role.[107]

III. Assessment of Legal Competences

As outlined in Section II, the EHDS significantly impacts national health systems – not only regarding data registration, availability, and flows, but also through the creation of new administrative bodies such as digital health authorities and HDABs. This raises concerns about the limits of EU legislative competence, particularly in light of the relationship between Articles 114 and 16 TFEU and Article 168(7) TFEU, which reserves health policy and the organisation of healthcare to the Member States. Although the EU is authorised to adopt legislation based on Article 114 TFEU that significantly affect national health systems, we argue that some EHDS provisions are at least doubtful to be covered by EU competence and that the EU should better justify its future legislative acts in the health sector with a view to Article 168(7) TFEU.

102 A data permit already issued may benefit from mutual recognition by other data access bodies (Art. 68(5) EHDS).

103 In the absence of other provisions in the EHDS, the same procedure likely applies as for a purely national data access application.

104 Art. 68(8) EHDS and Art. 75(9) EHDS.

105 Only non-personal electronic health data can be downloaded from SPEs, see Art. 73(2) EHDS.

106 Art. 75(9), (10) EHDS; the Commission may specify these roles by implementing acts, Art. 75(12)(d)(e) EHDS.

107 Art. 95(2), 94(2) EHDS.

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1. Constitutional EU Law Context (Articles 16, 114, 168 TFEU and the Principle of Subsidiarity)

Article 114 TFEU (internal market)

Through Article 114 TFEU, the EU can harmonise Member State law by eliminating obstacles to the internal market, one of the Union's central objectives (see Article 3(3) Treaty on European Union [TEU]).[108] The regulatory scope of this provision is not limited to specific subject matters[109] and also includes the harmonisation of laws to create an internal market for data as economic goods.[110] Article 114 TFEU requires internal market finality,[111] which may arise from a concrete[112] obstacle to cross-border trade addressed by harmonisation.[113] The European Court of Justice (ECJ) assesses internal market finality based on legislative intent and the measure's objective effectiveness in removing market barriers.[114] In addition, in the Court's view, the establishment of the internal market must be the main objective[115] or focus.[116] However, the measure may also pursue other objectives, in particular, the protection of health referred to in Article 114(3) TFEU, even if these objectives are of crucial importance.[117] Nevertheless, all the requirements under Article

108 Meinhard Schröder, 'Art. 114 TFEU' in: Rudolf Streinz (ed.), *TEU/TFEU* (3rd edn, C. H. Beck 2018), paras 6 f.; See also Christian Tietje, 'Art. 114 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), para. 5.

109 See Tietje (n. 108), para. 32.

110 See Jürgen Kühling, 'Art. 16 TFEU' in: Matthias Pechstein, Carsten Nowak and Ulrich Häde (eds), *TEU/GRC/TFEU* (2nd edn, Mohr Siebeck 2023), paras 36 et seq.

111 Schröder, 'Art. 114' (n. 108), para. 28.

112 ECJ, *Germany v. European Parliament and Council of the European Union*, judgment of 5 October 2000, case no. C-376/98, ECLI:EU:C:2000:544.

113 Schröder, 'Art. 114' (n. 108), para. 28.

114 Schröder, 'Art. 114' (n. 108), paras 33 et seq.

115 See ECJ, *Kingdom of the Netherlands v. European Parliament and Council of the European Union*, judgment of 9 October 2001, case no. C-377/98, ECLI:EU:C:2001:523, paras 27 f.; Tietje (n. 108), para. 129.

116 See in this respect, ECJ, *European Parliament v. Council of the European Union*, judgment of 23 February 1999, case no. C-42/97, ECLI:EU:C:1999:81, paras 39 f.; ECJ, *Kingdom of Spain v. Council of the European Union*, judgment of 30 January 2001, case no. C-36/98, ECLI:EU:C:2001:64, para. 59 ('one [objective] as the essential or paramount one'); see also Schröder, 'Art. 114' (n. 108), para. 30.

117 ECJ, *The Queen v. Secretary of State for Health ex parte: British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd,* judgment of 10 December 2002, case no. C-491/01, ECLI:EU:C:2002:741, para. 62; ECJ, *Arnold André GmbH & Co. KG v. Chief Executive of the District of Herford,* judgment of 14 December 2004, case no. C-434/02, ECLI:EU:C:2004:800, para. 32.

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114 TFEU must be met,[118] especially that establishing the internal market must not be a 'merely incidental or complementary objective' of the measure.[119]

Article 16(2) TFEU (data protection and free flow of data)

Article 16(2) TFEU allows EU legislation on the free movement of data on one side and on data protection[120] in application of EU law for both Union entities and Member States acting within the scope of Union law on the other.[121] While the latter requirement is not conclusively defined,[122] the prevailing view supports a broad interpretation including purely domestic processing without crossing borders.[123] The ECJ takes this view with regards to the GDPR's scope of application (Article 2(2)(a) GDPR), which, in accordance with Article 16(2) TFEU, ends where an activity does not fall within the scope of application of Union law.[124] According to some authors in the legal literature, the competence to regulate the *free movement of data* is a *lex specialis* in relation to the internal market competence under Article 114 TFEU,[125] and is therefore definitive for the internal market.[126] Other voices argue that Article 16(2) TFEU is not limited to regulating data flows that aim at establishing an internal market, but go beyond that.[127] In regulatory

118 ECJ, *British American Tobacco* (n. 117), para. 62, See also Schröder, 'Art. 114' (n. 108), para. 135.

119 See ECJ, *Kingdom of the Netherlands* (n. 115), paras 27 f.; Tietje (n. 108), para. 129.

120 Christoph Sobotta, 'Art. 16 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), para. 27.

121 Meinhard Schröder, 'Art. 16 TFEU' in: Rudolf Streinz (ed.), *TEU/TFEU* (3rd edn, C. H. Beck 2018), para. 9.

122 See in this regard Amadeus Wolff and Antje von Ungern-Sternberg, 'Grundlagen und bereichsspezifischer Datenschutz' in: Heinrich Amadeus Wolff, Stefan Brink and Antje von Ungern-Sternberg (eds), *BeckOK Datenschutzrecht* (53rd edn, C. H. Beck August 2025), Syst. A. para. 12.1.

123 Kühling, Art. 16 (n. 110), para. 33.

124 ECJ, *VQ v. State of Hesse*, judgment of 9 July 2020, case no. C-272/19, ECLI:EU:C:2020:535, para. 66; See on the Data Protection Directive: ECJ, *Court of Audit v. Austrian Broadcasting and Others and Christa Neukomm and Joseph Lauermann v. Austrian Broadcasting*, judgment of 20 May 2003, case no. C-465/00, C-138/01 and C-139/01, ECLI:EU:C:2003:294.

125 Thorsten Kingreen, 'Art. 16 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *TEU/TFEU* (6th edn, C. H. Beck 2022), para. 8; Schröder, 'Art. 16' (n. 121), para. 10; 'In Opinion 1/15, the CJEU […] state[d] that an EU legal instrument containing detailed rules concerning the use of personal data should be based on Article 16(2) TFEU', Hielke Hijmans, Author Notes, 'Article 1' in: Christopher Kuner, Lee A. Bygrave, Christopher Docksey and Laura Drechsler (eds), *The EU General Data Protection Regulation (GDPR): A Commentary* (Oxford University Press 2020), B.4.

126 Schröder, 'Art. 16' (n. 121), para. 10.

127 Kühling, Art. 16 (n. 110), para. 37.

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practice, however, the Union legislator also draws on Article 114 TFEU for legal acts that promote the free movement of data (such as the Data Act).[128] However, as Article 1(3) GDPR shows, the GDPR, which is based on Article 16(2) TFEU, as the fundamental data-related legal act of the Union, contains provisions on both *data protection* and the *free movement of data*. As a shared competence,[129] the exercise of Article 16 is also subject to subsidiarity (Article 5(3) TEU).

Article 168 TFEU (public health)

Within health care, Article 168 TFEU provides EU competence for *public* health only,[130] which is population-based and preventive in nature.[131] For individual sub-areas[132] listed in Article 168(4) TFEU, the EU has shared competence.[133] Beyond these areas, the Union's role is limited to supplementing, coordinating and supporting the Member States' policies in accordance with Articles 2(5) and 6 TFEU.[134] While the EU may adopt binding acts based on Article 168(5) TFEU, it may not harmonise Member State law.[135] However, the prohibition on harmonisation does not prevent the EU from influencing national systems under other legal bases, notably Article 114 TFEU, provided the requirements on subsidiarity are met.[136]

128 Kühling, Art. 16 (n. 110), para. 33.

129 Schröder, 'Art. 16' (n. 121), para. 8.

130 Brigitta Lurger, 'Art. 168 TFEU' in: Rudolf Streinz (ed.), *TEU/TFEU* (3rd edn, C. H. Beck 2018), para. 17.

131 Birgit Schmidt am Busch, 'Art. 168 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), para. 9; Lurger (n. 130), para. 17.

132 With regard to the regulation of quality standards for medical devices and medicinal products, with regard to measures to establish high quality and safety standards for organs and substances of human origin as well as for blood and blood derivatives, and with regard to measures in the areas of measures in the veterinary and phytosanitary fields with the direct aim of protecting public health.

133 See Art. 2(2) TFEU and Art. 4(2)(k) TFEU; regarding shared competences, see for example Martin Nettesheim, 'Art. 2 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), paras 23 et seq.

134 Schmidt am Busch (n. 131) para. 41; Lurger (n. 130), para. 53.

135 See Art. 168 (5) TFEU and generally for complementary, coordinating and supporting competences Art. 2 (5) subpara. 2 TFEU; examples of binding legal acts: EU4Health or ECDC; see also Schmidt am Busch (n. 131), para. 70.

136 According to the ECJ, Art. 114 TFEU can always be used as a legal basis despite Art. 168(5) TFEU if its internal market-specific conditions are met, see ECJ, *Federal Republic of Germany v. European Parliament and Council of the European Union*, judgement of 5 October 2000, case no. C-376/98, ECLI:EU:C:2000:544, paras 76 et seq.; ECJ, *British American Tobacco* (n. 117) para. 62; see also Schmidt am Busch (n. 131), para. 112 with further references on the case law of the ECJ.

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Article 168(7) TFEU reserves the responsibility for defining health care policy, organising the healthcare system and medical care to the Member States. According to the ECJ, although Union measures relating to these areas are not inadmissible *per se*, they must not interfere with the national sovereignty of the Member States in the areas referred to in Article 168(7) TFEU.[137] According to some authors, such interference is deemed to be present when Member States are forced by a Union measure to reorganise their healthcare system.[138] It is disputed whether Article 168(7) TFEU only applies to Union measures based on Article 168 TFEU, or also limits the exercise of other titles of competence, in particular Article 114 TFEU.[139] The ECJ has yet to give an explicit ruling on this issue. However, elements of case law seem to indicate that Article 168(7) TFEU also applies to other titles of competence.[140]

If a legal act based on Article 114 TFEU relates to the health sector, not only the question of the applicability of Article 168(7) TFEU arises, but also the question of the relationship between Article 114 TFEU and the prohibition of harmonisation set out in Article 168(5) TFEU. According to the ECJ, Article 168(5) TFEU may not be circumvented through the use of other legal foundations.[141] Nevertheless, a measure can be based on Article 114 TFEU, even if health protection is of crucial importance.[142] Article 168(1) TFEU also acts as a horizontal clause requiring health protection across all Union policies, which is reflected in Article 114(3) TFEU.

On subsidiarity & proportionality

Given that Articles 16, 114, and 168 TFEU concern shared EU competences, their exercise is subject to the principles of subsidiarity and propor-

137 See ECJ, *The Queen, on the Application of: Yvonne Watts v. Bedford Primary Care Trust, Secretary of State for Health,* judgment of 16 May 2006, case no. C-372/04, ECLI:EU:C:2006:325, para. 147; ECJ, *European Commission v. Grand Duchy of Luxembourg,* judgment of 27 January 2011, case no. C-490/09, ECLI:EU:C:2011:34, para. 45.

138 Schmidt am Busch (n. 131), para. 82.

139 For validity within the framework of Art. 168 TFEU only, Schmidt am Busch (n. 131), para. 83; for validity also outside the scope of Art. 168 TFEU, see Kingreen (n. 125), para. 26. Frank Niggemeier, 'Art. 168 TFEU', in: Hans von der Groeben, Armin Hatje and Jürgen Schwarze (eds), *European Union Law* (7th edn, C. H. Beck 2015), para. 73.

140 ECJ, *Novartis Farma SpA v. Agenzia Italiana del Farmaco (AIFA) and Others*, judgment of 21 November 2018, case no. C-29/17, ECLI:EU:C:2018:931, paras 47 et seq. Here, the ECJ had pointed out in relation to a directive based on Art. 100a EEC (now Art. 114 TFEU) that the directive in question also does not affect the competence of the Member States in the areas referred to in Art. 168(7) TFEU, only to then state that they must nevertheless comply with Union law when exercising their competence.

141 See ECJ, *Germany* (n. 112), para. 79.

142 ECJ, *British American Tobacco* (n. 117), para. 62. See also Schröder, 'Art. 114' (n. 108), para. 135.

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tionality (Article 5(3), (4) TEU). Under subsidiarity, EU action is only justified if the objectives of the measure cannot be sufficiently achieved by the Member States, but can be better achieved at Union level due to their scale or effects (Article 5(3) TEU). Under proportionality, Union action must not exceed what is necessary in scope or form to achieve the objectives of the Treaties (Article 5(4) TEU).

2. Articles 114 and 16 TFEU as the Basis of Competence for the EHDS Regulation

The EHDS Regulation is based on Article 16 and 114 TFEU. The choice of a dual basis of competence is possible, insofar as no clear attribution can be made after analysing the legislative proposal in accordance with its focus,[143] and Article 16 TFEU and Article 114 TFEU both follow the same legislative procedure. Article 168 TFEU could also be considered a relevant competence standard given the implications for health policy in the EHDS Regulation, in particular with regard to the rules on the primary use of electronic health data. However, this might not underpin the EHDS Regulation due to the prohibition of harmonisation in Article 168(5) TFEU. Nevertheless, as explained, the pursuit of health policy objectives alongside the objective of realising the internal market is not excluded under Article 114 TFEU.

Competence under Article 114 and 16 TFEU

A prerequisite of Article 114 TFEU is the internal market finality of the measure (see III. 1.), i. e. pursuing the objective of establishing the internal market. The provisions of Chapter III EHDS, which are not dealt with here, provide for the harmonisation of Member State regulations regarding requirements for EHR systems, the obligations of manufacturers and importers of EHR systems, and the introduction of market surveillance. There is also a specific barrier to free movement with regard to the exchange of health data.

143 Eckhard Pache, 'Art. 5 TEU' in: Matthias Pechstein, Carsten Nowak and Ulrich Häde (eds), *TEU/GRC/TFEU* (2nd edn, Mohr Siebeck 2023), para. 49, with reference to ECJ, *Commission of the European Communities v. Council of the European Communities*, judgment of 11 June 1991, case no. C-300/89, ECLI:EU:C:1991:244, para. 17; ECJ, *Commission of the European Communities v. Council of the European Union*, judgment of 11 September 2003, case no. C-211/01, ECLI:EU:C:2003:452, para. 40; ECJ, *Commission of the European Communities v. European Parliament and Council of the European Union*, judgment of 8 September 2009, case no. C-411/06, ECLI:EU:C:2009:518, para. 47.

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The Commission has analysed existing national regulations on, among other things, certification schemes for EHR systems and requirements for the processing of health data, and has identified these as contributing to a low level of interoperability of EHRs, as well as the availability and exchange of health data across the EU.[144] In this respect, internal market finality exists both subjectively (e. g. Article 1(2)(b), Recital 1 EHDS) and objectively, since the proposed provisions appear to be suitable for removing these existing barriers. This also applies to the secondary use of electronic health data, which also aims to promote innovation in health data-based products and services,[145] as well as to the primary use in that the EHDS aims at fostering a genuine internal market for digital health services and products (Recital 110 EHDS).

The Commission invokes Article 16 TFEU particularly with regard to the provisions on natural persons' rights that build upon the GDPR rights.[146] Some of the rights provided for in Articles 3-10 EHDS (in particular the right to cross-border data transfer) are designed to promote fundamental freedoms, especially the free movement of persons, and are therefore also instrumental to the internal market. While it could be argued, that the EHDS primarily concerns the free movement of data and data protection, warranting a basis in Article 16 TFEU, the choice of a dual basis with Article 114 TFEU seems justifiable, especially with regard to the provisions of Chapter III EHDS.

Given the dual basis of competence, it is questionable to what extent the limitation in Article 16(2) to the 'scope of EU law' restricts data protection regulation concerning Member States. Some EHDS provisions likely apply to purely national cases, such as access requests within the same Member State. However, the ECJ's broad interpretation of the 'scope of EU law' means this is unlikely to be problematic in practice. Moreover, the EHDS closely links national and cross-border issues, as cross-border access relies on rules also governing national matters.[147] Also, the EHDS complements rather than replaces existing national data access systems by establishing a Union-

144 See p. 7 of the draft EHDS Regulation; Johan Hansen et al., Assessment of the EU Member States' Rules on Health Data in the Light of GDPR, Specific Contract No. SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03, 2021, 134; European Commission, Communication of 25 April 2018, COM/2018/233 final, on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society, 1.

145 See Recital 61 EHDS; EHDS draft Regulation, 8.

146 See draft EHDS Regulation, COM/2022/197 final, under 2. Legal basis, subsidiarity and proportionality.

147 As an example, cross-border data access for secondary use also requires HDABs to request data from national health data holders upon a prior data permit, Art. 68(7) EHDS.

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wide framework alongside them thereby ensuring consistency with the scope of Union law.[148]

Limits of Competence: Article 168(7) TFEU, Subsidiarity and Proportionality

The EHDS Regulation does little to justify the competences of the Union with regard to safeguarding the responsibility of the Member States for their healthcare systems in accordance with Article 168(7) TFEU.[149] Although its applicability under other competence titles has not been conclusively established, the legislator seems to assume that it is applicable, or at least wishes to ensure conformity with Article 168(7) TFEU in the form of a consideration *in any case*. However, as we will show in section III. 3. and III. 4., a more detailed justification would certainly have been desirable.

The principle of subsidiarity (Article 5(3) TEU), which applies in relation to shared competences, presupposes that the objectives of the measures under consideration cannot be sufficiently achieved by the Member States at central, regional or local level, but can be better achieved at Union level because of their scale or effects.[150] The Commission has analysed the current status of data governance mechanisms and the possibilities of access to electronic health data for primary and secondary use in a comprehensive study and identified the existence of significant barriers and deficits – not least with regard to the fragmentation of Member State rules governing access, exchange and use of electronic health data.[151]

The EHDS objective of enabling cross-border data exchange and access appears to be more achievable through Union action than through Member State action alone.[152] The requirements of the principle of subsidiarity are

148 See Recital 52 EHDS; an example from Germany is the data access procedure under Section 303 e of the German Social Code, Book V.

149 This is only addressed in Recital 28 EHDS, albeit without any in-depth reason being given. Comparing Recital 21 of the draft EHDS Regulation to the final Recital 28 EHDS indicates a stricter application of Art. 168(7) TFEU. Art. 168 was also addressed in the justification for the choice of legal basis and subsidiarity, p. 6 and 7 of the draft EHDS Regulation.

150 Art. 5(3) TEU.

151 Recital 7 EHDS. Comprehensive and detailed in Hansen et al. (n. 144); see DG SANTÉ (n. 8), 3 f.

152 It should be noted that Member States had coordinated approaches in parallel to the EHDS legislative process, for example as part of the joint action 'Towards a European Health Data Space' (TEHDAS), see <https://tehdas.eu/app/uploads/2022/03/tehdas-leaflet-2022.pdf>, last access 19 November 2025, and continue to coordinate in TEHDAS2 by developing 'common guidelines and technical specifications […] to ensure a harmonised implementation', see <https://tehdas.eu/wp-content/uploads/2024/09/tehdas2-brief-leaflet-7.pdf>, last access 19 November 2025.

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therefore generally met. Compliance with the principle of proportionality within the meaning of Article 5(4) TEU, according to which measures of the Union do not go beyond what is necessary to achieve the objectives of the Treaties in terms of content and form, can only be assessed with regard to the specific provisions of the Regulation.

3. Obligations of Member States Regarding the Primary Use of Electronic Health Data in the EHDS

With regard to the provisions on primary use, the question of compatibility with Article 168(7) TFEU arises insofar as its applicability to Articles 114 and 16 TFEU is assumed.

According to Article 168(7) TFEU, the activities of the Union must respect the Member States' responsibility for the definition of their own health policies, the organisation and management of their health systems and the provision of health services and medical care. However, the ECJ holds that this does not preclude Member States from being obliged to make adjustments to their healthcare systems under other Treaty provisions or Union policies based on them, without this being seen as an encroachment upon their sovereign competence.[153] This applies in particular when the realisation of fundamental freedoms is at issue.[154] Conversely, it follows that interference in the competence of the Member States is not permitted. In German doctrine, interference is deemed to exist if the Union policy forces Member States to reorganise their healthcare systems.[155] In any case, all decisions relating to the system are reserved for the Member States.[156]

Articles 13(1), 12, 7(2), and 11(1) EHDS directly affect the provision of healthcare services by requiring healthcare providers to systematically store prioritised health data in EHR systems[157] and to have access to relevant patient data via professional access services – regardless of any cross-border context. Where providers are based in different Member States, the receiving

153 See ECJ, *Watts* (n. 137), para. 147 (with regard to the social security system); see also Schmidt am Busch (n. 131), para. 82.

154 ECJ, *European Commission v. Grand Duchy Luxembourg* (n. 137), para. 45; ECJ, *V. G. Müller-Fauré and Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA,* and between *E. E. M. van Riet and Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen,* judgment of 13 May 2003, case no. C-385/99, ECLI:EU:C:2003:270.

155 Schmidt am Busch (n. 131), para. 82.

156 Niggemeier (n. 139), para. 75.

157 Although Art. 13(1) EHDS is directly addressed to the member states and not to healthcare providers, the EHDS stipulates that health data must be stored in an EHR system.

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provider must accept data transmitted through MyHealth@EU at the patient's request. These rules shape the rights and obligations of healthcare providers and may be seen as an interference of Member States' competence. However, previous ECJ case law, according to which the realisation of fundamental freedoms may oblige Member States to make adjustments in the areas of Article 168(7) TFEU, would seem to argue against interference. Facilitating the free movement of natural persons through the cross-border availability of their electronic health data is almost inextricably linked to the availability of this data at a purely national level. The EHDS provisions serve this objective by enabling individuals to access, transfer, or request the transfer of their health data, thereby facilitating cross-border healthcare. Notably, Articles 13(1), 12, and 11(5) EHDS also allow Member States to adopt specific national rules in these areas.

The EHDS further requires Member States to designate a digital health authority, establish a national contact point for MyHealth@EU, and ensure connectivity with all national healthcare providers. It also assigns them extensive tasks, particularly regarding the implementation of Chapter II.[158] This effectively compels Member States to digitise and interconnect their healthcare systems. While such measures may appear to infringe on national responsibility for health system organisation, ECJ case law suggests otherwise for the reasons stated above. Nevertheless, a more explicit clarification of Article 168(7) TFEU by the EU legislator would have been desirable.

Commission Powers in Primary Use

In the wake of the Council's and the European Parliament's positions,[159] the Commission's far-reaching authorisations to adopt secondary legislation included in earlier EHDS drafts have been significantly constrained. For example, the Commission is no longer authorised to transfer further tasks to digital health authorities (Article 10(3) draft EHDS Regulation). This reflects better the principle of proportionality under Article 5(4) TEU, i. e. that Member State sovereignty must be protected as far as possible when measures become necessary, given that the EHDS already stipulates Member States to

158 Art. 19(1)(3) EHDS and Art. 23(2), (5) EHDS.

159 E. g. Council of the European Union, Proposal for a Regulation on the European Health Data Space – Mandate for Negotiations with the European Parliament, 7 December 2023, 16048/1/23, 77, <https://data.consilium.europa.eu/doc/document/ST-16048-2023-REV-1/en/pdf>, last access 19 November 2025) and European Parliament, Amendments Adopted by the European Parliament on 13 December 2023 on the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM/2022/0197 – C9-0167/2022 – 2022/0140(COD)), Amendment 162.

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adopt administrative structures in the health sector and assigns an extensive catalogue of tasks to digital health authorities under Article 19 EHDS.

4. Obligations of Member States Regarding the Secondary Use of Electronic Health Data in the EHDS

Given the growing integration of research and care in translational medicine, the provisions of Chapter IV EHDS also touch upon health policy and the organisation of healthcare (Article 168(7) TFEU). For example, under Articles 58(3) and 61(5) EHDS, health data users must report significant findings to the HDAB, which informs the data holder, who in turn notifies the data subject or treating healthcare professionals in accordance with national law. While this obligation affects healthcare provision by involving the communication of findings to healthcare professionals, the EHDS respects Member State competences by linking the duty to inform to national legal conditions.

The decision adopted in the EHDS Regulation to make electronic health data widely available for secondary use does not directly affect organisational issues of national healthcare systems in all areas. Nevertheless, some healthcare providers (e. g. public or private hospitals)[160] as data holders are affected by the provisions of the EHDS Regulation governing secondary use. They must establish organisational systems and processes, partly in cooperation with the HDAB, in order to make electronic health data available to them. While health data intermediation entities may perform these tasks if allowed by national law, their implementation may still be resource-intensive. However, this does not infringe Member State competences under Article 168(7) TFEU, as it concerns data availability for secondary use rather than healthcare provision.

Given the extensive range of tasks assigned to national HDABs and contact points, the EHDS is likely to significantly affect the administrative structures of the Member States.[161] In our view, however, it complies with the principle of proportionality under Article 5(4) TEU, as these tasks are necessary to enable the secondary use of electronic health data within the EHDS framework.

160 I. e. all healthcare providers that do not fall under the exception of SMEs, Art. 50(1) EHDS.

161 However, the establishment of the EHDS is also likely to mean an additional administrative burden for the data protection supervisory authorities (see Section II. 4. e.).

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Commission's Powers and Safeguarding Member States Sovereignty

The Commission's authorisations to adopt secondary legislation with possibly far-reaching impacts on the administrative structure of the Member States were significantly limited during the legislative process. In light of the principle of proportionality and Article 168(7) TFEU, such a development must be welcomed.

As a first example, Article 37(1) draft EHDS Regulation would have empowered the Commission to amend the list of tasks of HDABs, creating an additional possibility for the Commission to influence the administrative structures of the Member States. Beyond doubts about the necessity of this authorisation, given the already extensive cooperation structures established in the EHDS Regulation,[162] the Council's and the Parliament's opposition[163] reflected broader concerns about the extensive potential for unforeseen Commission-driven changes to national administrative structures.[164]

Second, Article 52(13)(c), (d) draft EHDS Regulation authorised the Commission to define the responsibilities of joint controllers and the Commission as processor for processing operations within the framework of Health@EU through delegated acts. This would have empowered the Commission to exert significant influence on the specific responsibilities and, thus, for example, on issues of liability in the internal relationship between the controllers. In the final EHDS, these authorisations were narrowed. Article 75(12) now limits the Commission's implementing powers to defining its processor obligations toward joint controllers, reflecting a more proportionate balance.

Comparing the draft EHDS Regulation with the adopted EHDS Regulation in terms of Commission's authorisations, it shows that these were limited during the legislative procedure in two ways. First, by deleting several authorisations entirely, secondly by limiting the material scope of the authorisation. For example, where the Commission was formerly empowered to amend the categories of healthcare providers, categories of health data and data quality standards (Article 7(3) draft EHDS Regulation), it is now mainly only empowered to define the latter (Article 13(4) EHDS).[165] This shift in legislative design is not only politically significant, but also doctrinally important in terms of how the balance of competences is maintained under the

162 EHDS Board and the later introduced Steering Groups.

163 European Parliament, *Amendments adopted by the European Parliament on 13 December 2023* (n. 159), Amendment 361; Council of the European Union, *Proposal for a Regulation on the European Health Data Space* (n. 159).

164 See in the context of Chapter 4 of the draft EHDS Regulation on the Establishment of the EHDS for Secondary Processing only Arts 33(7), 37(4), 39(3), 41(7), 42(6), 43(8), 45(6), 46 (8), 50(4), 51(2), 52(5),(7),(13), 53(3), 55(2), 56(4), 58 of the draft EHDS Regulation.

165 And amend Annex I EHDS (Art. 14(2) EHDS).

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treaties. With these changes the final EHDS Regulation was brought closer in line with the prevalent understanding of Articles 16 and 114 TFEU and the limits established by Article 168(7) TFEU.

In contrast, the authorisation of the Commission in Article 62(6) EHDS to lay down principles and rules for fee policy and fee structures through implementing acts seems reasonable. A standardised definition of these rules should benefit the purpose of the EHDS Regulation, which is, to promote cross-border secondary processing.

5. Infringement of the Procedural Autonomy of the Member States, Article 291(1) TFEU?

Given the significant impact on Member State administrative structures, in particular the planned establishment of the digital health authority and the HDABs, it is worth considering whether the EHDS Regulation aligns with the principle of procedural autonomy of the Member States enshrined in Article 291 TFEU.[166] This states that the implementation of Union law is primarily the task of the Member States' administration,[167] and also covers how Union law is organised and enforced.[168] This results in a rule-exception relationship between indirect enforcement by national administrations and direct enforcement by Union institutions, bodies, offices, or agencies.[169] However, the extent and scope to which Article 291(1) TFEU has the effect of limiting competences has not been conclusively established.[170] It cannot be assumed that traditional administrative organisational structures are *per se* resistant to changes from European Law,[171] meaning that the creation of

166 Wolfgang Kahl, 'Art. 4 TEU' in: Christian Callies and Matthias Ruffert (eds), *TEU/TFEU* (6th edn, C. H. Beck 2022), para. 127.

167 Matthias Ruffert, 'Art. 291 TFEU' in: Christian Callies and Matthias Ruffert (eds), *TEU/TFEU* (6th edn, C. H. Beck 2022), para. 5; See Martin Nettesheim, 'Art. 291 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), para. 5; See also German Federal Constitutional Court, BVerfGE 151, 202 (2019), para. 243.

168 Stefan Drechsler, '§ 8 Vollzug des Unionsrechts' in: Manfred Dauses and Markus Ludwigs (eds), *Handbuch des EU-Wirtschaftsrechts* (64 edn, C. H. Beck, August 2025), para. 140; Kahl (n. 166), para. 127; Raji (n. 3), 6.

169 Ruffert, 'Art. 291 TFEU' (n. 167), para. 5; BVerfGE 151, 202 (2019), (n. 167), para. 243; Contra: Claus Dieter Classen, 'Art. 197 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), para. 11.

170 See Drechsler (n. 168), para. 140.

171 Markus Ludwigs, 'Die Verfahrensautonomie der Mitgliedsstaaten', NVwZ 37 (2018), 1417-1422 (1420).

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national authorities with specific tasks for indirect enforcement can also be prescribed by Union law. Compared to the general limits imposed on the exercise of competences by Article 5 TEU (in particular the principles of subsidiarity and proportionality), Article 291 TFEU does not appear to place any further restrictions on competences in indirect implementation.[172] The principle of procedural autonomy of the Member States is therefore not violated by the requirements of the EHDS Regulation to set up digital health authorities and HDABs.

IV. Summary and Outlook

The EU is pursuing a large-scale project in the form of the EHDS with the aim of improving access to and the use of electronic health data across borders, both for healthcare and for research, innovation and policy-making. To that end the EHDS provides for harmonised rules on data access and sharing for primary and secondary use as well as unanimous safeguards and establishes two cross-border infrastructures. The final EHDS Regulation has clarified its relation to the GDPR in several aspects compared to the draft EHDS Regulation, e. g. its relation to Article 9(4) GDPR and national data protection law and the cooperation of EHDS public bodies to data protection supervisory authorities. Notably, the EHDS leaves important technical, organisational, information security, and data protection requirements to the Commission's implementing acts, such as those for joining and remaining connected to the cross-border infrastructures and those applicable to SPEs.

We analysed the EHDS from the perspective of EU legislative competence. While the ECJ has not yet explicitly ruled whether Member States' responsibilities for health policy, the organisation of health systems, and medical care under Article 168(7) TFEU also limit the exercise of other competence titles than Article 168 TFEU, such as Article 114 TFEU, its case law suggests that they do. The rules on both primary and secondary use of the EHDS Regulation foresee extensive influences on the administrative structures of the Member States.

The provisions on primary use in particular, will have a significant impact on national healthcare systems and the provision of healthcare. Although the EHDS provisions partially shape the rights and obligations of healthcare providers and effectively compel Member States to digitise and interconnect their healthcare systems (which they have done to varying degrees), previous ECJ case law would seem to argue against a violation of Article 168(7) TFEU.

172 Drechsler (n. 168), para. 140.

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The EHDS provisions on secondary use may partly affect actors in the health system, esp. as health data holders, but do not constitute an infringement of Article 168(7) TFEU.

As the final EHDS Regulation significantly curtailed the Commission's powers to adopt secondary legislation – thereby limiting its influence over national public bodies within the EHDS framework – it is now more consistent with the principle of proportionality.

A major challenge is the technical implementation of the EHDS. In this respect, the regulatory content of the EHDS Regulation remains somewhat abstract,[173] even though the Union, the Member States and healthcare providers are faced with significant tasks in this area. The implementation of an EU-wide European exchange format for hundreds of millions of potential users, the building of capacity to handle numerous data access applications and make health data available or the enormous effort involved in defining the 'implementation of technical solutions at national level' (Article 19(2)(c) EHDS) by the digital health authorities could pose major challenges.[174] Not only Member States but also healthcare providers might face considerable costs -for healthcare providers, for instance, if new EHR systems need to be introduced.[175] To that end, Recital 91 EHDS only states that a 'fair sharing of that burden between Union and national funds will need to be found'. Many details of the implementation are left to the Commission and the Member States. It will therefore be interesting to see the effective implementation of the EHDS.

173 Nikolaus Forgó, 'Der European Health Data Space im Kontext der MMR', MMR 26 (2023), 3-5 (4 f.).

174 Forgó (n. 173), 4 f.

175 See for example Parliament of the Czech Republic, 20 October 2022, Proposal for a Regulation on the European Health Data Space – Opinion on the Application of the Principles of Subsidiarity and Proportionality, accessible at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_13814_2022_INIT&from=EN>, last access 19 November 2025.

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Health Emergency Response at EU Level – Are There Legal Constraints?

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Abstract

This article explores the constraints of actions at the European Union (EU) level in the field of health emergency preparedness and response. It argues that although the EU has found a way to be better prepared for future public health emergencies, it is not without limitations due to the nature of the emergency legal basis upon which it relies. The appropriateness of health emergency measures is not assessed on a standalone basis (in terms of saving lives) but is to be assessed in the overall context of their appropriateness to the economic situation. Only the next public health emergency will show whether this is sufficient to take effective and efficient health emergency measures.

Keywords

HERA – Health – Emergency Preparedness – Authority – Legal Basis

* Dr., HERA, the European Commission. The views expressed by the author are purely personal and cannot be attributed to the European Commission.

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I. Introduction

The European Union (hereinafter 'the Union') has 'supporting competence' in the field of health, but is there a room to go beyond the supporting competence in the time of health emergency? As the saying goes: Where there is a will, there is a way. This article explores the constraints of actions at EU level in the field of health emergency preparedness and response. It argues that while the EU found the way to be better prepared for future public health emergencies, including the establishment of Health Emergency and Response Authority (HERA),[1] it is not without limitations. In particular, the appropriateness of measures to the economic situation needs to be assessed at the moment in time when health-driven measures are taken and only economic predictions, if at all, are available.

Currently, the supporting type of competence is envisaged for the incentive measures designed to protect and improve human health and, in particular, to combat the major cross-border health scourges.[2] Such measures could concern monitoring, early warning of, and combating serious cross-border threats to health.[3] Therefore, this competence does not replace those of Member States in this domain, and the Union cannot, like in other fields, propose binding measures of harmonisation.[4] So far, the only shared competence in the field of health concerns the security questions related to public health matters.[5] These aspects do not relate to cross-border health threats, but to measures setting quality and safety standards of various substances, as well as to medicinal products and medical devices.[6] The Conference on the Future of the European Union went even further and proposed new, shared competences of the EU in the field of health;[7] however, this has not been taken up by an intergovernmental conference.

1 Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, C(2021) 6712 final.

2 Art. 168 para. 5 TFEU.

3 Scott Greer and Anniek De Ruijter, 'EU Health Law and Policy in and After the COVID-19 Crisis', European Journal of Public Health 30 (2020), 623-624 (623); Scott L. Greer, 'EU Health Law and Policy: The Expansion of EU Power in Public Health and Health Care', Journal of Health Politics, Policy and Law 46 (2021), 205-210; Édouard Dubout and Fabrice Picod, *Coronavirus et droit de l'Union européenne* (Bruylant 2021).

4 Art. 2 para. 5 TFEU; Dubout and Picod (n. 3), 29-84.

5 Art. 4 para. 2 lit. k) TFEU.

6 Art. 168 para. 4 TFEU.

7 In order to achieve the necessary coordinated, long-term action at Union level, include health and healthcare among the shared competencies between the EU and the EU Member States by amending Article 4 TFEU. Conference on the Future of Europe, Report on the Final Outcome, May 2022, available at <https://www.europarl.europa.eu/resources/library/media/20220509RES29121/20220509RES29121.pdf>, last access 18 November 2025.

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The COVID-19 pandemic demonstrated that measures taken at that time were not enough to face public health emergencies on a global scale. There was a need for coordinated action at the Union level to respond to health emergencies, including the establishment of the needs for medical countermeasures and their swift development, manufacturing, procurement, and equitable distribution. This is the reason why HERA was born,[8] since the Union did not have a structure resembling that in the United States. The COVID-19 pandemic, as well as other outbreaks of infectious diseases, have shown the need to treat health security as a cross-border issue, leading to a broad consensus that a much closer coordination at European level is required.[9]

Additionally, COVID-19 led to the adoption of Council Regulation 2022/2372/EU[10] on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at the Union level. This Regulation was based on Article 122(1) Treaty on the Functioning of the European Union (TFEU)which stipulates that:

> 'Without prejudice to any other procedures provided for in the Treaties, the Council, on a proposal from the Commission, may decide, in a spirit of solidarity between Member States, upon the measures appropriate to the economic situation, in particular if severe difficulties arise in the supply of certain products, notably in the area of energy.'

This Article of the Treaty, used as a legal basis for the framework related to the supply of crisis-relevant medical countermeasures, is under the chapter of *economic policy* and comes with the notion of spirit of solidarity between Member States and the appropriateness of measures to the economic situation. The supply of 'certain products' is referred to, and yet there is no particular mention of health or medical products, whereas a very concrete reference is made to the area of energy. This poses a question on the limits of EU action in emergency time, due to the absence of the specific legal basis, as well as the interaction between health and economics.

8 See more Oliver J. Wouters et al., 'The Launch of the EU Health Emergency Preparedness and Response Authority (HERA): Improving Global Pandemic Preparedness?', Health Policy 133 (2023), 1-6.

9 Wouters (n. 8), 1.

10 Regulation 2022/2372/EU of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, OJ 2022 L 314/64.

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II. Article 122(1) TFEU and the Health Emergency Preparedness and Response Authority (HERA)

As invoked in literature,[11] Article 122 TFEU is a very special legal basis. It is called an 'emergency competence' and it has been argued in the literature that over the past five years, Article 122(1) TFEU has been significantly mobilised to address the policy crises the EU finds itself in.[12]

This provision allows the Council to adopt legal acts which are not, in accordance with Article 289 TFEU called legislative acts, since the adoption of those acts does not involve the European Parliament.[13] It is the legal basis which puts the Council in the driving seat and provides it with 'executive powers'.[14] Therefore, Council Regulation 2022/2372/EU *on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level* is a Union's act which has a very special legal architecture, requiring the Council to 'activate' the measures proposed by the Commission. And yet, the activation of these measures is preceded by the work of HERA, which is expressly mentioned by the preamble of this Regulation. It is uncommon for the EU legal act to refer directly to a service of the European Commission which was established by a separate decision, which, in itself, is also uncommon. This may be interpreted as the recognition of the limits of the regulation based on Article 122(1) TFEU, but also as the recognition of the fact that health emergency response cannot exist without health emergency preparedness. And health emergency preparedness is done not by the Council, but by the European Commission.

The Regulation 2022/2372/EU specifically refers to 'preparedness and response planning' carried out by HERA.[15] However, the health prepared-

11 See Eva Neumann and Dominik Römling, 'Die Notstandskompetenz des Art. 122 Abs. 1 AEUV und ihre Bedeutung in der Energieversorgungskrise', EuR 2 (2024), 93-135 (93).

12 Merijn Chamon, 'The Non-Emergency Economic Policy Competence in Article 122(1) TFEU', CML Rev. 61 (2024), 1501-1526 (1502); Merijn Chamon, 'The EU's Dormant Economic Policy Competence: Reliance on Article 122 TFEU and Parliament's Misguided Proposal for Treaty Revision', E. L. Rev. 49 (2024), 166-187; Bruno de Witte, 'The European Union's COVID-19 Recovery Plan: The Legal Engineering of an Economic Policy Shift', CML Rev. 58 (2021), 635-682; Daniel Calleja, Tim Maxian Rusche and Trajan Shipley, 'EU Emergency-Call 122? On the Possibilities and Limits of Using Article TFEU to Respond to Situations of Crisis', Columbia Journal of European Law 29 (2024), 520-558.

13 Art. 289 TFEU – only legal acts adopted by legislative procedure shall constitute legislative acts. The ordinary or special legislative procedure always involves the European Parliament, in contrast to Art. 122 TFEU.

14 Calleja, Rusche and Shipley (n. 12), 549.

15 Recital 4 of Regulation 2022/2372/EU (n. 10); Calleja, Rusche and Shipley (n. 12), 544.

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ness landscape is complex, with HERA's mission, at least currently, limited to preparedness and response planning in the area of medical countermeasures.

The President of the Commission called in the 2020 State of the Union address to draw lessons from the COVID-19 pandemic and advocated to build a European Health Union, including a dedicated European structure for biomedical advanced research and development to support capacity and readiness to respond to cross-border health threats and emergencies – whether of natural, accidental, or deliberate origin. As set out in the Communication 'Building a European Health Union: Reinforcing the Union's resilience for cross-border health threats' adopted in November 2020, the Health Emergency Preparedness and Response Authority was a key element for the establishment of a stronger European Health Union, together with a strengthened cross-border health threats legal framework, and with extended and improved crisis-related mandates for the European Centre for Disease Prevention and Control, the European Medicines Agency, and the Pharmaceutical Strategy for Europe. The creation of a new entity was recognised at a time as a bold action in preventing and managing health emergencies in the future.[16]

As it is clear from the Decision establishing HERA, its mission is to improve the preparedness and response to serious cross-border threats in the area of medical countermeasures. The focus is therefore on the improvement of the availability of medical countermeasures. However, medical countermeasures are not administrated in a vacuum, but form part of a general response to health emergencies by medical, civil, or military structures. The specific focus only on medical countermeasures therefore constitutes an important curtailment for the actions of HERA.

It follows that the complexity of interdependence between general health preparedness and specific emergency preparedness and response requires the cooperation of many actors, including the entire European Commission and EU agencies, to strengthen health security by bringing together Member States, industry, and relevant stakeholders in a joint effort. This becomes even more important in a changing international landscape where threats to health must be understood in a broad sense, and therefore, the preparedness in terms of access and availability of medical countermeasures is required for a much wider spectrum of security threats than before.

16 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM/2020/724 final, point 1.

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III. Article 122(1) TFEU and Council Regulation 2022/2372/EU – Health, Economics or Solidarity?

Council Regulation 2022/2372/EU, adopted on the basis of Article 122(1) TFEU, enables the Union to take appropriate measures in the spirit of solidarity between Member States. The reference to the 'spirit of solidarity' is a legal condition for the application of this Article. Therefore, the Council, when deciding about the measures, needs to weigh the interest of Member States as it is the solidarity between Member States that matters.

The choice of such legal basis was convenient, as the Treaty does not specify which measures could be taken and in which field. There is only an indication, by the use of the expression 'in particular', that it was meant to tackle the problems of severe difficulties arising in the supply of certain products, notably in the area of energy. The intention of focusing on the energy sector is confirmed by the number of measures actually adopted under this legal basis. Most of them concern the energy sector;[17] however, anti-inflation and COVID-19 financing measures (both addressing the pandemic as well as recovery from it) were also based on this legal basis.[18] Recently, a Regulation concerning the defence products, Security Action for Europe (SAFE) Instrument, was also adopted on the basis of Article 122 TFEU.[19] What differentiates Regulation 2022/2372/EU from other regulations based on Article 122 TFEU is that there has to be a declaration of health emergency recognised at the EU level for the measures to be activated. Other instruments adopted on the basis of Article 122(1) TFEU do not have a mechanism of a formal recognition of emergency.[20]

The recovery or energy measures have had a clear economic dimension and were adopted with a clearly defined economic situation in mind. Even if

17 There were many measures introduced previously in the fields of agriculture and fisheries. For the full list, see Calleja, Rusche and Shipley (n. 12), 532-548.

18 For a comprehensive review, see Calleja, Rusche and Shipley (n. 12), 521.

19 Regulation 2025/1106/EU of 27 May 2025 establishing the Security Action for Europe (SAFE) through the Reinforcement of the European Defence Industry Instrument, OJ 2025 L series. Through the SAFE instrument, the Council, in a spirit of solidarity between Member States, decided to provide to the Member States that wish to make use of it, a financial assistance mechanism tailored to address the unprecedented geopolitical context and the related public security challenges that justified the intervention under Article 122 TFEU as an emergency instrument. This mechanism allows Member States to engage quickly in public spending to the benefit of the European defence Technological and Industrial Base (EDTIB) with the objective to mitigate as soon as possible the severe difficulties in the supply of defence products that arise from this situation.

20 See the discussion on the constitutional implications of this and whether the emergency situation is indispensable to rely on Article 122 TFEU – Chamon, 'The Non-Emergency' (n. 12), 1502.

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many of them are still in force, their nature seemed to be reactive and temporary. Health emergency reaction is also hoped to be temporary and reactive to the crisis. Yet, it requires preceding health emergency preparedness, which is more a long-term goal.

The key element preceding emergency response are health prevention and preparedness measures. However, such measures are not part of the Council Regulation 2022/2372/EU and therefore there is no explicit legal basis for health prevention and preparedness measures to be more than 'supporting' in their nature. The preparedness measures are part of Regulation 2022/2371/EU on serious cross-border threats to health which excludes harmonisation or measures creating rights and obligations on third parties. The latter Regulation only focuses on the general facilitation of adequate Union wide preparedness and response and is not limited to medical countermeasures. The Regulation only stresses the importance and transparency of public investments in research, development, manufacturing, production, procurement, stockpiling, supply and distribution of medical countermeasures for the purpose of preparing for and responding to cross-border threats to health.[21] Even if the Commission is to prepare a Union health crisis and pandemic plan, the EU only supports Member States with the preparation of *their* prevention, preparedness, and response plans. Member States have only a reporting obligation with regard to 'prevention, preparedness and response planning' and its implementation at national level and where appropriate, cross-border interregional levels.[22]

Since Council Regulation 2022/2372/EU deals in principle only with the elements of response, i. e. creates a framework of measures for ensuring the supply of crisis-relevant medical countermeasures, it has limitations as regards the holistic approach to a response to health emergencies.

However, there are elements of preparedness and planning which are laid down in the Regulation. The Regulation seems to require health preparedness and response planning to provide an assessment for the purpose of activating emergency measures pursuant to that Regulation.[23] Moreover, the implementation of the emergency framework should be reviewed by the Commission. During the conduct of the review, the crisis activities of HERA should be

21 Regulation 2022/2371/EU of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU, OJ 2022 L 314/26, Recital 3.

22 Recital 4 of Regulation 2022/2371/EU (n. 21).

23 The preparedness, as such, is not precisely defined in EU law. If we look at tasks and mission of HERA, they do not include *expressis verbis* the three main components of preparedness, as referred to in literature, i. e. risk assessment, risk management, and risk communication – Simone Villa et al., 'HERA: a New Era for Health Emergency Preparedness in Europe?', The Lancet 397 (2021), 2145-2147.

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considered together with its preparedness activities. Yet, this can only happen when measures laid down in the Regulation are actually activated.

Moreover, it is surprising that there is no reference in Article 10 of Council Regulation 2022/2372/EU, which deals with the inventory of crisis-relevant medical countermeasure production and production facilities, to the Union prevention, preparedness and response plan, which, in accordance with Article 5(3) g of Regulation 2022/2371/EU, should include an overview of the production capacities for relevant critical medical countermeasures in the Union as a whole to address serious cross-border threats to health.

In any event, medical countermeasures should primarily respond and counter the health situation and only secondarily prevent the worsening of the economic situation. This may pose a problem when the economic consequences need to be assessed. The Regulation elegantly deals with this dilemma of 'health versus economic policy' by stating that 'this Regulation aims to establish an instrument of economic policy fundamental to avoid the adverse economic consequences of health crises, such as negative growth, unemployment, market disruptions, fragmentation of the internal market, and impediments to swift manufacturing – consequences which have been witnessed on a large scale in the context of the COVID-19 pandemic – with a view to ultimately safeguarding the economic stability of the Union and of its Member States'.[24]

This means that, legally, the major consideration is economic policy and not public health. Yet, the supply of medical countermeasures is predominantly a health measure and not the economic measure. As it is often the case, the public health emergency has, as it was experienced with COVID-19 pandemic, serious economic consequences. However, these are consequences of a health emergency and not the other way around. The limits of the approach based on Article 122 TFEU, in case of health emergency, are particularly visible in the necessity of the Commission to propose health measures 'appropriate to the economic situation'.[25]

The activation of measures does not depend therefore, as one may have thought, on the gravity of the health situation, but on the gravity of the economic situation. This is surprising for public health measures, but fully understandable for an (EU) economic policy, of which Article 122 TFEU forms part. The Council will have to demonstrate, in any event, that there is an economic situation that requires addressing.[26]

24 Recital 2 of Regulation 2022/2372/EU (n. 10), Villa et al. (n. 23).

25 On vagueness and abstract nature of 'appropriateness to the economic situation', see Ruth Weber, 'Die Neuordnung der EU-Wirtschaftsverfassung durch Art. 122 AEUV?', AöR 149 (2024), 82-122.

26 Laurent Muschel and Bartlomiej Kurcz, 'HERA le nouvel acteur dans le paysage européen de la santé publique', Revue du droit de l'Union européenne (2024), 143-154.

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The references to economic situation are visible throughout the whole Regulation. Any recognition of a public health emergency is followed by a possible activation of emergency framework measures which are appropriate to the economic situation.[27] The same applies to the prolongation of the emergency measures. Such prolongation also needs to be appropriate to the economic situation.[28] All of this implies some form of limitation of the action of the Commission and consequently that of the Council, as Article 1(3) Council Regulation 2022/2372/EU establishes an appropriateness test: measures '*may be activated only to the extent that it is appropriate to the economic situation*'.

It remains a challenge in practice to judge and justify the appropriateness of the activation of every measure in relation to the economic situation at the beginning of the crisis, where a quick action is required and economic consequences at that moment are not fully known. The appropriateness may involve some proportionality and precautionary considerations, but at the beginning of the crisis, when medical countermeasures are most needed to prevent the spread of a health threat, the economic situation may not be as bad as later and therefore certain measures may seem not to be justified at the moment in time when the decision is made. When the measures are activated, the Commission may have only access to historical data. Therefore, the prospective analysis would be needed, which will not focus on an *actual* economic situation but on the *future* – the prevention of actual economic situation getting significantly worse. It remains to be seen whether this limitation will have an influence on the actual activation of some of the measures (and excluding others) in a situation in which the state of actual economic situation is not known. In any event, the legal basis of Article 122 (1) TFEU is broad enough to allow to choose the most appropriate policy to respond to the health emergency in the spirit of a solidarity. It would seem that the Council is entitled to simply choose, on the basis of a proposal by the Commission, whichever measure seems to be best suited to the case at hand.[29]

Yet, there is no doubt that in times of emergency the economic and health considerations may be intertwined, in particular with regard to restrictions to the EU internal market. The closing of the markets may have immediate economic impact, as it was observed in the times of the COVID-19 pandemic, and led to shortages of products, including the shortages of medical countermeasures. Nonetheless, the public health considerations are also visi-

27 Regulation 2022/2372/EU (n. 10), Article 3.
28 Regulation 2022/2372/EU (n. 10), Article 4.
29 Calleja, Rusche and Shipley (n. 12), 520-558.

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ble in the Regulation. First, the framework cannot operate without the recognition of a health emergency at the Union level. Second, any activation of the measures set out in the legislation, such as the establishment of a Health Crisis Board or the monitoring, procurement, and purchase of crisis-relevant medical countermeasures and crisis-relevant raw materials, must take into account the need to ensure a high level of protection of human health. And it must also consider the general principles of Union law, such as the proportionality principle. This is embedded in the requirement of appropriateness of measures.[30]

Who will then coordinate all of those actions at EU level? The Regulation refers to the Commission (as a whole). It seems, however, that HERA plays a special role, as it is specifically referenced in the preamble of that Regulation. The Council, in its Regulation, refers specifically to HERA as regards the support of effective operation and swift decision-making by the Health Crisis Board. This support should take the form of providing an assessment for the purpose of activating measures pursuant to the Regulation, proposing the rules of procedure of the Health Crisis Board, drafting negotiating mandates and procedural rules for joint procurements, and providing relevant information for the establishment of an inventory of crisis-relevant medical countermeasure production and production facilities.[31] The legislator recognises, therefore, an important role of HERA in the preparatory phase, including in relation to the justification of activating of emergency measures and all practical steps related to the establishment of the Health Crisis Board and the supply of medical countermeasures.

It is important to stress that, in accordance with Article 122(1) TFEU, the actions related to the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level apply only to Member States. Therefore, in case there is any need of extending those actions, based on the principle of solidarity, to third countries (be it European Economic Area [EEA]/ European Free Trade Association [EFTA] States, candidate/ accession States or any other States), there is a need of some form of agreement with those other States. Here, however, the question is whether, and to what extent, the 'spirit of solidarity' between Member States could be extended to third countries. It seems that Article 122(1) TFEU referring to solidarity, and not health cooperation, implies some form of bond which is, in principle, reserved to those States who accept rights and obligations as Member States. Only then the trust could be built, so that solidarity is possible. It remains to be seen whether other States could cooperate with the

30 Calleja, Rusche and Shipley (n. 12).

31 Recital 4 of Regulation 2022/2372/EU (n. 10); Calleja, Rusche and Shipley (n. 12).

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EU so closely, without becoming Member States, that the spirit of solidarity could be created between them and the Member States. It is one of the key questions in the application of Article 122 TFEU measures, as the Treaty only focuses on the solidarity between EU States. Such solidarity would have to be extended to third countries.[32]

In the meantime, the Commission and any of the Member States may engage, as contracting parties, in a joint procurement procedure, in compliance with the Financial Regulation, with a view to the advance purchase of medical countermeasures for serious cross-border threats to health within a reasonable time frame. Such a possibility is open also to third countries, i. e. European Free Trade Association States and Union candidate countries, as well as the Principality of Andorra, the Principality of Monaco, the Republic of San Marino, and the Vatican City State.

However, in case of the application of Council Regulation 2022/2372/EU, only Member States can benefit from the Commission's assistance in procurement. This can be done either through the activation of existing contracts or the negotiation of new contracts. The Commission, represented as the case may be by HERA, could be mandated by Member States to apply a purchasing mode in which the Commission acts as a central purchasing body on their behalf. This requires a framework agreement to be signed by Member States that wish to be represented by the Commission ('participating Member States').[33] This agreement can only be signed once the Health Crisis Board is established, which means only when the Council activates one or several emergency measures set out in Articles 7 to 13 in accordance with Article 3 of the Regulation.

IV. Article 122(1) TFEU and Financial Aspects – Council Regulation 2016/369/EU

The response to health emergencies would be incomplete without funding. In case of an emergency of the type of COVID-19 there is likely a need for 'extraordinary' financing. This justifies the activation of the emergency support under Council Regulation 2016/369/EU of 15 March 2016.

32 See, in the field of health, the Council authorisation for the opening of negotiations between the Commission and Norway, Iceland, and Liechtenstein on health emergency measures in the area of medical countermeasures – Council Decision authorising the opening of negotiations with the Kingdom of Norway, Iceland and the Principality of Liechtenstein for one or more agreement(s) on health emergency measures in the area of medical countermeasures, 7389/25 public.

33 Article 8(1) and (2) of Regulation 2022/2372/EU.

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This Regulation is again based on Article 122(1) TFEU. This time, however, it is undoubtedly an economic policy measure, as it refers essentially to financial support. It lays down the framework within which Union emergency support may be awarded through specific measures appropriate to the economic situation in the event of an ongoing or potential natural or man-made disaster. Such an emergency support can only be provided where the exceptional scale and the impact of the disaster is such that it gives rise to severe wide-ranging humanitarian consequences in one or more Member States. It may only be done in exceptional circumstances where no other instrument available to Member States and to the Union is sufficient.

The Regulation was adopted to respond to the 'migration' crisis in 2015 to support countries facing large number of refugees and migrants.[34] Therefore, the Regulation lays down in the Annex the non-exhaustive list of eligible actions, among which, many actions related to medical countermeasures could be financed in case of pandemics with large-scale effect. Among them, specifically listed are activities to support diagnostics and testing, the development, production, or purchase and distribution of medical products, as well as the measures related to the increase of production capacities and the maintenance of the stocks.

The decision about the activation of the emergency support under Regulation 2022/2372/EU in case of an ongoing or potential disaster shall be taken by the Council on the basis of a proposal by the Commission, specifying, where appropriate, the duration of the activation. The emergency support under this Regulation shall provide a needs-based emergency response, complementing the response of the affected Member States aimed at preserving life, preventing and alleviating human suffering, and maintaining human dignity. The response should arise as a result of a disaster referred to in Article 1(1) of that Regulation. Without prejudice to the activation period, as referred to in its Article 2(1), the emergency support may also be granted in view of addressing needs in the aftermath of a disaster or preventing its resurgence. The Commission should implement the Union's financial support in accordance with the Financial Regulation.

V. Conclusion

The supporting competence in the field of health has its limits with regard to the effectiveness and efficiency of a response to future public health emergencies. The same applies to the competence enshrined in Article 122(1)

34 Calleja, Rusche and Shipley (n. 12).

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TFEU, as a legal basis, for the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

De lege ferenda, it can be argued that a separate legal basis for health emergency measures should be created which would be at least shared with Member States and which would not be subject to 'economic assessment' restrictions set out in Article 122 TFEU. Such a separate legal basis would also make the cooperation with other states in Europe, or outside it, much easier and more focused on a health dimension. However, this is not likely to happen in any foreseeable future. In addition, the separation of health emergency measures and health preparedness measures (for emergency) seems quite artificial. Yet, *de lege lata*, the lack of a separate health emergency legal basis has wide-ranging consequences which can only be mitigated by the cooperation of all actors involved in the preparedness times.

The creation of HERA was an important step this direction, i. e. in strengthening the availability of medical countermeasures during health emergencies, due to research and development starting already at the time of preparedness. The more that is done in the emergency preparedness phase, the better we will be prepared for future health emergencies, in particular for the situations in which the nature of the threats and health emergencies evolve. The recourse to Article 122 TFEU, however, as an 'emergency power' does not considerably facilitate the preparedness work. Only the next public health emergency will show whether the current legal framework is sufficient to take effective and efficient health emergency measures.

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Buchbesprechungen

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Undertaking the project of compiling and publishing an article-by-article – or, in the present case more precisely, a principle-by-principle – commentary on an international document like the 2011 United Nations (UN) Guiding Principles on Business and Human Rights that belongs to the realm of so-called 'soft law', although surely not entirely unheard of in the legal literature,[1] asks to a certain extent for an explanation and justification, already when considering the well-known fact that the academic genre of commentaries is in the realm of legal scholarship traditionally – and also as of today predominantly – reserved for 'hard law' instruments such as domestic constitutions and legislative acts, regulations, codes or – in particular more recently – individual international conventions. Although the editor of the work under review, *Barnali Choudhury*, is herself not directly and explicitly addressing this question, the overarching thoughts and elaborations she provides in her introductory section (pp. 1-10) as well as in particular also the general purposes outlined in the foreword written by *Surya Deva* (pp. xxvi-xxviii) indicate many of the main reasons in favor of the respective publication approach chosen as well as its intended benefits for interested scholars and practitioners.

The topic of international corporate social as well as legal responsibility and thus in particular also the question whether and, in the affirmative, on the basis of what governance approaches non-state corporate actors are expected or even obliged to contribute to the promotion and protection of global community interests like human rights has attracted very considerable attention in recent decades.[2] Nevertheless, viewed from the perspective of the international legal order in the narrow sense, public international hard law rules stipulating obligations in the policy field of business and human rights still remain also as of today scarce or at least controversially perceived as far as their regulatory content is concerned. This applies for example to the

1 See, e. g., Ilias Bantekas and Francesco Seatzu (eds), *The UN Sustainable Development Goals – A Commentary* (Oxford University Press 2023); Winfried Huck (ed.), *Sustainable Development Goals, An Article-by-Article Commentary* (Nomos/Beck/Hart 2022).

2 The contributions on this topic are by now more than legion. See, e. g., recently for a comprehensive comparative analysis of the respective discourses in the United States and Germany Richard Dören, *Business and Human Rights in den USA und in Deutschland* (Nomos 2024), with numerous additional references.

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disputed answer to the question whether states are under international human rights law normatively required to regulate the extraterritorial activities of private business entities under their jurisdiction.[3] However, it first and foremost also concerns the still dominant perception that non-state corporate actors are currently – aside from some notable but until now with regard to their scope of application only quite limited recent developments in international investment treaty-making[4] – neither under treaty law nor in the realm of customary international law addressees of direct obligations to promote and protect international human rights. With generally recognised international legal rules on the issue of business and human rights thus largely absent, it is in fact first and foremost international governance instruments belonging to the realm of soft law that have provided normative guidance and played a quite prominent role in this policy field in the course of the last fifty years.

As also rightly emphasised in the foreword and the introductory section of the present work under review, a very influential position is – ever since its endorsement by the UN Human Rights Council in June 2011 – currently occupied in this connection by the UN Guiding Principles on Business and Human Rights. Two somewhat intertwined reasons seem worth recalling in this regard: First, the UN Guiding Principles enjoy an accentuated status among the soft law instruments in the realm of international corporate responsibility because they constitute the central respective instrument that has been successfully developed under the auspices of the United Nations and received endorsement by this most authoritative global organisation. Second, the UN Guiding Principles are not to be regarded as another 'traditional' code of conduct that is confined to stipulating more or less specific societal expectations on the activities of economic actors and, in this regard, provides for a number of implementation mechanisms. Rather, they aspire to be 'an authoritative focal point' that is meant to serve as a 'coherent and comprehensive template' for the allocation of responsibilities in the realm of business and human rights.[5] Therefore, the UN Guiding Principles are most appropriately to be understood as an overarching conceptual outline of future directions for the application and development of other soft as well as

3 For a more in-depth assessment of this issue see for example Markus Krajewski, 'The State Duty to Protect Against Human Rights Violations Through Transnational Business Activities', Deakin Law Review 23 (2018), 13-39.

4 See thereto, e. g., Patrick Abel, *International Investor Obligations* (Nomos 2022), 36 et seq.

5 Human Rights Council, Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy' Framework, UN Doc. A/HRC/17/31, of 21 March 2011, Introduction, paras 5 and 14.

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hard law instruments in this field. And indeed, as nicely and convincingly summarised and illustrated by *Choudhury* in her introductory section (pp. 6-9), this soft law instrument, in the decade since its adoption, undoubtedly 'had a transformative and highly influential effect on a number of different initiatives' (p. 6) at the domestic, supranational, and international level in the realm of soft law and hard law – and are highly likely to continue to exercise a notable influence in the years to come. Against this background, and in particular taking into account the significant impact of the UN Guiding Principles on the progressive development of the business and human rights agenda on the national and international plane, the project initiated by *Choudhury* to publish a principle-by-principle commentary on this soft law instrument appears not only to be fully justified but in fact also a very laudable and felicitous undertaking.

In principle, a legal commentary on the UN Guiding Principles serves the same multiple purposes as the almost countless commentaries addressing hard law regimes. Three purposes stand out in this regard: As also accurately described by *Deva* in his foreword (pp. xxvii-xxviii), a commentary is always expected to provide clarification by identifying and elaborating the normative concepts embodied in the individual standards as well as by addressing and concretising ambiguities in the wording of the respective rules and principles. Moreover, a commentary should provide the reader with examples of how the principles have subsequently been applied in the practice of – in the context of the UN Guiding Principles – states, companies, and other stakeholders. Finally, a proper legal commentary also serves the purpose of identifying regulatory gaps and inconsistencies, thereby, adopting a legal policy perspective, drawing attention to the need or at least desirability to amend and update the normative instrument at issue. By striving to serve these overarching purposes, the commentators can provide helpful assistance and guidance to practitioners tasked with applying the respective governance instrument and – again in particular also in the context of the UN Guiding Principles – thus, ideally, also can promote and further enhance the acceptance as well as the transformative potential of the regulatory framework in question.

Having discussed and confirmed the justification for, and usefulness of, publishing a commentary on the UN Guiding Principles despite its normative character as a 'mere' soft law document, and having outlined the main purposes to be pursued by a good and thus recommendable book belonging to this academic genre, I will now turn more specifically to the individual contributions in the volume under review. For the commentaries on the individual principles, the editor has assembled a truly impressive total of forty-four scholars and practitioners from basically all parts of the world,

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most of whom with a legal background and all of whom with proven experience in the field of business and human rights. Interestingly though, the editor *Choudhury* herself is not among these commentators. While slightly unusual, the decision on the approach adopted in this regard is obviously for the respective editor to make and most certainly does not in itself negatively – or positively – affect the quality of the publication.

In a comparatively short book review, it is of course almost impossible – and I'm thus not even going to make an attempt – to comment on and do justice to all of the individual contributions included in this collected work. Nevertheless, and not the least in order to make this review as informative as possible for those who have been involved in the present work as well as of course in particular also for the broader business and human rights community, I will not confine myself to some general overarching impressions but rather make an honest attempt to first and foremost also highlight, and comment on, some more detailed aspects that I observed while reading, and that are more specifically related to, some of the individual contributions.

As already indicated, the introductory section to this collected work, appropriately written by the editor *Choudhury* herself, provides a concise and convincing overview of the topic at issue, thereby in particular also addressing the background, historical evolution and subsequent impact of the UN Guiding Principles as well as potential future directions for this governance instrument. Nevertheless, also two more or less minor inaccuracies are noteworthy in this regard. First, it is not entirely clear – and not explained by the author – why the Organisation for Economic Co-operation and Development (OECD) Guidelines for Multinational Enterprises and the International Labour Organisation (ILO) Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy, international codes of responsible business conduct originally adopted already in the 1970s, are in this introductory session occasionally referred to as 'non-voluntary standards for corporations' (p. 3), whereas they are – correctly – qualified as '[v] oluntary standards' in other parts of the same contribution (see, e. g., p. 2). While this thus very likely can be regarded as an avoidable 'slip of the pen' by the author, the second inaccuracy worth mentioning here seems to be more substantial. Contrary to the impression given by *Choudhury* (p. 3), the UN Global Compact was not initiated after the failure of the 2003 UN Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights but already a few years prior to it.

The first two commentaries on Guiding Principles 1 and 2 written by *Daniel Augenstein* and *Claire Methven O'Brien* respectively serve already as a clear indication for the overall very high quality of all of the numerous

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individual contributions included in this collected work. However, they unfortunately also already illustrate one of the more notable challenges potentially faced by the readers when consulting this book. Both commentaries address the issue of extraterritorial state obligations to prevent corporate human rights abuses committed while operating abroad and both contributions refer in this regard, and quote from, the same documents adopted by international human rights bodies (pp. 16-17 and pp. 26-27). Respective repetitions can also be found in various contexts in not only some of the subsequent individual commentaries (for example in connection with the relevance of National Action Plans). A more extensive recourse to cross-references and other more comprehensive efforts aimed at coordinating the content to be addressed in individual contributions throughout the collected work would have likely avoided such multiple treatments of the same legal issue and would have thus clearly further enhanced the readability of the book as a whole.

The commentary on Guiding Principle 3 by *Anil Yilmaz Vastardis* and *Rachel Chambers*, while providing an in principle very useful assessment of its regulatory content and implications, suffers – at least in the eyes of the present reviewer – to a certain extent from a quite extensive description – and quotations from – the 'official' Commentary to the UN Guiding Principles (pp. 32-33) and thus from a document that is available – and probably rather well-known – to the broader business and human rights community ever since it was published in 2011. Moreover, whereas the commentaries on Guiding Principles 4 and 5 written by *Larry Catá Backer* and *Humberto Cantú Rivera* serve as examples of very convincing and thoughtful analyses of their respective topics, the subsequent contribution by *Annamaria La Chimia* on Guiding Principle 6 is not only at least in part lacking the specific connection to the regulatory content of the principle at issue that one would expect from a commentary.[6] Rather, it also provides only a rather 'light' treatment of the relationship between international trade agreements and the contracting states' obligations under international human rights law (p. 53), given the fact that it is by now overwhelmingly recognised that the solution to respective normative conflicts should not be based on an approach that gives absolute preference to either trade agreements or human rights obligations, but rather by striving for an appropriate balance in individual situations.

The commentary by *Olga Martin-Ortega* and *Fatimazahra Dehbi* on Guiding Principle 7 dealing with the states' role in addressing the heightened danger of corporate human rights abuses when operating in conflict-affected

6 This is probably also a consequence of the fact that this commentary is partially based on a prior publication of the author as acknowledged by her in fn. 1 (p. 49).

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areas, while rightly mentioning the so-called 'Dodd-Frank Act' of 2010 (p. 61), could have been expected to also refer to other relevant governance instruments such as in particular the 2017 EU Conflict Minerals Regulation.[7] The same applies for example to the commentary by *Carolina Olarte-Bácares* on Guiding Principle 9 that concerns the need to maintain sufficient policy space for states to take adequately into account their human rights obligations when concluding, for example, international trade and investment agreements with other countries. In this regard, it could legitimately be doubted whether the assertation by the author that investment agreements basically only 'serve to safeguard the property-related rights and interests of investors' (p. 74) is still supported by more recent treaty-making practice. In fact, the perception that investment treaties – and regional free trade agreements – should also include provisions stipulating obligations for private business actors and provisions on corporate social responsibility is no longer confined to the realm of respective 'proposals' in the legal literature. Rather, there are by now a notable number of examples also in the realm of actual treaty practice in this regard and one, again, could have – and would have – expected the author to mention at least some of them in the course of her commentary.

The commentary written by *Sara L. Seck* on Guiding Principle 11 serves in particular also as a good introductory section to the so-called second pillar of the governance framework established by the UN Guiding Principles, namely the corporate responsibility to respect human rights. That said, the usefulness of this chapter would have probably benefited from an at least slightly more in-depth discussion of the – as rightly emphasised by the author – 'hotly debated' (p. 87) and also dogmatically quite complex and multi-faceted question as to the dogmatic basis and current recognition of international hard law obligations of private business actors to contribute to the protection and promotion of global community interests such as in particular in the realm of human rights. To a certain extent to the contrary, the subsequent commentaries addressing the individual principles of the UN Guiding Principles dealing with the various normative as well as practically relevant aspects of the corporate responsibility to respect human rights (Guiding Principles 12 to 24) provide each a succinct and thus quite helpful description and assessment of the respective regulatory content as well as the challenges in effectively implementing it in business practice. They for example rightly stress the limits inherent in voluntary approaches and thus empha-

7 Regulation (EU) 2017/821 of the European Parliament and of the Council of 17 May 2017 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas, OJ 2017 L 130/1.

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sise the desirability for, among others, effective due diligence regulation and non-financial human rights reporting requirements at the domestic level as well as the overall need for more precise governance guidance for private business actors in order to allow them to determine what procedures and other policies they are expected to adopt and implement in order to meet their responsibility to respect human rights. Respective examples are provided by the commentaries written by *Kishanthi Parella* on Guiding Principles 13 and 15 (pp. 108 and 117), the commentary by *Maddalena Neglia* on Guiding Principle 16 (pp. 122 et seq.), the commentary written by *Claire Bright* and *Celine da Graça Pires* on Guiding Principle 18 (pp. 143 et seq.), the commentary written by *Andreas Rühmkorf* concerning Guiding Principle 21 (pp. 166 et seq.), as well as the commentary written by *Salvador Herencia-Carrasco* on Guiding Principle 24 (p. 190).

The so-called third and final pillar of the expectational governance structure characterising the UN Guiding Principles, namely providing for access to remedies on the basis of state-based judicial and non-judicial remedies as well as non-state corporate based grievance mechanisms is convincingly introduced through the commentary written by *Dalia Palombo* on Guiding Principle 25 (pp. 191 et seq.). Structuring the commentary along the four main questions, namely 'Who is obliged?', 'To whom are the duties owned?', 'What type of remedies are expected?' and 'What is the territorial extent of these expectations?', and thus addressing the active personal scope of application, the passive personal scope of application, the material scope of application as well as the territorial scope of application, proves to be a very suitable approach aimed at clarifying the regulatory content of this principle and the third pillar as a whole. The subsequent commentaries concerning the Guiding Principles 26 to 31 provide each a very well-written and overall quite helpful description and evaluation of the individual remedies envisioned by this governance instrument and the various individual requirements foreseen in this regard in order to ensure the appropriateness and effectiveness of these central mechanisms aimed at ensuring that they create suitable and practically relevant options for people seeking remedy for business-related human rights harm. Particularly helpful, and thus especially worth noticing, are those commentaries that also mention, explain, and assess specific examples of state-based and non-state based judicial as well as other grievance mechanisms. This applies for example to the commentary on Guiding Principle 27 written by *Markus Krajewski* (pp. 213 et seq.) as well as to the commentary written by *Dorethée Baumann-Pauly* and *Lilach Trabelsi* on Guiding Principle 30 (pp. 234 et seq.). Aside from that, the commentary on Guiding Principle 31 written by *Anna Triponel* is worth mentioning in light of the short but quite enlightening and instructive explanation and evaluation of the

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individual effectiveness critera stipulated by the UN Guiding Principles in connection with non-judicial grievance mechanisms (pp. 242 et seq.).

The work under review is, however, and contrary to its title, not confined to a commentary on the individual UN Guiding Principles. Rather, it also includes a commentary on the ten Principles for Responsible Contracts (PRC) which – as also rightly highlighted by the editor *Choudhury* in her introductory section (p. 5) – were submitted by the Special Representative, *John Ruggie*, to the United Nations Human Rights Council as an addendum to the UN Guiding Principles in May 2011 with a view to enabling parties negotiating state-investor contracts to integrate the management of human rights risks into contract negotiations more effectively.[8] Particularly from a practice-oriented perspective, the decision made by the editor of this work to also include a commentary on this important governance instrument has to be regarded as very laudable and fortunate. Despite some clearly avoidable and more or less minor inaccuracies – for example the quotation given by *Daria Davitti* and *Sorcha MacLeod* in the first paragraph of their commentary on PRC 1 (p. 250) is not mentioned in the document cited[9] but only in the preface of the subsequently published document 'OHCHR, Principles for Responsible Contracts – Integrating the Management of Human Rights Risks into State-Investor Contract Negotiations: Guidance for Negotiators, 2015' on page 2 –, the individual commentaries on the ten principles overall provide an in general quite helpful and well-written explanation of the various individual issues addressed in this guiding document. To mention but one example, the commentary written by *Jernej Letnar Černič* on PRC 4 dealing with so-called 'stabilization clauses' (pp. 272 et seq.) is one of the best concise treatments I have read so far on this comparatively complex and multi-facetted regulatory topic.

In sum, despite some more or less minor points of criticism, the work 'The UN Guiding Principles on Business and Human Rights – A Commentary' edited by *Barnali Choudhury*, overall distinguishes itself as an important and in particular also practically relevant addition to the ever-growing literature on the topic of business and human rights. It is undoubtedly a notable contribution to the indeed indispensable global discourses and thus highly recommended to scholars and practitioners interested in this important issue of our time.

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8 See also OHCHR, Principles for Responsible Contracts – Integrating the Management of Human Rights Risks Into State-Investor Contract Negotiations: Guidance for Negotiators, 2015, 1-2.

9 UN Doc. A/HRC/17/31/Add.3 of 25 March 2011.

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***Sender, Omri* and *Wood, Michael*: Identification of Customary International Law.** Oxford: Oxford University Press 2024. ISBN 978-0-19-884822-6. xxix, 389 p. £145.-

'There is no doubt room for a whole treatise on the harm caused to the business of legal investigation by theory.'[1] Omri Sender's and Sir Michael Wood's excellent new book, *Identification of Customary International Law*, published by Oxford University Press in December 2024, is not that treatise. However, the spirit of Professor Brownlie's famous pronouncement runs through the work, which at points demonstrates some impatience with the 'theoretical speculations that sometimes accompany customary international law in the books' (p. 75).

This book, with a length of 432 pages, is a very welcome and useful addition to the extensive existing literature on customary international law. As stated in the introductory chapter, the book's aim is 'to complement the ILC's authoritative work [on identification of customary international law] by offering more information and analysis for those – practitioners and scholars alike – with the time or need to dig deeper' (p. 3). In this, the work generally succeeds. The twelve substantive chapters address the key topics within the identification of customary international law in a level of detail not found outside the International Law Commission's (ILC) own products.[2] In addition to drawing on the ILC conclusions and commentaries, the analysis in the book is derived from the reports prepared by Sir Michael, with the assistance of Mr Sender, in his role as Special Rapporteur for the topic 'Identification of customary international law'. Like those reports the book is characterised by very detailed and extensive reference to the practice of states and international tribunals, as well as both recent and classic literature. The book differs from these reports primarily in being more succinct and focused, as well as developing the analysis of some issues in greater detail, and including new discussion of topics not addressed in the Commission's work.

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1 Ian Brownlie, 'Recognition in Theory and Practice' in: Ronald St. John Macdonald and Douglas M. Johnston (eds), *The Structure and Process of International Law* (Brill 1983), 627-642 (627). For criticism see Iain Scobbie, 'Voyaging Towards Ithaca: Thinking About International Legal Theory' in: Malcolm Evans (ed.), *International Law* (6th edn, Oxford University Press 2024), 53-92 (54-58).

2 Existing book-length general studies of customary international law are now rather old: Anthony D'Amato, *The Concept of Custom in International Law* (Cornell 1971); Maurice Mendelson, 'The Formation of Customary International Law', RdC 272 (1998), 155-410 (188). Some more recent monographs analyse the identification of customary international law within a particular sub-field of international law, see, for example, Theodor Meron, *Human Rights and Humanitarian Norms as Customary Law* (Oxford University Press 1991); Patrick Dumberry, *The Formation and Identification of Rules of Customary International Law in International Investment Law* (Cambridge University Press 2016).

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Chapter two provides a concise history of customary international law as a source of international law and the ILC's work to date on 'access to evidence of customary international law', as well as a robust defence of custom's continuing importance to the international legal system (pp. 17-22). Filling a gap in the ILC's work on identification of custom, there is a brief but useful discussion of the distinction and relationship between customary international law and general principles of law (pp. 23-27). Chapter three then describes the history of the ILC's project on identification of customary international law, from its inception to the adoption of the conclusions by the Commission in August 2018, including relatively detailed accounts of the comments received and debates within the Commission and Sixth Committee at first and second reading. The most contentious issues remained the role of the practice and *opinio juris* of international organisations; the weight, if any, to be given to inaction as state practice; and the persistent objector rule. The concise summary of the process is convenient, although there is little to surprise readers who closely followed the ILC's work on the topic.

The final part of chapter three provides an assessment of the ILC's work on identification of custom (pp. 47-52). This assessment is unsurprisingly positive but provides some insightful reflections on the impact of the ILC project and its place within the broader international legal landscape. Addressing the charge of conservatism, the authors respond that:

'the aim was to be neither conservative nor progressive, but to reflect accurately the current position as regards the determination of customary international law. To the extent that the Conclusions restate widely-held positions, they are none the worse for that.' (p. 49)

The authors rightly emphasise the reception of the conclusions by states in the Sixth Committee, noting that reactions were mostly positive and '[a]s on previous occasions, no speaker questioned the basic two-element approach' (p. 44). Indeed, the conclusions have already been widely referred to, before the International Court of Justice (ICJ), International Criminal Court (ICC), and arbitral tribunals, by individual ICJ judges and domestic courts, and in scholarly writings (p. 47-48). Although it is probably overly optimistic to hope that 'The Commission's output should help to overcome some of the theoretical controversies that have bedevilled writings on customary international law' (p. 49).

Chapter four marks the beginning of the substantive heart of the book: it is the first of five chapters which address in detail the components and practicalities of the test for identification of custom: the two-element approach itself (chapter four); assessment of evidence for the two constituent elements (chapter five); practice (chapter six); generality (chapter seven); and acceptance as law (chapter eight). Chapter four begins by providing a per-

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suasive argument in support of the two-element approach to the identification of custom, relying primarily on an extensive array of state practice, and the jurisprudence of the International Court of Justice (pp. 54-63). Short but insightful subsections are devoted to two topics not addressed by the Commission. First, in relation to how customary international law changes, it is argued that 'there is in principle no difference between the emergence of a new rule of customary international law and the change of an existing rule; indeed, it does not seem useful to seek to make any such distinction', and that change in custom also requires satisfaction of the two-element approach (pp. 68-71). On the more controversial question of the 'interpretation' of customary international law, the authors are rightly sceptical, observing that 'identification of a rule of customary international law involves the determination of its scope and content, and once that determination has been made, what remains is the application of the rule to a given situation'. While state practice and *opinio juris* will need to be interpreted in the sense that their relevance and significance will need to be assessed, and this may involve interpretation of written materials, this does not amount to interpretation 'of the customary rule as such' (pp. 77-78).

Being based on the work of the ILC on this topic, the book naturally shares the strengths and shortcomings of the Commission's approach to the identification of customary international law. Chapter five opens by highlighting the tension between the stated need for 'rigour in appreciating, in each case, whether a general practice accepted as law may indeed be said to exist' and the reality that 'the application of the two-element approach involves an evaluation that is more an art than a science' (p. 80). This emphasis on the 'flexibility' of the two-element approach (pp.66-68), like the relatively abstract and high-level guidance provided in the ILC conclusions themselves, leaves the work open to criticism that it does not truly grapple with, nor provide helpful guidance for, the messy practical difficulties of determining whether the test is met in concrete cases. For example, chapter seven on 'generality' does a good job of explaining the various factors that affect how much and how consistent a practice is required to identify a customary international law rule, but arguably this highly contextual approach, with considerable work done by the word 'sufficiently' in the expression 'sufficiently widespread and representative', is of limited utility for practitioners seeking to apply the two-element test.

However, such criticism seems uncharitable: it is impossible for general guidelines to address all possible situations in which a customary rule may need to be identified. The practical guidance and examples prevent the discussion from becoming too abstract (pp. 139-144), and there is also an intellectual honesty in recognising the complexity of the task and avoiding the temptation to create neat, but overly simplified, rules of thumb. The great

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contribution of the book, like the ILC conclusions, is to provide a structured and systematic way to approach the identification of custom, even if inevitably much will come down to the judgment made by the identifier in the particular case. This is in addition to the clarification of key, but under-analysed aspects of the application of the two-element test, such as the overall context of the inquiry, the nature of the rule, the circumstances in which the evidence is found, and the order of ascertainment of the two elements and whether they must be assessed separately (pp. 81-85; 89-93). Chapter seven also contains an illuminating discussion of the development of the conclusion on specially affected states and the divisions within the Commission (pp. 144-150).

Chapter eight on acceptance as law makes a valuable contribution to demystifying the concept of *opinio juris*, and will be of great assistance to those trying to apply the test in practice. There are detailed analyses of key questions such as whose acceptance as law matters (pp. 174-178), distinguishing *opinio juris* from other motives (pp. 171-173), and an excellent subsection on when failure to react can evidence *opinio juris* (pp. 187-192). There is also a brief analysis of each of the commonly used forms of evidence of acceptance as law – public statements by states, diplomatic correspondence, national court decisions, and so on (pp. 178-187). As is common in writing about custom, heavy reliance is placed on dicta of the ICJ, but this is supported by reference to a variety of domestic and other international court decisions, as well as other practice.

Having analysed in detail the component elements of the test for identification of custom, chapters nine to thirteen address some of the more vexed issues that arise in practice and scholarship: resolutions of international organisations as evidence of customary international law (chapter ten); subsidiary means for the determination of customary international law (especially relevant in light of the ILC's ongoing work on this topic) (chapter eleven); particular customary international law (chapter thirteen); and, of course, the persistent objector rule (chapter twelve). Perhaps the most interesting is chapter nine, on 'The Significance of Treaties for the Identification of Customary International Law'. The approach is appropriately cautious, noting that '[t]he relationship between the two principal sources of international law is a dynamic one, and their separate validity and applicability must be acknowledged' (p. 200). The rigorous and detailed analysis is a valuable addition to classic texts on the subject,[3] updating the familiar tripartite

3 Richard Baxter, 'Treaties and Customs', RdC 129 (1970), 27-105; Rudolf Bernhardt, 'Custom and Treaty in the Law of the Sea', RdC 205 (1987), 247-330; Mark Villiger, *Customary International law and Treaties: a Manual on the Theory and Practice of the Interrelation of Sources* (Kluwer 1997); Yoram Dinstein, 'The Interaction Between Customary International Law and Treaties', RdC 250 (2007), 243-427 (322).

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framework of 'codifying, crystallising, and generating' with the most recent practice. In addition to the more abstract discussion of the relationship between the two sources, the chapter also includes useful practical guidance on factors to consider when determining whether a treaty rule has codified, crystallised, or generated a rule of custom: the extent of participation in the treaty; the position of non-parties; and possibly the faculty of making reservations to the treaty rule in question and the existence or not of a denunciation clause (pp. 220-229).

Returning, then, to the question of theory; the book does engage to some extent with the theoretical debates that underlie the identification of customary international law. Indeed, the discussion at the beginning of chapter eight, on 'Acceptance as Law', which skilfully summarises and analyses the theoretical debate about the nature of *opinio juris*, demonstrates the utility of understanding the 'theory' which stands behind well-accepted legal concepts, at least as context for the doctrinal debates. In chapter four, there is also a discussion of 'novel theories on the identification of customary international law, sometimes referred to as "modern approaches"' (pp. 72-76). However, the word 'theory' seems to be used, not as one might expect to refer to the various 'full-blooded' theoretical approaches to (customary) (international) law – natural law, feminism, Marxism, critical approaches, Third World Approaches to International Law (TWAIL), and so on – but to encompass any unorthodox approach or scholarly account of customary international law that departs from the two-element test. Frederick Kirgis's 'sliding scale' approach to custom,[4] and the International Law Association's 'single-element' approach,[5] while novel in their reconceptualisations of the test for custom, are hardly best described as theoretical.

Elsewhere, at times theoretical debates are dismissed in favour of a conclusion based on an analysis of the practice of states or, more dubiously, 'common-sense' (p. 104). This is certainly useful advice for a practitioner or domestic judge who encounters customary international law in the course of their work,[6] and indeed, as already noted, the purpose of the ILC's conclusions was to 'offer practical guidance' on how the existence and content of customary international law rules are to be determined. The consensus-based working methods of the Commission, and the input of the United Nations General Assembly (UNGA) Sixth Committee into its work, also inevitably mean that controversial theoretical issues are skated over or compromise

4 Frederic Kirgis, 'Custom on a Sliding Scale', AJIL 81 (1987), 146-151.

5 International Law Association, Statement of Principles Applicable to the Formation of Customary International Law, 2000, 741.

6 In this respect, the book has some similarities with the pragmatic approach taken in Anthony Aust, *Modern Treaty Law and Practice* (3rd edn, Cambridge University Press 2013).

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language must be found. However, in a scholarly work one is left hungry for deeper engagement with the conceptual and, yes, theoretical issues that lurk behind these practical puzzles. For example, in rejecting single-element approaches to the identification of custom, it is argued that '[i]n the absence of practice, customary international law would be a misnomer […] Nor can there be customary international law without acceptance as law: "[i]t is the element of conviction that lends customary law its authority; and if the conviction be missing, so pro tanto is the authority"' (p. 74).

The final quotation from Jennings seems to take the place of any analysis, or even discussion of possible accounts; of *why* it is the *opinio juris* of states that distinguishes mere usage from custom.

As a result, some highly interesting points are raised but addressed only rather superficially. On the question of the nature of the secondary rules of international law, and whether the conclusions themselves reflect or codify customary international law, it is noted that 'the Commission did not take a position on what seemed to be an essentially theoretical matter, without practical consequences' (p. 51). Fair enough; however, I suspect like many readers, I would have been very curious to read the analysis of two leading scholars of customary international law on this question, freed from the constraints that apply to a Special Rapporteur. As it is, the reader is left only with the sensible but terse statement that '[t]hese "rules of recognition" for the identification of customary international law are rules of law, and are best viewed as themselves forming part of customary international law' (p. 52). This view – that the secondary rules of law identification and change in international law are themselves rules of customary international law – likely explains the methodological approach of the book: questions that could be analysed conceptually, or using theoretical accounts of international law, are instead answered with a reference to practice or, sometimes, an ICJ judgment. However, if this is the premise that underlies the methodological approach of the book, a more detailed argument in support of the view that international law's secondary rules are themselves creatures of customary international law, and some discussion of the further, difficult questions this entails about how such customary rules are formed and identified, would have been desirable, as well as interesting.

Chapter six, entitled 'A General Practice: Whose Practice? What Practice?', elaborates on one of the more controversial issues in the ILC's work: whether and in what circumstances the practice of international organisations can contribute to the formation of customary international law. The authors take the view, based on an account of practice, that practice of international organisations 'as such' (p. 108) can be creative or expressive of customary international law, at least in their relations among themselves and with their

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members, or where member states have transferred powers to the organisation. They remark that '[t]he debate seems, however, to have been largely theoretical, as it turned for the most part on whether the practice in question was regarded as that of the international organization itself or of the member States acting through the organization' (p. 110). The book thus seems to dismiss the importance of a key question on which the practical matter of whether International Organisation (IO) practice can contribute to the formation of custom turns. Yet, in choosing between alternative analyses, while it may not be necessary to have a fully worked-out theoretical account of custom, one must at least have some underlying view on what (customary) international law is, why it binds, and the reason why (state) practice and *opinio juris* can create binding law.

For example, the ILC commentary is quoted with approval: 'the more directly a practice of an international organization is carried out on behalf of its member States or endorsed by them, and the larger the number of such member States, the greater weight it may have in relation to the formation, or expression, of rules of customary international law' (p. 109). Yet it is unclear *why* the authors believe both that practice that constitutes customary international law need not be practice of a state itself, *and* that practice on behalf of or endorsed by a state nevertheless has greater weight. If greater state involvement gives more weight to a practice, is this because it evidences the consent of states to the customary rule in question? Yet if this is the case, why is it acceptable – as it seems the authors and, in the end, the ILC conclusions accept – for an IO's own practice to be creative of customary international law even where the organisation is not acting directly on behalf of members or using transferred powers, and thus the link to state consent (at least through the practice element) is absent? Similarly, in chapter eight on *opinio juris*, the authors remark that '[t]he separate legal personality of international organizations makes them capable in principle of expressing a "juridical will" of their own, including acceptance as law', and simply note that '[e]stablishing such *opinio juris* on their part, notwithstanding the differences between them and States, does not seem to raise special difficulties' (p. 196). As others have observed, the risk is that, by failing to engage explicitly with the (legal) philosophical assumptions that underlie one's analysis, they cannot be subject to critical examination.[7]

To conclude, the book succeeds in providing a clear, focused account of a highly technical area of international law, effectively synthesising an impressive volume of practice and scholarship, while adding more detailed analysis of issues not covered by, or only touched on in, the ILC's work. The authors'

7 Scobbie (n. 1), 55, citing Rosalyn Higgins and Hersch Lauterpacht.

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own assessment of the ILC conclusions and commentary could be applied equally well to the book: 'While dealing with issues of considerable complexity and nuance, [it is] concise and user-friendly' (p. 49). As discussed above, this clarity may come at the expense of detailed engagement with more 'theoretical' questions, which are nonetheless discussed at least briefly and represented in the footnotes. However, overall, the authors have succeeded in producing that rare thing: an accomplished academic work that is sufficiently clear and accessible to be read by students studying the sources of international law for the first time and which will be a useful text for practitioners, but which also includes analysis of more complex debates within the subject, and detailed references to practice and literature, such as to make it a valuable research resource for scholars.

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***Fouchard, Felix*: The Standard of Review Before the International Court of Justice: Between Principle and Pragmatism.** Oxford: Bloomsbury 2024. ISBN 978-1-50997-130-5. xvi, 248. €85.- eISBN 978-1-50997-131-2. €76.50

By some measure, the essence of a commitment to international law is the willingness to relinquish the right to judge one's own conduct. Scholars and judges have long taken a dim view of so-called 'self-judging' clauses that reflect a distrust of international adjudication and risk abuse.[1] At the same time, states value rules that allow for discretion 'to opt out of their international legal commitments when political or economic pressures become too high'.[2] Otherwise put, they value those rules that contain an expectation of deference from courts and tribunals. But when adjudicators should accept the state's own assessment of what constitutes compliance with a norm remains sharply contested. It is also the subject of an ever-growing literature, especially as scholars have sought to compare practice across international courts and tribunals.[3]

'The Standard of Review before the International Court of Justice: Between Principle and Pragmatism' sets out to examine that practice at the principal judicial organ of the United Nations. Focused on the case law of the International Court of Justice (ICJ), *Felix Fouchard* defines 'standard of review' to mean the degree to which 'the ICJ scrutinises the first-hand assessments and determinations of a state in proceedings in which the latter's compliance with obligations under international law is at issue' (p. 7). He finds that the ICJ resorts regularly to deferential standards of review. He further argues that deference is a technique of 'judicial avoidance' that the Court can deploy strategically to dispose of difficult issues without undermining its mandate or compromising the judicial function (p. 12).

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1 See Fabian Eichberger, 'Self-Judgment in International Law: Between Judicialization and Pushback', LJIL 37 (2024), 915-938 (916). Consider *Judge Lauterpacht*'s hostility to reservations to optional clause declarations that purport to give states the exclusive power to decide whether an issue is a matter of national jurisdiction. Separate Opinion of Judge Lauterpacht, ICJ, *Certain Norwegian Loans* (France v. Norway), judgment of 6 July 1957, ICJ Reports 1957, 34.

2 Eichberger (n. 1) at 916. By one account, self-judging clauses may 'further international cooperation more than they impede it' by providing 'exit-valves in areas where important national interests are at stake, interests of such importance that states might prefer not to cooperate at all rather than to concede permanent restrictions on their sovereignty in such domains'. Stephan Schill and Robyn Briese, '"If the State Considers": Self-Judging Clauses in International Investment Agreements', Max Planck UNYB 61 (2009), 61-140 (138).

3 Recent contributions include Johannes H. Fahner, *Judicial Deference in International Adjudication: A Comparative Analysis* (Bloomsbury 2020) and Esme Shirlow, *Judging at the Interface: Deference to State Decision-Making Authority in International Adjudication* (Cambridge University Press 2021). For an enlightening assessment of both, see Joshua Paine, 'Deference and Other Standards of Review in International Adjudication', The Law & Practice of International Courts and Tribunals 21 (2022), 431-441.

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The book proceeds as follows. Chapter 2 ('Old Wine in New Skins?') provides an overview of the doctrine of non-justiciability. The author summarises the long-held idea that states are 'better-placed' than international courts and tribunals to make some types of determinations (p. 25) and that certain issues are simply incapable of 'judicial appreciation' (p. 29). The doctrine of non-justiciability has fallen into disfavour, but states tend to ask courts and tribunals to adopt deferential standards of review in disputes concerning the same types of situations that were once framed as non-justiciable – namely, cases that involve 'essential interests, domestic measures, "political" determinations, and scientific determinations' (p. 41). The invocation of deferential standards of review is therefore a 'newly wrapped, less offensive way' for states to advance the same ideas encapsulated by non-justiciability (p. 47).

Chapter 3 ('Something New under the Sun: Standards of Review as a Judicial Avoidance Technique') develops the claim that deferential standards of review provide a means for the ICJ to communicate to states that it will respect their 'prerogatives in certain, especially sensitive areas' (p 74).[4] This can lower 'the perceived cost of cooperation' and encourage states to consent to jurisdiction in the first place (p. 54). Whether or not the Court actually defers to state action, the reasoning inherent to engaging with arguments about discretionary standards (e. g., necessity, proportionality, capacity, due diligence) can enhance the legitimacy and predictability of the Court's decisions.[5] While states 'do not invariably expect' deference from the ICJ (indeed, they may staunchly oppose deference 'when they appear before the Court as applicants') (p. 56), the author suggests that a posture of deference can be part of a 'strategy of incrementalism' that generates trust over time (p. 76). This is an idea often associated with the European Court of Human Rights, but one that is difficult to extend to the ICJ given its smaller and more diverse case load.[6] Nonetheless *Fouchard* sees resolving a dispute by showing deference to the state accused of non-compliance as preferable to 'all-or-nothing' avoidance techniques that foreclose any consideration of the merits and conceal the Court's motives behind 'legalistic pretexts' (for example, the

4 This chapter draws on Felix Fouchard, 'Allowing "Leeway to Expediency, Without Abandoning Principle"? The International Court of Justice's Use of Avoidance Techniques', LJIL 33 (2020), 767-787.

5 This is a recurring idea in the literature. See, e. g., Vladyslav Lanovoy, 'Standards of Review in the Practice of International Courts and Tribunals' in: Gábor Kajtár, Başak Çali and Marko Milanovic (eds), *Secondary Rules of Primary Importance in International Law* (Oxford University Press 2022), 42-64 (43).

6 See Mikael Rask Madsen, 'The European Court of Human Rights and the Politics of International Law' in: Wayne Sandholtz and Christopher A. Whytock, *Research Handbook on the Politics of International Law* (Edward Elgar 2017), 227-268.

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Court's rejection of the applicants' standing in *South West Africa* or its finding that the 'dispute requirement' was unmet in the *Nuclear Disarmament* cases) (p. 75).[7] The author is careful to note, however, that recourse to avoidance techniques has costs and benefits in every case; if the Court is too cautious, it also puts its 'relevance and credibility' at risk. As he puts it: 'There is no magic formula' (p. 56).

The remainder of the book is divided into chapters on non-reviewability, good faith, reasonableness, and *de novo* review. The author draws upon 31 judgments and advisory opinions in which a participating state or a member of the Court 'advocated for a deferential standard of review' (p. 13).[8] Notably, he finds that the Court hardly ever accepts the argument that state action is entirely non-reviewable, despite a dozen cases (ranging from *Corfu Channel* to more recent cases such as *Diallo* and *Whaling*) in which states urged complete deference. This reinforces the general point that non-justiciability is a losing argument.[9]

A more significant challenge is presented by the effort to define and delineate the other standards of review that structure the analysis. The author describes good faith review to mean 'whether at the time that the state had taken the decision now under scrutiny, it could believe in good faith that the reasons for it were valid or that the conditions for the legality of the measure were indeed present' (p. 17). In turn, reasonableness review asks whether 'a rational actor could have arrived at the same assessment as [the] state' (p. 18). The author concedes that the line between good faith and reasonableness is 'blurred' but offers that reasonableness requires 'convincing' or 'serious' justifications, not simply '*any* rational basis' (pp. 18, 21). In contrast to both standards, *de novo* review means the ICJ 'will simply state in objective terms

7 ICJ, *South West Africa Cases* (Ethiopia v. South Africa; Liberia v. South Africa), judgment of 18 July 1966, ICJ Reports 1966, 6; ICJ, *Obligations concerning Negotiations relating to Cessation of the Nuclear Arms Arce and to Nuclear Disarmament* (Marshall Islands v. United Kingdom), preliminary objections, judgment of 5 October 2016, ICJ Reports 2016, 833.

8 This suggests that potentially relevant cases, where a deferential standard of review was possible, are left unconsidered. For example, interpretation disputes under Article 60 of the *ICJ Statute* may amount to a state asking the Court to defer to its interpretation of what compliance requires. See, e. g., ICJ, *Request for Interpretation of the Judgment of 31 March 2004 in the Case Concerning Avena and Other Mexican Nationals* (Mexico v. United States), judgment of 19 January 2009, ICJ Reports 2009, 3 (25); ICJ, *Request for Interpretation of the Judgment of 15 June 1962 in the Case Concerning Temple of Preah Vihear* (Cambodia v. Thailand), judgment of 11 November 2013, ICJ Reports 2013, 281 (41, 49, 84).

9 The author finds that the Court considered issues non-reviewable in only three proceedings: *Certain Norwegian Loans*, *South-West Africa*, and *Legality of Nuclear Weapons*. The inclusion of the latter two cases is curious because the author also presents them as illustrations of other types of avoidance techniques.

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whether or not the subsumption advanced by the concerned state is correct' (p. 21).

In principle, it makes sense that the degree of deference extended by the Court operates along a continuum (p. 7). However, the book's detailed review of the cases suggests that any fine line separating one standard of review from another is drawn with disappearing ink. As others have noted, 'attempts to define standards of review often boil down to a replacement of one indeterminate concept by another', such that the 'conceptual value' of terms such as good faith and reasonableness 'seems limited to expressing some degree of deference, rather than providing a clear analytical framework of analysis'.[10] Perhaps inadvertently, the book illustrates this critique. In particular, the effort to set out when the ICJ has applied a 'good faith' standard (Chapter 5) or 'reasonableness' standard (Chapter 6) tends to suggest a distinction without a difference.[11] Another difficulty is the Court's tendency to apply different standards of review to separate aspects of a case. The author identifies this phenomenon in cases ranging from *Nicaragua* and *Gabčikovo-Nagymaros* to *Whaling* and *Certain Iranian Assets*. This complicates any attempt to systematise the Court's approach and underlines the practical difficulties with distinguishing good faith from reasonableness and even between reasonableness and *de novo* review.

Take the author's use of the *ELSI* case as an example of good faith review. The dispute in that case turned on whether Italy's requisition of an industrial facility owned by two U. S. corporations was an arbitrary measure prohibited by the relevant bilateral treaty. This meant asking whether there had been any legitimate reason for the local official to have seized the facility. However, the author does not explain why assessing whether a measure is arbitrary is necessarily a question of good faith rather than reasonableness. Moreover, it is not entirely clear that this was how the Court proceeded. The author quotes the judgment for the Court's view that the measure 'cannot be said to have been unreasonable or merely capricious' (p. 121).[12] The term 'good faith' appears nowhere in the judgment. Similarly, in *Mutual Assistance*, it is difficult to know why the ICJ's decision to credit a French judge's determination that France's 'essential interests' were at stake (such that

10 Fahner (n. 3), at 146, 148.

11 *Vladyslav Lanovoy* describes the 'standard of good faith review' as 'closely intertwined with the notion of reasonableness'. Lanovoy (n. 5), 47. Compare further the Court's view that the requirement to perform treaties in good faith obliges states to apply treaty provisions 'in a reasonable way'. ICJ, *Gabčikovo-Nagymoros Project (Hungary/Slovakia)*, judgment of 25 November 1997, ICJ Reports 1997, 79 (142).

12 ICJ, *Electtronica Sicula S. p. A.* (United States v. Italy), judgment of 20 July 1989, ICJ Reports 1989, 15 (129). The Court may have used that phrase because counsel for the United States had described the requisition as an 'unreasonable or capricious exercise of authority'.

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France was within its rights not to transmit a sensitive file to Djibouti) should be understood as resort to good faith rather than reasonableness. The problem also runs in the opposite direction when the author turns to cases that adopt a reasonableness standard. For example, it is not entirely clear that the ICJ in *Corfu Channel* found that a coastal state's right to regulate innocent passage in exceptional circumstances was subject to a standard of reasonableness rather than good faith. Similarly, while the author treats *Rights of U. S. Nationals in Morocco* as a 'reasonableness' case, the Court itself described Morocco's right to adopt a customs calculation method as 'a power which must be exercised reasonably and in good faith' (p. 141). The author's focus on the relative intensity of the Court's review does not quite manage to explain why these cases illustrate one deferential standard rather than another. It also tends to blur the distinction that the author makes between the standard of review and the standard of proof (i. e., 'the degree of judicial conviction required') (p. 8). More generally, the book's approach reinforces a view that 'the formulation of specific standards of review, independent of the applicable legal norm, does not result in a better understanding of the adjudicator's intensity of review.'[13]

A more interesting example comes from the author's treatment of the *Bosnian Genocide* case, where the ICJ broadly set out every Contracting Party's obligation under Article I of the *Convention on the Prevention and Punishment of the Crime of Genocide* 'to employ all means reasonably available to them, so as to prevent genocide so far as possible'.[14] It further explained that responsibility would depend on whether 'the State manifestly failed to take all measures to prevent genocide which were within its power, and which might have contributed to preventing the genocide'.[15] Having determined that genocide took place at Srebrenica, the key question was whether Serbia and Montenegro 'had manifestly' failed to act – a standard that the author describes as a 'qualified standard of review' that corresponds to good faith (p. 126). Drawing on work by *Serena Forlati*, he considers that the Court consciously sought to establish a deferential standard of review for future cases 'to counterbalance the unlimited geographical reach' of the extraterritorial obligation to prevent genocide that it had just articulated (p. 127).[16] A pending action by Nicaragua against Germany in relation to the

13 Fahner (n. 3), 148.

14 ICJ, *Application of the Convention on the Prevention and Punishment of the Crime of Genocide* (Bosnia and Herzegovina v. Serbia and Montenegro), judgment of 26 February 2007, ICJ Reports 2007, 43 (430).

15 ICJ, *Bosnia and Herzegovina v. Serbia and Montenegro* (n. 14).

16 See Serena Forlati, 'The Legal Obligation to Prevent Genocide: *Bosnia v. Serbia* and Beyond', Polish Y. B. Int'l L. 31 (2011), 189-205 (203-204).

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situation in Gaza may test the author's claim and clarify what standard of review applies in disputes relating to the duty to prevent genocide.[17] At the provisional measures stage of that case, the Court suggested a willingness to extend significant deference to Germany and its internal risk assessment process.[18]

The author also posits an outward-looking explanation for the Court's approach in *Diallo*, albeit to establish a more demanding standard of review in future cases, not a low threshold. In this case, the Court used reasonableness to assess whether the Democratic Republic of Congo's ground for Mr. Diallo's expulsion (public order) was compatible with its obligations under the *International Covenant on Civil and Political Rights*.[19] According to the author, this was a 'stricter standard' than the Court needed to adopt 'under considerations of judicial economy' and can therefore be seen 'as a signal to the state community' about strict limits on the invocation of public order to justify police action (p. 137). This reads too much into the decision. It seems just as likely (if not more so) that the Court viewed reasonableness as the appropriate standard of review based on the relevant treaty text and core principles of international human rights law (i. e., that a restriction must be necessary and proportionate in pursuit of a legitimate aim).[20] In this light, there seems little reason to attribute the Court's decision to apply a reasonableness standard to broader considerations of community interest.

In its penultimate chapter, the book examines several cases in which the ICJ rejected calls for deference and engaged in *de novo* review. Among other examples, this includes detailed assessments of *Nicaragua*, *Oil Platforms*, and *Construction of a Road* (security interests), *Obligation to Prosecute or Extradite* (domestic measures), the *Namibia* advisory opinion (political determinations), and *Whaling* (scientific determinations). The author concludes that *de novo* review remains the Court's default posture and notes the 'near-constant, conspicuous absence of justification for its adoption of this standard', even when states have argued extensively for deference (p. 209). Again, however, the examples reveal that whether the ICJ has engaged in *de novo* review or applied a reasonableness standard may lie in the eye of the beholder. Is it

17 ICJ, *Alleged Breaches of Certain International Obligations in Respect of the Occupied Palestinian Territory* (Nicaragua v. Germany), provisional measures, order of 20 April 2024 (Nicaragua v. Germany).

18 ICJ, *Nicaragua v. Germany* (n. 17), (17). See also Separate Opinion of Judge Iwasawa, *Nicaragua v. Germany* (n. 17), (9, 11); Declaration of Judge Cleveland, *Nicaragua v. Germany* (n. 17), (11-13, 16).

19 ICJ, *Ahmadou Sadio Diallo* (Guinea v. DRC), judgment of 30 November 2010, ICJ Reports 2010, 639 (72-74).

20 Article 13 of the ICCPR provides that a lawfully present alien must have the opportunity to challenge his expulsion unless 'compelling reasons of national security otherwise require'.

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entirely clear that the Court eschewed some implicit consideration of reasonableness in assessing Liechtenstein's decision to grant nationality to Mr. Nottebohm?[21] Did the Court's approach in *Belgium v. Senegal* really establish that the Court would not consider reasonableness in future cases in which a state is alleged to have violated a treaty obligation by not initiating criminal proceedings against an alleged torturer?[22]

The book's assessment of the *Whaling* case merits special comment, especially since the case is often seen as a clear example of the ICJ directly addressing the standard of review. The dispute concerned whether a programme called JARPA II was 'for purposes of scientific research' under Article VIII of the *International Convention on the Regulation of Whaling* (ICRW) and therefore exempt from the moratorium on commercial whaling. Japan initially argued that its discretion to issue special permits for scientific whaling under JARPA II was non-reviewable on the basis of the treaty's plain language. It later asserted that the Court's review should be limited to whether it had issued the permits in good faith before it eventually accepted that a reasonableness standard should apply, even while maintaining that the treaty afforded it a 'margin of appreciation'. Australia (the applicant) and New Zealand (as an intervenor) argued for *de novo* review and rejected any notion of judicial deference, especially in light of 'the need to uphold the regime effectiveness of the ICRW' (p. 160).

First, the Court determined that JARPA II 'could broadly be characterised as "scientific research"'. *Fouchard* asserts that this reflected the Court's adoption of a reasonableness standard, not merely good faith, because the Court 'analysed the programme's characteristics – even if superficially' (p. 161). The Court then considered whether JARPA II was 'for purposes of' scientific research. In the Court's view, this turned on whether the programme's design and implementation were 'reasonable in relation to its stated objectives'.[23] On this point, *Fouchard* argues that 'despite its assertions to the contrary', the Court 'silently applied the *de novo* standard' (p. 205). He asserts further that by adopting this 'concealed *de novo* standard […] the ICJ only half-heartedly recognised its institutional limitations as a court of law' (p. 209). To reach that conclusion, the author emphasises that the Court dedicated over 30 pages to evaluating the details of JARPA II – an approach 'so demanding that it resembles the *de novo* standard to the

21 ICJ, *Nottebohm Case* (Liechtenstein v. Guatemala), judgment of 6 April 1955, ICJ Reports 1955, 4.

22 ICJ, *Questions relating to the Obligation to Prosecute or Extradite* (Belgium v. Senegal), judgment of 20 July 2012, ICJ Reports 2012, 422.

23 ICJ, *Whaling in the Antarctic* (Australia v. Japan: New Zealand intervening), judgment of 31 March 2014, ICJ Reports 2014, 226 (172).

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point of becoming indistinguishable from it' (p. 207). Yet rather than revealing some kind of judicial subterfuge, this highlights how difficult it may be to distinguish *de novo* review from reasonableness review in many cases.[24] By a different reading, the ICJ's approach in *Whaling* provided ample opportunity for Japan to persuade the Court that its assessment of JARPA II as a programme for purposes of scientific research was reasonable and therefore entitled to deference. It is not clear why adopting a reasonableness standard precludes a detailed assessment of the state's basis for claiming to have acted reasonably. This is arguably a fair description of what the Court set out to do in taking a forensic and exacting approach to JARPA II – an analysis that consistently identified points of 'contradiction or irrationality' in the programme.[25] In the end, the judgment conveys that Japan failed to persuade the Court that it had acted reasonably in granting special permits on the basis of JARPA II.[26]

In sum, 'The Standard of Review before the International Court of Justice' successfully demonstrates that while certain landmark cases might suggest that the ICJ is preternaturally opposed to resorting to deferential standards of review, 'the real picture is more complex' (p. 214). At the same time, the author's empirical study reveals 'no clear pattern' with respect to most types of cases; the exception is self-defence, where the Court has typically *rejected* calls for deference (p. 214). The author's detailed treatment of the cases is commendable, especially the attention given to party arguments. For practitioners, the material provides a resource to consult when mapping out the best means to advocate for or against a given standard of review. The book might have been even more useful if organised by case type (national security, domestic measures, political determinations, scientific determinations). The

24 For an insightful analysis of how the Court implemented a reasonableness standard of review in *Whaling* (drawing on notions of 'necessity' and 'adequacy'): Asier Garrido-Muñoz, 'Managing Uncertainty: The International Court of Justice, "Objective Reasonableness" and the Judicial Function', LJIL 30 (2017), 457-474.

25 Claire Brighton, 'Unravelling Reasonableness: A Question of Treaty Interpretation', Austr. Y. B. Int'l L. 32 (2014), 125-134 (132).

26 The author also suggests that the judgment reflected *de novo* review because the Court did not credit the views of 'involved experts' who considered that the annual sample sizes in JARPA II were reasonable (p. 207). This raises important questions about how expert testimony should play into the application of a deferential standard of review. In *Whaling*, one expert witness appeared for Japan, and his views on the reasonableness of sample sizes were contradicted by Australia's expert. *Whaling* (n. 23) (20, 130, 158, 190). In this context, it is not clear how the Court's failure to credit the testimony of Japan's expert defeats the proposition that the Court's standard was reasonableness. Japan's expert witness was not directly involved in the design of JARPA II. One might wonder how the Court would have dealt with testimony from a Japanese scientist who had been directly involved in JARPA II and was prepared to testify to the good faith and reasonableness of its design.

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concluding chapter contains a helpful set of tables that illustrates the material in this way.

However, the book does not go quite as far as some of the author's claims suggest. The core argument that 'the standard of review notion holds distinct advantages for the ICJ's institutional stability and credibility' compared to other techniques of judicial avoidance remains speculative (p. 213). Indeed, the study is not focused on the broader *impact* of how the Court has resolved any given case by adopting a particular standard of review or avoidance technique. Moreover, the author ultimately points to few examples in which the Court's adoption of a deferential standard seemed clearly aimed to avoid sensitive or highly political issues (in contrast to how the Court has purportedly used 'merits-avoidance' techniques in other cases).[27] For example, the author presents the adoption of a reasonableness standard to assess Nicaragua's regulation of navigation on the San Juan River in *Navigational Rights* as a means by which the ICJ avoided 'finding against Nicaragua on several of Costa Rica's claims' and gave itself leeway in future cases to defer 'to a state's power of regulation' (p. 228). But it is difficult to see why the Court would have been concerned about potential backlash from Nicaragua in the specific case or why it would have viewed this as a vehicle by which to 'set higher hurdles' to finding violations in future cases (p. 228) (especially since the Court's approach to reasonableness in *Navigational Rights* amounted to a test of 'strict necessity').[28] More convincingly, the author acknowledges that not every instance in which the Court adopts a deferential standard of review 'amounts to the use of this notion as an avoidance technique' (p. 227). Instead, the author concludes that the cases demonstrate that the Court has used the standard of review as an avoidance technique 'in far fewer proceedings than it could have' (p. 212). This speaks to the Court's broader view of its role and function.

The author has also sought to identify how decisions to adopt a posture of deference (especially when not outcome-determinative for the instant case) create options for avoidance in future cases (a 'forward-looking avoidance technique') (p. 228). However, there is also reason for scepticism here. First, there is scant evidence that the Court's decision-making process is as forward-looking as the author's claim assumes. Secondly, the author does not identify any example of a decision to adopt a deferential standard in one case that actually facilitated avoidance in a subsequent case. Thirdly, it is not clear

27 See, e. g., Manuel Casas, 'Functional Justiciability and the Existence of a Dispute: A Means of Jurisdictional Avoidance?', Journal of International Dispute Settlement 10 (2019), 599-621; Surabhi Ranganathan, 'Nuclear Weapons and the Court', AJIL Unbound 111 (2017), 88-95.

28 Garrido-Muñoz (n. 24), 469.

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why deciding that a measure of discretion is embedded into certain rules of international law – and examining whether state action falls within the limits of that discretion – should be construed as 'avoidance' at all, rather than simply reflecting the Court's best understanding of what the law requires.

As a result, some insights to be drawn from this book may differ from those emphasised by the author. These include the difficulty in distinguishing among various standards of deference or discerning a coherent approach across the Court's diverse jurisprudence.[29] Indeed, *Fouchard* concedes that his study shows that one cannot speak of a 'doctrine of deferential standards of review' at the ICJ (p. 214). For that reason, it is also difficult to conclude that resort to deferential standards of review has served to inject consistency and predictability into the Court's work. The author may be right that the ICJ sometimes makes 'rhetorical concessions' to deference that do not reflect how it actually decides an issue (p. 229). But this goes less to the idea that the ICJ treats the standard of review as a technique of judicial avoidance and more to the fact that the Court's practice remains fluid and contextual.

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29 Specialized dispute settlement regimes that adjudicate disputes arising out of a single treaty may be better positioned to 'fine-tune a uniform standard of review' than the ICJ, which hears cases relating to many different areas and instruments of international law. Lanovoy (n. 5), 49.

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***Hövelmeyer, Nicole*: Brexit als vermeintliche Rückkehr zur constitutional orthodoxy**. Selbstbindung des Westminster Parlament nach dem Austritt aus der Europäischen Union. Tübingen: Mohr Siebeck 2024. ISBN 978-3-16-163214-3. XVIII, 343 S. € 89,-

Das Westminster Parlament im Vereinigten Königreich wird allgemein als Ursprung des Parlamentarismus angesehen. Seine Vorgänger reichen bis in das Mittelalter zurück, wobei die heutige Form einer parlamentarischen Versammlung maßgeblich auf die *Curia Regis* zurückzuführen ist.[1]

Im britischen Staatsgefüge wird dem Westminster Parlament als Legislative besondere Bedeutung beigemessen, insbesondere da es nach der traditionell vorherrschenden Lehre der *constitutional orthodoxy* von *Dicey* als ungebunden angesehen wird.[2] Damit ist das jeweils amtierende Parlament frei in seiner Gesetzgebungsbefugnis, ohne dass es an eine kodifizierte Verfassung oder die Gesetzgebung vorausgegangener Parlamente gebunden wäre. Es gilt das Prinzip des *implied repeal*. Ob das britische Parlament in seiner Gesetzgebungsbefugnis aber tatsächlich *absolut* frei ist, untersucht Nicole Hövelmeyer in ihrer Dissertation. Anlass zu dieser Untersuchung besteht insoweit, als der *constitutional orthodoxy* Ansichten gegenüberstehen, die eine Bindungswirkung des Parlaments bei der Gesetzgebung dogmatisch begründen. Im Zentrum der Untersuchung steht die *new view*, die ihre Argumentation für die Bindungswirkung maßgeblich auf den *European Communities Act 1972* (ECA 1972) und den *European Union Act 2011* (EUA 2011) stützt. Beide Regelungswerke sind Gesetze, die die Anwendung von Unionsrecht im innerstaatlichen Recht des Vereinigten Königreichs erfassen. Der ECA 1972 regelte die Integration von Unionsrecht in das britische Rechtssystem, während der EUA 2011 für bestimmte Vertragsänderungen und -erweiterungen bei der Kompetenzübertragung an die Europäische Union das Erfordernis der Abhaltung eines nationalen Referendums einführte (*referendum conditions*). Mit dem *European Union (Withdrawal) Act 2018* (EUWA 2018) wurde das Austrittsabkommen zwischen dem Vereinigten Königreich und der Europäischen Union geregelt. Zugleich wurde mit der Aufhebung des ECA 1972 die Geltung des Unionsrechts im innerstaatlichen Recht formell beendet. Vor diesem Hintergrund verdeutlicht die Dissertation erstens, dass sich eine *gewisse* Selbstbindung des Parlaments durchaus begründen lässt und zweitens, inwiefern die genannten Gesetze auch nach dem Brexit hinsichtlich der Selbstbin-

1 Karl Loewenstein, *Der britische Parlamentarismus. Entstehung und Gestalt* (Rohwolt 1964), 17 f.; Kurt Kluxen, *Geschichte Englands* (Kröner 1991), 113.

2 Siehe dazu insgesamt Albert Venn Dicey, *Introduction to the Study of the Law and the Constitution* (10. Aufl., Palgrave Macmillan 1979).

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dung des Parlaments noch fortwirken. Dies begründet schließlich auch die Annahme der Verfasserin, dass der Brexit mit seinen rechtlichen Folgewirkungen nicht notwendigerweise eine Rückkehr zur *constitutional orthodoxy* bewirkt hat.

Für die Einordnung der rechtlichen Befugnisse des Westminster Parlaments im britischen Staatsgefüge ist eine Abgrenzung zwischen der normativen und der politischen Selbstbindung eine Grundvoraussetzung. Mit dieser Differenzierung befasst sich auch Nicole Hövelmeyer intensiv und setzt den Begriff der normativen Selbstbindung in einen engen Zusammenhang mit dem Verständnis von der Parlamentssouveränität.

Mit der politischen Selbstbindung setzt sich das britische Parlament in seiner Funktion als Gesetzgeber lediglich politischen Schranken aus. Diese tatsächliche Bindung wird erst durch die weiteren politischen Akteure und ihre Reaktionen auf einen Verstoß gegen den Selbstbindungsmechanismus bewirkt. Anknüpfend an diese These erörtert die Arbeit verschiedene Kategorien politischer Schranken, beispielsweise rechtlich nicht bindende Konventionen, die direkte Beteiligung außerparlamentarischer Akteure, internationales Recht und das parlamentarische Mandat, das nach der sog. *doctrine of the mandate* indirekt an die Umsetzung von Wahlversprechen geknüpft ist (vgl. S. 23 ff.). Nach der Ansicht der *constitutional orthodoxy* ist die politische Bindung, insbesondere durch die Verpflichtungen der Wählerschaft gegenüber, die einzige Einschränkung, der das britische Parlament unterliegt. Ihre Wirkungskraft wird gleichwohl als erheblich und als ein Kernbestandteil der britischen Verfassungstradition eingeschätzt.

Neben der politischen Selbstbindung steht die normative Selbstbindung als die Fähigkeit des Parlaments, sich selbst durch ein Gesetz gerichtlich durchsetzbare Grenzen seiner legislativen Gewalt für die Zukunft zu setzen (S. 51). Es handelt sich hier also um eine rechtliche Selbstbindung. Das Verständnis der normativen Selbstbindung wird maßgeblich über das Prinzip der Parlamentssouveränität hergeleitet. Die nähere Diskussion Hövelmeyers zum Begriffsverständnis von *parliamentary souvereignty/supremacy* mit den dahinterstehenden Konzepten „Parlamentssouveränität" oder „Parlamentssuprematie" mag auf den ersten Blick etwas aufgebauscht wirken (vgl. S. 8 f.). Diese Erklärung ergibt indes aus Sicht der Autorin Sinn, um die eigene Positionierung für den Begriff Suprematie zu erläutern,[3] ins-

3 Vgl. auch die Arbeit ihres Doktorvaters Gernot Sydow, Parlamentssuprematie und Rule of Law. Britische Verfassungsreformen im Spannungsfeld von Westminster Parliament, Common-Law-Gerichten und Europäischen Einflüssen (Mohr Siebeck 2005).

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besondere da im Schrifttum ansonsten der Begriff Parlamentssouveränität weit verbreitet ist.[4]

Das Prinzip der Parlamentssouveränität enthält in positiver Hinsicht die Befugnis, Gesetze jeglichen Inhalts zu erlassen oder abzuändern. Geht es um das Parlament als Gesetzgeber, ist die Zusammensetzung der Akteure in der parlamentarischen Trias als *King in Parliament*, bestehend aus Krone, House of Lords und House of Commons, entscheidend. Um ein Gesetz als *act of parliament* handelt es sich bei einem im Gesetzgebungsverfahren erlassenen Rechtsakt (*primary legislation*). Bei einer Gesetzeskollision mit einem vorausgehenden Rechtsakt, kommt dem späteren Gesetz der Vorrang zu. Zugleich besagt die Parlamentssouveränität auch, dass jegliche Staatsgewalt ein Parlamentsgesetz zu beachten hat. Überdies kann der britische Supreme Court ein Parlamentsgesetz nicht außer Kraft setzen.

Eine normative Selbstbindung des Parlaments wird nach der *new view* auf der Grundlage der *rule of recognition* begründet.[5] Hiernach wird die Rechtsanwendung anhand verschiedener Ansätze in der englischen Literatur, beispielsweise nach *Hart*, weiter in Normgruppen systematisiert und ein Vorrang des Parlamentsrechts begründet, allerdings ohne dass die *rule of recognition* zwingend die Abwesenheit von jeglichen rechtlichen Beschränkungen für das Parlament bedeuten würde (S. 54 ff.). Nicole Hövelmeyer stellt klar, dass sich die Frage nach dem Ursprung der *rule of recognition* aber nicht eignet, auch die Herkunft der Parlamentssouveränität zu erklären, wenngleich diese beiden Aspekte thematisch miteinander verwoben sind.

Unabhängig davon, welche Ansicht zur Selbstbindung des Parlaments vorzugswürdig ist, kann diese nur im Kontext der Parlamentssouveränität verstanden werden, wobei auch die historische Herleitung dieses Prinzips von Bedeutung ist. Sie ist ein Resultat aus dem beständigen Machtkampf zwischen dem Monarchen und dem Parlament im Königreich Großbritannien des 17. Jahrhunderts, als sich nach der *Glorious Revolution* im Jahre 1688 mit der *Bill of Rights 1689* die Ansicht behaupten konnte, dass der Monarch nur in einem Zusammenspiel mit beiden Parlamentskammern legislativer Souverän sein könne. Mit der Entwicklung dieser Grundstruktur im britischen Staatsgefüge ging auch das damals vorherrschende Verständnis der

4 Siehe nur Maximilian Alter, 'Der Brexit zwischen Parlamentssouveränität, Prärogativbefugnissen und regionaler Autonomie', Juristen Zeitung 72 (2017), 405-413; Almut Mareen Fröhlich, *Von der Parlamentssouveränität zur Verfassungssouveränität. Der britische Verfassungswandel am Beispiel des Human Rights Act 1998* (Duncker & Humblot 2009); Markus Ogorek, *Die Lehre von der sogenannten Parlamentssouveränität in rechtsvergleichender Perspektive*, Juristische Arbeitsblätter 2006, 151-155.

5 William Jennings, The Law and the Constitution (5. Aufl., University of London Press 1959), 152 ff.; Michael Gordon, Parliamentary Souvereignty in the UK. Process, Politics and Democracy (Bloomsbury Publishing 2015), 74 f.

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constitutional orthodoxy einher, mit der der Souverän eben nicht an eine *common law constitution* gebunden sei, sondern seine Gesetzgebungsbefugnis also absolut gelte.

Durch die Abwesenheit einer geschriebenen Verfassung im Vereinigten Königreich kommt den historisch verwurzelten Verfassungsprinzipien entscheidende Wirkung zu, dies ist neben der Parlamentssouveränität die *Rule of Law*. Im britischen Verfassungsrecht erfüllt gerade die Parlamentssouveränität einen Großteil der Funktionen, die in anderen Rechtsordnungen einer geschriebenen Verfassung zukommen, wie die Einrichtung und Ausübung der staatlichen Gewalt (*constituing function*) und die Beschränkung der staatlichen Gewalt (*restraining/conditioning function*) (S. 73). Die *Rule of Law* schreibt – vergleichbar mit dem Rechtsstaatsprinzip nach Art. 20 Abs. 3 GG – vor, dass die Ausübung jeglicher Staatsgewalt im Einklang zu geltendem Recht stehen muss, jedoch ohne Aussage darüber, welcher Akteur diese Staatsgewalt auszuüben hat oder wer sie legitimiert. Wenngleich im Zusammenhang mit der *Rule of Law* auch eine starke Strömung den *common law constitutionalism* vertritt, steht sie als eigenes Rechtsprinzip neben der Parlamentssouveränität, die grundlegend durch die *constitutional orthodoxy* geprägt ist. Im Hinblick auf das Zusammenspiel der Verfassungsprinzipien wäre auch eine nähere Auseinandersetzung mit den Positionen der britischen Verfassungstheoretiker *Coke* und *Hobbes* für das Verständnis der Stellung des legislativen Souveräns hilfreich gewesen.[6]

Nicole Hövelmeyer stellt überzeugend klar, dass die *new view* keine Abkehr von dem Prinzip der Parlamentssouveränität bedeutet, sondern ein neues Verständnis, um die Parlamentssouveränität an neue Gegebenheiten der britischen Verfassung anzupassen und ihre Fortgeltung zu ebnen (vgl. S. 86). Aus ihrer Sicht lassen sich sowohl die *constitutional orthodoxy* als auch die *new view* trotz des widersprüchlichen Konzeptes rechtstheoretisch begründen.

Die *new view* begründet ihre Ansicht zur Selbstbindung des Parlaments in der englischen Literatur vornehmlich mit der *manner and form theory*. Danach wird eine Selbstbindung bei der formellen Rechtmäßigkeit eines Gesetzes angenommen. Verfahrens- und Formerfordernisse bei der Gesetzgebung entstammen der Verfassung selbst oder der parlamentarischen Gesetzgebung. Zur Begründung der Selbstbindung des Parlaments werden maßgeblich Parlamentsgesetze im Kontext des Europarechts herangezogen. Relevant sind zunächst Verfahrenserfordernisse, wie die Beteiligung des Volkes in Referenden und qualifizierte Abstimmungsmehrheiten in beiden Par-

6 Dazu Bernhard Willms (Hrsg.), Thomas Hobbes, Dialog zwischen einem Philosophen und einem Juristen über das englische Recht (Wiley-VCH Verlag 1992), 10.

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lamentskammern (vgl. S. 90 f.), wobei der inzwischen aufgehobene *Fixed-term Parliaments Act 2011* als prominentestes Beispiel gilt. Auch das Erfordernis von *section 2(1)(c) EUA 2011* statuierte als ein Verfahrenserfordernis ein Referendum bei Regelungsmaterien zur Änderung oder Ersetzung des Vertrags über die Europäische Union (EUV) und des Vertrags über die Arbeitsweise der Europäischen Union (AEUV). Damit ist das sogenannte Brexit-Referendum zu einer innerstaatlichen Voraussetzung des Verfassungsrechts für den Austritt des Vereinigten Königreichs aus der Europäischen Union gemäß Art. 50 Abs. 1 EUV geworden.

Bei den Formerfordernissen ist das Wortlauterfordernis relevant, mit dem bestimmte Regelungen ausdrücklich getroffen werden müssen; das heißt, das Parlament muss im Wortlaut des Gesetzes eindeutig ausdrücken, dass eine bestehende Regelung geändert oder aufgehoben werden soll (vgl. S. 92). Der ECA 1972 mit Regelungen zur Anwendbarkeit von Unionsrecht im britischen Recht stellte hier ein grundlegendes Beispiel dar. Gemäß *section 2(4) ECA 1972* konnte das Parlament in Westminster zwar auch europarechtswidrige Gesetze erlassen, musste dabei aber im Wortlaut klarstellen, dass es mit dem von ihm erlassenen *Act of Parliament* und der dadurch bewirkten Aufhebung der bestehenden Norm auch gegen Unionsrecht verstoßen wollte (*rule of express repeal)*. Nicole Hövelmeyer stellt heraus, dass gerade section 2(1), 2(4) und 3(1) ECA 1972 entscheidende Regelungen für die Begründung der normativen Selbstbindung des Parlaments sind (vgl. S. 156 ff.).

Neben diesen theoretischen Grundlagen zur Begründung einer normativen Selbstbindung des Parlaments kommt es entscheidend auf die Akzeptanz in der Rechtsprechung an. Hier ist jedenfalls die Tendenz zu einer Abkehr von der *constitutional orthodoxy* erkennbar, die eine fehlende Normhierarchie vertritt.[7] Allerdings wird die Rechtsprechungslinie nicht konsequent fortgeführt. Während sich die Richter in *R (Jackson) v. Attorney General*[8] noch per *obiter dictum* für eine Bindungswirkung des Parlaments aussprachen, hat der Supreme Court sich später in der viel diskutierten Entscheidung *Miller (No. 1)*[9] wieder von dieser Annahme distanziert. Die Autorin vertritt die Ansicht, dass die eingesetzte Entwicklung weg von einem starren Verständnis einer absoluten Parlamentssouveränität nach der *constitutional orthodoxy* auch mit *Miller (No. 1)* und der weiteren Rechtsentwicklung um den Brexit nicht revidiert wurde (S. 312 f.).

7 Vgl. UKHL, R (Jackson) v. Attorney General, 2005 UKHL 56; UKHL, R (Buckinghamshire County Council) v. Secretary of State for Transport, (HS2) 2014 UKSC 3.

8 UKHL, *R (Jackson) v. Attorney General* (n. 7).

9 UKSC, R (Miller) v. Secretary of State for Exiting the European Union, 2017 UKSC 5.

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Der große Verdienst der Arbeit liegt in der detaillierten Aufarbeitung der rechtswissenschaftlichen Positionen und der vertieften Auseinandersetzung mit der englischen Literatur. Hervorzuheben ist dabei auch die Argumentationstiefe. Die Ausarbeitung zum britischen Teil ist umfassend und in sich geschlossen, sodass der Mehrwert durch das Kapitel zu Neuseeland (§ 6) etwas in den Hintergrund tritt. Da die Arbeit auch ein äußerst relevantes Thema des britischen Verfassungsrechts aufgreift, das nicht zuletzt durch die verschiedenen Fragestellungen um den Brexit und seine Folgen ebenso für die deutsche Leserschaft immer interessanter wird, ist das Buch als fachliche Lektüre dringend zu empfehlen.

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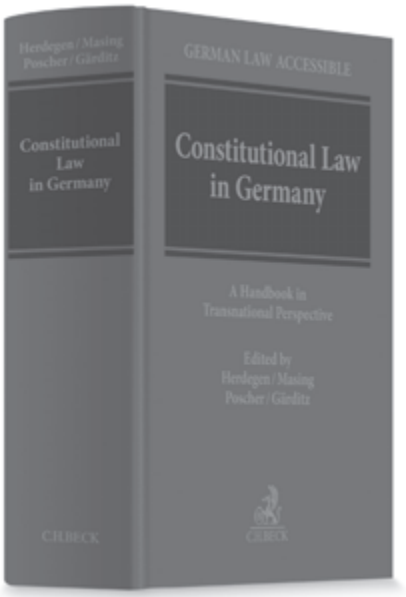

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