

# Health Emergency Response at EU Level – Are There Legal Constraints?

Bartłomiej Kurcz\*

HERA, European Commission, Brussels, Belgium

*bartlomiej.kurcz@ec.europa.eu*

Abstract	1195
Keywords	1195
I. Introduction	1196
II. Article 122(1) TFEU and the Health Emergency Preparedness and Response Authority (HERA)	1198
III. Article 122(1) TFEU and Council Regulation 2022/2372/EU – Health, Economics or Solidarity?	1200
IV. Article 122(1) TFEU and Financial Aspects – Council Regulation 2016/369/EU	1205
V. Conclusion	1206

## 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.

## 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),<sup>1</sup> 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.<sup>2</sup> Such measures could concern monitoring, early warning of, and combating serious cross-border threats to health.<sup>3</sup> 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.<sup>4</sup> So far, the only shared competence in the field of health concerns the security questions related to public health matters.<sup>5</sup> 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.<sup>6</sup> 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;<sup>7</sup> however, this has not been taken up by an intergovernmental conference.

---

<sup>1</sup> Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, C(2021) 6712 final.

<sup>2</sup> Art. 168 para. 5 TFEU.

<sup>3</sup> 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).

<sup>4</sup> Art. 2 para. 5 TFEU; Dubout and Picod (n. 3), 29-84.

<sup>5</sup> Art. 4 para. 2 lit. k) TFEU.

<sup>6</sup> Art. 168 para. 4 TFEU.

<sup>7</sup> 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.

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,<sup>8</sup> 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.<sup>9</sup>

Additionally, COVID-19 led to the adoption of Council Regulation 2022/2372/EU<sup>10</sup> 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.

---

<sup>8</sup> 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.

<sup>9</sup> Wouters (n. 8), 1.

<sup>10</sup> 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.

## II. Article 122(1) TFEU and the Health Emergency Preparedness and Response Authority (HERA)

As invoked in literature,<sup>11</sup> 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.<sup>12</sup>

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.<sup>13</sup> It is the legal basis which puts the Council in the driving seat and provides it with ‘executive powers’.<sup>14</sup> 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.<sup>15</sup> However, the health prepared-

<sup>11</sup> 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).

<sup>12</sup> 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.

<sup>13</sup> 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.

<sup>14</sup> Calleja, Rusche and Shipley (n. 12), 549.

<sup>15</sup> Recital 4 of Regulation 2022/2372/EU (n. 10); Calleja, Rusche and Shipley (n. 12), 544.

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.<sup>16</sup>

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.

---

<sup>16</sup> 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.

### 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;<sup>17</sup> 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.<sup>18</sup> Recently, a Regulation concerning the defence products, Security Action for Europe (SAFE) Instrument, was also adopted on the basis of Article 122 TFEU.<sup>19</sup> 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.<sup>20</sup>

The recovery or energy measures have had a clear economic dimension and were adopted with a clearly defined economic situation in mind. Even if

---

<sup>17</sup> 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.

<sup>18</sup> For a comprehensive review, see Calleja, Rusche and Shipley (n. 12), 521.

<sup>19</sup> 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.

<sup>20</sup> 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.

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.<sup>21</sup> 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.<sup>22</sup>

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.<sup>23</sup> 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

<sup>21</sup> 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.

<sup>22</sup> Recital 4 of Regulation 2022/2371/EU (n. 21).

<sup>23</sup> 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.

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’.<sup>24</sup>

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’.<sup>25</sup>

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.<sup>26</sup>

---

<sup>24</sup> Recital 2 of Regulation 2022/2372/EU (n. 10), Villa et al. (n. 23).

<sup>25</sup> 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.

<sup>26</sup> Laurent Muschel and Bartłomiej Kurcz, ‘HERA le nouvel acteur dans le paysage européen de la santé publique’, *Revue du droit de l’Union européenne* (2024), 143–154.

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.<sup>27</sup> The same applies to the prolongation of the emergency measures. Such prolongation also needs to be appropriate to the economic situation.<sup>28</sup> 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.<sup>29</sup>

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-

---

<sup>27</sup> Regulation 2022/2372/EU (n. 10), Article 3.

<sup>28</sup> Regulation 2022/2372/EU (n. 10), Article 4.

<sup>29</sup> Calleja, Rusche and Shipley (n. 12), 520-558.

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.<sup>30</sup>

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.<sup>31</sup> 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

---

<sup>30</sup> Calleja, Rusche and Shipley (n. 12).

<sup>31</sup> Recital 4 of Regulation 2022/2372/EU (n. 10); Calleja, Rusche and Shipley (n. 12).

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.<sup>32</sup>

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').<sup>33</sup> 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.

---

<sup>32</sup> 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.

<sup>33</sup> Article 8(1) and (2) of Regulation 2022/2372/EU.

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.<sup>34</sup> 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)

---

<sup>34</sup> Calleja, Rusche and Shipley (n. 12).

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.

