EMA, the mutual recognition procedure[18] and the decentralized one.[19] The decentralized procedure (DCP) for medicinal products, which have not been authorized before in any member state, allows for the marketing authorisation application to be submitted simultaneously in several Member States, one of which acts as the reference member state and coordinates the process. At the end of this procedure national marketing authorisations are granted in all the Member States involved. If the medicinal product has already been granted a marketing authorisation in one of the EC member states, then the mutual recognition procedure (MRP) is used.[20]

Article 3 and the Annex of the Regulation[21] define the types of products which fall within the scope, in particular article 3(1) and the Annex define the medicinal products for which the centralized procedure is mandatory.[22]

## C. Generic Drugs Approval.

As far as generics are concerned, pre-clinical tests and clinical trials are not necessary if it has been demonstrated that the generic product has "the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product[23], and whose bioequivalence with the reference medicinal

18 Regulation (EC) 764/2008, 2008, O.J. (L 218) 21.

19 Directive (EC) 2004/27, 2004, O.J. (L 136) 34.

20 EMA, *EMA procedural advice for users of the centralised procedure for generic/hybrid applications*, http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004018.pdf (last visited March 5, 2012).

21 *Supra* note 17.

22 *Supra* note 17, Art. 3(1) and Annex.

23 Art. 10(1) and Art. 10(2)(a) of Council Directive (EC) 2004/27/EC of 31 March 2004, OJ L 136, 34, 39 (2004): "Reference medicinal product shall mean a medicinal product authorised under Article 6, in accordance with the provisions of Article 8", and "which is or has been authorised under Article 6 for not less than eight years [Data exclusivity 8+2 market exclusivity +1 for new indication] in a Member State or in the Community".

product has been demonstrated by appropriate bioavailability studies."[24]

In the case where the results of the appropriate pre-clinical tests or clinical trials shall be provided,[25] studies and trials required for applying for a MA in a Member State do not constitute patent infringement under the so-called "Bolar exemption".[26] However, the exact scope of the exemption is unclear and left to interpretation by the national Courts.[27] Up to April 2009, "the aim to harmonize the laws of the different EU countries regarding the treatment of the acts performed in order to gain the data necessary to obtain a market authorization has been reached only in part."[28]

24 *Id.* Art. 10(2)(b).

25 *Id.* Art. 10(3): "In cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided.".

26 *Id.* Art. 10(6): "Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.".

27 Stéphanie Michiels, Béatrice Holtz, *Patent exemption for clinical trials: current status of the Bolar-type provisions in Europe*, Life Sci. IP Rev. 68, (2008).

28 See *Brief report on the so called "Bolar" Exemption* Annex of Union of European practitioners in intellectual property – Biotechnology Commission, Newsletter, (May 1, 2009), found at http://www.union-ip.org/union/WebObjects/union.woa#viewedmember, (last visited Sept.1, 2012).