EU Regulation

NEW COMPETENCES FOR THE EUROPEAN MEDICINES AGENCY

cep**PolicyBrief** 12/2021

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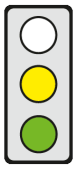
KEY ISSUES

Background: During the COVID-19 crisis, there have been shortages of critical medicinal products and critical medical devices. This could not be efficiently addressed due to the lack of an adequate legal framework for corresponding prevention and problem-solving capacities at EU level.

Objective of the Regulation: The European Medicines Agency (EMA) will be enabled to provide a more coordinated and faster response before and during a public health crisis.

Affected parties: All citizens, pharmaceutical companies and manufacturers of medical devices.



Pro: (1) With a reliable crisis preparedness system for medicinal products and medical devices, Member States are less likely to impose restrictions on the free movement of these goods, minimising the risk of a negative impact on the internal market.

(2) The free scientific advice for developers of medicinal products within 20 days saves costs and supports faster and more efficient development and authorisation of medicinal products with the potential to address public health emergencies.

Contra: The definition of "major event" is too wide. Uncertainty in this regard can be balanced by clear rules on how such a "major event" is declared. Member States must be more than formally involved in this decision as the declaration triggers special powers at EU level.

The most important passages in the text are indicated by a line in the margin.

CONTENT

Title

Proposal COM(2020) 725 of 11 November 2020 for a **Regulation on a reinforced role for the European Medicines Agency**

Brief Summary

- **Background and Context of the Proposal**
  - According to the EU Commission, the COVID-19 pandemic has shown that the EU is not sufficiently equipped to ensure availability of medicinal products and medical devices during an emergency. Ad-hoc solutions were found to mitigate the risk of shortages, e.g. of ventilators, surgical masks and test kits. The EU Commission wants to build on that experience and integrate these rules into the legal framework. [p. 1]
  - With regard to medicinal products which purported to treat or prevent COVID-19, the EMA [p. 1]
    - was unable to formulate coordinated EU-wide recommendations due to inadequate access to sufficient data;
    - provided scientific advice, but outside of a formal crisis management structure, without fast-track scientific advice procedures and without obligations for Member States and developers to cooperate.
  - In order to tackle these problems, the Commission's vision of a European Health Union encompasses three regulation proposals concerning
    - the European Medicines Agency (EMA) [this cep**PolicyBrief**],
    - the European Centre for Disease Prevention and Control (ECDC) [COM(2020) 726; cep**PolicyBrief** to follow]
    - serious cross-border threats to health [COM(2020) 727; cep**PolicyBrief** to follow].
- **Aims of the Proposal**
  - A legal basis is needed for the EMA to provide a more coordinated and faster response before and during public health emergencies and major events [p. 1]. It will complement the EMA's existing responsibilities [p. 2].
  - The EU wants to [p. 2]
    - strengthen its ability to manage public health emergencies and
    - ensure the functioning of the internal market for medicinal products and medical devices during public health emergencies.
  - The proposal aims to [p. 2]
    - monitor and mitigate shortages of medicinal products and medical devices needed to address a "public health emergency" or – regarding medicinal products – other "major events" which could seriously impact public health;

Authors: Nathalja Nolen and Dr. Patrick Stockebrandt | stockebrandt@cep.eu
cep | Kaiser-Joseph-Straße 266 | 79098 Freiburg | Germany | Telephone + 49 761 38693-0 | www.cep.eu

- a "public health emergency" is determined by the Commission [Art. 23 (1) COM(2020) 727];
- a "major event" means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State [Art. 2 (f)].

- ensure timely development of medicinal products, particularly addressing public health emergencies;
- ensure the functioning of expert panels for the assessment of some high risk medical devices and the availability of essential advice in crisis situations with regard to the use of medical devices.

– The proposal covers three "cases":
- shortages of critical medicinal products [Art. 3-13];
- medicinal products potentially addressing public health emergencies [Art. 14-18] and
- shortages of critical medical devices [Art. 19-28].

► **Case 1: Shortages of Critical Medicinal Products [Art. 3-13]**

– During a public health emergency such as the COVID-19 pandemic, export restrictions may be put in place by and amongst Member States. This would have negative effects on the internal market. [recital 7]
– Shortages of medicinal products can result in serious risks to patient health [recital 7].
– In the event of a public health emergency or major event, an EMA "Executive Steering Group on Shortages and Safety of Medicinal Products" will
- define and list "critical medicinal products" to ensure their monitoring [Art. 6 (1, 2, 3)];
- provide advice on actions to safeguard the quality, safety and efficacy of the medicinal products concerned [Art. 5].

– Firms who hold an authorisation to market critical medicinal products must
- submit information requested by the EMA, including but not limited to [Art. 10 (1), Art. 9 (3) (d, f, h)]
  - information on shortages of their own medicinal products,
  - details of available alternative medicinal products, including those marketed by other firms and
  - information from the wholesalers and other suppliers of the medicinal product;
- provide the EMA with any additional information on critical medicinal products which provides evidence of a potential or actual shortage [Art. 10 (5)].

– Member States must
- submit data on critical medicinal products requested by the EMA, which includes data on volume of demand [Art. 11 (1) (a)];
- gather information on stock levels [Art. 11 (2)].

► **Case 2: Medicinal Products with the Potential to Address Public Health Emergencies [Art. 14-18]**

– It is important that medicinal products that are capable of addressing public health emergencies are developed and made available as fast as possible [recital 17].
– An EMA "Emergency Task Force" will, in the event of a public health emergency
- provide scientific support for developers of medicinal products in order to establish joint clinical trials, which would promote their alignment and shorten the time span between trial results and the issuing of marketing authorisations [Art. 14 (2) (c) and recital 20];
- provide scientific recommendations on the use of such medicinal products [Art. 14 (2) (e)];
- provide scientific advice on clinical trial protocols, within 20 days of submission and free of charge, to developers who engage in an accelerated scientific advice process [Art. 15 (2)];
- review scientific data on medicinal products that may be able to address the public health emergency [Art. 16 (1)].

– Marketing authorisation holders will have to provide information and data for the preparation of the review of medicinal products which may be able to address a public health emergency [Art. 15 (6) and Art. 16 (2)].

► **Case 3: Shortages of Critical Medical Devices [Art. 19-28]**

– Shortages of essential medical devices during a public health emergency (e.g. test kits) may have a significant negative impact on controlling the spread of a pathogen [recital 7].
– An EMA "Executive Steering Group of Medical Devices" will, in case of a public health emergency,
- define and list "critical medical devices" [Art. 20 (1)];
- monitor critical medical devices to identify shortages [Art. 21 (1)];
- provide recommendations on measures to mitigate and prevent shortages [Art. 22 (3)].

– Manufacturers of critical medical devices are obliged to
- submit information requested by the EMA, including but not limited to details of the potential or actual shortage and information on supply and demand [Art. 24 (1) in conjunction with Art. 21 (1)]
- provide any additional information to the EMA on potential or actual shortages [Art. 24 (4)].

– Member States are obliged to
- submit information about critical medical devices including data on the volume of demand [Art. 25 (1) (a)];
- gather information from manufacturers, importers, distributors and notified bodies [Art. 25 (2)];
- provide any additional information [Art. 25 (3)].

Statement on Subsidiarity by the Commission

The Commission's statement on subsidiarity is three-fold: (1) Due to the risk of disproportionate national stockpiling and restrictions to the internal market, potential and actual shortages of medicines and medical devices in times of crisis (e.g. COVID-19-pandemic) can be better dealt with at EU level. (2) Providing scientific advice on medicinal products which potentially address public health emergencies at EU level can facilitate their market entry, ensure their harmonised use and eliminate duplication of efforts and unnecessary research. (3) An uncoordinated approach to the development and use of medicinal products, which are needed in times of a public health emergency, and the limited access of national regulators to EU-wide health data, can cause delays when time is of the essence. [p. 4 et seq.]

Legislative Procedure

11 November 2020	Adoption by the Commission
14 December 2020	Committee referral announced in Parliament
15 June 2021	Agreement in the Council on the general approach
Open	Adoption by the European Parliament and the Council, publication in the Official Journal of the European Union, entry into force

Options for Influencing the Political Process

Directorates General:	DG SANTE (Health and Food Safety)
Committees of the European Parliament:	Environment, Public Health and Food Safety (leading), Rapporteur: Nicolás González Casares (S&D, Spain)
Federal Germany Ministries:	Federal Ministry of Health
Committees of the German Bundestag:	Committee on Health
Decision-making Mode in the Council:	Qualified majority (55% of Member States & 65% of the EU population)

Formalities

Competence:	Art. 114 TFEU (Internal Market) and Art. 168 (4) (c) TFEU (Standards of Quality and Safety for Medicinal Products and Devices for Medical Use)
Type of Legislative Competence:	Shared competence (Art. 4 (2) TFEU)
Procedure:	Art. 294 TFEU (ordinary legislative procedure)

ASSESSMENT

Economic Impact Assessment

With a reliable crisis preparedness system for medicinal products and medical devices, Member States are less likely to impose restrictions on the free movement of these goods, thereby **minimising the risk of a negative impact on** the smooth functioning of **the internal market. It may also have a positive effect on their availability** in the EU **in times of crisis**, as inefficient stockpiling could be reduced thereby allowing for better redistribution of these critical goods. A prerequisite for this, and one of the Commission's main aims, is that the EMA be provided with sufficient information from firms and Member States to fulfill its tasks.

Case 1: **The obligation for marketing authorisation holders to provide data on critical medicinal products causes** some **practical problems as** accurate details on shortages can be difficult to provide for various reasons. Firms should be able to provide information on their own products, but **they do not always have comprehensive data** available **on alternative medicinal products.**

The obligation for Member States to provide data on critical medicinal products raises practical issues as well**.** Their obligation to provide data on volume of demand may help to estimate shortages. However, this data can only be predicted based on theoretical assumptions, for example using simulations for intensive care beds.

Case 2: **The free scientific advice** on clinical trial protocols **for developers** who engage in accelerated scientific advice **on medicinal products within 20 days saves costs and supports the faster and more efficient development and authorisation of medicinal products with the potential to address public health emergencies**. Correspondingly, more developers are likely to engage since it increases the chances of obtaining a marketing authorisation, which in return will benefit them and patients.

The provision of scientific support for developers of medicinal products in order to establish joint clinical trials will lead to more efficiency in conducting the trials and save resources. This lowers costs for the development of new medicinal products and gives faster access to the market, benefiting patients in times of crisis.

Case 3: Not all EU Member States currently have a mechanism in place to report shortages of medical devices at national level, which may cause practical problems in meeting their obligations to provide required data. For example, it

is difficult for Member States to provide data and information on the volume of demand for medical devices. This can only be predicted based on theoretical assumptions and estimates. It also depends on whether and to what extent, or for which groups, the use of certain medical devices, such as facemasks, is made mandatory. As public health emergencies can have different causes, experience from previous public health emergencies does not always provide an accurate prediction of the demand for medical devices.

In general, **the proposal is too broad in terms of the** kind of **information on medicinal products and medical devices that needs to be submitted by firms and Member States**. For example, the list of information that firms are obliged to provide in cases of a shortage of medicinal products and medical devices are not exhaustive. This leads to a certain unpredictability as to what kind of data is needed and, subsequently, to possible delays in providing this data. Whilst flexibility is needed in times of crisis, firms have to know in advance what can be asked of them in order to be prepared. Furthermore, Art. 11 (1) and Art. 25 (1) oblige Member States to submit information requested by the EMA on critical medical devices and critical medicinal products. At the same time, Art. 11 (3) and Art. 25 (3) require the submission of "any additional information". With regard to medical devices in particular, Art. 25 (2) obliges Member States to gather information from several actors in the supply chain, without specifying the kind of information. A concrete list of data on what needs to be submitted would help Member States to provide information quickly when time is of the essence. Again, whilst there is a need for flexibility in a crisis situation, reporting standards are also of the essence: the current pandemic has shown that a comparison of the situations in the Member States was difficult. This was primarily due to the differing approaches to data collection and data reporting. Thus, a reliable picture of the spread of the virus at any one time has not always been possible [see cep**Input** Three Steps Towards a European Health Union, p. 9].

Cooperation between the EMA and the producers of critical medicinal products and critical medical devices, especially the exchange of information regarding stock levels and demand, will help to reduce possible shortages as the producers will be able to plan their production more efficiently in extraordinary situations caused by a public health emergency or major event.

Legal Assessment

Legislative Competence of the EU

Unproblematic. Art. 168 (4) (c) TFEU allows measures setting high standards of quality and safety for medicinal products and devices for medical use. Art. 114 TFEU allows measures for the approximation of laws for the establishment and functioning of the internal market (see in general also cep**Input** Three Steps Towards a European Health Union).

Subsidiarity

Potential and actual shortages of medicinal products and medical devices in times of an EU-wide crisis can be better dealt with at EU level.

Proportionality with Respect to Member States

The definition of "major event" is too wide and therefore difficult to verify. Additionally, **uncertainty in that regard can be balanced by clear rules on how such a "major event" is declared.** The corresponding provisions [Art. 4] need to be revised and the **Member States must be more than just formally involved in this decision** via a "steering group", **as the declaration** of a "major event" **triggers special powers at EU level** as well as obligations for Member States and private companies.

Summary of the Assessment

With a reliable crisis preparedness system for medicinal products and medical devices, Member States are less likely to impose restrictions on the free movement of these goods, minimising the risk of a negative impact on the internal market. It may also have a positive effect on their availability in times of crisis. The obligation for marketing authorisation holders to provide data on critical medicinal products causes practical problems as they do not always have comprehensive data on alternative medicinal products. The free scientific advice for developers of medicinal products within 20 days saves costs and supports the faster and more efficient development and authorisation of medicinal products with the potential to address public health emergencies. The proposal is too broad in terms of the information on medicinal products and medical devices that needs to be submitted by firms and Member States. The definition of "major event" is too wide. Uncertainty in that regard can be balanced by clear rules on how such a "major event" is declared. Member States must be more than just formally involved in this decision as the declaration triggers special powers at EU level.