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Legislative Analysis of the European Union's Response to Public Health Emergencies

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ABSTRACT: Although the European Union has long faced the problem of shortages of medicines in recent years, both due to increased global demand and the COVID-19 pandemic, the problem has worsened exponentially. The shortage of medicines is a growing threat to public health, with a serious negative impact on health systems and on the right of every patient in the EU to have access to appropriate medical treatment. The COVID-19 pandemic has highlighted the importance of a smoothly functioning internal market and strong supply chains for medicines and medical equipment, as well as EU dependence on third countries in the health sector, given that 40% of finished medicines marketed in the EU come from third countries. Although Europe has a large production capacity, the supply chain still depends to a large extent on non-EU subcontractors for the production of active substances, where labor costs and environmental standards are often lower (60 to 80% of the active chemicals in medicines are produced outside the EU, mainly in China and India). In this context, this article aims to examine the legislative measures taken at the EU level to prepare for crisis situations in the field of medicines, mitigate shortages of medicinal products, and improve the security of supply.

KEYWORDS: EU legislation, shortages of medicinal products, public health emergencies, COVID-19 pandemic, medical devices

Introduction

The unprecedented experience of the COVID-19 pandemic has demonstrated the need to strengthen the Union's role, in order to be more effective in managing the availability of medicines and in developing medical countermeasures to address public health threats at an early stage and in a harmonized way that ensures cooperation and coordination between the competent authorities at Union, national and regional level, the pharmaceutical industry and other stakeholders in the supply chains of medicines, including health professionals. Although the EU needs to give higher priority to health, its ability to ensure the provision of high-quality medical services without syncope and to be prepared to deal with pandemics and other health threats has been severely affected by the lack of a clearly defined legal framework for managing its pandemic response and the limited nature of the mandates and resources of its health agencies, as well as the limited readiness of the Union and the Member States for public health emergencies that impact most Member States.

Medicine shortages pose a growing threat to public health, severely affecting health systems and patients' right to access adequate medical treatment.

Addressing medicine shortages has been a priority for Member States and the European Parliament for many years, as evidenced by several European Parliament reports, such as the European Parliament's resolution on the shortage of medicines (2020/2071 (INI)), as well as by the discussions held within the Council of the European Union.

The increase in global demand for medicines, which has been exacerbated by the COVID-19 pandemic, has led to new medicine shortages, weakening Member States' healthcare systems and creating significant risks to patients' health and care. In the case of the COVID - 19 pandemic, the shortage of treatments for this disease had several causes, from production difficulties in third countries to logistical or production difficulties in the Union, where the shortage of vaccines was due to an inadequate production capacity.

Disruptions of complex medicine supply chains, export restrictions and bans at national level, the closure of borders, which prevented the free movement of such goods, uncertainties regarding the supply and demand of such goods in the context of the COVID-19 pandemic, and the fact that certain medicines or active substances are not produced in the Union have created significant obstacles to the proper functioning of the internal market and to addressing serious threats to public health in the Union, with serious consequences for EU citizens.

The COVID-19 pandemic has exacerbated the shortage of certain medicines considered essential to deal with the pandemic and highlighted the Union's dependence on external resources for domestic medicine production, the lack of coordination and the structural limitations on the capacity of the EU and its Member States to respond quickly and effectively to such challenges in the context of public health emergencies. It also highlighted the need to support and strengthen the industrial capacity to produce those medicines through appropriate policies, as well as the need to involve more actively and more widely the EU's institutions, bodies, offices and agencies in protecting the health of EU citizens.

Theory

Medicine shortages may pose serious risks to the health of patients in the Union, resulting in medication errors, prolonged hospitalizations, side effects and an increased risk of death due to the administration of inappropriate medicines used as substitutes for unavailable medicines.

The rapid evolution of the COVID-19 pandemic and the spread of the virus have also led to a sharp increase in demand for medical devices (mechanical ventilators, surgical masks and test kits for COVID-19), while the disruption of production or the limited capacity to quickly increase it, as well as the complexity and global nature of the supply chain for medical devices have resulted in major supply difficulties and, at times, in major shortages of medical devices. This also led Member States to compete to meet the legitimate needs of their citizens, thus contributing to uncoordinated actions at national level, such as hoarding and stockpiling. Those issues also led to the involvement of new entities in the accelerated production of such medical devices, which subsequently led to delays in conformity assessment and the prevalence of expensive, non-compliant, unsafe and, in some cases, forged medical devices.

It was therefore necessary to urgently establish long-term structures within the European Medicines Agency (EMA) to ensure more consistent and effective monitoring of medical device deficits that may occur during a public health emergency and to coordinate the management of those deficits and the need for a more sustained and early dialogue with the medical device industry and with health professionals was also highlighted in order to prevent and mitigate such shortages.

Uncertainties on supply and demand and the risk of shortages of medicines and medical devices during a public health emergency of the magnitude of the COVID-19 pandemic may lead to export restrictions between Member States and other national protection measures, which may have a serious impact on the functioning of the internal market, thus exacerbating the consequences for public health, and also leading to the need for temporary mechanisms to ensure export transparency and export authorization.

Considering all these aspects, was highlighted the importance of having an appropriate framework at EU level to coordinate the Union's response to the shortage of medicines and medical devices and to strengthen and formalize the monitoring of essential medicines and medical devices, in the most efficient way and in a way that avoids creating unnecessary burdens for stakeholders, which can put resources under pressure and cause additional delays.

The need to increase the effectiveness of emergency preparedness and response required the establishment of a specially created central structure, the Health Emergency Preparedness and Response Authority - HERA (Commission Decision of 16 September 2021), as a

Commission service, complementary and in synergy with existing Union structures and mechanisms, including the Union's crisis preparedness and management system.

As mentioned in the Communication from the Commission (COM/2020/724 final) adopted in November 2020, HERA will be a key element in establishing a stronger European Union in terms of health, together with a strengthened legal framework for cross-border health threats and extended and improved crisis-related mandates for the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and the Pharmaceutical Strategy for Europe.

The EU4Health programme and the recovery and resilience facility of the European Parliament and of the Council are some of the instruments that provide additional support to national competent authorities in relation to medicine shortages, including through the implementation of actions to alleviate medicine shortages and to improve the security of supply.

Results and discussions

Considering the provisions of 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, according to which, in defining and implementing all its policies and actions, the European Union must ensure a high level of protection of human health and that the public health emergency following the COVID-19 pandemic has shown that a better coordinated approach at Union level is needed in crisis management, Regulation (EU) 2022/123 was adopted.

The regulation aims to ensure a high level of protection of human health by ensuring the proper functioning of the internal market for medicinal products and medical devices, as well as ensuring the quality, safety and efficacy of medicines that have the potential to respond to public health emergencies.

The legislative framework established by the regulation leverages the ad hoc solutions identified so far in the context of the response to the COVID-19 pandemic that have proved effective, as well as the experience, good practices and examples from third countries, while remaining flexible enough to address any public health emergency or major event in the future in the most efficient way possible, for the benefit of public health and patients.

To facilitate the prevention, monitoring and reporting of medicine shortages, the EMA should create an IT platform known as the European Shortages Monitoring Platform (ESMP), which has the capacity to process information on the supply and demand of essential medicines during public health emergencies or major events and, in addition to these situations, to allow reporting on medicine deficiencies that could lead to public health emergencies or major events.

To facilitate the development of the ESMP, existing IT systems should be mobilized and used, where possible. The ESMP should allow competent national authorities to transmit and monitor information on unsatisfied applications, including information received from marketing authorization holders, wholesale distributors and other legal persons or entities that are authorized or entitled to supply medicinal products to the public, to prevent medicine shortages. The ESMP may also process additional information received from marketing authorization holders, wholesale distributors and other legal persons or entities that are authorized or entitled to supply medicinal products to the public, to prevent a public health emergencies or major events.

The ESMP, when fully operational, should act as a unique portal through which marketing authorization holders provide the information needed during public health emergencies and major events, to increase efficiency and predictability during public health emergencies and major events and to speed up the decision-making process, while avoiding duplication of effort and imposing unjustified burdens on stakeholders. In order to facilitate the coordinating role of the Agency, the interoperability of data with existing deficit monitoring IT

platforms and other Member States' systems, as appropriate, it is essential to allow the exchange of relevant information with the ESMP, which should be managed by the Agency.

To strengthen the role of the European Medicines Agency in crisis preparedness and management of medicines and medical devices, Regulation (EU) 2022/123 provides a framework and means for:

- preparation, prevention, coordination and management of the impact of public health emergencies on medicines for human use and on medical devices and the impact of major events on medicines and medical devices at EU level;
- monitoring, prevention and reporting shortages of medicines and of medical devices;
- the creation of an interoperable IT platform at EU level to monitor and report shortages of medicines;
- providing counselling regarding medicines which have the potential to answer to public health emergencies;
- providing support to the expert groups mentioned in article 106 paragraph (1) of Regulation (EU) 2017/745.

The Medicine Shortages Steering Group (MSSG) was set up within the EMA, consisting of a representative of the Agency, a representative of the Commission and a representative appointed by each Member State.

The MSSG shall facilitate, in coordination with the national competent authorities for medicinal products, appropriate communication with marketing authorization holders or their representatives, manufacturers, other relevant actors in the supply chain and representatives of health professionals, patients and consumers, in order to receive relevant information on actual or potential shortages of medicinal products considered essential during a public health emergency or during a major event, as provided for in article 6.

The Agency, in cooperation with the Member States, shall monitor on an ongoing basis, through the points of single contact or the European Shortages Monitoring Platform (ESMP), connected to the medicines database, any event that may generate a public health emergency or a major event. As required, the EMA shall cooperate with the European Centre for Disease Prevention and Control (ECDC) and, where appropriate, with other EU agencies.

If a competent national authority informs the EMA of a shortage of medicinal products, it shall provide the Agency with all information that it has received from the marketing authorization holder if that information is not available on the ESMP.

If the EMA receives a report on an event from a national competent medicine authority, it may request information from the competent national authorities through the MSSG working group, to assess the impact of the event in other Member States.

Following the recognition of a public health emergency or major event, the MSSG shall assess the information on the public health emergency or major event and analyse the need for urgent and coordinated action regarding the quality, safety and efficacy of the medicinal products concerned.

Pursuant to Article 6 of Regulation (EU) 2022/123, the MSSG will draw up a list of the main therapeutic groups of medicinal products that are needed for emergency medical care, surgery and intensive care, in order to contribute to the development of the lists of essential medicinal products to be used to respond to a public health emergency or major event. This list must be drawn up by 2 August 2022 and updated annually and whenever necessary.

Immediately after the recognition of a public health emergency, the MSSG shall adopt a list of medicinal products authorized in accordance with Directive 2001/83/EC or Regulation (EC) No. 726/2004, which are considered essential during the public health emergency, list which will be published without delay on the EMA web portal.

When the EMA assesses the medicine shortage and provided recommendations to healthcare professionals and patients, it creates a publicly accessible webpage on its website

that provides information on actual medicine shortages included in the lists of essential medicines.

Following the recognition of a public health emergency or the recognition of a major event, the MSSG monitors the supply and demand of medicines on the lists of essential medicines in order to identify any actual or potential shortages of the concerned medicines throughout the public health emergency, until it is confirmed that the major event has been satisfactorily addressed.

The European Commission, within the limits of its powers, takes into account the information and recommendations of the MSSG and takes all necessary measures to mitigate actual or potential shortages of essential medicinal products on the lists of essential medicinal products and facilitates the coordination between marketing authorization holders and other relevant entities to respond to increased demand.

To mitigate actual or potential deficiencies of medicinal products on the lists of essential medicinal products or of their active substances, where those medicinal products or active substances are imported into the Union and those actual or potential deficiencies have international implications, the Commission shall cooperate with relevant third countries and international organizations and inform the MSSG of any such actions as well as of the results of those actions.

Conclusions

Given that the COVID-19 pandemic is not over and that the duration and evolution of public health emergencies, such as pandemics, are uncertain, a review (Rotaru 2020, 71-82) of the effectiveness of the functioning of the structures and mechanisms established in accordance with this Regulation should be provided for. Based on that review, those structures and mechanisms should be adjusted, if necessary.

The COVID-19 pandemic has had and continues to have a very serious impact on Europe. Although Europe's response has shown strengths, existing vulnerabilities were highlighted, including those related to the availability of data, the provision of medicines or the availability of production capacities to adapt and support the production of medicines. In this context, the Commission proposes a new pharmaceutical strategy for Europe. It is a patient-centred strategy that aims to ensure the quality and safety of medicines, while stimulating the global competitiveness of the sector.

As announced in the Commission's Communication of 25 November 2020 entitled the *"Pharmaceutical Strategy for Europe"*, the Commission will propose a revision of pharmaceutical legislation to increase the security of supply and to address medicine shortages through specific measures.

That legislation could include an additional coordinating role for the Agency in monitoring and managing medicine shortages. Where enhanced measures to monitor and report on the supply and demand of medicines at EU level are required following the reviews, the ESMP should be considered as an appropriate system to facilitate any new provisions on the monitoring and reporting of medicines shortages.

In order to prepare for medicine shortages during public health emergencies and major events and to support the monitoring of such deficits, capacity building should be considered with the support of European Union funding mechanisms, in order to strengthen cooperation between Member States. This could include exploring good practice and coordinating the development of IT tools for monitoring and managing medicine shortages in Member States and connecting to the ESMP. To ensure the full use of ESMP and to identify and anticipate supply and demand issues for medicines, where appropriate, ESMP should facilitate the use of high-volume data processing techniques and artificial intelligence.

References

Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02, published in the Official Journal of the European Union C 393 of 29.9.2021.

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.

European Commission, *Pharmaceutical Strategy for Europe*, 2020, available at: https://ec.europa.eu/health/system/files/2021-02/pharma-strategy_report_en_0.pdf

European Parliament Resolution of 17 September 2020 on the shortage of medicines - ways to address an emerging problem (2020/2071 (INI)), published in the Official Journal of the European Union C 385, 22.9.2021, p. 83.

Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility, published in the Official Journal of the European Union L 57 of 18.2.2021.

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014**,** published in the Official Journal of the European Union L 107 of 26.03.2021.

Regulation (EU) 2022/123 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, published in the Official Journal Official Journal of the European Union L 20 of 31.1.2022.

Rotaru, Ioan-Gheorghe. 2020. "Spiritual lessons observed through the Coronavirus Crisis." *Dialogo*. *Issue of Modern Man,* Vol.6, No.2: 71-82.