Background note

Session I: Medicine safety

Introduction

EU Member States and institutions have attached considerable importance to ensuring security for EU citizens, including health security. Medicine safety constitutes a very important aspect of these pursuits. The regulations of individual Member States as well as the EU binding legislation focus on *ensuring the quality and safety of medicines while boosting the sector's global competitiveness* (Pharmaceutical Strategy for Europe, COM (2020) 761 final, p. 2). As indicated in the aforementioned Communication, Europe has a comprehensive pharmaceutical system, ranging from the development and authorisation of medicines to their post-authorisation monitoring. The system has been supplemented and strengthened in recent years in response to the emerging challenges and threats. When discussing directions and tools for strengthening the system, it is important to note that the pharmaceutical industry in Europe is fundamental to development, innovation, and welfare growth. At the same time, this industry, like other European industries in recent decades, has been subject to a general trend of globalisation and relocation of production facilities outside Europe.

Current context

The actions proposed in the Pharmaceutical Strategy for Europe are unquestionably of relevance. Nevertheless a discussion on their practical implementation and adaptation to a rapidly changing global situation is required. The ongoing work at the EU level can be divided into two main, complementary processes.

I – Ensuring the supply of critical medicines in the EU

On 11 March, the EC presented a Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the accessibility of, and availability of, medicinal products of common interest (COM (2025) 102 final). Its objective is to strengthen the security of supply and availability of critical medicines in the EU, and to improve the availability and affordability of other medicines where this is not otherwise ensured by the functioning of the market, while taking due account of the rationale for ensuring such affordability. The Proposal envisages facilitating investment in manufacturing capacities for critical medicines, their active substances and other key inputs in the EU, reducing the risk of supply disruptions and strengthening availability by incentivising supply chain diversification and resilience in the

public procurement procedures for critical medicines and other medicinal products; leveraging the aggregated demand of participating Member States through collaborative procurement procedures; and supporting the diversification of supply chains also by facilitating the conclusions of strategic partnerships.

The Proposal complements the ongoing revision of EU pharmaceutical legislation and the main actions of the Pharmaceutical Strategy for Europe. It aligns with its objectives of increasing access to medicines, improving security of supply and addressing shortages, whilst giving due consideration to the affordability of medicinal products. It complements the main provisions on the availability and security of the supply of medicinal products proposed in the new pharmaceutical legislation.

II – The revision of existing pharmaceutical legislation

As of today, the European Union has been carrying out the first in 20-years-time revision of pharmaceutical legislation, with two proposals being debated– a new medicine directive (COM (2023) 192 final) and a new medicine regulation (COM (2023) 193 final) (the pharmaceutical package).

The starting point for the discussion is the European Commission's proposals, which are being analysed by the Parliament and the Council of the European Union.

The Proposal for a Directive on the Union code relating to medicinal products for human use focuses mainly on issues related to incentivising market innovative medicines, basic period of data protection and its extensions, the exception to intellectual property rights (the Bolar exemption), paediatric medicinal product awards, marketing authorisations and environmental risk assessment (ERA).

The Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency covers issues related to the general rules on package leaflets, transferable exclusivity voucher (TEV), shortages of medicines and countering medicine shortages, marketing authorisations, environmental risk assessment (ERA), and orphan medicinal products.

The ongoing revision process seeks to balance the interests of both the innovation and generic industries.

Challenges

The actions outlined above aiming to ensure medicine safety in the EU need to be accelerated. They also need to take into account changes in the geopolitical situation. The EU's current pledges to increase spending on developing Member States' defence capabilities stem from the threat of armed conflict. This threat must also be taken into consideration in the context of ensuring medicine safety in situations of armed conflict and warfare. Therefore, the proposed

regulations for enhancing health security and medicine safety in the EU must also account for such adverse and unprecedented situations.

Another challenge is the pace, firstly, - of the adoption of the proposed regulations and secondly, even more importantly, of their actual implementation. This legislation will have the effect of strengthening and relaunching the EU pharmaceutical industry that meets the health needs of the EU population, leading to the elimination or reduction of dependence on non-EU suppliers (of both active substances and ready-made medicines).

One cannot ignore the differences between Member States in the development and production structure (innovative/generic medicines) of the pharmaceutical industry . It is important to ensure that there is equal competition for support measures while undertaking or developing the production of medicines or active substances.

In addition to the actions directly aimed at eliminating negative phenomena affecting the pharmaceutical sector -as outlined above – it is crucial to reduce or eliminate the causes (including EU policies) that have in recent decades resulted in such a high dependence of the EU and its industry on non-EU suppliers, in particular on suppliers from just two Asian countries. Only by reducing such barriers can the outcomes of the Pharmaceutical Strategy for Europe be sustainably achieved.

Points for discussion

1. How to increase the production of active pharmaceutical ingredients (APIs) and ready-made medicines in EU countries?
2. What regulations should be implemented to secure the continuity of medicine production in the event of emergencies related to disruption of supply chains, energy crises and workforce availability?
3. Critical medicines list – how to develop procedures for early identification of critical medicines and methods to secure critical medicines for EU Member States?
4. The pharmaceutical package – what is the impact of the single market for medicines on EU patients?