European Commission

EU Pharmaceutical Reform:
Addressing shortages of medicines and ensure security of supply

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Problem

Medicines shortages can have serious consequences for Europe's national health systems and for the health of patients in the EU, including their right to access appropriate medical treatment. Shortages can be triggered by many factors, including highly complex and specialised supply chains, the lack of geographical diversification when sourcing certain key ingredients and medicines and perceived regulatory complexity.

Why the reform?

The EU's pharmaceutical reform aims to mitigate and address shortages of medicines and enhance security of supply so that medicines are available for citizens across the EU at all times.

There is a clear need for greater EU-wide coordination, increased legal empowerment of authorities and appropriate measures to safeguard the supply and availability of medicines for EU citizens, not only during public crises but at all times. Continued coordinated action is also needed to address potential challenges in the supply of critical medicines and to make Europe's medicine supply chains more resilient in the long run.

What does the reform address?

The proposed measures are focused on two main areas of actions:

1. Monitoring and management of shortages and critical shortages (Shortage monitoring)
2. Enhancing security of supply of critical medicines (Security of supply)

1 SHORTAGE MONITORING

Context:

- Member States manage most shortages at the national level, but for critical shortages that cannot be resolved at national level, they work, through their Head of Agency (HMA), with the European Medicines Agency (EMA) and the Commission.
- The HMA-EMA Task Force was established in 2016 to develop joint policies and guidance for shortage management. In 2019, the Medicine Shortages Single Point of Contact Network (SPOC Network) was mandated and later formalised with the extension of the EMA's mandate in 2022, as the SPOC Working Party (SPOC WP).
- Today, the system consists of the SPOC WP and a high-level steering group called the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). The SPOC WP is responsible for monitoring and reporting on critical shortages while the MSSG coordinates urgent actions within the EU.
- While the extension of the mandate of the EMA's in 2022 focused on crisis preparedness and response, this Commission's proposals aim at extending this system to all times.

What changes?

Prevention

- **Shortage prevention plans for all medicines**. All companies will be obliged to establish a shortage prevention plan, to anticipate any potential future shortages. Shortage prevention plans provide essential information to quickly resolve notified medicine shortages. They also include key information to identify supply chain challenges of critical medicines.
- Harmonisation of definitions and the required data submissions for companies to notify shortages and withdrawals of medicines.
    - *Earlier* notifications to allow Member States and the EMA to identify preventative and mitigation measures (see box below).
- Wholesale distributors and other entities (e.g. pharmacists) are not obliged, but may report a shortage to the relevant Member State's authority - **to avoid overburdening shortage monitoring systems.**

Mitigation/Response

- **Reinforced coordination at EU level**: Extending the scope of existing coordination mechanisms such as SPOC Working Party and MSSG outside crisis times, to offer prevention and mitigation measures, on-going monitoring and a set of recommendations on measures to resolve or to mitigate critical shortages.
- **Companies are obliged to draw up a Shortage Mitigation Plan** that identifies actions to mitigate a given shortage.
- **Clarification of roles and stronger obligations on companies and different actors**, e.g. wholesale distributors and other entities must submit any information requested by the relevant authority.

NOTIFICATION OBLIGATIONS

Companies will have to notify relevant authorities 12 months in advance if they plan to permanently withdraw a product from the market or permanently withdraw the marketing authorisation. For a temporary market suspension or a temporary supply disruption lasting more than 2 weeks, companies will have to notify relevant authorities 6 months in advance or, if justified (because the information was not available previously), as soon as they become aware of the temporary supply disruption.

2 SECURITY OF SUPPLY

Context:

The COVID-19 pandemic and the recent flu seasons have further highlighted the importance of ensuring the continued supply of medicines. This is especially true for the most critical medicines which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe.

What changes?

Our proposed reform will establish a legal framework to address issues of security of supply for critical medicines. This includes a legal basis for the list of medicines critical for EU health systems, identifying supply chain vulnerabilities and measures to improve security of supply:

1. Identifying Critical Medicines for EU health systems – Medicines that are considered most critical for EU health systems are identified in an EU list, to be adopted by the Commission. A first version of such list was adopted in December 2023.
2. Analysing supply chain vulnerabilities – The supply chain of those critical medicines is analysed to identify vulnerabilities.
3. Taking appropriate measures to ensure their supply – MSSG provides recommendations to strengthen the security of supply of critical medicines with vulnerabilities in their supply chain. The Commission may adopt an implementing act imposing appropriate measures, including contingency stock requirements of active pharmaceutical ingredients or finished dosage forms on marketing authorisation holders or other relevant entities.