Ad-hoc Pharmaceutical Committee meeting on contingency stocks

Tuesday 9th July 2024

Unit D2 – Medical products: quality, safety, innovation

DG SANTE, European Commission

3. Setting the scene on contingency stock requirements

European Commission

Recent developments

- Nov 2023: First discussion during the **101st meeting of the Pharma Committee** → Launch of CZ survey
- May/June 2024: Exchanges within the **Medicines Shortages Single Point of Contact (SPOC) Working Party**
- *June 2024*: AOB point during the last **EPSCO Council**

Contingency stock requirement

- **Obligation imposed on economic operator(s) and/or other actors of the supply chain** to establish buffer stocks of certain medicines to mitigate the risk of supply disruption
- Can be imposed by law and/or may result from mandatory contractual requirements (e.g., public procurement contracts)
- To be distinguished with **national, regional and or local 'stockpiling'** of medicines by a (public) health institution in order to anticipate and manage a specific crisis.

Implementation of Directive 2001/83/EC

- Article 81, second paragraph, prescribes that: *“*

  The holder of a marketing authorisation for a medicinal product and the distributors […] shall, within the limits of their responsibilities, ***ensure appropriate and continued supplies of that medicinal product*** *to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.”*
- According to Article 81, third paragraph, the arrangements for implementing that Article should be justified on grounds of public health protection and **be proportionate in relation to the objective of such protection**, in compliance with the TFEU rules, particularly those concerning the free movement of goods and competition.

Scope of national measures

- Several Member States have already implemented national measures imposing contingency stocks to actors of the supply chain.
- Very **heterogenous** requirements:
  - Format: by law and/or by other means (e.g. mandatory contractual requirements)
  - Scope: type of medicines and actors in the supply chain concerned by the obligation
  - Extent: different volumes and storage requirements

Legal requirement

Compliance with the internal market and free movement of goods principle.

- Impact on the internal market, including on availability of products concerned in other Member States, is a focus of the assessment by the Commission (and other Member States) once measures, introducing contingency stock requirements, are notified under Directive (EU) 2015/1535 (SMTD).
- Notification is mandatory for any measure that fulfils the definition of ‘technical regulation’ within the meaning of the SMTD.

Objectives of the meeting

- The purpose of this meeting is twofold:
  - Sharing of information on **existing/planned national measures focusing on contingency stocks** and their scope of application;
  - First exchange on possible **common principles related to these national measures** to ensure the security of supply of medicines in one Member State without undermining availability in other EU countries.

Thank you

European Commission