PHARM 845

PHARMACEUTICAL COMMITTEE
9 July 2024

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Subject: National contingency stock requirements

Background

Several Member States have implemented national measures to prevent shortages by imposing contingency stock requirements for certain medicines. These requirements are very heterogenous as they may be imposed by law or by other means for different categories of products, on different actors in the supply chain, with different volume requirements, different storage requirements (national territory versus EU) and different owners of the stocks.

These measures are taken through the national implementation of Article 81, second paragraph of Directive 2001/83/EC on the Community code relating to medicinal products for human use, which prescribes that: *"The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State 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.

Notion of 'national contingency stock requirements'

To frame the discussion, we consider as 'national contingency stock requirement' an obligation imposed on one or several economic operator(s) and/or other actors at different levels of the supply chain to establish buffer stocks of certain medicines in order to cover the consumption needs during a certain period of time and therefore mitigate the risk of supply disruption. These measures can be imposed by law and/or may result from mandatory contractual requirements (e.g., public procurement contracts between health system actors and suppliers).

A distinction should be drawn between 'national contingency stock requirements' imposed to economic operators and other actors of the supply chain to mitigate a risk of supply disruption/shortage and national, regional and or local 'stockpiling' of medicines by a (public) health institution in order to anticipate and manage a specific crisis.

Discussion

Building on the recent discussions on national measures to prevent medicine shortages during the 101st meeting of the Pharmaceutical Committee in November 2023 ([1]) and at the last EPSCO Council on 21st June 2024 ([2]), Member States are invited to provide additional feedback on the following aspects:

- **Existing/envisaged national contingency stock measures and their scope of application;**
- **Possible common principles on national contingency stock requirements.**

Member States will be invited to provide additional contributions in writing by Friday 6 September 2024.

Taking into account the outcome of the discussion, the contributions from Member States will be used as a basis to prepare common principles for Member States for the implementation of Article 81, second paragraph of Directive 2001/83/EC, in relation to contingency stock requirements.

([1]) https://health.ec.europa.eu/latest-updates/summary-record-101st-meeting-pharmaceutical-committee-23-november-2023-2024-01-23_en

([2]) https://www.consilium.europa.eu/en/meetings/epsco/2024/06/21/