EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

PHARM 846

AD-HOC PHARMACEUTICAL COMMITTEE MEETING ON CONTINGENCY STOCKS
9th July 2024

SUMMARY RECORD

The meeting was organised in an online format and was attended by representatives from the Commission, 25 EU Member States, Norway, Iceland and the European Medicines Agency (EMA).

1. Opening by Sandra Gallina, Director-General for Health and Food Safety

Sandra Gallina emphasized the importance of this ad-hoc Pharmaceutical Committee meeting and reminded the concerns expressed by several Member States regarding the potential impact of national contingency stock requirements on the availability of medicines in other countries. The two objectives of the meeting are: 1) to increase transparency at EU level - in line with the measures included in the pharma package - with an invitation to all Member States to share relevant information on existing or planned national requirements during the meeting; 2) to develop common principles with a view to ensuring proportionality and solidarity among EU countries.

2. Adoption of the draft Agenda of the meeting

The draft agenda (PHARM 844) was adopted without changes.

3. Setting the scene on contingency stock requirements

The Commission presented the recent developments on this topic: first discussion at the Pharma committee meeting in Nov 2023, followed by exchanges during SPOC Working Party and EPSCO Council in June 2024. It was clarified that the notion of ‘contingency stock requirements’ refer to obligations imposed on actors in the supply chain to establish buffer stocks of certain medicines to cover the consumption needs during a certain period of time and mitigate the risk of supply disruption whereas ‘stockpiling’ refers to stocks held by a (public) health institution at

national/regional or local level to anticipate and manage a specific crisis. National measures on contingency stocks are taken in implementation of the provisions of article 81 (para 2 and 3) of the directive 2001/83/EC. These requirements are very heterogenous in terms of format (imposed by law and/or resulting from mandatory contractual requirements), scope (type of medicines and actors concerned by the obligations) and extent (size of the stocks, storage localisation and timeframe to build such stocks). SANTE also reminded the legal requirements related to these national measures that must comply with the Internal market rules. 'Technical regulations' within a meaning of Single Market Transparency Directive, that is measures that set on requirements applicable to specific products, are subject to mandatory notification (TRIS notification procedure). The notified measures are scrutinized by the Commission and other Member States.

The objectives of the meeting are to foster the sharing of information between Member States and to discuss potential common principles to support the security of supply of medicines in one country without impacting other countries.

4. Presentation of CZ survey results

CZ recalled the context behind their initiative and the added value of sharing information at technical level and mutual learning on existing and planned national measures not only in terms of scope but also impact on other countries. Then, CZ presented its legislative measures to address medicines shortages, which include: the mandatory supply of medicines by MAH after notification of supply disruption (1-2 months), the monitoring of medicines with limited available at different levels of the supply chain (shortage management plan by MAH, regulatory flexibilities, timely limited export ban and limited stockpiling at the level of pharmacies) and safety stocks of critical medicines at distributor level (1 month). Finally, CZ reported on its survey on national measures related to security of supply of medicines, which was circulated among Member States after the Pharmaceutical Committee meeting held in November 2023. The focus of this survey was national measures taken during the past year or considered by Member States in the upcoming year to solve and prevent current medicine shortages. 20 responses from 19 Member States were received. Only 4 Member states indicated that they do not plan or implemented national measures to address medicines shortages during the concerned period, 4 countries implemented export restrictions, 6 countries introduced contingency stock requirements while 10 countries took specific pricing and reimbursement measures. CZ concluded that the most frequently used measures, according to their survey, were: stockpiling, price incentives and export restrictions.

5. Preliminary discussion on:

a. National contingency stock measures in place or considered by Member States – tour de table

Member States were invited to provide further details on existing/planned national requirements focusing on contingency stocks. During the tour de table, 14 countries indicated that they have either general or specific measures resulting in contingency stock requirements for the actors of the supply chain. These countries shared information on the specificities of their national requirements, which are very heterogenous in terms of scope (covering either all medicines or a specific range of medicines) but also extent (size/volume of the buffer stocks ranging from 2 weeks

until 10 months but also various lead time for building such stocks). Furthermore, 3 countries informed that they have measures under preparation. Finally, 6 countries indicated that they do not have requirements on contingency stocks in place or planned for the future.

b. Common principles on contingency stock requirements

Several countries supported the development of common principles and emphasised the need for proportionality when defining the scope of products concerned by a contingency stock obligation, the size of required stocks but also the need to ensure a sufficient timeframe for companies to build such stocks. The importance of supporting other countries via the Voluntary Solidarity Mechanism was also highlighted during the discussion. The need to ensure coordination with other ongoing initiatives was mentioned. Member States are expected to provide additional contributions in writing by early September.

6. Conclusion and next steps

The Commission thanked the participants for their active participation during the meeting and emphasised the general support from Member States to develop common principles in the spirit of solidarity. There will be a follow up to this discussion based on the (oral and written) contributions from Member States.