EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public Health, Cancer and Health security
Medicines: policy, authorisation and monitoring

PHARM 843

PHARMACEUTICAL COMMITTEE
23 November 2023
101st meeting

SUMMARY RECORD

The meeting was organised in hybrid format and was attended (online and physically) by representatives from the Commission, 27 EU Member States, Norway, Iceland, the European Medicines Agency (EMA) and the Council of Europe (EDQM).

1. Adoption of the draft Agenda of the meeting

The draft agenda (PHARM 842) was adopted without changes.

2. Updates on actions related to the security of supply of medicines and shortages

a. **Update on Communication on "Addressing Medicine Shortages in the EU"**
b. **Update on compilation of initial version of the Union list of critical medicines by the end of 2023 (under HMA EMA Task Force on Availability of Authorised Medicines for Human and Veterinary Use)**

[joint debate]

The Commission presented the main objectives and actions of its Communication adopted in October 2023. Overall, the meeting covered critical medicines methodology, approval processes, vulnerability analysis, procurement guidance, and national perspectives on proposed measures. The following key points were discussed.

EU critical medicines list: A methodology had been developed under the Commission's Structured Dialogue. Medicines deemed critical by the European Medicines Regulatory Network will be included in the EU list. The HMA/EMA task force on the availability of authorised medicines for human and veterinary use (TFAAM) is set to meet at the end of November to agree on the inclusion of an initial selection of around 240 INNs (International Non-proprietary Names) on this critical list, for subsequent agreement by the HMA and the EMA Management Board. By mid-December, there will be a joint publication by EMA, EC, and HMA of the Union list of critical medicines and the associated methodology, expected in the week of December 11. The Union list will be progressively expanded in 2024 and will then be updated regularly. Following the establishment of the Union list of critical medicines, the focus will shift to vulnerability

analysis and supply chain vulnerability and determining specific measures for individual products. The list will be an important tool to support the EU's efforts in ensuring supply security and preventing shortages of critical medicines.

Member States mentioned national measures taken on shortages, such as guidance on procurement by Public/Regional authorities. The work of the NCAPR group was also mentioned as a forum mandated to examine procurement methods and practices. The work on the implementation of the directive on the resilience of critical entities related to medicines was highlighted to avoid duplication and ensure coordination with the ongoing work on critical medicines.

c. Discussion on certain national security of supply measures (discussion based on national examples)

The Czech Republic presented national challenges with shortages of medicines, particularly antibiotics, over the past year, a situation reportedly shared by several other EU Member States. The country has previously presented a non-paper at the EPSCO Council meeting last March, emphasising the need to leverage EU-level structures like EMA, ECDC, DG SANTE, DG HERA, and DG GROW to secure essential medicine supplies through active global negotiations.

The Czech Republic stressed the importance of understanding and sharing information about national and EU-level measures to prevent and mitigate medicine shortages. They proposed a discussion aimed at learning about targeted national measures in the various Member States for essential medicines and assessing whether these measures could impact supply in other Member States. Evidence gathering at technical level would be useful to inform decision-making processes both nationally and at the EU level.
Several countries reported experiencing shortages of medicines, particularly antibiotics, over the past year, with similar national measures taken in response. Export bans in case of unavailability and prescription restrictions for specific medicinal products were implemented, with no reported impact on other Member States.

Member States that took the floor stressed the need for a coordinated approach to share national developments on shortage measures. National measures in place reportedly include the establishment of national safety stocks, requirements for Marketing Authorization Holders (MAH), operational task forces on shortages involving stakeholders, and national shortage coordination. These measures were reported to have no impact on other Member States.

National incentives for the production of critical medicines in the EU were mentioned. Various measures were implemented to address regional shortages (at national level), such as quotas and price adjustments for low-price medicinal products. An early warning system and data provision by hospital pharmacies were in place, with no reported impact on other MS.

Common points across Member States included the notification of shortages, management plans, fines for industry's non-compliance, ongoing surveillance, and the possibility of pharmacy magistral preparations. Questions were raised about the potential for e-prescriptions to inform healthcare professionals about impending shortages. The possibility of informing doctors and involving pharmacists through e-prescription was noted, with no reported impact on other MS. Coordinated dispensing and electronic communication between pharmacies and doctors were also highlighted.

The ongoing work as part of the Joint Action Chessmen was also mentioned.
The European Commission (EC) recalled that the specific situations of shortages can be addressed in the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and EMA's Medicine Shortages Single Point of Contact (SPOC) working party.
The Committee supported conducting a survey led by CZ to identify specific national measures to address shortages that can potentially impact security and continuity of supply in other MS. The Commission expressed its readiness to provide information to the CZ authorities to avoid duplications of their survey with other initiatives. Finally, the EDQM referred to activities they develop that link to security of supply.

3. Joint Action on regulatory flexibilities, including magistral preparations

The Commission (DG SANTE) presented the main points and objectives of the Joint Action (JA) on regulatory flexibilities, including magistral preparations, included in the October 2023 Commission Communication 'addressing shortages in the EU'. The aim of the discussion was to listen to the Member States' opinions on the scope of cooperation under the JA. The Commission confirmed that the JA was not intended to repeat the identification of regulatory flexibilities as such, but rather to focus on practical implementation and identifying best practices. They invited the Member States to provide further written feedback which will be considered when designing the action.

Member States welcomed the possibility for a joint action and noted that experience on regulatory flexibilities in the COVID-19 setting was mixed. Member States also stressed the importance of linking with the work done in EDQM and Chessman.

4. Joint Action on stockpiling

The Commission (DG HERA) presented the main points and objectives of the Joint Action (JA) on stockpiling included in the October 2023 Commission Communication 'addressing shortages in the EU'. Member States and Commission followed up with exchanges on the details of the planned JA, the modalities of the types of stocks and future planning.

5. Pharmacy preparations under the current framework

The Netherlands presented the national situation regarding preparations of medicines at pharmacy level focusing on the cases where this is done to respond to temporary or permanent withdrawals from the market.

The Commission presented the current rules and latest jurisprudence as regards pharmacy preparations.

Members of the Committee that took the floor stressed these should be considered as 'last resort' measures and that ensuring quality and good manufacturing practices is key when applying the flexibilities given by legislation regarding pharmacy preparations. Member States recognised nevertheless the utility of the practice in tackling shortages

and welcomed such flexibilities when an authorised medicine is not available.

6. Pharmaceuticals in the Environment: Presentation of the work conducted in the ad-hoc Working Group Pharmaceuticals in the Environment (WG PiE) and finalisation of its work programme

The Chair of the EC ad-hoc Working Group on Pharmaceuticals in the Environment (MPA SE) delivered a presentation on three parts. First, he presented the challenges arising from pharmaceuticals in the environment and concluded that further action is needed to limit the effects on our ecosystems. The second part was an overview of the mandate of WG PiE, its composition (13 MS +EC+EMA) and its work so far. This includes recommendations, good practice sharing and guidelines in 7 areas. Furthermore, a concept paper had been developed in the context of the pharmaceutical reform with proposals for "Strengthening the environmental risk assessment (ERA) requirements and conditions of use for medicines".

Members of the Committee welcomed the work conducted so far and expressed support for an extension of its mandate subject to formal endorsement by the Committee in a forthcoming meeting. One MS mentioned the need to also discuss the urban wastewater Directive in conjunction with the work done by the ad-hoc WG.

The Committee decided to further discuss about ERA matters and the potential extension of the mandate of the ad-hoc WG in its next meeting.

7. Point of information: Draft Commission delegated Regulation, amending Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use

The Commission informed the Committee of the Commission Expert Group on a Draft Commission delegated Regulation, amending Commission Regulation (EC) No 1234/2008 on variations which was scheduled to take place on 23 November 2023 in the afternoon.

8. A.O.B.