EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 803

PHARMACEUTICAL COMMITTEE

2 July 2020
Brussels
88th meeting

SUMMARY RECORD

Meeting chaired by Unit B5 – *Medicines: policy, authorisation and monitoring* - Directorate-General Health and Food Safety. The meeting was organised via video conference and was attended by representatives from the Commission, 24 EU Member States, Norway, Iceland and the European Medicines Agency (EMA).

1. Adoption of the draft Agenda

Draft agenda (PHARM 800) was adopted.

2. Adoption of the draft minutes of the 87th meeting

The draft minutes (Pharm 799) were adopted.

3. Pharmaceutical Strategy for Europe

The Commission updated Member States on the state of play on the strategy after the publication of the roadmap. The Commission made a summary of the elements raised by the Member States in the previous meeting about COVID-19 and the pharmaceutical strategy in general. The Commission presented the roadmap and its objectives for an exchange of views with the Member States.

Member States welcomed that the strategy covers the complete life cycle of medicines and mentioned that it should also cover medical devices. They also stressed the role of repurposing of off-patent medicines especially after the lessons learnt from Covid-19. Member States mentioned shortages especially due to Covid as regards manufacturing-distribution of medicines where regulators need to provide incentives for patented but also to ensure from marketing authorisation holders the

continuation of production and distribution of off-patent medicines. Many Member States called for a common agenda on access combined with concrete actions and follow-up and the importance of a partnership between the European Commission and Member States with respect for the mutual roles and competences. They also mentioned the need to further discuss basic principles such as 'strategic autonomy' (in order to have a clear and common understanding of its meaning) and unmet medical needs. The importance of HTA was also mentioned as well as data utilisation. Regulatory administrative simplification, which must safeguard efficacy, safety, quality of medicines and provide availabilities for electronic product information. Some Member States noted that there are trade-offs between the objectives of the strategy, which should be discussed.

EMA focused its intervention on antimicrobials, and mentioned the various actions in veterinary legislation to reduce AMR.

The Commission clarified that the strategy will look if the existing system is equipped to address innovative combination products of pharmaceuticals with medical devices recognising that there is relatively recent legislation on medical devices, which is under implementation. A holistic approach (across policies and multi-faceted design of actions) is needed to keep the right balance between actions and objectives. A discussion on the basic principles such as unmet medical needs is important and the Commission noted the comments made. SANTE also mentioned that it is conducting a knowledge gap exercise to inform the implementation phase of the strategy and asked Member States to communicate information on studies they may have. More focused discussions on specific points of the strategy will be included in the agendas of following meetings of the Committee to provide input to the Commission Communication on the Pharmaceutical Strategy.

4. EU dependency on APIs

The discussion followed the Commission's call to Member States to provide information in order to identify and assess potential solutions. The Commission reported on some Member States' input received so far and indicated that the issue of security of supply would need a multidimensional approach as part of the Pharmaceutical Strategy for Europe. A majority of participants in the meeting believe that there is a dependency on APIs sources from third countries, and that some of the structural shortages in their Member States are due, at least in part to that. Member states share the opinion that the shortages due to dependency of APIs affect the supply of essential medicines from the point of view of public health and that the issue of dependency should be discusses more in depth and addressed at EU level.

The German delegation informed on the proposal by German Presidency for the discussion on the same subject planned at the informal health Council on 16 July. Member States drew the attention to the necessity of increasing transparency on the EU's manufacturing capacity, as well as finding incentives for supporting the EU manufacturing capacity using existing funding instruments. Some Member States expressed the view that improving the transparency of API suppliers, strengthening

inspections to ensure active substances quality and as well as promoting cooperation on inspections and harmonised inspection standards are a part of solution. Another view expressed was that non-equivalent environmental standards or lack of their enforcement outside EU is one of the reasons for the EU losing its manufacturing capacity. The focus should be on health security and security of supply and on development of resilience within the EU supply chains and diversification of supply rather than self-reliance. Essential medicines should be strategic products only, including broad-spectrum antibiotics. Some Member States agreed that a strategic approach is essential for the creation of such a list and that a specific sub-group of the committee on this question could help. Member States pointed out that the criteria for a definition of "essential medicines" should be carefully analysed. Clarification was sought from Member States about the extent of overlap of such sub-group with ongoing activities on the same topic being conducted at HMA/EMA levels

The committee agreed to create an ad hoc working group in the pharmaceutical committee to further discuss some of the questions linked to this file and reflect on a concrete action.

5. A.O.B.

The Commission updated Member States on:

- the orphan and paediatrics legislation evaluation;
- the state of play of the pilot project 'Market Launch Intentions of Centrally Authorised Products';
- the Commission Communication on a vaccines strategy.
- next meetings scheduled in September (post meeting note: 18 and 21 September) and on 21 October.