



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 799

PHARMACEUTICAL COMMITTEE

26 May 2020
Brussels
87th 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 798) was adopted with additions under AOB.

2. Pharmaceutical Strategy for Europe

The Commission presented the state of play of EU's Pharmaceutical Strategy and held a discussion with Member States on the elements that COVID-19 raised from national perspectives. The Commission explained that the publication of the roadmap was put on hold due to COVID-19, due to imminent need to focus policy activities on the management of the extraordinary pandemic situation, but also to allow to factor in the initial lessons learned from the crisis. It is clear that the current crisis has shown the need for an ambitious strategy that will address the challenges already identified, now highlighted even further.

The main issues raised by the Committee were availability of medicines, shortages, dependency on active pharmaceutical ingredients and medicinal products from 3rd countries, possibilities of diversification of supply, joint procurement of medicines/medical devices, personal protection equipment (PPE) and stockpiling for essential medicines and equipment, mechanisms for crisis management. Participants agreed that more coordination and clarity about the role of each actor is needed across

the EU as well as increased transparency as regards medicines stocks and needs. Regulatory flexibility and/or new authorisation tools to allow for timely authorisation while respecting safety and efficacy standards. Moreover, member states mentioned the need for a holistic approach that goes beyond the crisis management to support innovation in therapeutics and diagnostics. In addition, member states highlighted the important role played by medical devices during the crisis.

As the pandemic brings these challenges to the fore, the strategy needs to be ready to investigate fundamental questions and give viable solutions to the challenges identified. These issues will be covered in the upcoming Pharmaceutical Strategy (scheduled for adoption in Q4 2020) outlining the pillars of the future EU pharmaceutical policy. In order to properly identify and address issues holistically and to benefit from experience on national levels, the Commission will maintain the privileged communication with Member States, using especially the Pharmaceutical Committee. At the same time, the Commission will launch consultation activities and engage with stakeholders to collect feedback. The aim of the strategy will be to retain its wide purpose and objectives and at the same time take into account any initial learnings from the crisis.

Post meeting note: The [roadmap](#) for the EU Pharmaceutical strategy was published on 2 June 2020.

3. A.O.B.

- The Commission updated the Committee on developments with the ongoing evaluation of legislation on orphan and paediatrics medicines and informed that a Commission report will be published alongside the study performed by an external contractor in July. Member States were invited to consult the Commission report in preparation of a brainstorming session scheduled for one of the next Pharmaceutical Committee meetings.
- The Commission updated the Committee on the work on **shortages of medicines and dependency on APIs** and outlined the consultations scheduled to take place with Member States and stakeholders, mentioning that the Commission is reflecting on ways to organise engagement with industry and fill knowledge gaps.
- The Commission updated the Committee on the **outcome of the second meeting of public health payers and pricing and reimbursement authorities** held on 25 May 2020 which included a reflection on the possible actions under the Pharmaceutical Strategy.
- The Commission informed the Committee that the Commission decisions concerning COVID-19 related indications would be adopted through an accelerated procedure, including adaptation of the consultation of the Standing Committee.

- Next meeting scheduled on 2 July 2020.