



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 811

PHARMACEUTICAL COMMITTEE
21 October 2020
Brussels
90th meeting

SUMMARY RECORD

Points 1 to 3 were chaired by Unit B5 – *Medicines: policy, authorisation and monitoring* – the rest were chaired by Unit B4 - *Medical products: quality, safety, innovation* 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, Lichtenstein, Iceland and the European Medicines Agency (EMA).

1. Adoption of the draft Agenda and draft minutes of the 89th meeting

Draft agenda (PHARM 808) was adopted.

The draft minutes (Pharm 809) were adopted.

2. Pharmaceutical strategy for Europe

The Commission presented the state of play of the preparation for the Communication focusing on the elements of the text, which will be going to formal ISC. The contents received positive comments from Member States and EMA who reiterated their readiness to work with the Commission on its implementation.

3. Vaccine strategy update

The Commission informed the Committee about the publication of the Memorandum of Understanding (MoU) on labelling and packaging flexibilities for COVID-19 vaccines in its website. The link to the published document was circulated to members after the meeting.

4. Vulnerability of the global supply chain (endorsement of a draft mandate for the ad-hoc working group)

The Commission updated the Pharmaceutical Committee on the work of the ad-hoc working group and encouraged to provide input to the written consultation (questions shared as a follow up of the meeting of 16 September 2020).

Ad hoc working group on vulnerabilities, including dependencies, of global supply chain is created to:

- 1) provide an opportunity for an exchange of information between the European Commission, Member States and EMA, and;
- 2) identify and coordinate EU level actions and initiatives; to address the problem of vulnerabilities of global supply chains of medicinal products destined for the EU, as part of the implementation of the Pharmaceutical Strategy.

The group is open to representatives from all Member States, including from national departments and agencies that are involved in the issue of supply chain security from complementary points of views (including industrial, research, procurement, trade, competition), and to EMA.

Committee members were requested to express their interest in participating to the ad-hoc working group.

After the discussion, the Committee endorsed the mandate and the title of the ad-hoc WG on “vulnerabilities, including dependencies, of the global supply chain”.

5. Pharmaceuticals in the environment (endorsement of an action plan of the ad-hoc working group)

The Commission informed about adoption of the European Parliament resolution of 17 September 2020 on a strategic approach to pharmaceuticals in the environment (2019/2816(RSP)) and adoption of the EU Chemicals Strategy for Sustainability.

Chair of the ad-hoc working group on pharmaceuticals in the environment presented the Strategic approach on pharmaceuticals in the environment and updated the Pharmaceutical Committee on the work, scope and structure and overview of the action plan of the working group. The ad-hoc working group is set up to focus on the EU strategic Approach on pharmaceuticals in the environment, in relation to human medicines, in particular on the actions and measures of the Commission Communication (COM(2019) 128 final of 11 March 2019) that fall under the competence of the Member States. The ad-hoc group established seven sub-groups (human medicines).

Norway and Committee members that are not already members of the ad-hoc working group focused on pharmaceuticals in the environment were requested to express their interest in participating the relevant ad-hoc working group.

The Committee endorsed an action plan of the ad-hoc working group on pharmaceuticals in the environment.

6. A.O.B.

- Extraordinary meeting on 17 November 2020. Next scheduled meetings: 11 December 2020, 3 February 2021 (Date TBC)