EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 797

PHARMACEUTICAL COMMITTEE

12 March 2020
Brussels
86th 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, 21 EU Member States, Norway, European Medicines Agency (EMA), and the Council of Europe.

1. Adoption of the draft Agenda

Draft agenda (PHARM 790) was adopted without changes.

2. Pharmaceutical Strategy for Europe

DG SANTE presented the EU's Pharmaceutical Strategy, its objectives, challenges, consultation actions, timeline and analysed the role of the pharmaceutical committee and Member States in the preparation process. A first deliverable will be a Commission Communication by the end of the year. Member States welcomed the news of the strategy as an opportunity to address issues that have been high on the agenda for some time. The objectives of the strategy were supported by the Member States which signalled their readiness to work with the Commission on the basis of a specific agenda once more detailed actions are presented. The Commission informed that it is working on a roadmap for the Communication. The roadmap will be published on the Commission's better regulation website. Once the roadmap is published, a more detailed discussion will take place at the next meeting of the Committee. The Pharmaceutical Committee will become an important forum of interaction with Member States on this initiative.

3. Evaluation of orphan & paediatrics regulations

DG SANTE presented the preliminary findings on the evaluation of orphan & paediatrics regulations. The publication is expected for later in spring 2020. Participants mentioned the need to focus on areas of societal value and to address disproportionate benefits where relevant and better direct incentives in areas of unmet medical needs, while retaining innovation. The concept of a list of unmet medical list was discussed and its possible advantages and disadvantages were considered.

4. Study on medicines shortages

DG SANTE presented its planned study on shortages including the timeline, data to be collected and main deliverables. Member States welcomed the study and stressed their wish for actions at EU-level to address shortages. Participants also requested that the study take into account the EU's dependency on manufacturing of active pharmaceutical ingredients in third countries, as this is one important cause of shortages. Member States agreed to share their national data on shortages with the future contractor. DG SANTE explained that Member States would be consulted during the study and will be informed of interim results when available.

5. COVID-19

DG SANTE presented the actions of the EU executive steering group on shortages of medicines caused by major events, which is chaired by the EC, with EMA and Member State membership and which is monitoring the situation. The initial feedback by Member States is that no shortages/disruption of supply due to Covid-19 are apparent to date (12 March 2020) but they are closely monitoring the situation. EMA referred to several activities at EU and national level as regards development of vaccines and therapeutics. The EMA stressed the need to prioritise large randomised controlled studies because they are most likely to generate the conclusive evidence needed to enable rapid development and approval of potential treatments of COVID-19. It also emphasised the need to have a harmonised approach to data collection and a robust methodology for such clinical trials. As regards to possible shortages SANTE asked Member States to closely monitor the situation and be prudent on decisions related to stockpiling, or restrictions of export to other Member States.

6. Market launch of Centrally Authorised Products

DG SANTE and EMA presented the conclusions of the ad-hoc WG on market launch of centrally authorised products (CAPs) and follow-up actions including a planned pilot project to request marketing authorisation applicants to voluntarily inform the regulators of their market launch intentions in the pre-authorisation phase. The pilot is intended to increase awareness of companies on the issue and collect information that will help regulators to better understand the mechanism behind the problem of delayed market launches. The pilot was endorsed by the Committee and is scheduled for launch in mid-2020 after a targeted consultation with industry has taken place. In addition, the committee was reminded that applicants are already legally required to inform EMA of the actual market launch of authorised medicines. In order to increase

transparency and the usability of this information, EMA will develop an IT tool which will facilitate the processing of notifications received from companies on the actual market status of their CAPs, and to share this with the Member States. This will better inform the Commission and Member States about the actual availability of medicines in the Member States.

7. EU dependency on APIs

DG SANTE analysed the current situation mentioning that the Commission is working on receiving more quantitative information on the actual dependency on active pharmaceutical ingredients (API) such as volume of imports and the percentage of APIs, sourced in third countries, used to produce medicines for the EU market. DG SANTE asked the Member States to provide information by replying to several questions covering information on most critical medicines reliant on the APIs sourced in third countries, the state of play regarding shortages due to manufacturing dependence as well as addressing the existing APIs manufacturing capacity etc. The Member States stressed that the APIs dependency issue is not independent from shortages and that it should be examined in relation to that question. It is also important to discuss the question of further investment in APIs production and EU competitiveness.

BREXIT SESSION

8. Implications from the withdrawal agreement and transitional period

The Commission updated the committee on the application of the transition period and future developments and stressed that by the end of the transition period (end of 2020) the UK will be a third country in all respects (special conditions apply to Northern Ireland). The Commission stressed that it has given ample time, warning and guidance on compliance to EU law post Brexit, both for the public and the private sectors, therefore, at the end of 2020 no exceptions will be made to companies who are not fully ready. The EC will soon publish an updated Q&A document on Brexit and invited Member States to continue their efforts of preparing industry for full compliance with the EU legislation by the end of the transition period.

[Post-meeting note: the updated guidance was published: https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_medicinal_products.pdf]

9. A.O.B.

- DG SANTE updated the committee on the work of the ad-hoc working group on pharmaceuticals in the environment and the committee endorsed the ad-hoc working group's mandate.
- Next meetings: a meeting is scheduled for 2 July 2020. There will possibly be an extraordinary meeting on 7 May 2020 if practical conditions allow.