EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 782

PHARMACEUTICAL COMMITTEE

7 November 2019
Brussels
84th meeting

SUMMARY RECORD

Meeting chaired by Andrzej Rys, Director *Health systems, medical products and innovation* and Olga Solomon, Head of Unit B5 – *Medicines: policy, authorisation and monitoring* - Directorate-General Health and Food Safety. Present: representatives from the Commission, 26 EU Member States, EFTA (Norway, Iceland), European Medicines Agency (EMA).

1. Adoption of the draft Agenda

Draft agenda (PHARM 776) was adopted without changes[1].

2. Pharmaceutical Committee: mapping policy needs and working method

a. Initial identified priorities and new Commission

DG SANTE made an introduction of the new Commission its structure and the first priorities identified by the President-elect in her mandate letter. DG SANTE stressed that the Committee, being an advisory body for Commission-led legislative and policy actions, needs:

1) a results-oriented work plan; and
2) to establish synergies with initiatives taking place in other fora such as the Council and other actions in the network of NCAs and EMA.

Member State representation in the Committee should be high level and strategic-oriented.

[1] The agenda and copies of relevant documents are available on the webpage of the Pharmaceutical Committee: https://ec.europa.eu/health/documents/pharmaceutical-committee/human-meeting_en

- Member States welcomed the Commission's initiative to bring the network closer together.

b. Presentation of a process supporting priority actions in the Pharmaceutical Committee

The Commission presented a visualisation of the Committee's working method and its interaction with other relevant fora (the working method is annexed to document Pharm 777).

Main elements of the working method:

- Cooperation with other fora and initiatives (including at the level of the HMA, EMA, the Council and if needed, holding joint meetings of the Committee with other Committees or ad hoc participation of experts and stakeholders for advisory purposes);
- Prioritising actions according to challenges/opportunities identified in the Committee whilst avoiding duplication with work conducted within other fora;
- Possibility to mandate dedicated ad-hoc Working Groups (led by the EC or Member States) to examine technical issues and make recommendations to the Committee;
- Output to form advice to EC on optimisation of implementation of current legislation, legislative action (if necessary), guidance or other measures.

- The Member States supported the proposed working method, which was endorsed by the Committee.

c. Identifying specific policy needs, work strands

The Commission presented key priorities and challenges for pharmaceutical policy, as identified at the last meeting of the Committee. These were organised around three themes as described in working document Pharm 777. The members of the Committee discussed the priorities included in the working document and made additions/changes which are reflected in the final version of the document to be published after the meeting.

Main conclusions:

- Due to finite resources, the Committee will start work on priority actions;
- Actions for which work is ongoing must take precedence (shortages, AMR, Pharmaceuticals in the environment, ATMPs, supply chain integrity and action plan to enhance global oversight of APIs, market launch of Centrally Authorised Products evaluation of Orphan Paediatrics legislation, drug repurposing);

- MSs supported the priorities proposed and added elements which should be addressed in a possible future revision of the legislation. Their input focused on sustainability from health system budgetary perspective, reduction of regulatory burden and creating a future proof framework.

3. Pharmaceuticals in the environment

DG SANTE presented the Communication from the Commission on the EU Strategic Approach to Pharmaceuticals in the Environment and its links to the EU Green deal. The presentation was complemented by DG ENV and EMA.

The Member States supported the actions and exchanged views on the nature and role of the Environmental Risk Assessment and its effect on the approval of medicines.

The Committee decided to set-up an ad-hoc group focusing on the areas of action identified in the communication falling under Member State competence, exchange best practices and report to the Pharmaceutical Committee. Sweden, Ireland, Germany, Slovenia, Spain, Netherlands, Finland and the EMA expressed interest in joining the ad-hoc WG. The Commission invited more Members to join as well.

- The mandate of the WG will be discussed/endorsed in the next meeting of the Pharmaceutical Committee

4. Anti-Microbial Resistance

a. Therapeutic use of bacteriophages: Member States experience and policy options

Belgium presented the results of a survey on bacteriophages launched in the last Pharmaceutical Committee meeting with a view to gain clarity on the issue in the form of guidance within the current framework or its possible review in the future. The survey gathered replies from 18 Member States. The Committee discussed whether bacteriophages should be considered medicinal products (as regards those industrially manufactured vs those developed for personalised treatments), their use in magistral preparations and the lack of evidence and rigorous clinical trials to demonstrate efficacy.

- The Committee concluded that more scientific evidence is needed on these products. DG RTD engaged in the discussion and mentioned the need to fund research in this field (the few bacteriophage developers are small companies and individual hospitals).

b. Development of antimicrobials: how to address market failures

The EC presented its initial thoughts on economic models that could take into consideration the right balance between rewarding innovation and ensuring that new classes of effective antimicrobials are available and affordable. The discussion focused on “pull” incentives, however it was stressed that an adequate combination of “push” and “pull” incentives is needed.

The preliminary debate indicated that the issue is complex and in many ways the market failure for antimicrobials is different from other medicinal products. The possibility of incentives on the basis of knowledge acquired from the orphan and paediatric legislation was explored and Member States agreed that further reflection is needed. The discussion showed that solutions will derive both from within the pharmaceutical framework and beyond. Member States also flagged that the global dimension of this problem should be taken into consideration in order to minimise potential global challenges such as access and inappropriate use.

- Discussions will continue in the next Pharma Committee and Member States were invited to send further ideas in advance.

5. Duplicate marketing authorisations for biological medicinal products

The Commission presented a summary of the replies received during the targeted stakeholder consultation relating to the possible revision of the note on the handling of duplicate marketing authorisation applications for biological medicines in order to avoid unintended effects for biosimilar products. The summary report to be published after the Committee meeting and annexed to working document Pharm 780. The Commission also outlined its preliminary reflections on revising its interpretative note on duplicate marketing authorisations stressing the exceptional nature of such authorisations and exchanged views with the members of the Committee. Member States shared their experiences and thoughts on the effect of duplicate marketing authorisation of biological medicinal products on the uptake of biosimilars.

- Member States welcomed the summary of the targeted public consultation and exchanged views with the Commission and EMA on the proposed amendments to the Note.

6. Market launch of centrally authorised products

The Commission informed the group about the activities of the ad-hoc WG on market launch of centrally authorised products and presented the initial findings of the three work strands:

- Improve knowledge on the roll out of CAPs
- Increase transparency on the actual roll out of CAPs
- Legal interpretation of the sunset clause

- The work on this issue is ongoing and specific proposals will follow in a forthcoming Pharmaceutical Committee meeting for endorsement by the Committee.

7. Presentation of the Ernst & Young final report: "Study on Marketing Authorisations"

The contractor presented the final conclusions of the study and the Commission responded to questions on the next steps of the process. The report will be shared with Member States and EMA for comments ahead of final publication.

8. International relations

The Commission provided a state of play regarding the WHO Listed Authorities (WLAs) initiative following the ongoing discussions at the HMA. As this WHO initiative is progressing, it is important for the EU to speak with one voice and act in a coordinated manner.

The Commission also updated the members of the Committee on the ICH Q12 guideline ("Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management") which is expected to be adopted by the ICH Assembly at its next meeting

in mid-November 2019 and exchanged views on the position it will take.

9. A.O.B.

- Next Pharmaceutical Committee meetings: 17 December, 2 April 2020 (TBC), 21 October 2020 (TBC)

- 2-3 December 2019: SANTE/B1 workshop for Member States on Oncology Medicines, in Brussels.

- 28 November 2019: publication of the EU State of Health Companion Report with a dedicated chapter on breaking down silos for safe, effective and affordable medicines.

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