



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 767

PHARMACEUTICAL COMMITTEE

1 April 2019

82nd meeting

SUMMARY RECORD

The Pharmaceutical Committee held its 82nd meeting on 1 April 2019, in Brussels. The meeting was chaired by Olga Solomon, Head of Unit SANTE B5 – *Medicines: policy, authorisation and monitoring*.

1. ADOPTION OF THE AGENDA

The draft agenda (PHARM 761) was adopted without changes¹.

2. MODUS OPERANDI OF THE PHARMACEUTICAL COMMITTEE, LESSONS LEARNT FROM THE STAMP AND UPDATE ON ITS ACTIVITIES

The Commission set the scene by inviting Member States to bring the Pharmaceutical Committee closer to its roots of being a consultative committee, where the focus is on the discussion of certain policy matters, rather than being a forum for exchanging information and updates on current activities.

The Committee members agreed with the Commission's proposals and recognised that the STAMP has been very suitable for more in-depth and technical discussions, but the mandate for such a specific expert group is limited in time. It was agreed to apply the learnings from STAMP and to have more strategic and technical discussions in the Pharmaceutical Committee also given its policy and regulatory relevance.

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

The Commission highlighted the need to create synergies when relevant (e.g. with Heads of Medicines Agencies (HMA) and its sub-groups; colleagues dealing with health technology assessment) and to avoid duplication with other working groups.

The Commission gave a short update on the STAMP work on repurposing of medicines. In June 2018, the proposal for a framework on repurposing was discussed and further developed in the December 2018 and March 2109 STAMP meetings. STAMP had reached an agreement on the principles of the framework and the idea that these should be tested through a pilot. The Committee members acknowledged the work carried out so far and the challenge of protecting innovation. The next steps concern the implementation of a pilot to test and monitor the framework. The final documents will be presented at a future meeting of the Pharmaceutical Committee.

3. AVAILABILITY AND ACCESS

i. Access to orphan and paediatric medicines: discussion in the context of evaluation of the current legislation

The Commission introduced the topic including the timelines (background document: PHARM 763). The results of the evaluation of the EU Orphan and Paediatric Regulations should be published before the end of the year (Staff Working Document²). The contractor for the study supporting this evaluation presented preliminary main findings, following the better regulation principles (relevance, effectiveness, efficiency, coherence, added-value).

Several Member States shared their views on the findings.

ii. Market launch of centrally authorised products

The Commission made a brief introduction to the topic and the main points for discussion (background document: PHARM 764).

The topic of access to medicines is of recurrent debate and, more recently, has focused on the accessibility and availability of centrally authorised products across the EU. Reasons include delayed market launches and staggered roll-out of those products by companies, or even their decision to market those products in a selected number of countries only. Those decisions are often triggered by commercial strategies or pricing and reimbursement considerations. The lack of availability of products in many Member States is a concern and concomitantly a challenge to the underlying principle of the centralised authorisation procedure.

In some Member States additional transparency measures are in place, which include publishing online information regarding market launches, as well as information on prices.

² The key document that will inform stakeholders and policy makers on the outcome of the evaluation, presenting judgements and lessons learned.

The Committee members welcomed the intention to consider additional actions within the current legal framework, which could provide more transparency on the actual situation and help improve company engagement for a wider roll out of those products. A working group with Member States and the EMA will be created to follow up the discussion and further develop the initiative.

4. INNOVATION AND ACCESS FROM THE REGULATORY, COMPETITION ENFORCEMENT PERSPECTIVES

The Committee had a first reflection on the topic of innovation in the pharmaceutical sector. Particularly, on whether the current legislation has put forward enough/the right incentives for innovation, and catered sufficiently for unmet medical needs of patients.

The Commission presented a recent report on competition enforcement in the pharmaceutical sector³ and its experience with the innovation principle from the broader competition policy perspective. The presentation included several examples of antitrust actions against practices preventing innovation or limiting choice and competition rules supporting procompetitive co-operation on innovation.

The presentation was followed by an engaging discussion. Suggestions of future areas of focus included the need for a lifecycle strategy (beyond price-based incentives), more funding to generate sufficient clinical data, and smarter solutions to make the industry lean more towards patients' needs.

The Commission also invited the Committee members to reflect on need-driven innovation in the context of Horizon Europe and on how to bring the healthcare system needs into the research agenda.

5. HOSPITAL EXEMPTION FOR ATMPs

Hospital exemption for advanced therapy medicinal products (ATMPs) is part of the EU pharmaceutical framework, but its application is a national competence. The application of Article 28 of the ATMP Regulation has led to divergent practices across the EU.

The Committee had a first discussion based on a background document prepared by the Commission services in the light of exchange of views with experts from 17 Member States. The aim was to reach out to the Member States that had not been involved, and to generate more ideas.

Discussion topics included: elements to define “non-routine” basis of production/use of an ATMP in a hospital; decentralised manufacturing; boundaries between hospital exemption and Article 5 of Directive 2001/83/EC; hospital exemption and clinical trials framework; safety monitoring and efficacy monitoring; information to patients/advertising and promotion.

Some feedback was gathered and the Committee members were invited to send further reflections by the end of May. The discussions will continue in the next Committee.

³ <http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/index.html>

The next Pharmaceutical Committee meeting is planned to be held on July 11 2019, in Brussels. The Committee has put forward suggestions of topics for upcoming agenda, which include antimicrobial resistance (AMR), pharmaceuticals and the environment, medicines shortages, and repurposing of medicines; and identified long-term priorities.

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