EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 789

PHARMACEUTICAL COMMITTEE

17 December 2019
Brussels
85th meeting

SUMMARY RECORD

Meeting chaired by Unit B5 – *Medicines: policy, authorisation and monitoring* - Directorate-General Health and Food Safety. The meeting was attended by representatives from the Commission, 25 EU Member States, Norway, European Medicines Agency (EMA), and OECD.

1. Adoption of the draft Agenda

Draft agenda (PHARM 784) was adopted with changes in the sequence of points 4 and 5[1].

2. Adoption of the summary record of the last meeting (Pharm 782) and high level summary of working method and priorities of the Committee (Pharm 783)

The Committee adopted the documents without changes. Both documents to be published on the Committee's webpage after the meeting.

ENSURING ACCESS AND AFFORDABILITY WHILE ADDRESSING SHORTAGES, UNMET NEEDS

3. Evaluation of orphan & paediatrics regulations

The Commission delivered a preliminary report on the main findings of the evaluation. The presentation covered the structure and logic of the evaluation and the results. In essence, the evaluation focused on five main criteria, as laid down in the Better Regulation Toolbox – relevance, effectiveness, coherence, efficiency and EU added-value of the two regulations.

[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

The presentation was followed by an exchange of views with Member States, which were asked to prepare their input around 3 topics:

- Ways to improve the use of **incentives** to redirect investments in areas of unmet need.
- Identify the **limitations of the legal criteria** used in the two regulations to classify products that may receive orphan designations or are subject to the obligations to perform paediatric studies.
- Reflect on mechanisms within the scope of the two Regulations that may contribute to improving **access.**

The discussion brought forward ideas as regards, among others, the system of incentives, determining what is an 'unmet need', innovative clinical trials design, the low prevalence criterion and interaction with ATMPs / personalised medicines, availability and the roll-out of the products in the entire EU combined with public service obligations, interaction with downstream decision-makers, ways to identify which medicinal products may receive orphan / paediatric indication. The outcome of this discussion will further inform the Commission in drafting its Staff Working Document[2]. The SWD will be published in the first quarter of 2020 and a further discussion with the Committee on this issue is scheduled in a follow-up meeting on 12 March 2020.

4. Challenges in access to medicines: updates from the EU/OECD project on pharmaceuticals

The OECD provided an update on its Health Committee work on pharmaceutical policy. Specifically on the two (out of a total of 5) reports on "Capacity building for negotiations and improving the use of managed entry agreements"[3] and "Addressing challenges in access to oncology medicines". The presentation outlined the challenges linked to oncology medicines, which include: escalating upfront costs, uncertainty in clinical benefit and cost-effectiveness, increased budgetary impact, cascades of indications, inequity of access and high patient expectations. The final report on oncology medicines will be available as an OECD Health Working Paper as of March 2020.

5. Development of antimicrobials: how to address market failures

The Commission presented the ideas provided by Member States on new mechanisms that could address the market failure for antimicrobials following the previous meeting of the Committee. The discussion focused on: 1) incentives for new antimicrobials; 2) continuous availability of existing ones and prudent use; and 3) decrease dependence for APIs from third countries.

Sweden presented an innovative pilot project aimed at ensuring access to (existing) critical antibiotics. The pilot is based on public procurement allowing multiple contract

[2] The staff working document for evaluation (SWD) is the key deliverable of the evaluation process, presenting the lead DG's evidence-based judgements and answers to the evaluation questions.
[3] Available for download: https://www.oecd.org/els/health-systems/pharma-managed-entry-agreements.htm

winners, and is planned to start in 2020.

The Committee concluded that all potential solutions focusing on providing the right incentives need to be examined (including those of legal and of non-legal nature). However, before any decisions are made, their impact would need to be carefully assessed without neglecting the aspect of prudent use of antimicrobials, which must be the first response to the problem. While several Member States expressed the view that solutions at EU level are needed, the issue of market failure needs to be approached in a horizontal manner and discussed (potentially in the context of a wider reflection on AMR) within different services of the Commission as well as different decision makers (including payers, HTA bodies) and stakeholders (incl. international bodies).

SUSTAINABLE INNOVATION

6. Pharmaceuticals in the environment

The initiative of the Commission to establish the WG on pharmaceuticals in the environment was welcomed by the Committee, with various Member States expressing an interest in joining. The Commission presented the mandate and objectives of the newly established ad-hoc WG which includes the development of guidance in relation to certain actions and measures foreseen in the Commission Communication that fall under the competence of the Member States [4]. The WG will examine measures aiming to increase awareness and promote prudent use of pharmaceuticals, medical training and professional development programmes. It will also discuss how environmental considerations can be taken into account in the information to be provided to prescribers and, where applicable, in advertising of medicinal products. Finally, it will examine the possibility of reducing waste by optimising the package size of pharmaceuticals and explore ways of collection of pharmaceutical residues. Sweden agreed to chair the group and its first meeting will be held via teleconference call in principle in January 2020. The WG will further discuss the mandate and this will be presented at a next meeting of the Pharmaceutical Committee.

ENSURING SECURITY AND OVERSIGHT OF THE GLOBAL MANUFACTURING SUPPLY CHAIN

7. Update on enhancing oversight of the global manufacturing and supply chain of Active Pharmaceutical Ingredients

One of the priorities identified by the Committee is to enhance the security and oversight of global manufacturing chain. The Commission, relying on the internal analysis, took actions in order to remedy the identified shortcomings of the existing system ensuring the availability of API of sufficient quality. In light of that analysis, the written confirmations do not necessarily provide the desired level of the assurance on the API quality for API's coming from third countries. The Commission presented an update on the actions

[4] COM(2019) 128 final https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

undertaken in order to address this issue among which is to promote listing third countries, explore possibilities towards ensuring better oversight but also to address the issue of increased dependency on third countries for APIs.

8. Update on the ICH Q12 guideline

The Commission updated the Committee on the issue mentioning that the Q12 guideline on the Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management adopted by the Regulatory Members at the ICH Assembly in Singapore (November 2019). The introduction of the Q12 guideline clarifies that the extent of the flexibility provided for in ICH Q12 is subject to the regulatory framework in place and therefore encourages Regulatory Members of ICH to provide publicly available information about the implementation of ICH Q12 in their region. The CHMP is expected to adopt the ICH Q12 guideline in the first months of 2020.

9. A.O.B.

- The Commission briefly presented an information point on State of Health in the EU and explained what these reports are about (the big trends in transformation of health systems, vaccine hesitancy, digital transformation, access to healthcare, skill mix innovations, affordability of medicines). A dedicated chapter in the companion report analysed ways in which national health systems can conduct sound governance principles, appropriately use medicines in hospital settings, incur savings resulting from the use of generics and biosimilars, build capacity to appraise comprehensively the value of medicinal technologies and share best practices on pricing and procurement methods to avoid potential negative effects on patients' access to medicines.

- The next Committee meeting is scheduled on 12 March 2020.

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