EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public Health, Cancer and Health security
Medicines: policy, authorisation and monitoring

PHARM 841

PHARMACEUTICAL COMMITTEE
21 October 2022
100th meeting

SUMMARY RECORD

The meeting was organised in hybrid format and was attended (online and physically) by representatives from the Commission, 27 EU Member States, Norway, Iceland, the European Medicines Agency (EMA) and the Council of Europe (EDQM).

1. Adoption of the draft Agenda of the meeting

The draft agenda (PHARM 839) was adopted with the addition of a point under A.O.B.

Key questions arising from the technical analysis of the revision of the general pharmaceutical legislation

2. Novel incentives for the development of antimicrobials addressing antimicrobial resistance (AMR) and prudent use measures

The Committee discussed *novel incentives for the development of antimicrobials addressing AMR*. In that context the members of the Committee discussed the the option of a transferable exclusivity voucher (TEV) as a possible solution to address the market failure to develop novel antimicrobials that address Antimicrobial Resistance (AMR). Such a voucher could, in principle, extend the data protection period of a medicine. It could be used on another product of the company's own portfolio or sold to another company. The discussion covered the principles applicable to such voucher, the conditions of granting, use and transfer, as well as its advantages and disadvantages with regards to rewarding innovation for antimicrobials and limiting the costs for health systems. Several Member States expressed concerns in relation to the potential high cost of such vouchers for the health systems.

The Committee also discussed *prudent use* of antimicrobials, as a way of addressing AMR. Among other suggestions made, discussions included the prescription status of antimicrobials, the possibility for the introduction of an AMR lifecycle management plan and an enhanced environmental risk assessment.

3. Revised hospital exemption for ATMPs

Members of the Committee discussed how to achieve more harmonisation and standardisation of the hospital exemption clause and how to ensure better evidence generation of this process.
The Committee also discussed the need for increasing transparency through information of state of play of the implementation of the measure and the impact of such a measure on all the actors administering therapies under the hospital exemption, taking also into account the safety and efficacy of such products.

4. Formal recognition of HMA network in legislation

The aim of this point was seeking the feedback on a possible formal recognition of Heads of Medicines Agency (HMA) network in the legislation. HMA network is an established cooperation between the national regulatory authorities to support the implementation and application of the EU pharmaceutical legislation. The Committee also discussed aspects relating to the governances provision of the HMA network.

5. Measures to improve access to medicines and market launch in all Member States

With the aim of increasing patients' access to medicines, the Committee discussed the principles of the modulation of incentives around market launch and practical aspects of implementation. The principle behind the measure was explained by the Commission. In addition, the Committee discussed how to ensure continuous supply and access to medicines if such incentive is given, as well as the relationship of this measure with post authorisation decisions.

6. Strengthening the Environmental Risk Assessment (ERA) of medicines

The Committee examined the possibility of strengthening the ERA. Members of the Committee exchanged views on how a strengthened ERA should be carried out. The role of manufacturing in ERA was also discussed, as well as the relationship with antimicrobials. A stepwise application of the measure, covering some categories of medicines first, was also raised. Moreover, it was also discussed if insufficient data on environment could be considered as a ground for refusal of a marketing authorisation. In this regard, some of the Member States that took the floor supported an enhanced ERA but highlighted that overall access to medicines should not be negatively impacted by the measure.

7. Active substance master file

This topic covered the principles of the establishment of a certification of the active substance master file (ASMF), granted by the Agency. This certificate would be relevant for subsequent marketing authorisation applications using the same active substance master file, in order to avoid the duplication of assessment. The Committee discussed the relationship that this certificate would have with the Council of Europe (EDQM) Certificates of European Pharmacopeia (CEPs). Most members that took the floor agreed that there should be no duplication of work between CEP and ASMF. One participant argues that there should be a harmonisation between the two systems, i.e. in case there is a CEP it should be used. Others MS argued that applicants should be able to choose freely between CEP and ASMF and that there is no need to prioritise one ahead of the other.

8. Creation of a 'sandbox' provision

The Commission seeked the Member State's experience at national level with regulatory sandbox. The measure was examined as it could be a useful tool in the future-proofing of pharmaceutical legislation and could provide a solution for applying the regulation to innovative products that do not directly 'fit' with the established procedures and enable proactive regulatory learning. The possible use of sandboxes under specific conditions, for very limited medicinal products and for a limited period of time under strict supervision was discussed. The Committee also discussed the safeguards that would be necessary for the measure to be effective. It was highlighted that sandboxes are resource intensive and therefore they should be limited in time. They would need to respect the principles and the high standards set by the legislation and should not replace clinical trials. During the discussion it was also highlighted that data from sandboxes should be used for only regulatory purposes and when robust enough evidence became available, 'normal' marketing authorisation should be the appropriate path for these innovative products.

9. Establishment of a mechanism to clarify the regulatory status of products

The Committee discussed the creation of a central classification mechanism, based on a non-binding scientific recommendation from an EMA scientific committee. Such scientific advice would help clarify the regulatory status of borderline products. The Committee discussed different levels of ambition for the mechanism and its interplay with similar mechanisms in other legal frameworks.

10. **Points of information**

a. Review of the variations Regulation in 2023

The aim of the revision of the variations Regulation by the end of 2023 was explained. This revision will take place under the current legal framework to address some identified weaknesses and it is not linked with the revision of the general pharmaceutical legislation.

b. Conclusion of the market launch pilot

The conclusions drawn on the market launch pilot were shared. The conclusions will be taken into account in the ongoing revision of the pharmaceutical legislation was by Members of the Committee.

11. A.O.B.

The Committee held an update on the state of play of the Repurposing Observatory group actions on Repurposing. It was announced that EMA was selected as the new chair of the group supported by Spain.