EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 817

PHARMACEUTICAL COMMITTEE
11 December 2020
Brussels
92nd meeting

SUMMARY RECORD

The meeting was organised via video conference and was attended by representatives from the Commission, 25 EU Member States, Norway, Iceland and the European Medicines Agency (EMA) and EDQM.

1. Adoption of the draft Agenda of the meeting

The draft agenda (PHARM 812) was adopted.

2. Revision of the orphan and paediatrics medicines legislation

The Commission presented the **inception impact assessment and the options for revision of the orphan and paediatric legislation** aiming for a legislative proposal in Q1 2022.

Apart from the baseline scenario, common elements and four options were presented for each of the legal acts. The paediatrics legislation includes variations of the linkage to supplementary protection certificates (SPC) and incentives in combination with new modalities for the paediatric use marketing authorisation scheme, the level to which a product addresses an unmet paediatric need and the possibility of introducing novel incentives.

For orphan medicines, policy options vary from introducing fixed and variable elements to the duration of the market exclusivity, changes to the prevalence threshold to the possibility for novel incentives beyond the current market exclusivity to incentivise unmet medical need in rare diseases and links of incentives to availability/competition/access requirements.
Some members of the Committee mentioned that critical review of the incentives system is also needed and that the forthcoming impact assessment should examine the burden on national competent authorities. A public consultation is planned for 2021 where more ideas could be collected to refine the options.

The Commission also **presented the concept of unmet medical needs and possible criteria** in the context of orphan and paediatric medicines (available treatments, disease burden and patient population).

Members of the Committee discussed this concept, including the possibility of a more principle-based (criteria) approach, and urged to take the concept broader than orphan and paediatrics. More specific discussions will follow including on the link between unmet medical needs and incentives in e.g. STAMP meeting in January.

3. Updates

a. Off label use, compassionate use, repurposing Observatory Group

Spain presented the activities of the work on these issues.

b. Vaccines strategy

The Commission presented the temporary flexibilities and timelines of authorisation for possible COVID-19 vaccines stressing the need for an extraordinary permanence to accommodate the decision making process for authorisation both at EU and national level.

c. Market launch pilot project

After final endorsement from the ad-hoc working group in January there will be an online publication to raise awareness and launch the pilot in mid-March 2021. The pilot project is planned to run for 18months.

4. Pharmaceutical Strategy for Europe: Presentation of the actions in the Commission communication and next steps

The Commission presented some of the 55 actions foreseen in the Commission Communication on a Pharmaceutical Strategy for Europe. These were presented in an action table and covered the following areas:

- Antimicrobial resistance (AMR)
- Unmet medical needs
- Access to medicines
- Affordability of medicines for patients and health systems' sustainability
- Providing a fertile environment for Europe's industry
- Enabling innovation and digital transformation
- A sound and flexible regulatory system
- Enhancing Europe's crisis response mechanisms
- Securing supply of medicines and avoiding shortages
- High quality, safe and environmentally sustainable medicines
- Ensuring a strong EU voice globally

The Commission also gave an overview of the timeline of the strategy's main deliverable, which is the revision of the basic pharmaceutical acts with a view for a proposal in Q4 2022.

Finally, the Commission presented its proposal for the governance of the implementation of the strategy which will be based on existing structures and fora such as the Pharmaceutical Committee. The following meetings will include joint sessions with policy makers in relevant fields (e.g. pricing and reimbursement, medical devices, health technology assessment) as well as a more thematic discussion agenda, which caters to the specific deliverables' timelines.

In the next meeting, the Committee will discuss a proposed work plan implementing those actions relevant to its remit.

5. Update on Brexit readiness

This meeting point was chaired by Unit B4 - *Medical products: quality, safety, innovation* Directorate-General Health and Food Safety. The meeting was organised via video conference and was attended by representatives from the Commission, 18 EU Member States, Iceland, Norway, the European Medicines Agency (EMA), and representatives from CMDh. HMA representatives were also invited.

The Commission stressed that we are close to the end of transition period (end of 2020).
The Commission UK task force (UKTF) updated Member States on the state of play of negotiations of the future partnership agreement, implementation of the Withdrawal Agreement, IE/NI Protocol, readiness and contingency for the end of the transition period.
The Commission stressed that as from 1st of January 2020 UK has withdrawn from the EU and has become a third country.
The Commission presented the draft of the Commission Notice on the Application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period.
This Notice brings the necessary clarifications as regards the application of the EU pharmaceuticals legislation in view addressing the outstanding BREXIT issues in the EU Member States concerned (i.e. Malta, Cyprus, Ireland) and Northern Ireland, and in particular as regards the rules for the importation requirements for the human and veterinary medicinal products, the batch testing and the requirements relating to the implementation of the falsified medicines Directive. The time is limited to 31 December 2021.
Member States were requested to monitor the situation and report to the Commission on a monthly basis the progress on the derogation mentioned in the Notice.
Member States asked if the batch testing waiver based on Art 20b applies only to the small markets as no MRA is foreseen. The Commission replied that some Member States may still have products for which the testing is in the UK. We now expect all markets others than the Member States concerned and mentioned in the Notice to act on the operators maintaining the batch testing in the UK after the transition period is over and alternative medicines exist. Nevertheless, the Commission cannot prevent the competent authorities to waive the batch testing based on Article 20b in justifiable cases.

6. A.O.B.

Next scheduled meeting: 17 and 22 February 2021