EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 828

PHARMACEUTICAL COMMITTEE
17 September 2021
96th meeting

SUMMARY RECORD

The meeting was organised via video conference and was attended by representatives from the Commission, 23 EU Member States, Norway, Iceland and the European Medicines Agency (EMA). Council of Europe (European Directorate for the Quality of Medicines) (only part 1)

1. Adoption of the draft Agenda of the meeting

The draft agenda (PHARM 826) was adopted.

2. Titanium dioxide: prohibition as a food additive and its impact for medicinal products

The Commission informed MS of the rationale behind the May 2021 EFSA recommendation to ban the substance in food (additive - E171) due to its possible genotoxicity. EMA presented its impact analysis on pharmaceutical quality based on the data contained in the EFSA assessment. The prohibition of Titanium Dioxide as a food additive has a knock-on effect on medicines as there is a legal relationship between the pharmaceuticals legislation and the food additives legislation whereby the use of colours in human and veterinary medicinal products is allowed only if they are authorised as additives in food. The substance is very widely used in human and veterinary essential medicines. Alternatives are at present technically possible, but its immediate implementation would have a negative effect on the quality, safety and efficacy of medicinal products, and on their availability. The possibility of reformulation of affected medicinal products was also discussed. Several Member States raised concerns of the impact of this proposal on the availability of medicinal products, especially on older products (end of life cycle) with low volume sales and/or low margins.
In order to address any concerns and to avoid any negative effects of an immediate withdrawal, the Commission presented a draft legal proposal which foresees that the

substance should remain provisionally on the list of authorised additives to allow its use in medicinal products as a colourant, pending the development of adequate alternatives to replace it while ensuring the quality, safety and efficacy of the medicinal products concerned. It also foresees that the pharmaceutical industry makes any possible efforts to accelerate the research and development of alternatives that would be used as a replacement for titanium dioxide (E 171) in medicinal products, and to submit the necessary variation to the terms of the marketing authorisations concerned. Within three years of the entry into force of the legal measure, in consultation on the European Medicines Agency, the Commission will review the necessity to maintain titanium dioxide (E 171) or to delete it from the Union list of food additives for the exclusive use as colour in medicinal products.

3. Therapeutics strategy

The Commission presented the strategy explaining that it entails the establishment of a broader portfolio of ten potential COVID-19 therapeutics by October 2021 and identifying five of the most promising ones. The current selection contains both repurposed medicines and monoclonal antibodies. There are currently no particular rewards nor financial instruments linked to the portfolio. However, relevant candidates will be able to benefit from regulatory flexibilities, scientific support from EMA, funding opportunities under the Innovation Booster, HERA and EU-FAB. Also match-making events, joint procurement, advance purchase agreements, innovation partnership and RescEU stockpiling could be deployed. A European Expert Group on SARS-CoV-2 variants will be responsible for compiling the Union portfolio on COVID-19 therapeutics. The members of the committee discussed the selection criteria and target product categories.

4. Updates on:

a. Revision of general pharmaceutical acts

The Commission presented the first results of the consultation process, namely the feedback received to the roadmap/inception impact assessment of the revision of the general pharmaceuticals legislation, which was published in March 2021. A public consultation will take place between 28 September to 21 December 2021. The pharmaceutical committee will continue to be the main forum for discussion with policy questions (unmet needs, system of incentives and others). The Commission also presented the topics selected to feature in a series of technical concept papers which are documents prepared by the regulatory network (HMA/EMA) to support the review and future-proofing of the pharma legislation with regard to technical aspects of the legislation. Member States fully support the concept papers and are ready to engage in the consultations. A specific question on the solutions considered for medicines containing GMOs as referred to in the pharmaceutical strategy was asked. The EC replied that the issue of GMO is being discussed in a separate forum with GMO authorities. The Commission will also address the use of GMOs in medicines under the pharmaceutical strategy.

b. Revision of the orphan and paediatrics legislation

The Evaluation of the EU orphan and paediatric legislation was published in August 2020. An impact assessment of revision of EU legislation on medicines for children and rare diseases is ongoing. The relevant Open Public Consultation ended on 30 July. Targeted surveys and interviews with stakeholders are being analysed. The proposal for revision of legislation is due in the 4th quarter of 2022.

c. Activities on security of supply

The Commission updated the Committee on the study on shortages the final report of which is due in November. It will contain quantitative data on shortages in the EU and their causes, an assessment of current legal provisions, identification of potential policy solutions to shortages. Its findings will feed in the revision of the general pharmaceutical legislation. The Commission also updated on the structured dialogue the first phase of which ended in July after a number of meetings with stakeholders representing industry, patients' and health professionals', Member States and academia. They make a series of observations and recommendation on (1) how robust the EU supply chains are, (2) how to identify critical medicines and to map manufacturing capacities (3) analyse the vulnerabilities along the supply chain, taking account of different supply chain stages and specificities of different products (4) the key innovation needs to preserve and enhance EU manufacturing footprint; the identification of barriers or challenges to manufacturing in the EU being globally competitive and challenges that are linked to the digital and green transitions.

d. Pharmaceuticals in the environment

The Commission informed the committee about the ongoing EU Survey on the pharmaceuticals in the environment: The members of the ad-hoc Working Group on pharmaceuticals in the environment prepared a questionnaire for Member State authorities to provide a comprehensive overview of the practices in all EU/EEA Member States concerning pharmaceuticals in the environment.

POST BREXIT SESSION

5. Post-Brexit medicines supply issues and the implementation of the Protocol on Ireland / Northern Ireland: the proposed solution for continued access to medicines for human use in Malta, Cyprus, Ireland and Northern Ireland

The Commission informed about the elements of the two draft Commission acts to address the outstanding post-BREXIT issues for human medicines due to the implementation of the IE/NI Protocol:

- The draft Commission legislative proposal that will amend in a targeted manner Directive 2001/83/EC and the clinical trials rules.
- the draft Commission Delegated Regulation amending COM Delegated Regulation 2016/161 to address the issues related to the safety features and the falsified medicines.

These acts are the Commission Services solution with a targeted and conditional derogatory regime from certain regulatory requirements for human medicines to ensure access to nationally authorised medicines in Malta, Cyprus, Ireland and in UK in respect to Northern Ireland and ensure implementation of the IE/NI Protocol, while including the necessary safeguards, not to jeopardize the internal market.

The Member States, in particular those most concerned by the post-BREXIT challenges, welcomed the presented amendments. The Commission will follow-up bilaterally with the Member States concerned, as needed.

6. A.O.B.

Next scheduled meeting: 17 November 2021