EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 807

v.2

PHARMACEUTICAL COMMITTEE

18 September 2020
And
21 September 2020
Brussels
89th meeting

SUMMARY RECORD

Session of 18/9 chaired by Unit B5 – *Medicines: policy, authorisation and monitoring* – Session of 21/9 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, 25 EU Member States, Norway, Iceland and the European Medicines Agency (EMA).

1. Adoption of the draft Agenda and draft minutes of the 88th meeting

Draft agenda (PHARM 804) was adopted.
The draft minutes (Pharm 803) were adopted.

2. Pharmaceutical strategy for Europe

The Commission presented the state of play of the preparation for the Communication focusing on the results from the feedback mechanism and the messages from other consultation actions. The aim of the meeting was to discuss specific comments and proposals on actions coming from the Member States. The Commission explained that it is not possible to share at this time the actual draft Communication text as is being discussed internally at inter services level, therefore the discussion was supported by a background document focusing on actions coming from the Member States' input in the consultation process. Most Member States stressed the importance of having insight in the direction of the Communication's Strategy in order to be able to make specific comments on what the Commission is contemplating and reiterated their expectation to be involved in the process. The Commission explained that the Communication actions will be on a rather high level and that more detailed discussions would take place at the implementation phase.

Concrete actions were discussed in the following areas:

- Crisis preparedness and security of supply (understanding shortages and need for diversification of supply)
- Research, innovation and digital transformation (adaptation of evidence requirements, digital infrastructure and knowledge/ resource capacity to deal with innovation as well as repurposing).
- AMR and other unmet medical needs (discussion of a common definition of unmet medical need, incentives, new ways to generate public value and funding).
- Affordability (aligning all steps of the documentation chain, transparency on pricing, joint procurement and good practices on procurement, competition, conditionality of public funding for innovation linked to fair prices).
- Regulatory efficiency (division of the market in patented and off patent medicines, use of leaflets and multicountry/ multi-language packaging, variations, active substance master file)
- International aspects (international regulatory leadership, cooperation with WHO, environmental and quality considerations in our relations with international partners to ensure level playing field, supply chain transparency).

3. Memorandum of Understanding (MOU) on regulatory flexibilities for COVID-19 vaccines

The Commission provided updates on the MOU for regulatory flexibilities of COVID 19 vaccines. The part on the labelling and packaging flexibilities for authorised COVID-19 vaccines is now considered agreed and endorsed; no specific comments were received during the written consultation period. With regards to the emergency use part of the MoU, it was decided to currently pause further work in this area.

End of session of 18 September 2020

Session of 21 September 2020

4. Brexit readiness

The Commission recalled the BREXIT three years of intensive preparedness efforts so far.

The Commission stressed that as from 1st of February 2020 UK has withdrawn from the EU and has become a third country. The Commission underlined that BREXIT preparedness with the outstanding issues is essential and should be stepped up to ensure BREXIT readiness by the end of transition period (end of 2020). As of January 2021, Member States should be ready to implement the IE/NI Protocol that is part of the WA. EU pharmaceuticals acquis applies to and in UK in respect to NI. Commission notice on BREXIT readiness of March 2020 provided guidance on what this means for the pharmaceuticals sector.

Overall, from our previous meetings, there is high level of preparedness in our area so far and changes and efforts continue during the transition period. Some Member States due to their market ties with UK are more affected than others. The meeting took stock of the

BREXIT readiness in view of ensuring that the remaining outstanding issues are solved as soon as possible.

The Commission UKTF gave a state of play of the Withdrawal Agreement, IE/NI Protocol and the EU-UK Negotiations. The HMA Brexit Task Force followed with a presentation with the readiness activities, EMA on the state of play of the centrally authorised products and CMDh on the state of play of the nationally authorised products The open discussions with the Member States demonstrate that BREXIT efforts are stepped up and overall there is high level of preparedness.

The situation of the centrally authorised products is under control, no critical product of concern and the EMA continues to monitor the ongoing regulatory changes to be done by the industry by the end of the transition. EMA will further follow this up directly with the industry stakeholder and also with a possible event also in view of addressing the IE/NI Protocol implementation. EMA also addresses the upcoming changes related to the UK partial access to its IT databases/systems to implement the IE/NI Protocol.

The situation for the nationally authorised products, under the Member States remit, is more complex. Member States invested a lot of efforts in getting ready by the end of the transition period. Commission support in this regards and Commission notices/guidance were much appreciated. However, there are ongoing regulatory changes to be made by industry. There are still some outstanding issues for some Member States that have stronger ties with the UK. Overall, certain medicines are affected as they rely on the UK and the industry is the one to make the needed regulatory changes. Some Member States reported that the companies with a QP in the UK do not have a commercial interest to move their activities from UK.

The Commission welcome the HMA decision to reactivate its Brexit Task Force for at least the remainder of 2020 and coordinating platform in months ahead and bring together heads of national agencies and EMA, if and when needed. HMA will organise also a BREXIT state of affairs in November 2020. CMDh will further discuss within the network to have a coordinated approach for the outstanding issues and bring further support to the Member States, and in particular to the ones mostly concerned. CMDh will further reach out to stakeholders as well via their press releases and within an interested parties event also in November 2020 to further check on the outstanding issues.

The Commission stressed that BREXIT readiness activities are imperative and urged Member States to step up even further their BREXIT preparedness efforts and to further reach out to industry to make the outstanding regulatory changes until the end of the transition period to be fully ready for BREXIT, monitor the progress made as regards their compliance in due time and also to apply/implement as of January 2021 the Withdrawal Agreement and IE/NI Protocol. In view of addressing the outstanding issues, Commission had fruitful discussions with the Member States, replied to Member States questions further raised and offered further cooperation and collaboration to facilitate as much as possible the BREXIT readiness of the network.
The Commission also gave the state of play for the readiness for the Falsified Medicines Directive and the Clinical Trials.

5. A.O.B.

Next meeting. 21 October 2020