EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 813

Extraordinary PHARMACEUTICAL COMMITTEE

17 November 2020
Brussels
91st meeting

SUMMARY RECORD

This meeting 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, 22 EU Member States, Iceland, the European Medicines Agency (EMA), and representatives from CMDh and HMA.

1. Adoption of the draft Agenda

Draft agenda (PHARM 812) was adopted.

2. 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 The Commission stressed that as from 1st of February 2020 UK has withdrawn from the EU and has become a third country.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, MS 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 MS 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. In this meeting the remaining issues were discussed for which the Commission presented a way forward.

The Commission UKTF gave a state of play of the Withdrawal Agreement, IE/NI Protocol and the EU-UK Negotiations. EMA gave a presentation 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 MS 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, with no critical medicines at risk of supply. EMA continues to monitor the ongoing regulatory changes to be done by industry by the end of the transition. EMA will further follow this up directly with the industry stakeholder and will also organise a BREXIT industry stakeholders meeting on 30th of November, in view of addressing the IE/NI Protocol implementation. EMA is also addressing the upcoming changes related to the UK partial access to its IT databases/systems to implement the IE/NI Protocol following the Commission decision.

The situation for the nationally authorised products, under the MS remit, is more complex. MS 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. Some changes were made and the situation was a bit improved since the last meeting, however there are still some outstanding issues for some MS 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.

CMDh discussed with the UK the approach forward as regards the ongoing and future MRP/DCP procedures with UK in respect to NI, and the discussions should continue to clarify the divergences in views. Like EMA, CMDh will also make the necessary technical changes as regards to the UK partial access to its databases granted via the Commission decision.

The Commission stressed that BREXIT readiness activities are imperative and urged MS 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 presented a pathway to compliance to address the outstanding issues related to the BREXIT readiness, IE/NI Protocol, the batch testing and for implementing the falsified medicines directive. The proposed solutions were appreciated by the MS and we had fruitful discussions with the MS. Some MS asked to clarify if the measures are only applicable for the BREXIT affected Member States. A Member State indicated that June 2021 could be too short to have the regulatory changes.

Two Member States asked if the negotiation of the future relationship may lead to mutual recognition agreement on GMP and waiver on batch testing. The UKTF explained that it is not foreseen. A Member State asked if we can confirm that batches placed on the market can circulate after then end of the transition period without retesting. UKTF referred to Articles 41 and 42 of the Withdrawal Agreement which allows that batches placed on the market (with a transaction with a wholesaler) can continue to circulate on the internal market and the burden of proof is on the operators to demonstrate that. A Member State raised the outstanding issue of the Article 126a authorisations as it mostly relies on the UK and indicated that the fees of the procedures are a factor that determines in practice the inclusion of the Member State in the MRP/DCP procedures for repeated use. The promotion of a "zero day procedure" could be a solution and could ensure that also smaller markets affected by BREXIT could be included in the procedures under the current framework. The HMA representative also offered its support in further discussing in the next HMA meeting the outstanding issues related to the nationally authorised products in smaller markets to find further support from the HMA network, in particular to address the situation of the 126a marketing authorisations to ensure that the Member States affected

could be included in the MRP/DCP procedures for repeated use. MS were asked to provide their input to the Commission proposed approach forward in writing by Wednesday 18 November eob.