EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 821

PHARMACEUTICAL COMMITTEE
17 and 22 February 2021
Brussels
93rd 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), European Free Trade Area. Council of Europe (European Directorate for the Quality of Medicines) (only part 2) and Chairperson of the Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) and UK Task Force representative (only part 1)

Part 1
Wednesday, 17 February 2021

1. Adoption of the draft Agenda of the meeting

The draft agenda (PHARM 818) was adopted.

2. Post Brexit framework

The Commission presented the state of play of the post-BREXIT framework, the revised Commission BREXIT Notice and the Commission Delegated act to address the Falsified Medicines Directive and other outstanding issues.

The Commission presented the approach for any non-compliant products and suggested that Member States coordinate its implementation within the CMDh as regards the nationally authorised products (NAPs). The Commission indicated that we are now in the implementation phase of the two EU-UK Agreements: the Withdrawal Agreement, which includes the Protocol on Ireland / Northern Ireland, and the Trade and Cooperation Agreement (provisionally in force since 1 January 2021). Guidance was already provided by the Commission, EMA and CMDh to stakeholders and Member States. EMA informed that there were no regulatory non-compliances for the centrally authorised products for human medicines. (There were just three veterinary products that EMA will further monitor and follow up). Two Member States concerned by the recent Commission Notice on markets historically dependent on medicines supply from

or through Great Britain [1].informed that many companies applied for the batch testing exemption and they were currently implementing the other aspects of the Notice as well. The CMDh representative informed there were still some outstanding issues for which companies needed to make the required changes, in particular as regards compliance with establishment requirements. Bilateral discussions on these matters were ongoing between the Commission and the UK authorities in the framework of the implementation of the Protocol on Ireland / Northern Ireland.
The EU-UK Trade Cooperation agreement was also presented and in particular its Annex on medicines: it was underlined that Member States and UK can on this basis exchange the inspections documents and Good Manufacturing Practices Certificates as before the end of the transition period.

The Commission informed that implementation of the above Commission Notice should continue and the Member States concerned and UK in respect to Northern Ireland were expected to report on the progress made during 2021 as required by the Notice.

[1] Commission Notice – 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
(2021/C 27/08) OJ C 27, 25.1.2021, p. 11 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0125(01)&from=EN)

Part 2
Monday, 22 February 2021

3. Discussion of a work plan of the Committee on the revision of the general pharmaceutical acts

The Committee adopted a proposal made by the Commission for a work plan supporting the revision of the pharmaceutical legislation by 2022. Discussions will focus on certain topics grouped under the following thematic areas: access to affordable medicines, innovation, antimicrobial resistance (AMR), pharmaceuticals in the environment, supply chain, resilience and attractiveness of the regulatory system.

The topics to be discussed will be fine-tuned based on written comments by the Committee and discussions will take place in workshop and full committee format with the involvement of the group of pricing authorities and payers, health technology assessment (HTA) bodies and medical devices authorities where relevant. Workshops among regulators will take place as of March. These discussions will feed the evaluation and impact assessment of the pharmaceutical legislation.

Additional workshops and meetings with stakeholders will be organised as well once there has been an initial dialogue among regulators.

4. Revision of the orphan and paediatrics medicines legislation: discussion of the concept of "unmet medical need" following the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) discussion

The link between unmet medical need (UMN) and the options included in the Inception Impact Assessment of the revision of the orphan/paediatric legislation were discussed. The exchange will feed the impact assessment study and to better define the options for the revision of the Regulations.

The outcome of the discussions in the STAMP meeting held on 29 January 2021 was presented. Several participants underlined the importance to balance the market exclusivity with timely competition and uptake of generic and biosimilar medicines, and the need for graduation of the incentives and to consider rewarding real innovative products. The availability of a product in all Member States was flagged as a critical aspect in the discussion about the incentives, although the link to pricing and reimbursement was also acknowledged.

Additional meetings on the concept of unmet needs will take place in April and May.

5. Updates: "Ad hoc group on vulnerabilities, including dependencies, of the global supply chains" and on the structured dialogue

The Commission updated the Committee on the activities of the ad-hoc working group and the 26 February 2021 launch event with high-level representation from the Commission, European Parliament, industry, Member States, patient groups, health professionals and the research community.
The Commission also informed the Committee about the launch the operational phase

and discussed the work areas of the first phase of the structured dialogue (information gathering) which will end in September that will allow to inform other actions under the strategy and proceed to policy recommendations.

6. A.O.B.

Next scheduled meeting: 26 May 2021 (TBC)