EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 760

PHARMACEUTICAL COMMITTEE

23 October 2018

81th meeting

SUMMARY RECORD

The Pharmaceutical Committee held its 81th meeting on 23 October 2018, in Brussels, chaired by Olga Solomon, Head of Unit SANTE B5 – *Medicines: policy, authorisation and monitoring*.

Agenda

- **The draft agenda (PHARM 751) was adopted.**

1. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

i. Update on Court cases

The Commission called the Pharmaceutical Committee's attention to recent rulings of the European Court of Justice, and the General Court, especially:

- Case T-80/16, judgment of 22 March 2018 (orphan product designation)
- Case C-680/16P, opinion of 4 October 2018 (EU review procedure under Article 31 of Directive 2001/83/EC)
- Case C-557/16, judgment of 14 March 2018 (decentralised procedure – responsibilities of concerned Member States)
- Cases C-423/17, opinion of 4 October 2018 (carve-out of indications due to patent reasons)
- Additionally, reference was made to some pending cases, including case C-29/17 (off-label use).

2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

i. Feedback from the 9th meeting of the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP)

The Commission presented an update on the 9th meeting of the STAMP which had taken place on 8 June 2018. There had been a continuation of the discussion on the repurposing of established medicines/active substances during which a proposal for a framework for repurposing had been presented to STAMP. There had also been presentations and updates on activities related to real world data, the study report in the impact of pharmaceutical incentives on innovation, availability and accessibility of medicinal products and the ad hoc Synergy Group of health technology assessment and regulatory bodies.

Related documents and presentations can be found on the webpage of the STAMP Expert Group:
http://ec.europa.eu/health/documents/pharmaceutical-committee/stamp/index_en.htm.

ii. Members States' reports on the audits of their pharmacovigilance systems

The Commission presented an overview of Member States biennial reports on audits of their pharmacovigilance systems submitted for the reporting period ending in September 2017 (PHARM 755).

3. LEGISLATIVE ISSUES

i. Update on the state-of-play of the evaluation of the orphan and paediatric regulations

The Commission presented an update about the ongoing evaluation of the EU Orphan and Paediatric Regulations, which started in December 2017 by the publication of a 'Roadmap' (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-6059807_en).

This evaluation, among others, will be based on the findings of three studies and replies received to targeted and public consultations. The targeted consultations are open until 21 November 2018 and a public consultation until the beginning of 2019.

The Commission will develop a staff working document on the basis of the evaluation results. The finalisation of the document is expected in the 3rd quarter of 2019.

ii. Commission's Report on Product Information Leaflets and related activities

The Commission and the EMA representative provided an update on the activities related to the Commission's report on the current shortcomings in the summary of products characteristics and package leaflet that was adopted in March 2017[1], and subsequent EMA Action Plan[2]. The highest priority was given to electronic product information formats and work towards its implementation started last year.

Members of the Committee were informed that a multi-stakeholder workshop on electronic product information will take place on 28 November 2018 in London organised by the Commission, EMA and Heads of Medicines Agencies (HMA). The aim of the workshop will be to develop and agree on a proposal for key principles for the use of electronic product information in the EU and to set the base for a common electronic standard for EU electronic product information. A 6-month public consultation on the document will be launched at the end of January 2019.

iii. Evaluation of the legislation on blood tissue and cells

The Commission presented a state of play on the evaluation of the EU legislation on blood, tissues and cells. The process is advancing well and consisted a.o. an open public consultation, stakeholder event and several bi- and multi-lateral meetings. National competent authorities (several of which also responsible for pharmaceuticals) and actors in the field of plasma derivatives and advanced therapies participated actively in these activities.

Overall message of the consultation report was that this EU legislation makes blood, tissues and cells safer but needs to keep pace with developments. The presentation highlighted findings that have come forward on donor safety, compensation, (emergency) supply, scope and burdensome oversight tasks. Further points mentioned on coherence and possible inconsistencies towards the pharmaceutical legislation include borderline definitions, starting materials and alignment of oversight. Participants are invited to

[1] Commission report on product information leaflets
https://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf
[2] EMA Action Plan in relations to the Commission report on product information leaflets
https://ec.europa.eu/health/sites/health/files/files/committee/pharm740_3ii_report-on-pil-and-ema-action-plan_0.pdf

discuss possible comments with colleagues in national authorities competent for blood, tissues and cells.

The Commission clarified that it aims to publish the staff working document begin 2019, including an overview of issues related to the legislation, while it is too early to decide on possible follow-up actions.

Participants can send possible comment to SANTE-SOHO@ec.europa.eu by 14 December 2018.

iv. Study on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use

The Commission provided information on the state of play and updated timing of the above-mentioned study.

The purpose of the study is to gather necessary evidence for the next Commission report to the European Parliament and the Council under Art. 86 of Regulation (EC) 726/2004 and Art. 38(2) of Directive 2001/83/EC that is to be adopted by the Commission in 2020. The work on this study by an external contractor started in the beginning of June 2018 and the final version of this external study is to be delivered within 12 months, i.e. by the end of May 2018. The study should cover five "work packages":

1. The European Medicines Regulatory Network
2. Procedures preceding submission of marketing authorisation applications
3. Initial marketing authorisation procedures
4. Post-marketing authorisation procedures
5. Support activities.

The scope of the study comprises centralised, decentralised and mutual recognition procedures (except for subjects falling exclusively within the competence of the Member States). Purely national authorisation procedures are excluded from the scope. The study focuses on the period from 2009 to 2017 and only on the medicinal products for human use.

The data and evidence will be collected through documentary review, interviews, surveys and consultations with the key actors (including the EU institutions, national competent authorities, patient organisations and industry) and national case studies.

4. AOB

i. Shortages of medicinal products

The Commission informed the Members of the Committee on the outcomes of the ad-hoc meeting on shortages of medicines on 25 May 2018. The ad-hoc meeting was an opportunity for the Commission to present the results of their survey of Member State

measures implementing Articles 23a and 81 of Directive 2001/83/EC. The Commission further explained that a 'Paper on the obligation of continuous supply' was agreed at the meeting on 25 May that outlines the responsibilities of marketing authorisation holders and wholesale distributors in relation to Article 23a and 81 of the Directive. The paper also outlines the general principles for Member States considering introducing restrictions of sales within the internal market to address shortages stemming from parallel trade. The summary record of the meeting, summary of Member State responses and the paper on continuous supply have all been published on a dedicated page of the Commission website (https://ec.europa.eu/health/documents/pharmaceutical-committee/ev_20180525_en).

ii. Follow up to the questionnaire on safety measures

The Commission updated Committee members on the questionnaire results on health and safety preventive and protective measures for the workers in a healthcare area while handling cytotoxic pharmaceuticals.

The questionnaire was initiated after the request from the European Society of Oncology Pharmacy (ESOP) for a "Yellow Hand" symbol to be added on the packaging of pharmaceuticals for human use to raise awareness about the issues of handling of cytotoxic pharmaceuticals by healthcare professionals at their working place (e.g. pharmacies and hospitals).

The Commission explained how EU pharmaceutical legislation regulates the particulars that appear on the outer and/or immediate packaging (labelling) and on the leaflet of the medicinal products. Concerning the safety of employees at their work place, the Commission explained that there are several specific EU laws for occupational health. These legal requirements put obligation on the employers (e.g. hospitals and pharmacies) to determine and assess the risks posed by the chemical and biological compounds and to take appropriate preventive and proactive measures.

In order to acquire information on safety measures the Commission asked the Member States to fill questionnaire on national measures put in place for handling such substances.

iii. ICH Q12 public consultation

The Commission reminded the Committee members of that the public consultation period in the EU on the draft ICH Q12 guideline on technical and regulatory considerations for pharmaceutical product lifecycle management expires on 18 December 2018.

iv. Note on the handling of duplicate marketing authorisation applications: the case of duplicates of biologicals/Public consultation.

The Commission presented the case of duplicate marketing authorisations of biological medicinal products, on which a targeted stakeholder consultation was organised from 18 May to 10 September 2018. The objective of this consultation was to gather stakeholders' view on the possible impact of such duplicate marketing authorisations on the biosimilar market (including potential anticompetitive effects) and the undermining of treatment options available to patients. In order to gather Member States views also it was agreed that participants can provide written comments by 30 November 2018 (on the basis of a background note that will be prepared and sent to the Committee members by email).

v. Austrian Presidency proposal - measures to address the disparity in access to medicines

The Commission informed the Committee members about a proposal of the Austrian Presidency to present in the next meeting of the Committee the work of the Health Ministries directors responsible for pharmaceutical policy in the Member States. In particular, they will present their work on proposals for concrete measures to address the disparity in access to medicines between Member States.

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