EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARMACEUTICAL COMMITTEE
8 March 2018

Subject: Minutes of the 80th meeting of the Pharmaceutical Committee
8 March 2018, **10.00 am – 1.00 pm**

Venue: Centre Albert Borschette, 36, rue Froissart, Brussels, meeting room **AB-4A**.

PHARMACEUTICAL COMMITTEE
MINUTES
80th meeting, 8 March 2018
Centre Albert Borschette, Brussels, **AB-4A**

AGENDA

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 C-179/16, judgment of 23 January 2018 (off-label use – competition law)
- Case C-567/16, judgment of 7 December 2017 (SPC Regulation – legal value of the end of procedure notice in a decentralised procedure)
- Case C-557/16, opinion of 7 December 2017 (decentralised procedure – responsibilities of concerned Member States)
- Cases T-235/15, T-718/15 and T-729/15 (EMA transparency policy)
- Additionally, reference was made to some pending cases, including case C-29/17 (off-label use).

ii. Legal and Regulatory news

The Committee was informed about new regulatory acts guidelines namely Guideline on Good Manufacturing Practices (GMP) specific to Advanced Therapy Medicinal Products and Guideline on excipients in the labelling and package leaflet that have been adopted since the last Pharmaceutical Committee held in October 2017.

2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

i. Falsified Medicines Directive – Update on the implementation of the safety features:

The Commission informed the delegates of the state of play of the implementation of the safety features and the new medicine verification system applicable as of February 2019. The overall setting up of the repositories system is currently behind schedule, with approximately half the repositories which are late. In addition, wholesalers, pharmacies or hospitals are not integrated in a number of National Medicines Verification Organisations, although the situation varies across Member States. Preparedness of hospitals is also still a concern. On the positive side, an agreement was finally found on access of National Competent Authorities to data in the repositories system.

Delegates were informed that the Commission had sent letters to both European

stakeholder associations and Member States encouraging a stepping up of efforts to ensure a timely implementation of the safety features. Delegates were invited to maintain a continued dialogue and work closely with stakeholders, particularly publicly-owned hospitals, to help them implement the new rules.

Finally, the Commission informed the delegates of the publication in the Official Journal of the report on the penalties EU countries apply to those involved in the production and circulation of falsified medicines.

One of the Member States asked for solutions to facilitate implementation of the new rules in hospitals. The Commission pointed out that some pragmatic solutions were outlined in Questions & Answers (Q&A) 6.6 of the Q&A document published on the Commission website.

Another Member State asked about the possibility of using the repositories system in case of shortages. The Commission stressed that, the system not being a full track-and-trace system, the data in the repositories system may not necessarily be helpful in case of shortages.

Upon question from another Member States the Commission confirmed that a revised version of the Q&A document would be circulated to the expert group by the end of March together with the other preparatory documents for the upcoming expert group meeting.

One of the Member States asked what would happen if not every national repository is up and running by 2019. The Commission replied that everybody should use the remaining 10 months to make sure the repositories system is ready and running by the deadline.

ii. Initiatives to improve the regulatory framework for ATMPs:

The Commission services recalled the great potential of advanced therapy medicinal products (ATMPs) to address some of today's unmet medical needs and also the risks that may be linked to the uncontrolled administration of these products. An overview of activities to support the development of ATMPs was presented (i.e. Guidelines on GMP for ATMPs, adapted application of GLP for ATMPs, Guidelines on GCP for ATMPs, Guideline on investigational medicinal products, optimisation of the interplay between the GMO and the medicinal products legislation, etc.) and Member States were invited to join the reflection process on the application of the hospital exemption.

iii. Feedback from the 8th meeting of the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP)

The Commission presented an update on the 8th meeting of the Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) which had taken place on 8 December 2017. The meeting included continuation of the discussion on the repurposing of established medicines/active substances. Industry representative organisations will prepare a document on how industry can engage in repurposing activities and what a repurposing framework might look like. There was a presentation on the Expert Panel on Effective Ways of Investing in Health draft opinion on Innovative payment models for

high-cost innovative medicines[1]. Other presentations included the EURopean Integrated Price Information Database project (EURIPID)[2], a project of OECD on access to medicines. There were updates on the activities of the Heads of Medicines Agencies Subgroup on Timely Access 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

3. LEGISLATIVE ISSUES

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

The Committee was updated on the state of play of the ongoing evaluation of the orphan and paediatric regulation.

The purpose of the evaluation is twofold. First, it will give an assessment about the strengths and weaknesses of the two legal instruments separately and combined, thereby focusing on the outputs/results in products catering for a real unmet medical need taking into account the way pharmaceutical are developed, scientific advances and changing business models. Second, it will among others give insight on how the various incentives that are related to the legislation have been used, and the financial consequences this has resulted in (in general and per stakeholder). The evaluation will give a sound evidence base about the functioning of the two legal instruments from a public health and a socio-economic perspective that will be used to consider the possible need for any future changes. The evaluation will moreover build on the 2017 Commission Report on the Paediatric Regulation.

The scope of the project is further explained in a roadmap published by the Commission in December 2017.

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

The Commission provided a follow up activities on the Commission's assessment report that was adopted on 22 March 2017[3] on current shortcomings in the summary of product characteristics (SmPC) and the package leaflet (PL). The report identified a number of recommendations on how to improve them in order to better meet the need of patients and healthcare professionals. EMA Action Plan[4] was prepared on the basis of the Commission report for the implementation of the recommendations of the report with outlined priorities and indicative timelines. The highest priority is given to the activity on electronic leaflet formats.

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[1] The final opinion was published on 9 February 2018:
https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/opinion_innovative_medicines_en.pdf

[2] *http://ec.europa.eu/chafea/news/news492.html*

[3] Commission report on product information leaflets
https://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf

[4] 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

The EMA representative informed the Committee about a public survey presented the preliminary information of the survey that was launched in November to collect information on ongoing initiatives regarding electronic/digital formats for the product information leaflets[5].

Different stakeholders participated in the survey providing information on the activities in this area. Based on the feedback from the survey the Commission and EMA will map all existing initiatives across the EU in area of digital/electronic leaflet formats.

Members of the Committee were also informed that a multi-stakeholder workshop on electronic product information will be organised in Q4 2018 and by the Commission, EMA and Heads of Medicines Agency (HMA).

iii. General Data Protection Regulation:

DG JUST from C3 unit gave a presentation on the General Data Protection Regulation (GDPR).

iv. Shortages of medicines

The Commission referred to questionnaire distributed to the Members of the Committee end of October 2017 and updated the participants with the information that a draft summary of the responses received is being prepared and will be circulated for comments after the meeting. The Commission emphasised that all EU Member States should reply to the questionnaire or provide input to the draft summary report to allow the Commission to take stock of the implementation of the measures related to Article 81 and subject of the questionnaire.

The Commission called the Members of the Committee to provide nominations for an expert group meeting to identify examples of best practice by 15th March and to provide amendments/corrections to the draft summary report by 1st April 2018. The Commission also explained that the feedback received on the questionnaire and the summary report will be shared with the HMA/EMA task force on availability of medicines.

4. AOB

i. Introduction to the Commission proposal for a Regulation on health technology assessment (HTA) amending Directive 2011/24/EU Initiatives:

The Commission presented the key elements of the legislative proposal for sustainable EU cooperation on HTA adopted on 31 January 2018. It was underlined that the proposal comes after more than a decade of voluntary cooperation in this area and responds to the calls of the Council and the European Parliament to strengthen the EU cooperation on HTA beyond 2020. It focuses on clinical aspects of HTA, i.e. on relative clinical effectiveness of health technologies, whilst the assessment of more context-specific HTA domains (e.g. economic, organisational, social, ethical) and decisions on pricing and reimbursement remain at Member States level. The proposal foresee four main areas of joint work: 1) joint clinical assessments focusing on the most innovative health

[5] EMA survey on the initiatives on electronic/digital formats for the product information leaflets

technologies with the most potential impact for patients (e.g. medicinal products subject to an EU central marketing authorisation procedure, more precisely new active substances and new therapeutic indications); 2) joint scientific consultations whereby developers can seek advice from HTA authorities; 3) identification of emerging health technologies to identify promising technologies early (i.e. horizon scanning); and 4) continuing voluntary cooperation in other areas (e.g. on non-clinical aspects). The Member State driven approach was also highlighted – joint work will be coordinated and carried out by experts designated by the Member States, with the Commission providing administrative, technical and IT support to the cooperation. The proposal will allow sufficient time for both industry and Member States to adapt to the new EU system. EU cooperation on HTA on a sustainable basis should provide benefits for all EU countries in terms of high quality and timely reports and efficiency gains. EU patients will benefit from greater transparency and faster uptake of promising innovative technologies and industry should benefit from clearer rules and greater business predictability.

ii. Personalised medicine activities at EU level

DG RTD presented the latest development implementations in the area of Personalised Medicine.

iii. Questionnaire on safety measures

The Commission presented a questionnaire on health and safety preventive and protective measures for the workers in a healthcare area while handling cytotoxic pharmaceuticals a request from the European Society of Oncology (ESOP) for a "Yellow Hand" symbol on the packaging and package leaflets of pharmaceuticals for human use. Such symbol would awareness about the issues of handling cytotoxic pharmaceuticals along supply chain by workers/employees in a healthcare area at their working place (e.g. pharmacies and hospitals) in all EU Member States.

While no measures to this effect can be taken under the EU pharmaceutical legislation, the Commission have sent a questionnaire[6] to the National Competent Authorities of the Member States after the meeting in order to gather information on national measures for handling such substances facilitate the reflections of ESOP. The contribution from Member States is expected by 19 April 2018.

iv. Shortages of medicines in Romania – Immunoglobin

The Commission informed the Members of the Committee regarding the shortages of medicines, in particular Immunoglobin, in Romania, and asked Member States to liaise with Romanian members if they could provide assistance.

[6] Questionnaire on health and safety preventive and protective measures for the workers in a healthcare area while handling cytotoxic pharmaceuticals
https://ec.europa.eu/health/sites/health/files/files/committee/pharm750-4iii_questionnaire-safety-measures.pdf