EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

STAMP 5/27
Record

STAMP Commission Expert Group
28 June 2016
5th meeting

RECORD

The Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) held its 5th meeting on 28 June 2016, in Brussels, chaired by Unit B5 - *Medicines: policy, authorisation and monitoring* of Directorate General Health and Food Safety. Representatives from 21 Member States and the European Medicines Agency participated at the meeting.

1. APPROVAL OF PREVIOUS MINUTES

The record of the 4th STAMP meeting (STAMP 4/24) was approved without changes.

2. ADOPTION OF THE AGENDA

The draft agenda (STAMP 5/25) was adopted without changes.

3. REPURPOSING OF ESTABLISHED MEDICINES/ACTIVE SUBSTANCES

The Commission services (DG Health and Food Safety) gave an overview of the previous discussions in the Group and the main issues that had been identified. In addition, the Commission services (DG Research and Innovation) gave an overview of the past, ongoing and possible future DG Research and Innovation funded research activities that could be relevant to the repurposing of medicines. In reply to questions from the Member States, the Commission services explained that the research agenda is focused on competitiveness of the EU industry and public health interest. When relevant

there is encouragement to include patient groups in research consortia. In the case of studies involving clinical trials the researchers have to demonstrate their engagement with national authorities. Some members of the Group noted that for established medicines the involvement of the marketing authorisation holder (MAH) can be important if the research is to lead to the extension of the marketing authorisation to new indications.

In the 4th STAMP meeting it had been agreed that a questionnaire should be circulated to seek information on important authorised medicines widely used off-label. The UK Medicines and Healthcare products Regulatory Agency (MHRA) presented a summary of the replies to the questionnaire. It was not possible to identify a list of medicines that are widely used off-label across the Member States due to the variation in the available medicines in the different Member States. The following points were made by members of the Group: encouragement of repurposing through incentives (such as fee waivers); the practicalities of monitoring of use of medicines whether on- or off-label; the encouragement to a MAH to provide relevant data for the extension of a marketing authorisation; consideration of an opinion from a scientific body; the need to involve the pharmaceutical industry in the consideration of repurposing of medicines; the potential impact of the low intervention clinical trials with the implementation of the new Clinical Trials Regulation.

It was concluded that the discussion on repurposing of established medicines should continue and that the views of stakeholders (industry, patient representative organisations) would be important.

4. OFF-LABEL USE OF MEDICINAL PRODUCTS

The Commission services have commissioned a study of off-label use of medicines. The contractor is the Netherlands Institute for Health Services Research (NIVEL), in cooperation with, the National Institute for Public Health and the Environment (RIVM) and the European Public Health Alliance (EPHA). Representatives from NIVEL and RIVM outlined the draft study report to the Group. The members of the Group provided feedback and were invited to send comments in writing.

The Belgium Federal Agency for Medicines and Health Products gave a presentation on the report of the Belgian Healthcare Knowledge Centre (KCE): 'towards a better managed off label use of drugs'. The presentation outlined the questions which had been addressed in the KCE report; the regulatory framework and jurisprudence; and the proposal for a step plan with regard to off-label use of medicines.

5. HEALTH TECHNOLOGY ASSESSMENT (HTA) NETWORK REFLECTION PAPER ON REGULATORY AND HTA ISSUES

A draft reflection paper on 'The interaction between regulatory and HTA issues on pharmaceuticals' has been prepared by the HTA Network. Commission services (DG Health and Food Safety) presented the aim of the paper, the process for the drafting of it and the consultation of STAMP and the Heads of Medicines Agencies (HMA).

The possible areas for synergies or collaboration between the regulatory and the HTA bodies in the lifecycle of the development and marketing of a medicine had been identified. The Group was invited to comment on the draft paper.

Members of the Group mentioned the importance of identifying the key players and clearly delineating the roles of the regulatory and the HTA bodies. This was acknowledged and it was explained that following the adoption of the reflection paper the next steps would involve an analysis of the roles and interactions in the areas which had

been identified for collaboration. It was noted that in the case of authorisation, if an application complies with the requirements of the legislation a marketing authorisation must be granted whilst there is no obligation for HTA bodies to recommend reimbursement.

The Group was asked to send their comments by 1 September 2016. It is planned that following the consultation of STAMP and HMA the paper will be updated and presented to the HTA Network with a view for its adoption by the Network in the next meeting scheduled for 10 November 2016.

6. UPDATE ON EUROPEAN MEDICINES AGENCY ACTIVITIES:

a. Adaptive Pathways

EMA updated the Group on the latest activities in the adaptive pathways pilot the findings from the pilot with respect to the products which had been submitted. The learnings included that prospective, life span discussion between different stakeholders is possible; product selection for the enhanced support, input from patient representatives, making use of real world data and prescription controls are important. The final report on the pilot would be published on the EMA website[1].

b. PRIority MEdicines (PRIME) Scheme, CHMP scientific guidance on Conditional marketing authorisations, CHMP scientific guidance on Accelerated assessment

The EMA gave a presentation on the first experience of the PRIME scheme with respect to submission and evaluation of medicinal products for inclusion in the scheme. It was noted by EMA that there had been a high number of requests (37 in the first 3 months of the scheme), although a number of the products submitted were in late stage of development. The EMA considered that cross-committee collaboration helps to ensure consistency of implementation and that the HTA engagement through the parallel scientific advice procedure would be important. Further information on the PRIME scheme is available on the EMA website[2].

7. COUNCIL CONCLUSIONS ON STRENGTHENING THE BALANCE IN THE PHARMACEUTICAL SYSTEM IN THE EU AND ITS MEMBER STATES

The Netherlands Ministry of Health presented the background to the Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States which were adopted on 17 June 2016[3]. The theme of strengthening checks-and balances in the pharmaceutical system had been one of the priorities of the NL presidency as they consider that authorisation of medicines, health technology assessment, pricing and reimbursement, and the market as such are interconnected but there are mismatches in the system. The Council conclusions aim to look at the system as a whole and identified certain actions for the Member States and the Commission.

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1 Post meeting note - EMA, Final report on adaptive pathways pilot, EMA/276376/2016 was published on 3 August 2016 http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/08/WC500211526.pdf.

2 http://www.ema.europa.eu/ema/index.jsp%3Fcurl%3Dpages/regulation/general/general_content_000660.jsp%26mid%3DWC0b01ac058096f643

3 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XG0723(03)

ACTION POINTS AND POINTS TO CONSIDER FOR THE NEXT MEETINGS:

- Members States to send comments on the draft report of the study on off-label use of medicinal products.
- Member States to send comments on the HTA network reflection paper on 'The interaction between regulatory and HTA issues on pharmaceuticals'.

The next meeting of the STAMP Expert Group is to be confirmed**.**

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