EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

STAMP 10/44

STAMP Commission Expert Group
3 December 2018

Subject: Repurposing of established medicines/active substances

Agenda item 3

The issue of repurposing of established medicines had been discussed in previous meetings of the Safe and Timely Access to Medicines for Patients (STAMP) Expert Group[1]. During the 9th meeting on 8 June 2018 there was a discussion on the proposal for a framework for repurposing existing medicines which had been developed through the collaboration of the representative industry associations. The STAMP agreed that the proposal for the framework should be further developed within a working group.

A working group including representatives from Member States and stakeholders from industry, patient, healthcare and payer representative organisations was formed. The following Member States and stakeholder groups were represented - Belgium, the Netherlands, Norway, Spain, Sweden, the United Kingdom, European Medicines Agency (EMA), Anticancer Fund, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Organisation for Rare Diseases (EURORDIS), European Patients' Forum (EPF), European Society of Paediatric Oncology (SIOPE), International Association of Mutual Benefit Societies (AIM), Medicines for Europe (MfE). The group was led by the UK and Spain and worked through exchange of emails and regular teleconferences.

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[1] STAMP 4/20 (https://ec.europa.eu/health/sites/health/files/files/committee/stamp/2016-03_stamp4/3_repurposing_of_established_medicines_background_paper.pdf)
STAMP 5/26 (https://ec.europa.eu/health/sites/health/files/files/committee/stamp/2016-06_stamp5/3_repurposing_of_established_medicines_reflection_paper.pdf)
STAMP 6/29 (https://ec.europa.eu/health/sites/health/files/files/committee/stamp/stamp6_repurposing.pdf)
STAMP 7/33 (https://ec.europa.eu/health/sites/health/files/files/committee/stamp/stamp_7_repurposing_background.pdf)
STAMP 8/37 (https://ec.europa.eu/health/sites/health/files/files/committee/stamp/stamp_8_repurposing_established_medicines_background.pdf)
STAMP 9/40 (https://ec.europa.eu/health/sites/health/files/files/committee/stamp/stamp_9_40_en.pdf)

The group considered the following 3 aspects (objectives) for a proposal for a repurposing framework:

- Complete the steps of the pathway
- Test run the pathway
- Supporting materials and communication

Sub-groups were created to consider objectives 1 and 2, objective 3 was considered by the group as a whole. The work on objective 1 was led by Sweden, EMA and the UK, the Anticancer Fund led the work on objective 2.

The following documents have been prepared by the group:

- For objective 1 – **Proposal for a repurposing pathway within the current regulatory framework**
- For objective 2 – **Learnings and outstanding issues**
- For objective 3 – **Supporting materials and communication**

Points for consideration:

Objective 1 – Complete the steps of the pathway

- Any comments on the suggested steps of the pathway identified in the ***Proposal for a repurposing pathway within the current regulatory framework***?
- Any points for consideration for the following **outstanding aspects** mentioned in the document?

    1. Develop a repurposing checklist and topics to cover for the repurposing scientific advice meeting
    2. Consider ways to support the Champion, including if and how a fee waiver for a scientific advice meeting could be made for a champion (innovative medicines initiative (IMI) interaction, other initiative), provide contact points from industry to aid communication with MAH, other support?
    3. Develop further guidance that clarifies in more detail the individual identified roles and pathway milestones.
    4. Determine the feasibility and practicalities of the pathway by piloting with a live asset and Champion.

Objective 2 - Test run the pathway

- Any comments on the suggested template for the check list for the Champion to prepare for making a request for scientific advice presented in paper on ***Learnings and outstanding issues***?
- Any additional points that should be included in the template?
- Views on the suggested candidate molecule and indication for a pilot?

Objective 3 – Supporting materials and communication

- Any comments on the suggested communication activities and supporting materials?
- Any points for consideration for the following **outstanding aspects** mentioned in the document concerning ***Supporting materials and communication***?

    1. Is there a need for the development of a specific "toolbox" for the repurposing framework?
    2. How to facilitate the collaboration of the Champions and industry? Any previous experience?
    3. How to reach out to the potential Champions? How the increase awareness of the marketing authorisation holders who could take forward an application to include a new indication in their product information?
    4. How do we move the theoretical framework to the practical application? Who or which groups should lead on generating the supporting documents and processes?
    5. What would be relevant for the EU Coordination and Support Action STARS (Strengthening training of academia in regulatory sciences & supporting regulatory scientific advice) to consider in their activities that would support the proposal for a repurposing framework?