EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

STAMP 7/33

STAMP Commission Expert Group
27 June 2017

Repurposing of established medicines/active substances

The STAMP expert group discussed the issue of repurposing of established medicines/active substances on the 10th March, 28th June 2016 and 13 - 14 March 2017[1].

On 13 March 2017 a half day *ad hoc* session had been arranged to discuss certain aspect of repurposing of established medicines/active substances with invited representatives of patient, consumer, industry, not-for-profit organisations, health technology assessment and pricing and reimbursement bodies.

The aim of the *ad hoc* session was to have a brainstorming around possible options and solutions to support the introduction of:

- new indications for off-patent medicines in new marketing authorisations;
- extension of indications for existing marketing authorisations (variation applications).

In the 27 June meeting of the STAMP the aim is to further consider the main areas identified that could potentially create opportunities for inclusion of new indications for existing marketing authorisations with the aim to produce an overview document in which the proposed actions are mapped, specifying if they can be followed up, which fora should be involved and who could lead on the follow up of the identified actions.

To support this initiative further, STAMP members are invited to consider their replies to the following questions for the potential options identified during the brainstorming session.

[1] Background documents and the notes of the meetings are available via the following webpage: http://ec.europa.eu/health/documents/pharmaceutical-committee/stamp_en

Q.1 Is there any experience of the suggested activities at the national level?

Q.2. Which of the activities are considered to best address the identified issues and challenges?

Q.3 Which of the suggested activities are considered feasible and desirable?

Q.4 Are the suggested activities sustainable?

Q5 What action(s) could be taken forward in the short–term? And in the longer term?

Q.6 Would there be a need to update the regulatory framework to accommodate the identified actions?

Q.7 Would EU level activity be relevant and added value?

Q.8 Which fora (EU or national) could take forward, and follow up the action(s)? And who should take the lead and coordination?