

EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

STAMP 9/40

STAMP Commission Expert Group 8 June 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 Group¹. During the 8th meeting on 8 December 2017 it was agreed that the industry representatives would prepare a document on how industry can engage in repurposing activities and what a repurposing framework might look like.

Representatives of European Federation of Pharmaceutical Industries and Associations and Medicines for Europe have collaborated and prepared a presentation of a repurposing framework proposal. Members of STAMP are invited to consider the proposal for detailed discussion in the meeting.

In addition to considering the proposal from the industry, the aim is to agree overall conclusions from the discussions on repurposing of established medicines. The intention is to prepare a document summarising the STAMP activity and presenting conclusions regarding specific actions that could be followed up by the different stakeholders, working alone or through collaborative activities.

Participants are therefore asked to consider the background papers circulated for this meeting and to refer to the previous background papers¹, in particular, to consider the points for

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

^{(&}lt;a href="https://ec.europa.eu/health/sites/health/files/files/committee/stamp/stamp">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)

discussion and potential recommendations outlined in background document STAMP 8/37. Consideration should be given to whether actions can be identified that can be followed up directly, any other recommendations that could be taken forward in the future, and if a model scheme is identified whether it can be piloted.

Points for consideration of the group:

- Views on the industry repurposing framework proposal.
- If a model scheme is identified, should it be piloted?
- Are there specific actions that can be followed up directly? Led by whom? Who else should be involved?
- Any other recommendations to be investigated further? Led by whom? Who else should be involved?