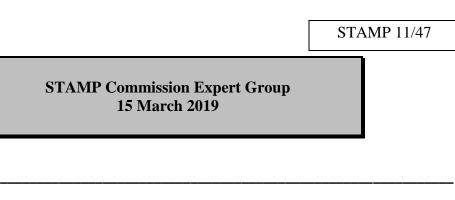EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

STAMP 11/47

STAMP Commission Expert Group
15 March 2019

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Subject: **Repurposing of established medicines/active substances**

Agenda item 3
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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. During the 10th meeting on 3 December 2018 there was a discussion on the proposal for a framework for repurposing existing medicines which had been developed by a working group including representatives from Member States and stakeholders from industry, not-for-profit, patient, healthcare and payer representative organisations. The STAMP agreed that the proposal for the framework should be further developed within the working group.

The group has completed the following activities:

- Updated the document outlining the proposed repurposing framework including the objectives and deliverables of the pilot of the framework, a proposal for a 'repurposing monitoring board' to monitor the pilot and an initial list of resources/sources of information for Champions
- Considered potential candidate molecules for a pilot of the proposed repurposing framework
- Prepared an overview of the aims of objectives of the EU Coordination and Support Action - STARS: Strengthening training of academia in regulatory sciences & supporting regulatory scientific advice

The STAMP participants are asked to consider the documents which have been prepared by the working group, specifically considering the following points:

1. Is the suggested framework clear? Are there aspects of the proposed framework that need to be clarified before the start of the possible pilot projects?

2. Are the objectives and deliverables of the pilot of the repurposing framework appropriate? Are there any gaps?
3. The proposal for a 'repurposing monitoring board', is this supported and are the suggested role and activities considered appropriate and complete? Who should be represented on the board?
4. Regarding the list of useful resources etc., are there other resources and contacts that should be included in the list?
5. The suggested candidate molecules/medicines, are there any which are not appropriate to be included in the pilot?
6. What should be the process to identify other candidate molecules?