



**PHARMACEUTICAL COMMITTEE**  
**1 April 2019**

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**Subject: Modus operandi of the Pharmaceutical Committee, lessons learnt from the STAMP and update on its activities**

**Agenda item 2**

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The Pharmaceutical Committee was set up<sup>1</sup> as a consultative committee to the Commission to provide advice with regard to the pharmaceutical legislation including on policy issues. The Committee should consist of senior experts in public health matters from the Member States. In this context we would like to review with the members of the Committee its working arrangements to maximise the effectiveness of the Committee.

The STAMP expert group of the Pharmaceutical Committee has been meeting since January 2015. It is composed of representatives of the Member States but frequently other external experts were invited to the meetings on ad hoc basis. In the particular case of the discussions on repurposing of existing medicines, there has been an extensive engagement with representatives of industry, healthcare professionals, patients, not-for-profit organisations, health technology assessment and pricing and reimbursement bodies. These have been in the form of participation in a brainstorming session, participation in meetings as well as further development of ideas through working groups between the meetings. These interactions have enriched the discussions and considerations of the STAMP.

STAMP has successfully concluded work on several topics and gave input into initiatives such PRIME, conditional marketing authorisation guidelines etc. Some topics such as off-label use and compassionate use programmes were taken up by other bodies notably Heads of Medicines Agencies subgroups. The proposed new working arrangements of the Pharmaceutical Committee is an opportunity for the role and activities of STAMP to be discussed.

Finally, we are asking the Committee to consider whether the involvement of external stakeholders could be relevant for certain agenda items of future Pharmaceutical Committee meetings.

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<sup>1</sup> [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dec\\_1975\\_320/dec\\_1975\\_320\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dec_1975_320/dec_1975_320_en.pdf)