Subject: Shortage of medicines – Commission Summary of Responses to the Questionnaire on measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC

Agenda item 3iv

BACKGROUND

The European Commission is currently preparing a draft summary report of the responses received to the questionnaire launched after the last Ph. Committee on 27 October 2017. The questionnaire concerned the systems, measures and practices implemented by the Member States in the context of continued supply obligation stipulated by Article 81 of Directive 2001/83/EC. The background for initiating this work is linked to the call of the Council and the European Parliament to examine and monitor Article 81 (see document PHARM 730 and the EP report1).

The European Commission has aimed to take stock of the measures implemented by the national competent authorities in order to facilitate sharing of best practices between the Member States. 24 responses were received (AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, NL, NO, PT, SE, SI, SK, UK). The Netherlands provided a report of a Dutch working party on drug shortages in lieu of the responses to the questionnaire. No feedback has been received from BG, IS, LI, LU, MT, PL and RO.

The EU Ph. Committee members, who have not sent their responses, are kindly requested to provide feedback on their national measures and practices as complementary amendments/comments to the draft summary report by 1st April 2018. The Commission will ask for a review of the draft summary report directly from the persons who submitted the responses with the same deadline. The draft report will be circulated after the meeting of the Pharmaceutical Committee.

As a next step the Commission proposes that the summary report including all responses to the questionnaire is shared with appointed experts from the Member States for the purpose of identification of examples of best practice.

The expert group meeting is planned to take place on 25th May 2018. The Commission kindly requests the Member States to nominate experts for this working group by 15th March 2018.

The feedback collected through the questionnaire and the summary report will also be shared with the HMA-EMA Task Force on availability of medicines.

Please send your proposed amendments/comments on the draft report and the nominations of experts to SANTE-PHARMACEUTICALS-B4@ec.europa.eu.

**Action to be taken:**
For information and action