



EUROPEAN COMMISSION  
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 752

**PHARMACEUTICAL COMMITTEE**  
**23 October 2018**

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**Subject: Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines, 25 May 2018**

**Agenda item 4i**

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On 25 May 2018, the Commission held a meeting with Member State experts to discuss shortages of medicines. The meeting was held in response to the calls from the Council and European Parliament for the Commission to monitor the obligation of marketing authorisation holders to ensure continuous supply of medicines laid down in EU legislation (Article 81 of Directive 2001/83/EC).

At the meeting, the Commission presented the results of a survey of Member State measures implementing the continuous supply obligation launched 27 October 2017 in the Pharmaceutical Committee (see PHARM 730 and the European Parliament report<sup>1</sup>). The summary report outlines a number of national measures introduced to mitigate the risk of shortages, including national definitions of shortages, measures for critical medicines, the obligation to notify temporary or permanent interruption of supply, export restrictions and penalties.

A paper on the obligation continuous supply to tackle shortages was also agreed at the meeting. The paper outlines the supply obligations for marketing authorisation holders and wholesalers in a Member State or region. It also clarifies the limits of their responsibilities to supply medicines. The paper also outlines the general principles for Member States to consider when introducing restrictions of sales to another Member State to address shortages stemming from parallel trade.

Both the report of Member State measures and the paper on continuous supply have now been published on the Europa website ([https://ec.europa.eu/health/documents/pharmaceutical-committee/ev\\_20180525\\_en](https://ec.europa.eu/health/documents/pharmaceutical-committee/ev_20180525_en)).

**Action to be taken:**

For information

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<sup>1</sup>[https://ec.europa.eu/health/sites/health/files/files/committee/78meeting/pharm730\\_6ii\\_shortages\\_of\\_medicines.pdf](https://ec.europa.eu/health/sites/health/files/files/committee/78meeting/pharm730_6ii_shortages_of_medicines.pdf)  
<http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A8-2017-0040&format=XML&language=EN>