



PHARM 792

PHARMACEUTICAL COMMITTEE
12 March 2020

Subject: Study on medicines shortages¹

Agenda item 4

BACKGROUND

Shortages of medicines form one part of the greater problem of access, affordability and availability of medicines in the EU. A shortage of a medicinal product occurs when supply of an already marketed medicine does not meet demand at a national level from healthcare professionals or patients in response to clinical needs.

Medicines shortages pose risks for patient health due to under-treatment, medication errors, increased length of hospital stay and adverse reactions from attempts to substitute unavailable medicines. Shortages are more and more frequent for essential products that have been on the market for many years and are widely used.

On 25 May 2018, the European Commission held a meeting with Member State experts to discuss shortages of medicines². Further information can be found on the Europa website: https://ec.europa.eu/health/documents/pharmaceutical-committee/ev_20180525_en.

DG SANTE is currently reflecting on additional measures to address shortages of medicines beyond the current legal obligation for the pharmaceutical industry to ensure supply of marketed medicines.

As a first step, a study will be launched this year to provide data on the causes of medicine shortages, to assess the current legal obligations to ensure continued supply, and to identify and benchmark possible future actions that could address risks of shortages. The expected results are a summary on the number of shortages in the EU and their causes, an assessment of current legal provisions and an outline of the pros and cons of the possible future actions

Action to be taken:

Member States will be asked to cooperate and share available data on shortages with the contractor once the study is launched.

¹ This document has not been adopted by the European Commission and, therefore, it does not reflect an official position of the European Commission. It is only meant to be a tool for discussion and the views expressed therein do not necessarily reflect those of the Commission and its services.

² Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines, 25 May 2018