



PHARMACEUTICAL COMMITTEE
27 March 2017

Subject: Shortages of medicines

Agenda item 6ii

The issue of shortage of medicines is a growing problem with potentially serious consequences for the health of patients. The causes of shortages are mainly due to manufacturing problems and economic reasons (e.g. pricing and tendering policies). Shortage of medicines is one element of the broader problem of access to medicines.

In 2016, the NL Presidency invited the Commission to assess the impact of protection mechanisms and incentives¹ on shortages of medicines and the SK Presidency made "shortages of medicines" a priority for its presidency. During the Working Party on Public Health at Senior level on 15 July 2016 and the informal Health Council on 3-4 October, all Member States agreed that the topic deserves action at EU level. During the informal health council, many Member States supported more specifically the SK proposal to examine Article 81 of the pharmaceutical legislation which is difficult to implement and enforce. This Article establishes that "*the holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered*". The provision lays down under the rules on distribution of medicinal products in the pharmaceutical legislation.

Many Member States called for the Commission to better clarify the obligations of the marketing authorisation holders and wholesaler distributors and what the limits of their responsibilities are.

¹ such as market exclusivity and Intellectual property rights

In March 2017, the European Parliament also adopted some recommendations on shortages of medicines in the context of the report on access to medicines in Europe.²

This report calls on:

- the Commission and the Council to formulate a better definition of the concept – and analyse the causes – of shortages of medicines, and, in this regard, to assess the impact of parallel trade and supply quotas, to establish and update together with the Member States, the EMA and relevant stakeholders a list of essential medicines which are short of supply, using the WHO list as a reference, to monitor compliance with Article 81 of Directive 2001/83/EC on shortages of supply, to explore mechanisms to address the withdrawal of effective medicines from the market purely for commercial reasons, and to take actions to remedy these shortages;

- the Commission and Council to establish a mechanism whereby medicine shortages across the EU can be reported upon on an annual basis;

- the Commission and Council to review the statutory basis of the EMA, and to give consideration to enhancing its remit to coordinate pan-European activity aiming at tackling medicines shortages in the Member States;

Following the call of the Council and the European Parliament, the Commission would like to have the views of the Member States to discuss the problem of shortage of medicines in the Pharmaceutical Committee.

It is important to avoid duplication of work carried out by the Heads of Agencies and the European Medicines Agency (HMA-EMA Task force on availability).

Therefore, the Commission would be open to work jointly with the Member States on the problem of shortages of medicines due to manufacturing problems or the implementation of the legal environment.

More specifically, the Commission would like to have the views of the Member States to discuss the implementation of the Article 81 of the obligation of continuous supply without changing the legislation.

The objective would be to help the Member States to exchange information and good practices to address more efficiently the problem of shortage of medicines.

Action to be taken:

For discussion

² <http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A8-2017-0040&format=XML&language=EN>