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

Agenda item 3v

The issue of shortages of medicines remains a serious problem with potentially serious consequences for the health of patients. The Commission would like to have the views of the Member States to discuss the implementation of Article 81 of Directive 2001/83/EC of the pharmaceutical legislation which introduces an obligation for continuous supply of medicinal products.

The background for initiating this questionnaire 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 would like to take stock of the measures implemented by the Member States with the aim of finding examples of best practice which could be shared with the Member States.

The feedback collected from this questionnaire will be shared and discussed in the Pharmaceutical Committee and with the HMA-EMA Task force on availability.

Please provide your responses by 5 December 2017 to SANTE-PHARMACEUTICALS-B4@ec.europa.eu.

Questionnaire – Measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC

Article 81 of Directive 2001/83/EC:

With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of a distribution authorisation which has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.

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 arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.

Please provide replies to the below questions (maximum 20 lines per reply).

1. How is the obligation of continued supply transposed in your country as far as marketing authorisation holders (MAH) are concerned?

2. What are the responsibilities of wholesale distributors in your country stemming from the transposition of the obligation of continued supply (i.e. public service obligation)? Do you distinguish between full-line distributors and other distributors?

3. What are the limits of their responsibilities in your country?

4. What are the responsibilities of manufacturing authorisation holders and how are they connected to the responsibilities of the marketing authorisation holder and the wholesale distributors? Is consultation with the authorities and notification of shortages obligatory?

5. Is there a specific definition of product supply disruption or shortage in your national legal order or other regulatory guidance? If yes, please describe it including a reference. Is it linked to a specific medicinal product and to a specific territory? Is it linked to the public service obligations referred to under questions 1 and 2?

6. Are there specific legal and/or other regulatory measures for critical or essential medicines (e.g. buffer stock)? If yes, do you have a definition of critical or essential medicines, do you use the WHO list of essential medicines or apply another solution? Please provide the definition and describe how you maintain and update the list of critical or essential medicines and describe any practical implementation issues.

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2 Do you assess the shortage in the light of a specific authorised medicinal product or a class of products
3 Do you assess the shortage in the light of the situation in a specific region affected or at national level
7. Which other actions (not mentioned under questions 1 and 2 and not related to Article 23a) are the MAH, distributors, or pharmacies required to take when anticipating or experiencing product supply disruption? Which legal or regulatory measures are in place (e.g. supply continuity plan for the production, information obligations in the supply chain)?

8. Article 23a of Directive 2001/83/EC obliges the marketing authorisation holder to notify the authority if a product ceases to be placed on the market even temporarily. Do you make this information available to the distributors or pharmacies? Is there any other compulsory reporting of interruption of supply to the NCA, to distributors or pharmacies or to patients? Is this information publicly available? Are there penalties for non-compliance?

9. Do you have any specific export restrictions in place to mitigate the shortage or the risk of shortage of medicines? If yes, what is their precise scope and what criteria are they based on? (e.g. prior notification for shipments within a certain timeline, dynamic list of products...).
   (a) Do they apply in the same way for the exports to other EU Member States and to third countries?
   (b) Are they based on generally applicable measures only 4 or also on individual decisions of the state authorities 5 ?
   (c) Are substitutable medicinal products/therapies taken into account in such export restrictions?
   (d) Are such export restrictions considered as part of transposition of the public service obligations under Article 81?
   (e) What kind of information do you publish regarding the specific export restrictions taken?

10. How are you determining and monitoring the shortage situation (e.g. by comparing supply and consumption data) for a particular medicinal product?
    (a) Is this monitoring linked to the export restrictions referred to in question 8?
    (b) Do you plan using, for the purpose of monitoring the data gathered, the secure repository system developed in the scope of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015?

11. Are there specific penalties for interruption of supply/shortages? (e.g. suspension of distribution authorisation or marketing authorisation, fines for export or shipment of medicines to other Member States in case of shortages)? If yes, did you impose sanctions during the last 10 years and have the penalties for shortage resulted in reluctance from the MAH to inform you about shortages, or in deregistration of the medicinal product?

12. In the case of a MAH informing you of its plans to discontinue the marketing of a medicinal product (deregistration), where no other alternative is available, what actions are taken? Is there a dialogue with the MAH, concerning the consequences of the shortage?

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4 e.g. general ban for all exports applicable for all economic operators
5 e.g. individual decision to block the export for an individual economic operator (decision on case by case basis)
13. Can you describe some real life examples on how to act on shortage of essential medicinal products, in order to minimize the consequences of the shortage? What has worked, and what has not worked? Please share your experience.