EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
**Medical products: quality, safety, innovation**

**Paper on the obligation of continuous supply to tackle the problem of shortages of medicines**
**Agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018**

*Response to the calls by the Council[1] and the European Parliament[2] to monitor the implementation of Article 81 [and 23a] of Directive 2001/83/EC[3]*

This document aims to facilitate the implementation of Articles 81 and 23a of Directive 2001/83/EC on the Community code relating to medicinal products for human use.

It sets out frequently asked questions and answers regarding the implementation of the rules applying to marketing authorisation holders and wholesale distributors of medicinal products. It is without prejudice to national legislation.

This document is based on Member State responses to the questionnaire on measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC launched in autumn 2017. Where appropriate, relevant jurisprudence is taken into account. Further information on specific national measures adopted to address shortages of medicine can be found in the Commission summary of responses to the Member State questionnaire.

The views expressed in this discussion paper are not a formal interpretation of Union law, nor are they legally binding. Ultimately, only the European Court of Justice can give an authoritative interpretation of Union law.

**Provisions of EU legislation**

Article 81 states that: *The holder of a marketing authorisation for a medicinal product and 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.*

Article 23a states that: *If the product ceases to be placed on the market of a Member State, either temporarily or permanently, the marketing authorisation holder shall notify the competent authority of that Member State. Such notification shall, other than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product. The marketing authorisation holder shall inform the competent authority of the reasons for such action in accordance with Article 123(2). Upon request by the competent authority, particularly in the context of pharmacovigilance, the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product, and any data in his possession relating to the volume of prescriptions.*

**What are the responsibilities of the marketing authorisation holders in relation to the obligation of continuous supply?**

The marketing authorisation holder should ensure supply sufficiently in advance and in adequate quantities to cover demand from patients in a Member State. To this end, marketing authorisation holders should ensure a continued supply that covers the need of wholesale distributors of medicinal products (including full-line distributors) and persons entitled to supply medicines to the public. Marketing authorisation holders should be particularly vigilant for products for which (a part of) the manufacturing process is dependent on a single facility (e.g. one starting material source, active ingredient manufacturer, finished product manufacturer or batch release site). The marketing authorisation holder should also be particularly vigilant where it markets medicines for which no or only limited alternatives are available, and where discontinuation of supply will result in a potential risk for public health, e.g. medicines for

[1] Informal Meeting of Health Ministers, Informal EPSCO – Health Agenda, 3-4 October 2016
[2] http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A8-2017-0040&format=XML&language=EN
[3] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)

life threatening conditions, critical[4] or essential medicines[5] (e.g. vaccines). For those products, competent authorities may require marketing authorisation holders to develop a shortage prevention plan, as part of their obligation to ensure continuous supply.

Reading Article 23a and 81 together, marketing authorisation holders should notify any interruption of supply of medicinal products in good time (at least two months in advance). This notification should include, in particular, data on sales volumes and the volume of prescriptions and, where possible, indicate possible alternative medicinal products. It should also include information on the estimated duration of the supply interruption as well as any corrective action taken to remedy the situation. The notification should also describe with sufficient detail the reasons for the interruption in order to allow the competent authority to evaluate the situation. Member States may also request marketing authorisation holders to provide data on sales volumes and volumes of prescriptions in order to monitor shortages on their market.

**What are the responsibilities of the wholesale distributors in relation to the obligation of continuous supply?**

Wholesale distributors should ensure continuous supply to pharmacists and the person entitled to supply to the public to cover the needs of the patients on the territory where the distributor is established. Depending on the public service obligations[6] in the Member State(s) concerned, the wholesale distributor may be required to supply all (in the case of full line wholesalers) or a set of pre-defined medicinal products at regular intervals (such as daily) for a specific geographic area. Wholesale distributors may supply other wholesale distributors subject to their ability to meet their public service obligations and the demand of the pharmacies and person entitled to supply to the public in the geographic area under their responsibility.

**What are the limits of their responsibilities?**

The limits of the responsibilities of marketing authorisation holders and wholesale distributors should be evaluated on a case-by-case basis by the Member States. Examples were marketing authorisation holders may not be responsible are:

- shortages caused by the export/supply by a distributor of medicinal products to another customer in a different Member State for which they are not aware (as long as they have not failed to meet ordinary orders in relation to the size of the market of the Member State concerned);
- shortages caused by increased demand from a shortage in the Member State of an alternative medicinal product produced by another company;

Wholesale distributors may not be responsible if marketing authorisation holders fail to enable supply of sufficient stocks of medicinal products to cover the needs of pharmacies or persons entitled to supply to the public in a Member State.

**Can a Member State introduce restrictions on the supply of medicines to operators in other EU Member States to mitigate the risk of shortages of medicines?[7]**

Member States may take measures to prevent or address shortages of medicines by restricting the free movement of goods within the EU.[8] Member State authorities may restrict supply of medicinal products to operators in other EU Member States by wholesale distributors and require prior notification or authorisation for this activity, as long such restrictions are justifiable as appropriate, necessary and proportionate to protect the life and health of humans by preventing the occurrence of shortages of medicines.[9] The scope of the notifications or authorisations should be restricted to medicines already in shortage or at risk of shortage, taking into account the availability of alternative treatments.

Restrictions of supply outside of the Member State must be adopted based on transparent, publically available and non-discriminatory criteria that are known in advance by economic operators, in such a way as to ensure that any restrictions imposed are not placed arbitrarily. Decisions by Member State authorities should be open to appeal before the relevant national administrative or legal bodies. Any decision of refusal to export must be open to challenge before the Courts.[10]

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[4] Where defined at national level or referred to in the paper prepared by the European Medicines Agency http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/01/WC500159381.pdf

[5] http://www.who.int/medicines/news/2017/20th_essential_med-list/en/

[6] Obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question

[7] Commonly known as 'export restrictions'

[8] Joined Judgments C-468/06-C-478/06, para. 75

[9] See Article 36 of the Treaty on the Functioning of the European Union

[10] Judgement in Canal Satélite Digital, C-390/99

Furthermore, the notification or authorisation procedures themselves must be proportionate in relation to their duration and the costs to which they give rise, so as not to deter operators. The information requested from distributors must be restricted to the minimum necessary to make an informed decision (e.g. the amount of products to export/supply, the name of the medicinal products).

Restrictions of supply for specific listed medicinal products may be considered suitable if:

- the list applies only to pharmaceuticals for which a shortage is likely or certain, such as those medicines where the volume available does not meet current needs of patients in the Member State;
- the list is established through criteria that are known in advance;
- the list takes into account the availability of alternative treatments in the Member State;
- the list is revised on a regular basis taking into account the latest occurrences or risks of shortages of medicines for public health;
- the decisions implementing its application are taken within a reasonable time period; and
- the decisions are open to be contested before the relevant administrative bodies or courts of justice.