EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 793

PHARMACEUTICAL COMMITTEE
12 March 2020

Subject: **COVID-19 outbreak and the availability of medicines**[1]

Agenda item 5

BACKGROUND

On 13 February 2020, the Council of the European Union adopted Council Conclusions on COVID-19.[2] The Ministers of Health of the European Union were concerned that manufacturing shutdowns in China may affect the supply of medicines in the EU.

The Council Conclusions call on the Commission, in cooperation with the EMA and the national medicines agencies, to *evaluate the consequences of global health threats like COVID-19 for the availability of medicines within the EU and the security of supply chains*.

Although there are currently no reports of shortages caused by the outbreak, EMA continues to monitor the situation. At the meeting, EMA will report on their mapping of manufacturing sites in China and the risk of supply disruptions for centrally authorised medicines.

Additionally, there are reports of some Member States introducing export restrictions for medicines. Wide-ranging export restrictions, particularly on MAHs, may create shortages in other MS and problems for supply across the EU. The Member States should carefully monitor their stock for medicines at risk of shortages linked to COVID-19 and only introduce restrictions on a case-by-case basis when necessary to protect public health.

Further information on the obligation of continuous supply[3] is published in the Europa website and best practices to tackle shortages of medicines are presented in Annex 1.

Marketing authorisation holders should be reminded of their obligation to ensure continuous supply to cover the needs of patients and to notify authorities of any interruption of supply at least two months in advance of the interruption.

Action to be taken:

Member States are asked to provide oral updates of their monitoring at the meeting, in particular for nationally authorised medicines.

[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] https://data.consilium.europa.eu/doc/document/ST-6038-2020-INIT/en/pdf
[3] https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_rd01_en.pdf

Member States are asked to continue to send any new or additional information on potential disruptions through the SPOC network[4] after the meeting.

[4] https://www.ema.europa.eu/en/news/ema-management-board-highlights-december-2019-meeting

Best practices available to national competent authorities to tackle shortages of medicinal products

	Legal tools
1	Article 126a of Directive 2001/83/EC on the use of medicinal products authorised in another Member States: "*In the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State in accordance with this Directive, a Member State may for justified public health reasons authorise the placing on the market of the said medicinal product".*
2	Article 81 of Directive 2001/83/EC on the obligation of continuous Supply: "*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".*
3	Article 5.1 of Directive 2001/83/EC on the use of unauthorised medicinal products: "*A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility".*
4	Article 23a of Directive 2001/83/EC on the notification of cessation of marketing: "*After a marketing authorisation has been granted, the holder of the authorisation shall inform the competent authority of the authorising Member State of the date of actual marketing of the medicinal product for human use in that Member State, taking into account the various presentations authorised.* *The holder shall also notify the competent authority if the product ceases to be placed on the market of the Member State, either temporarily or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than 2 months before the interruption in the placing on the market of the product. 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.*
5	Article 63.3 of Directive 2001/83/EC on labelling exceptions: " *When the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, grant an exemption to the obligation that certain particulars should appear on the labeling and in the package leaflet. They may also grant a full or partial exemption to the obligation that the labeling and the package leaflet must be in the official language or languages of the Member State in which the medicinal product is placed on the market.*"
6	Article 5(3) of Regulation (EC) No726/2004 on CHMP opinion: *At the request of the Executive Director of the Agency or the Commission representative, the Committee for Medicinal Products for Human Use shall also draw up an opinion on any scientific matter concerning the evaluation of medicinal products for human use.[..].*

7	Article 20 of Regulation (EC) No 726/2004 on referral for medicinal products that have been authorised via the centralised procedure: 1. *Where the supervisory authorities or the competent authorities of any other Member State are of the opinion that the manufacturer or importer established within the Community territory is no longer fulfilling the obligations laid down in Title IV of Directive 2001/83/EC, they shall forthwith inform the Committee for Medicinal Products for Human Use and the Commission […].* *2. The Commission shall request the opinion of the Agency […]* *3. Following an opinion by the Agency, the Commission shall adopt the necessary provisional measures, which shall be applied immediately. […]"*
8	Article 31 of Directive 2001/83/EC on EU interest referral for medicinal products that have been authorised via the decentralised procedure or mutual recognition procedure: "1. *The Member States, the Commission, the applicant or the marketing authorisation holder shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee for application of the procedure laid down in Articles 32, 33 and 34 before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation which appears necessary. […]"*.
Possible remedies	
9	Request to MAH when notifying the competent authority the interruption[5], either temporary or definitive, of a medicine on the territory: – the volume of sales of the concerned medicinal product and data in his possession relating to the volume of prescriptions; – when possible an indication of the expected dates of the shortage and possible alternatives.
10	Identify alternative medicinal products/treatments in the EU or in third countries: – meet other MAHs of "equivalent" medicinal products asking to increase their production in order to cover the shortage; – import from third countries (variations); – or authorisation to place on the market.
11	Identify alternative manufacturers: – speed up variations of marketing authorisations; – import from third countries and invite MAH to apply for a marketing authorisation.
12	Contact with MAH: – increase shelf-life and re-label shelf-life for existing batches (speed up variation to the existing marketing authorisation); – re-allocate and repackage from another MS; – encourage the use of alternative manufacturing sites already authorised; – facilitate the registration of new sites through submission of relevant variations (shorter procedural timetables, advice before submission).

[5] See also https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf

13	Contact with Health Care Professionals – Advice on the use of alternative treatments and establish therapeutic strategy plans; – Switch to other available pharmaceutical forms; – Introduction of temporary dose reduction; – Restrict the use of the product to specific categories of patients who have no adequate alternative; – Rationalisation of prescriptions; – and accounting of the distribution.
Communication	
14	Use the single point of contact network (SPOC) to exchange information on shortages;
15	This includes expected timeframe for resumption of supply;
16	Inform without delay other competent authorities of results of the GMP inspection in the manufacturing plant or any interruption of import of API from importers;
17	As per the Good practice guidance for communication to the public on medicines' availability issues[6], update relevant websites to give accurate information to patients and healthcare professionals on known or expected shortages on your territory.
18	Ensure communication at national level complements and is consistent 'core' communication issued at EU level. Communication at EU level should be consistent and coexist with national communication strategies: - when status and impact of the shortage differ from country to country; - when clinical practices and recommendations vary between Member States.

[6] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guidance-communication-public-medicines-availability-issues_en.pdf