

McKesson Europe Policy Position Annex

Supporting Material to accompany the McKesson EU Policy Position Paper 'Managing Medicines Shortages'

Managing Medicines Shortages – Supporting Material

January 2021

The causes of medicines shortages

The main European trade associations representing medicines supply chain stakeholders (AESGP, EAHP, EAEPC, EFPIA, EIPG, GIRP, Medicines for Europe, PGEU) acknowledged in their *Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages* in February 2017: ¹

'The causes of shortages are understood to be multifactorial, including problems in production, global consolidation of manufacturing, unintended impacts of pricing and tendering policies, as well as problems within the supply chain.'

Belgium

In October 2018, 357 products were reported as unavailable in community pharmacies according to medicines regulator **AFMPS-FAGG**. ² Of these, 175 were easily replaced by generics from another brand. Of the remaining 182 products, the following reasons were given for their unavailability:

- 100 medicines - new batch not available
- 40 - production problem
- 15 - logistic problem
- 10 - temporary suspension of marketing
- 2 - packaging problem
- 12 - other reason

France

In February 2019, branded manufacturer association LEEM published a survey³ of the reasons for shortages of 400 medicines given by regulator **ANSM**⁴ in 2018:

- 25% - Global tension between demand and production capacity
- 23% - Unpredictable market fluctuations
- 20% - Production problems
- 15% - API supply problems

¹ https://www.efpia.eu/media/25913/joint_supply_chain_actors_statement_on_information_and_medicinal_products_shortages.pdf

² https://www.famhp.be/en/human_use/medicines/medicines

³ <https://www.leem.org/sites/default/files/2019-02/DP-Leem-P%C3%A9nurie-VF.pdf>

⁴ [https://www.ansm.sante.fr/L-ANSM/Une-agence-d-expertise/L-ANSM-agence-d-evaluation-d-expertise-et-de-decision/\(offset\)/0](https://www.ansm.sante.fr/L-ANSM/Une-agence-d-expertise/L-ANSM-agence-d-evaluation-d-expertise-et-de-decision/(offset)/0)

- 10% - Regulatory constraints
- 7% - Economic constraints

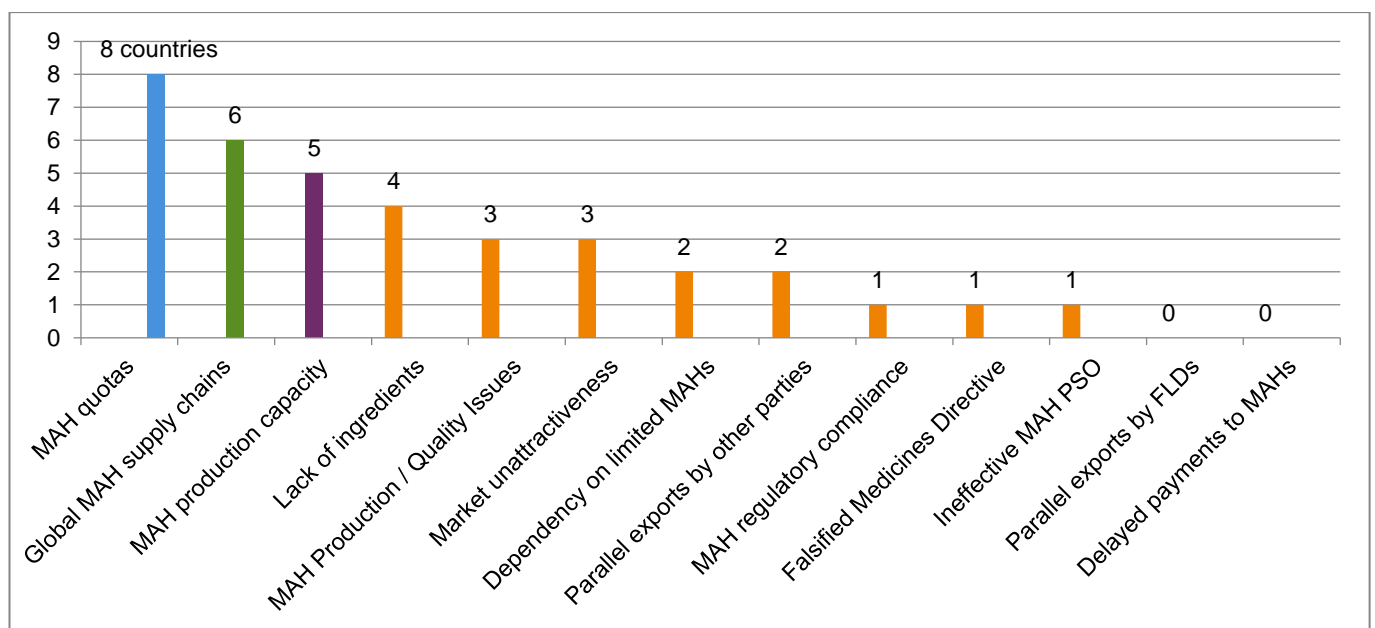
Germany

On 31 October 2018, the **Bundesinstitut für Arzneimittel und Medizinprodukte** ⁵ reported total of 313 medicines shortages, which it attributed to the following causes:

- 270 medicines - production issues
- 6 - delay within production procedure
- 4 - notified as out of distribution
- 2 - notified as out of trade
- 31 - other reasons

McKesson Europe countries

The most common causes identified in twelve countries⁶ by survey of McKesson Europe Managing Directors in May 2019 were as follows:



⁵ https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/Arzneimittelinformationen/Lieferengpaesse/_functions/Filter suche_Formular.html

⁶ Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Norway, Portugal, Slovenia, Sweden, UK

Obligation of continuous supply

Directive 2001/83/EC on the Community code relating to medicinal products for human use

Article 81 states:

'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.'

Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak

'Export bans and national stockpiling, within and outside the EU, can easily lead to inequitable supply and shortages in the EU and worldwide. Total export bans for medicines are not in line with the Treaty and impede the functioning of the single market. The European Commission is calling on all Member States to lift unjustified export bans for medicines within the internal market.'⁷

Paper on the obligation of continuous supply to tackle the problem of shortages of medicines

The **European Commission** stated in this Paper published in June 2018:⁸

'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... 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.'

Stakeholder positions on medicines shortages

European Federation of Pharmaceutical Industries and Associations (EFPIA)

'In line with manufacturers' public service obligation defined by Article 81 of Directive 2001/83/EU industry stakeholders have agreed to define a shortage of a medicinal product for human use as arising in the situation "when supply does not meet patient need at a national level for a period of more than two weeks".⁹

⁷ [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0408\(03\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0408(03)&from=EN)

⁸ https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_rd01_en.pdf

⁹ <https://www.efpia.eu/media/413448/policy-proposals-to-minimise-medicine-supply-shortages-in-europe.pdf>

European Healthcare Distribution Association (GIRP) position on the use of EMVS for shortages monitoring

'The current EMVS has not been built for the collection and publication of information on shortages. Without specific features of the information system for that purpose, the EMVS does not allow to identify the genuine reasons of supply difficulties that have a negative impact to patient care.'¹⁰

Policy solutions to shortages

Ireland

In September 2018, the medicines regulator (HPRA) and all the major medicines supply chain players agreed *A framework for a multi-stakeholder approach to handling shortages of human medicinal products*.¹¹ This is based on two pillars:

1. Reporting of potential shortages to HPRA at an early stage

- any stakeholder may do this
- this communication is confidential to allow discussion of potentially sensitive information with HPRA

2. Notification to HPRA of an actual shortage

- this can only be given by MAH
- must be ranked low-, medium- or high-impact
- medium- / high-impact shortages must include proposal for how to handle
- assessment to be based on availability of therapeutic alternatives and expected impact on patients

HPRA communicates high / medium shortages and has discretion to communicate low-impact or potential shortages. It also recommends that stakeholders adopt preventative strategies.

Netherlands

In 2013, the Ministry of Health established a Working Group on shortages, with representatives from the medicines supply chain, patients, the medicines regulator (CBG) and healthcare inspectorate (IGJ). One outcome was that the Ministry of Health mandated CBG and IGJ to establish an official platform for manufacturers to report medicines shortages.¹²

Pharmacists can report shortages to their association (KNMP), which has a website showing shortages.¹³ Information about the causes is only available to pharmacist subscribers. Pharmacists may also report shortages to their distributor; distributors may report to KNMP or to the MAH.

¹⁰ http://girp.eu/sites/default/files/documents/girp_position_on_use_of_emvs_for_monitoring_of_shortages.pdf

¹¹ <https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/adv-g0020-medicines-shortages-framework-v2.pdf?sfvrsn=4>

¹² <https://www.meldpuntgeneesmiddelenkortendefecten.nl/>

¹³ <https://www.farmanco.knmp.nl/>

The Working Group also agreed a series of measures, ¹⁴ each with allocated responsibility, e.g.:

Manufacturers

- Fallback plans in case of calamities
- More attention to fulfilling the obligation to supply

Distributors

- Set up a warning system
- Quota deliveries to pharmacies in the event of shortages

Pharmacies

- Security of delivery in contracts with distributors
- Freedom for the pharmacist to be able offer patients the best alternative in the event of a shortage, without financial consequences for the pharmacist and patient

Health insurers

- Freedom for the pharmacist to be able offer patients the best alternative in the event of a shortage, without financial consequences for the pharmacist and patient

Public Health Ministry

- Active participation in the EMA task force on medicines shortages

Healthcare inspectorate (IGJ)

- Enforcement of the obligation to supply by manufacturers and distributors
- Enforcement of the timely reporting of shortages

¹⁴ <https://www.rijksoverheid.nl/documenten/publicaties/2016/06/23/overzicht-te-onderzoeken-maatregelen-werkgroep-geneesmiddelenkortening-met-eerstverantwoordelijke-partij>