McKesson Europe Policy Position

Managing Medicines Shortages

January 2021

Introduction – a major health concern for patients

Medicine shortages remain a major health issue for patients and their healthcare professionals. Unexpected or prolonged unavailability of any medicines can lead to serious health consequences for patients and can have a major impact on healthcare systems. Medicine shortages occur in all European countries and there is evidence that the number has continued to grow over recent years. A 2019 survey by the Pharmaceutical Group of the EU[1] revealed that 87% of respondents regarded the shortages situation as worse compared to 2018.

Whilst medicine shortages are frequently characterised as the problem, the real issue is the underlying reasons for shortages occurring in the first place. For example, what identifies as a shortage of a medicine could be the result of a manufacturing difficulty, or an Active Pharmaceutical Ingredient (API) supply problem. Such issues require strategic management and coordination across the supply chain. As one of Europe's largest pharmaceutical Full Service Healthcare Distributors and pharmacy owners, **McKesson Europe takes the issue of medicine shortages very seriously**. This Position Paper looks at key issues surrounding the reasons for medicine shortages and proposes **solutions** for managing this major health concern. In all cases, McKesson Europe promotes pragmatic and proportionate solutions with patient needs being our focus.

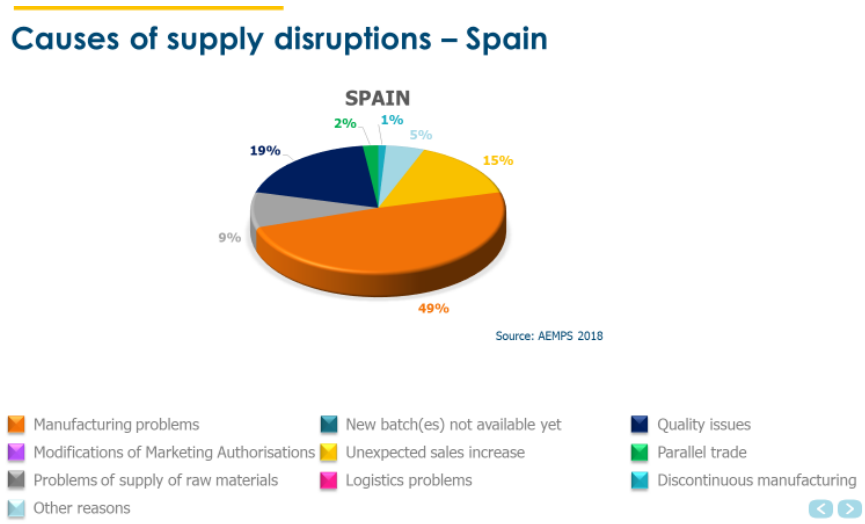
What is a medicine shortage?

The answer depends on your perspective. The European Medicines Agency (EMA) defines a medicines shortage as *'**when supply does not meet demand at a national level**'*. If you are a patient, a shortage is when your pharmacy cannot supply your medicine when you need it. However, a manufacturer will see it from their perspective: "when supply does not meet patient need at a national level for a period of more than two weeks". So, as well as being complex, medicine shortages can also be subjective.

It is critical to remain objective and patient focussed, and for this reason McKesson Europe again focusses on the patients and their needs, which would exclude the two-week definition used by some manufacturers.

As the recently published **EU Pharmaceutical Strategy** outlines, the causes of medicine shortages are complex and include scarce APIs and raw materials, weak public service obligations (PSOs), manufacturer supply quotas, quality issues, manufacturing problems, and, in some limited circumstances, irresponsible exporting by non-Full Service Healthcare Distributors. The graph below shows typical causes identified by the Spanish medicines' regulator in 2018, indicating that 92% of the problems relate to manufacturer-related issues. Given the scale, this must be the focus for identifying solutions.

[1] https://www.pgeu.eu/wp-content/uploads/2019/03/PGEU-Medicine-Shortages-Survey-Results-2019.pdf



There is often a lack of clarity in identifying the root cause of a shortage as it may be the result of several contributory factors or, for instance, due to different national reporting mechanisms.

For example, the Belgian Constitutional Court overturned in 2019 a law that effectively placed a ban on medicine exports, which the Belgian government had misguidedly singled out as being responsible for shortages, without producing any evidence. The Constitutional Court noted that *'there is no evidence suggesting that the activity of the exporters affected the availability of certain medicines in Belgium'*.

The wide range of causes and the complexity of shortages means that instead of trying to solve medicine shortages, all efforts should be directed towards the active management of the supply chain and better cooperation between all relevant stakeholders.

What we are calling for

We believe that **medicines agencies** are best placed to strategically coordinate the active management of medicine shortages. We call on them, and on national policymakers, to take action to incentivise collaborative solutions involving all responsible stakeholders. These include the following examples.

Better monitoring and reporting of medicine shortages

McKesson Europe endorses the draft '*Regulation on a reinforced role for the EMA in crisis preparedness and management for medicinal products and medical devices'* published on 11 November 2020. The Draft Regulation emphasizes the role of information sharing between supply chain stakeholders and regulators to address shortages of critical medicines at EU level. However, establishing communication channels is not enough. **We call upon the European Medicines**

Our key messages

- *Medicines shortages are a growing problem and of great concern to patients.*
- *There are many causes for shortages – they are often complex and overlapping, which makes this a difficult issue to resolve.*
- *As one of Europe's largest full service healthcare distributors and pharmacy owners, McKesson Europe takes shortages very seriously. We are already engaged in our countries to contribute to effective solutions.*
- *Policymakers can help us through supporting a range of measures which would allow full service healthcare distributors and pharmacies to address shortages.*
- *We also call on manufacturers to play their part fully, as the majority of shortages are manufacturer related.*

Agency (EMA) and policy makers to insist on the implementation of already available monitoring mechanisms and enforce reporting of medicine shortages. Due care and attention must be given to ensure harmonised and inclusive reporting. This will enable transparency on the stage of manufacturing and logistics process where shortages occur and support the development of shortage mitigation plans.

McKesson Europe remains **strongly opposed to any monitoring solutions involving the European Medicines Verification System (EMVS) at this time**. As reflected by our European Healthcare Distribution Association (GIRP) in their position paper from 2019[2], the EMVS is not designed for the purpose of monitoring shortages. The EMVS could only be used for this purpose with a set of pre-conditions, including the possibility of checking the EMVS data against availability of medicinal products in the real world. The EMVS figures presenting the number of decommissioned products could be misleading as only products that are available can be decommissioned. Uploaded does not equal available. This means that the EMVS data reflects actual supply and not actual demand for medicinal products. For this reason, we are fully aligned to the GIRP position and we do not support the prioritisation of this EMVS approach over existing coordination measures.

Substitution powers for pharmacists

Highly trained pharmacists are experts in the safe and appropriate use of medicines. When one product is in short supply, they should be allowed temporary use of emergency substitution rights so they can recommend clinically appropriate alternatives. If an alternative is not readily available, pharmacists could, if permitted, respond in several other ways, including dispensing a reduced quantity (rationing), a therapeutic equivalent, an alternative dosage form or an imported (unlicenced) medicine. **We call upon policy makers to support emergency substitution rights for pharmacists** allowing them to dispense clinically appropriate alternatives whenever a prescribed medicinal product is not available**. We would also ask medicine agencies to ensure that when a manufacturer is notifying a shortage or product withdrawal, they must also provide a suitable alternative for patients, where available.**

Right to be supplied

EU legislation requires both pharmaceutical manufacturers and Full Service Healthcare Distributors to ensure *'appropriate and continued supplies'* of medicines to pharmacies. Furthermore, many countries oblige Full Service Healthcare Distributors to hold certain stock levels: for example, in Italy and France we must supply 90% of all medicines available on the market. McKesson Europe understands that manufacturers must, according to EU law, equally be held to account to make *appropriate and continued supplies* to distributors. This law must be enforced. But rather than ensuring *appropriate and continued supplies*, manufacturers frequently impose their own commercially motivated product restrictions known as supply quotas, which from our understanding remain contrary to the Treaty on Functioning of the EU (TFEU). In the context of the ongoing review of EU Pharmaceutical Legislation, **we ask policy makers to prohibit commercially motivated manufacturer supply quotas and commit to supporting the right of Full Service Healthcare Distributors to be supplied by manufacturers** thereby ensuring that patients get their medicines whenever and wherever they need them.

[2] http://girp.eu/sites/default/files/documents/girp_position_on_use_of_emvs_for_monitoring_of_shortages.pdf

Better stock management at pharmacy level

In certain instances, shortages occur due to inefficient stock management. COVID-19 has demonstrated how panic buying by pharmacists, and consumer level stockpiling can lead to sporadic and temporary shortages although medicines are still "available" on the market. Increasing daily deliveries to pharmacies by Full Service Healthcare Distributors is not the answer. Better stock management by pharmacies is needed. Full Service Healthcare Distributors can support pharmacies to better manage their stock by using digital tools. For example, in France, our trading company OCP has implemented a new centralised platform to calculate the needs of our distribution centres in synchronisation with actual pharmacy demand. **We ask policy makers to further support digitalization of medicine supply chain** and integration of digital tools in the wider digital healthcare ecosystem at national level.

Greater flexibility on moving stocks around the EU

In certain instances, medicine shortages in one Member State occur whilst the same medicines may be generally available in other Member States. To ensure shortages are mitigated whenever and wherever they occur in the EU, **we call upon policy makers to allow greater flexibility in moving medicine stocks around the EU**. This should include relaxing language requirements for labelling medicinal products, relaxing Full Service Healthcare Distributors' PSOs in terms of stock levels they need to keep (if the purpose of lowering stock levels is to mitigate shortages in other Member States) and issuing emergency import licenses for Full Service Healthcare Distributors and pharmacies.

Export restrictions

Related to the above point, McKesson Europe supports export restrictions but only as a last resort and only when they are in line with the European Commission's "list of principles" set out in its "*Paper on the obligation of continuous supply to tackle the problem of shortages of medicines"*, published in June 2018. **We call upon policy makers to refrain from blanket export bans and consider restrictions of supply only for a limited list of critical medicines.**

McKesson Europe supports the temporary restriction of supply for specific listed medicinal products where this:

- is established through criteria that are known in advance by all supply chain stakeholders and mediated by the Medicines Agency
- takes full account of the availability of similar or alternative treatments in that Member State or in other Member States
- is revised on a regular basis and takes account of the most up-to-date risks of shortages, removing products no longer at risk
- the decisions implementing its application are taken within a reasonable period and
- the decisions are open to be contested before the relevant administrative bodies or courts of justice

How McKesson Europe is making a dfference on shortages today

McKesson Europe companies never knowingly **export medicines that are in short supply** as **we always prioritise our national customers and their patients**. Moreover, McKesson Europe's trading companies are already actively engaged in providing their own national solutions to medicines shortages, for example through:

- **Calculating need based on actual demand:** OCP France has implemented a new centralised platform to calculate the needs of our distribution centres in synchronisation with actual patient demand,
- **Special delivery channels:** Under Portugal's 'Green Way of Medicines', manufacturers supply certain amounts of critical medicines and OCP Portugal then delivers them to pharmacies,
- **Structured discussions** with regulators, manufacturers, or pharmacies,
- **Import of medicines** from other Member States to help alleviate shortages of unavailable treatments.

What other medicine supply chain stakeholders can do

McKesson Europe also calls on all other relevant parties to play their part in proactively managing this major healthcare issue. This includes health ministries and medicine agencies – and last but not least, as most medicine shortages are due to manufacturing-related reasons as evidenced earlier in our paper, **McKesson Europe will support our manufacturer partners to address their responsibilities and to develop solutions that improve supply chain reliability**, e.g. providing more buffer stock or bringing back manufacturing to Europe.

About McKesson Europe

With strong brands and about 38,000 employees, McKesson Europe is active in 13 European countries. Every day, the company serves over two million customers – at around 2,300 McKesson-owned pharmacies and at over 7,000 participants in brand partnership schemes. With more than 100 wholesale branches across Europe, we supply more than 55,000 pharmacies and hospitals every day with more than 100,000 pharmaceutical products.

McKesson Corporation, Irving, Texas, USA, is the majority shareholder in McKesson Europe AG. McKesson Corporation is a global leader in healthcare supply chain management solutions, retail pharmacy, community oncology and specialty care, and healthcare information technology.

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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 survey[3] 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

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[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

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

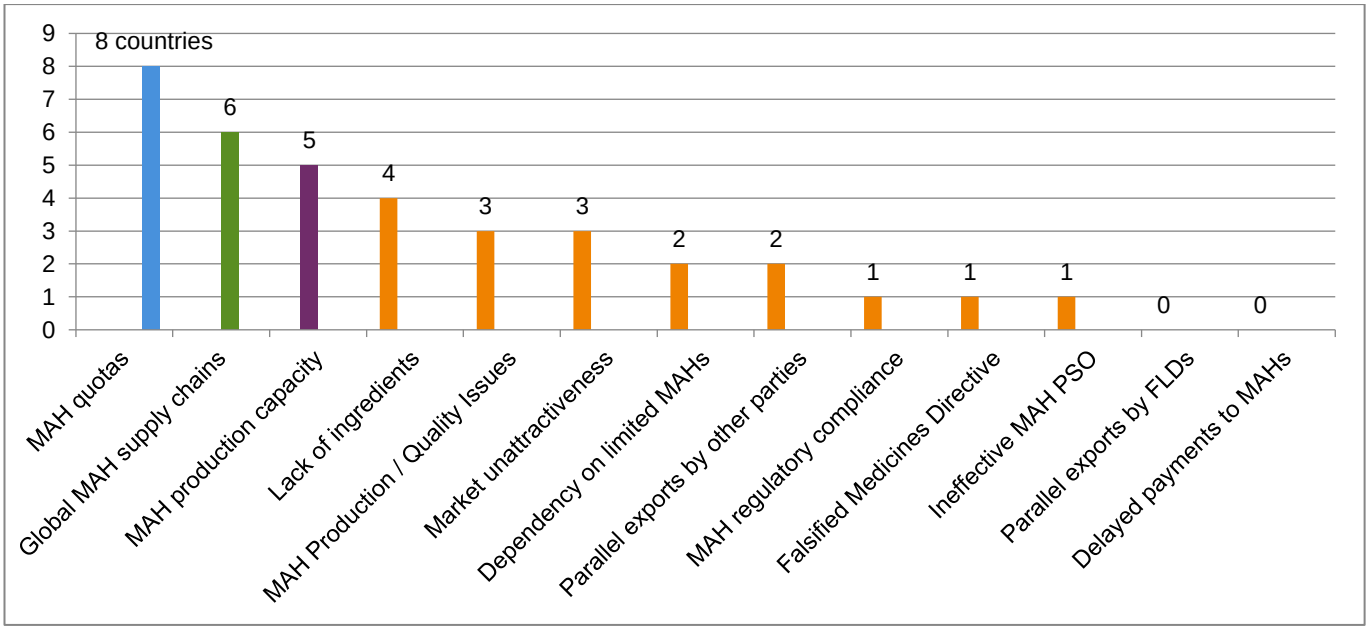
Germany

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 countries[6] by survey of McKesson Europe Managing Directors in May 2019 were as follows:



[5] https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/Arzneimittelinformationen/Lieferengpaesse/_functions/Filtersuche_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

[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.meldpuntgeneesmiddelentekortendefecten.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-geneesmiddelentekorten-met-eerstverantwoordelijke-partij