

# Managing Medicines Shortages

August 2019

## Introduction – a growing problem for patients

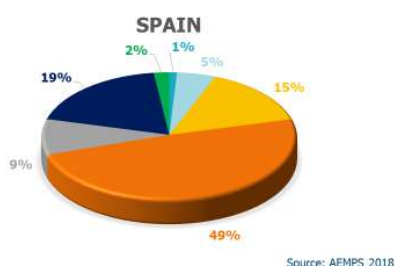
Medicines shortages are an increasing concern for patients and their healthcare professionals. Unexpected or prolonged shortages can lead to serious consequences. Shortages occur in all European countries and there is evidence that their number has continued to grow over recent years. A 2018 survey by the European Association of Hospital Pharmacists revealed that 91.8% of respondents regarded shortages as a current problem compared with 86.2% in 2014.

Such issues require strategic management and coordination across the supply chain. As one of Europe's largest pharmaceutical Full Line Distributors (FLDs) and pharmacy owners, **McKesson Europe takes the issue of shortages very seriously**: this Position Paper proposes some solutions.

## The real causes of medicines shortages

The European Medicines Agency (EMA) defines a medicines shortage as 'when supply does not meet demand at a national level'. Supply issues can be due to global supply chains, failed GMP inspections, lack of Active Pharmaceutical Ingredients, market unattractiveness or manufacturer quotas, among many others. The graph below shows typical causes identified by the Spanish medicines' regulator in 2018.

### Causes of supply disruptions – Spain



- Manufacturing problems
- Modifications of Marketing Authorisations
- Problems of supply of raw materials
- Other reasons
- New batch(es) not available yet
- Unexpected sales increase
- Logistics problems
- Quality issues
- Parallel trade
- Discontinuous manufacturing

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Furthermore, there is often a lack of clarity in identifying the causes, as a single shortage may itself be the result of several contributory factors or may be due to how different national reporting mechanisms have been set, among other reasons.

For example, the Belgian Constitutional Court recently overturned a new law that effectively placed a ban on medicine exports, which the Belgian government had misguidedly singled out as being responsible for shortages. 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 this issue is unlikely to be solved anytime soon, so it requires active management and 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 communication between stakeholders**

McKesson Europe endorses the *'Good practice guidance for communication to the public on medicines' availability issues* adopted by the EMA in July 2019. These include recommendations for how national competent authorities should work with all relevant stakeholder groups to collate supply chain information and to communicate about shortages, e.g. sharing information regarding possible alternative treatments.

### **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 powers** 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 or an alternative dosage form.

### **Right to be supplied**

EU legislation requires both pharmaceutical manufacturers and FLDs to ensure *'appropriate and continued supplies'* of medicines to pharmacies. Furthermore, many countries oblige FLD companies to hold certain stocks: for example, in Italy and France we must supply 90% of all medicines on the market. On the other hand, manufacturers are not always obliged to supply FLDs, and instead frequently impose their own commercially motivated product restrictions known as quotas. **We therefore call on governments to restrict application of quotas and introduce and fully enforce a right for FLDs to be supplied by manufacturers** (where this does not already exist) to ensure that patients get their medicines whenever and wherever they need them.

## 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 medicines 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 distributors and pharmacies to address shortages.*
- ❖ *We also call on manufacturers to play their part fully, as many shortages originate with their sector.*

## How McKesson Europe is offering solutions today

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

- **Supplying manufacturers with product data:** In Germany, GEHE's ALLOCARE reporting system determines actual patient need for a medicine based on prescriptions. GEHE transmits to the manufacturers a reliable proof of domestic demand, and in turn the pharmacies receive the products they need;
- **Calculating our 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 pharmacy 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 with additional operational costs for no extra fee;
- **Structured discussions** with regulators, manufacturers or pharmacies;
- **Import of medicines** from other EU countries 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 addressing this serious healthcare problem. This includes Health Ministries and medicine regulators – and last but not least, as shortages are commonly manufacturing-related, **we call on manufacturers to address their responsibilities and bring forward solutions to improve supply chain reliability**, e.g. regarding how to bring back manufacturing to Europe.

## About McKesson Europe

McKesson Europe, part of McKesson Corporation, is a leading company in the healthcare sector, with strong brands across 13 European countries. McKesson Corporation, currently ranked 7th on the Fortune 500, is a global leader in healthcare supply chain management solutions, retail pharmacy, healthcare technology, community oncology and specialty care. McKesson partners with life sciences companies, manufacturers, providers, pharmacies, governments and other healthcare organizations to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively. United by our ICARE shared principles, our employees work every day to innovate and deliver opportunities to improve patient care in every setting – one product, one partner, one patient at a time. For more information visit [www.mckesson.eu](http://www.mckesson.eu).

## Facts and Figures

Please see our online Annex at:

<https://www.mckesson.eu/mck-en/company/public-affairs/position-papers/medicinesshortages/32238>