Medicine shortages

Introduction

A medicine shortage (also known as a supply shortage or stock-out) can either be a temporary shortage of medicines or diagnostics that will resolve over time, or a market withdrawal by the Marketing Authorisation Holder (MAH) where the shortage becomes a permanent cessation of supplies in the affected area (country).

Most medicine shortages are dealt with at national level by the national competent authorities. The European Medicines Agency (EMA) can also be involved in certain situations, for example when a medicine shortage is linked to a safety concern or when it affects several member states.

Causes of medicine shortages

Medicine shortages can occur for many reasons, such as:

- manufacturing difficulties or problems affecting the quality of medicines that can impact patient care;
- unexpected demand (for example, sudden viral outbreaks, natural disasters)
- problems of a financial nature
- problems in supply chains

There have been a number of public health crises caused by acute and chronic supply shortages.

These have occurred as a result of one or more of the following:

Problems with manufacturing practice

Non-compliance with Good Manufacturing Practice (GMP), for example the failure of a GMP inspection due to inadequate control of raw materials, can lead to a temporary shortage of supply.

Quality defects

The discovery of a quality defect in a production batch may result in the batch being withheld from distribution to the market or the recall of a medicine – for instance, the contamination of a sterile medicine due to equipment failure.

For shortages due to GMP non-compliance/quality defects, the EMA has documents (see further reading below) that support regulators who are involved at the EU-level. The EMA has established a public catalogue of shortages that have been assessed by the EMA's Committee for Medicinal Products for Human Use (CHMP) and/or the Pharmacovigilance Risk Assessment Committee (PRAC). It is designed to communicate clear information to patients, healthcare professionals, and other stakeholders on shortages assessed by the EMA.

Supply chain issues

Many sources of active substances for life-saving medicines – for instance antibiotics – are located outside the EU, and some are in countries that have uncertain political and regulatory systems, or which may be prone to natural disaster, such as the 2011 tsunami in Japan.

The globalisation of manufacturing can lead to just one, or very few, manufacturing sites supplying at a global level. Failure at these sites can therefore lead to global supply shortages. It is possible that the production of single key products may rely on a single contract manufacturer.

Economic causes

- Global or regional crises affecting a country's health budget
- The decision to withdraw a medicine from a market for a variety of reasons – for instance, supply-chain reliability, cost of distribution, and other business reasons
- The result of parallel import/export, where the supply intended for one country is rerouted to another due to pricing difference between the countries

Unexpected rise in demand

When a Marketing Authorisation Holder (MAH) enters a new market, they may underestimate the demand for the medicine. The resulting imbalance between their planned supply and the actual demand can cause a temporary shortage.

Unforeseen world or regional health crises – for instance, a flu pandemic – may also result in unexpectedly high demand for a medicine.

Impacts of medicine shortages

Medicine shortages may impact patients in a number of ways:

- Failure to treat
- Treatment interruptions (omission of medicine doses with sometimes serious consequences)
- Substitution with less effective or more expensive alternatives (which may not always be reimbursed)
- Risk of an increase in adverse events (AEs)

European regulatory authorities aim to minimise the impact of medicine shortages on patients. They do this by:

- Working with pharmaceutical companies to resolve

manufacturing and distribution issues;
- Sharing information with international partners about alternative sources of supply;
- Seeking input from patients and healthcare professionals on the impact of medicine shortages to support decision-making;
- Taking measures to allow alternative medicines or suppliers to be used.

Further Resources

- European Medicines Agency (2013). *EMA/314762/2013 Criteria for classification of critical medicinal products: Shortages due to GMP non-compliance/quality defects*. Retrieved 14 September, 2015, from http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/01/WC500159381.pdf
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