AVAILABILITY MANAGEMENT

Responsibilities of stakeholders

The national and European regulations focusing on medicines' availability were revised in 2019, due to disruptions in the medicines' supply. The changes to the legislation aimed at the improvement of regulatory instruments and the strengthening of responsibilities of stakeholders in the availability of medicines to patients. All parties involved in the supply chain must guarantee the appropriate, continuous availability of medicines and have an important role in the prevention and management of shortages.

Infarmed has the responsibility of coordinating the response to shortages to minimize its impact, in collaboration with all relevant entities. It is also responsible for utilizing all the regulatory tools to support stakeholders in preventing and mitigating shortages' impact.

Manufacturers

- Ensure the adequate and continuous supply of medicines in line with the market demand and patients' needs.
- Development of management strategies to respond to significant changes in demand.
- Development of risk management strategies to prevent and reduce shortages and their impact.
- Identify manufacturing issues or constraints that may affect several marketing authorisation holders and products.

Market Authorisation (MA) Holders

- Ensure the adequate and continuous supply of medicines in line with the market demand and patients' needs.
- Permanently hold 2 months safety stocks for each product.
- Provision the orders from wholesalers.
- Continuous monitoring of the quantities being supplied in light of the market demand.
- Supervise the supply chain of their medicines at national and global level.
- Development of risk management strategies to prevent shortages based on the assessment of the potential public health impact.

- Notify Infarmed on all the disruptions to the normal supply of medicines with at least 2 months' notice. These should be notified regardless of being either temporary or permanent, or potential or real. The notification itself does not absolve the marketing authorisation holder from its responsibilities of supplying the market and implementing the adequate measures to avoid the shortage.
- Have an available and up-to-date mitigation plan for medicines with limited or no therapeutic alternatives.

Wholesalers

- Ensure the adequate and continuous supply of medicines in line with the market demand and patient needs.
- Permanently hold minimum stocks, in quantities not lower than the average monthly sales.
- Monitoring stock levels and ensure the equitable distribution of medicines.
- Identify potential or expected shortages.
- Development of risk management strategies for shortages.
- Notify medicines unavailabilities through the dedicated web service.

Pharmacies

- Abide to the principles of ensuring a continuous public service to the community and the rational dispensing of medicines to the patients.
- Notify pharmacy unavailabilities through the dedicated web service.

Healthcare professionals and hospitals

- Participate in the preparation of clinical guidelines to identify therapeutic alternatives to medicines in shortage situation.
- Report shortages in healthcare facilities to Infarmed by phone or email (disponibilidade@infarmed.pt).

Patient associations

- Collaborate with Infarmed in providing the general public with relevant information on availability.
- Collaborate in the notification of medicines shortages.
- Provide additional information on shortages impact.
- Report shortages to Infarmed by phone or email (disponibilidade@infarmed.pt).

Principles

The management of shortages is a key area of the current legislation and part of a commitment from all stockholders involved. This commitment rests on the following principles:

1. Guarantee of access by patients to the medicines they need.
2. All the parties involved in the medicine supply chain are committed and collectively responsible for avoiding, preventing and managing medicine shortages.
3. Marketing authorisation holders and wholesalers are responsible for maintaining stocks to supply market demand.
4. The notification of marketing shortages or cessations with at least 2 months' notice is a fundamental tool for the adequate management of shortages. Marketing authorisation holders can be fined for non-compliance with this requirement.
5. When notifying a shortage, the marketing authorisation holder must have prepared mitigation measures beforehand in order to minimize its impact.
6. The marketing authorisation holders of medicines with no or limited therapeutic alternatives, whose production is concentrated in one manufacturing site and with high impact in public health, must have at all times an updated shortage prevention plan. This plan must be presented to Infarmed whenever a shortage is classified with a high or medium impact.
7. All parties involved in the supply chain of medicines must keep the records of all the orders and deliveries, as well as all the documentation relating to their activities.
8. Infarmed must pursue all legally available regulatory tools to allow for a better access and supply of medicines to patients.

Impact Assessment on Public Health

The impact assessment considers the following criteria:

- Availability of similar medicines;
- Availability of other authorized medicines with the same active substance, dosage, pharmaceutical form or route of administration;
- Availability of other medicines authorized in other pharmaco-therapeutic groups and with the same indications;
- Market share;
- Available stocks;
- Impact for the patient.

The impact assessment will be classified into one of three levels, as follows:

- Low – medicines with similar medicines available;

- Medium – medicines with limited therapeutic alternatives available;

- High – medicines without therapeutic alternatives.

Shortage Prevention Plan

The marketing authorisation holder must have a shortage prevention plan permanently updated whenever:

- Any part of the medicine's manufacturing process is carried out in a single manufacturing site and the medicine does not have therapeutic alternatives or has limited therapeutic alternatives.
- The interruption of the supply has a serious impact on the health of patients.

The plan must have:

- Identification of the necessary actions on the global markets in order to ensure the regular supply of the national market.
- Instruments for the continuous assessment of demand and supply of the product, including the analysis of national and international stocks.
- Information on safety stocks, which ensure a regular supply of the market by at the least two months.
- A risk assessment in the event of unavailability.
- The identification of therapeutic alternatives, if available.
- The identification of an alternative active pharmaceutical ingredient manufacturer or a secondary manufacturer of finished product.
- The risk management procedures for an effective supply chain.
- Communication proposal to the concerned parties.