



Addressing Challenges to Shortages of Pharmaceutical Products

Project brief

Pharmaceutical product shortages remain an ongoing challenge for healthcare systems globally. The study aimed to evaluate the challenges associated with pharmaceutical product shortages by identifying and analysing factors leading to shortages, evaluate existing mitigation and prevention strategies, measure perceptions of stakeholders on regulatory flexibilities, national and European practices for managing shortages. The perspectives of key stakeholders on the use of digital technologies to prevent shortages was evaluated. Evidence-based guidelines for the prevention and management of active pharmaceutical product shortages were developed

Methodology

1. Two questionnaires were developed to evaluate the impact of shortages in practice. Questionnaires measured the awareness on regulatory flexibilities and digital tools for shortages. (Figure 1)
2. Distribution of questionnaires electronically via the Pharmacy Council, College of Family Doctors and to registered suppliers
3. A Shortage prevention guideline for the prevention of shortages and an action plan for use during active shortages were developed. These were based on the results of the questionnaire and European guidelines.
4. These outputs provide a structured framework with defined roles and responsibilities and risk assessment based on the criticality of the shortages.
5. Documents validated through focus group discussion and updated accordingly



Figure 1: Method Overview

Shortages Prevention Guidance Document:

- Evidence-based recommendations
- Reducing the risk of shortages
- Proactive measures including early risk identification, communication pathways and coordination between stakeholders

Shortages Action Plan:

- For use during active shortage
- Targets various stakeholders
- Immediate notification, risk classification, coordination and escalation, supply management, regulatory flexibility and communication and shortage resolution

Figure 2: Layout of the Guidance document and Action Plan.

Results & conclusions

51 HCPs and 23 Suppliers participated in the study. Manufacturing issues and logistics delays were the main cause of shortages. There is limited awareness on regulatory flexibilities among HCPs.

AI-based forecasting and supply chain monitoring were identified as tools for the reduction of shortages.

The Guidance document and the action plan developed as a shortage framework are outlined in Figure 2.

Shortages are complex and multifactorial and require a coordinated approach combining both preventive and reactive approaches to reduce the impact on patient care.