

The supply of plasma-derived medicinal products in the future of Europe

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Identification of the root causes of observed medicines shortages

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Introduction

Work package 5 (WP5) is responsible for the identification and analysis of the root causes of medicine shortages.

Useful information:

Lead beneficiary: AEMPS, Spain

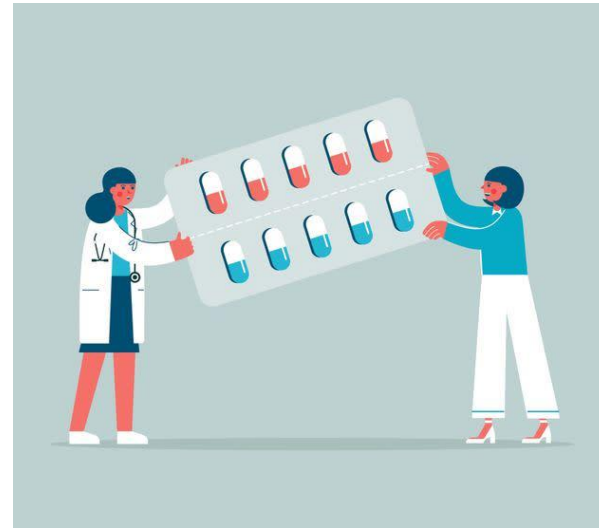
Partners: 15, from 13 countries



Introduction

Shortages can occur for many reasons, such as manufacturing difficulties, problems affecting the quality of medicines or increased demand¹.

MAH ↔ NCA



(1) Available at: <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues>

Introduction

Main objectives:

1. Build a comprehensive **LIST OF KEY DEFINITIONS** and terminology related to shortages of medicines.
2. **REVIEW** of existing topic-related documents that include information related to root causes of medicine shortages at EU level.
3. **ANALYSIS** and categorization of root causes.



1. List of key definitions relating to shortages of medicines

Objective:

Standardise key terminology related to shortages of medicines at EU level, in order to improve data analysis and management and prevention of future shortages.

Methodology:

- Literature review to identify relevant terminology related to shortages
- Update of National definitions of medicine shortage in EU/EEA countries
- Questionnaire to collect updated information on the definition of shortage and its characteristics in each member state



1. List of key definitions relating to shortages of medicines

Main result:

List of key definitions relating to shortages on the basis of existing and published definitions in the EU.

Demand

Shortage

Quality issue

Medicinal product



2. Review on existing documents relating to root causes of medicine shortages in the EU

Objective:

Identification of the causes for medicine shortages reported in the literature.

Main results:

- Manufacturing issues are responsible for most of Europe's medicine shortages.
- There is a lack of harmonization among EU/EEA countries in the classification and registration of root causes of medicine shortages.



3. Analysis report on root causes

Objective:

Analyze in depth the reasons that lead to medicine shortages.

- Analysis of the causes of medicine shortages extracted from the national registers of shortages
- Collect more detailed information (via surveys)



Thank you

