

Shortages

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ELENA PETELOS (EFPC AND EUPHA) AND ANNA MIRABILE (EAHP)
ON BEHALF OF THE POG DRAFTING GROUP

Why do HCP communities need such a document/paper?

- ▶ To understand the **evolving EU regulatory framework** on medicine **shortages** and the **expanded role of the EMA**.
- ▶ To clarify and legitimise **the role of Healthcare Professionals (HCPs)** in **shortage prevention, reporting, and mitigation**.
- ▶ To support safe and **consistent clinical decision-making** during shortages, including **therapeutic substitution**.
- ▶ To provide a **shared EU-level reference** across Member States with differing national rules and practices.

Scope

- ▶ This document captures the **views of HCPs on policy developments and practice implications** regarding **medicinal product shortages**. Its intended audience is HCPs, but also regulators at the EMA, other bodies, payers, patients and, indeed, everyone, given the importance of this critical public health issue.
- ▶ The document bridges a gap in terms of sharing a comprehensive **overview of opinions to the EMA**, clarifying aspects pertaining to current policy and instruments stemming from its extended mandate.
- ▶ Considering the requests of consumer and patients, a separate part of the document will capture comments and views provided by them aiming to inform discussions and support more structured exchanged across HCP communities.



Content of this document/paper?
A chasing game!

Content in detail - I

Problem definition

- ▶ Overview of medicine shortages, their clinical impact, and root causes.

EU Regulatory and policy context

- ▶ Explanation of EMA's extended mandate and relevant EU legislation.

Role of HCPs

- ▶ Current gaps, challenges, and evidence from clinical practice.

Good Practice Guidance (GCP)

- ▶ Preventive and mitigation strategies, including therapeutic substitution.

Content in detail -II

Special Clinical Contexts (to be further expanded?)

- ▶ High-risk therapeutic areas and time-critical medicines.

From Challenges to Opportunities

- ▶ Data-driven tools, forecasting, and system integration.

Policy and System Recommendations

- ▶ Actions to strengthen HCP integration and EU coordination.

Conclusion – going forward

- ▶ Reframing shortages as a clinical governance issue requiring HCP engagement.

Updated timeline

- ▶ POG Review: Feb 2 – Feb 16
- ▶ Consolidation Feb 16 – Feb 20
- ▶ HCPWP Review Feb 20 – Mar 08
- ▶ EMA Review in parallel with HCPWP
- ▶ Consolidation Mar 08 – Mar 15
- ▶ Interim progress presentation in POG meeting





Thank you!