

# SPEAKING THE SAME LANGUAGE

**WP5** | Identifying the root causes of observed  
shortages of medicines

## **Causes of Shortages (Part 2)**

The terms and definitions presented here are the result of the collaborative work carried out under Work Package 5.

They do not represent official definitions but rather proposed and agreed-upon interpretations that were considered for the work conducted within the project. These proposals aim to support future harmonisation efforts across the EU.

# DISTRIBUTION ISSUES

Distribution channel structures, parallel trade (also includes export to outside of the EU), quotas, supply chain policy (e.g. DTO), logistic issues.

# COMMERCIAL REASONS

Company-driven decisions linked to business aspects such as pricing negotiations; discontinuation; change in reimbursement status; low sales (i.e. low number of patients); business strategies prioritising other markets.

## REFERENCE

HMA/EMA. (2020). Reader's guidance: SPOC system – Pilot phase.

# REGULATORY ISSUES

When requirements or obligations relating to the grant of the authorisation have not been fulfilled after authorisation and ‘placing on the market’, e.g. Brexit. Failure to implement safety features, i.e. MAH failure to implement the unique identifier and the tamper evident features on the pack are also considered regulatory issues.

## REFERENCE

HMA/EMA. (2020). Reader's guidance: SPOC system – Pilot phase.

# UNPREDICTED MAJOR EVENTS OR NATURAL DISASTERS

May indirectly lead to shortages of medical products,  
e.g. the ongoing swine fever in China or the earthquake  
in Japan in 2011.

## REFERENCE

HMA/EMA. (2020). Reader's guidance: SPOC system – Pilot phase.

