

Update on Shortage Prevention and Mitigation Plans (SPP/SMP) pilot

14th Industry Standing Group (ISG) meeting

Point 4

Presented by Maria Alcaraz on 30 September 2025

Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

A brief recap...

Good practice guide for industry on prevention/management of shortages of medicinal products for human use

- Document [published](#) in May 2023
- Recommendations for MAHs, manufacturers and other actors in the supply chain to draft SPP and SMP

New pharma legislation

- SPMPs included as one of the structural measures to improve availability of medicines

EC communication on shortages published on 24 October 2023 announced the development of SPPs as one of the elements of the upcoming pharmaceutical legislation implementation that could/should be anticipated

SPMP templates published on 18 June 2024



SPMP Pilot

- ☑ Voluntary for MAHs and CAs
- ☑ **Pilot** endorsed by the MSSG in November 2024

Objectives



- Facilitate the implementation of SPMPs by MAHs and CAs
- Collect information from industry on the templates and challenges they might identify during the process

Scope*



- Alteplase
- Amoxicillin
- Amoxicillin with clavulanic acid
- Verteporfin

Timelines



- Starting date: 9 December 2024
- Duration: 6 months

** Other molecules upon request from the SPOC WP: etoposide, fludarabine, vincristine & peginterferon alfa 2a*

Voluntary participation: trabectedin, amoxicillin and amoxicillin with clavulanic acid

SPMP pilot: data collected and analysis

- **MAHs** in scope of the pilot:
 - 19 MAHs were invited to participate but only **15 MAHs** agreed to participate (~80%)
 - 8 MAHs requested an extension of the DL to submit the SPP
- **SPPs** submitted for review:
 - 37 SPPs included in the pilot but only **29 SPPs** submitted by MAHs (~80%)
- **SMPs** submitted for review:
 - Only **10 SMPs** were submitted by MAHs
- **All SPMPs** submitted during the pilot were **evaluated** and feedback was provided to MAHs
- A **SURVEY to MAHs** on the experience with the pilot was undertaken to identify areas for improvement (12/15 replies - 80%)



SPMP pilot: findings

- **SPPs:** different quality and granularity in the information provided by MAHs
 - Difficult to compare SPPs
 - For many SPPs received, it was difficult to identify vulnerabilities in the supply chain with the information provided by MAHs
 - Information was missing in most SPPs evaluated
- **SMPs:** only a few SMPs received during the pilot (need for additional experience).





Next steps

- The MSSG has agreed with the closure of the pilot with the possibility to request SPPs by the SPOC WP and MSSG
- Report to be drafted and published by the end of 2025
- Templates to be simplified and further guidance/clarity about the information requested: Q1 2026



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Thank you

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