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Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

Shortage Prevention Plan (SPP) and Shortage Mitigation Plan (SMP) pilot report

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1. Introduction

In May 2023, the EMA/HMA Task Force on Availability of Authorised Medicines (TFAAM) published the good practices for industry for the prevention of human medicinal product shortages. This guidance included the recommendation for Marketing Authorisation Holders (MAHs) to develop shortage prevention plans (SPP) and shortage mitigation plans (SMP).

Additionally, the draft proposal for the revised pharmaceutical legislation introduces an obligation for MAHs to develop SPPs and SMPs. According to the Communication on addressing medicine shortages in the EU, published on 24 October 2023, the implementation of SPPs and SMPs was one of the elements of the upcoming legislative revision which could be anticipated.

The TFAAM published the templates for SPP and SMP in June 2024, followed by guidance documents (SPP guidance and SMP guidance) in December 2024 to facilitate a harmonised implementation of the SPPs and SMPs. Until the revised pharmaceutical legislation enters into force, the development of SPPs and SMPs for medicinal products for human use marketed in the EU/EEA remains voluntary, except during Public Health Emergency (PHE) or Major Event (ME) according to the Regulation (EU) 2022/123.

Following the formal closure of the TFAAM activities in December 2024, the SPPs and SMPs activities were transferred to the Executive Steering Group on Shortages and Safety of medicinal products (MSSG) under its Working Group on Voluntary Solidarity Mechanism (VSM) and Policy.

2. SPP and SMP pilot

The MSSG endorsed the pilot for the SPP and SMP implementation in November 2024 and officially launched it on 9 December 2024 with a planned six-month duration.

The pilot was conducted as part of the MSSG recommendations to strengthen supply chains of critical medicinal products.

The objective of the pilot was to support the harmonised implementation of SPPs and SMPs and to collect feedback from MAHs and National Competent Authorities (NCAs) on challenges encountered during the process and potential simplification of the templates.

Participation in the pilot was voluntary for both MAHs and NCAs.

A drafting group composed of 8 NCAs from 7 countries (Belgium, Finland, France, Germany, Portugal, Spain and Sweden) and EMA participated in the pilot. The group was responsible for developing the templates, designing the pilot, and evaluating the SPPs and SMPs received.

In September 2025, the MSSG endorsed the pilot closure while maintaining the option for both the SPOC WP and MSSG to request SPPs and SMPs when necessary.

2.1. Scope

The pilot initially included **4 molecules** selected from the Union List of Critical Medicines: **alteplase, amoxicillin, amoxicillin with clavulanic acid and verteporfin**. For these products, 13 MAHs were proactively contacted and 2 additional MAHs joined the pilot voluntarily.

Four additional molecules — **etoposide, fludarabine, vincristine and peginterferon alfa 2a** — were added at the Medicine Shortages Single Point of Contact Working Party (SPOC WP) request. For these products 3 MAHs were contacted.

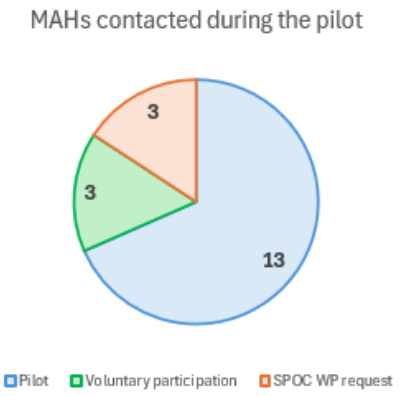
A call for voluntary participation was launched through different forums, and as a result, an additional SPP was submitted for trabectedin by one MAH.

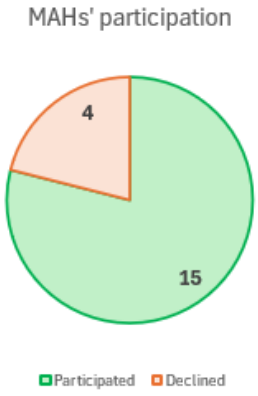
MAHs were requested to submit their SPPs within three months upon the request.

Companies participating in the pilot were requested to submit SMPs for actual or potential shortages of the molecules included in the pilot. MAHs were requested to submit the SMP template when reporting a shortage of any of the products involved in the pilot.

2.2. Participation.

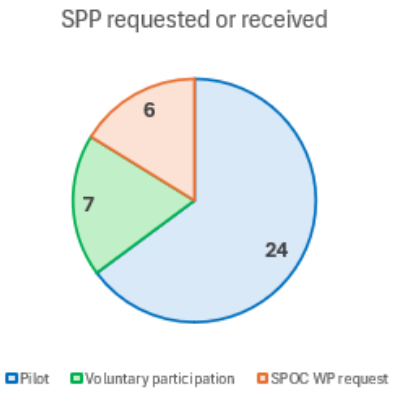
Nineteen MAHs were included within the scope of the pilot of which 15 participated.

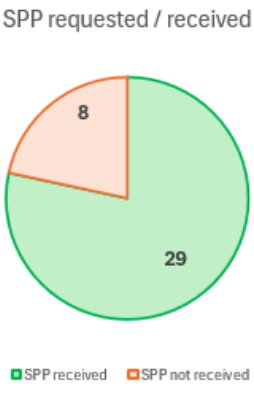




Eight MAHs requested an extension to submit their SPPs, with delays in reception ranging from two weeks to three months.

Fifteen companies replied, providing **29 SPPs** and **10 SMPs** for inclusion in the pilot.





All SPPs and SMPs submitted during the pilot were **evaluated** and feedback was provided to the 15 participating MAHs.

2.3. Findings

SPPs findings

Three companies provided comprehensive replies, while another 6 provided acceptable replies, and the remaining 6 companies provided insufficient information. One company demonstrated inconsistencies in the information provided across different molecules.

Of the 9 companies that submitted adequate replies using the current SPP template, the information provided on patient impact, likelihood of shortages and shortage management measures, could support the identification of vulnerabilities in the supply chain of the medicines concerned, although

additional information would be required in all cases. In addition, the shortage management measures described by 8 of these companies was clear.

In contrast, the remaining 6 SPPs contained insufficient information, as many required fields were left blank or the information provided was inadequate to inform the identification of vulnerabilities in the supply chain or assess the adequacy of the proposed shortage management measures.

Upon review, the replies received varied significantly in quality and granularity. The replies were diverse, inconsistent (comparability was not easily possible) and not standardised, pointing to issues with the understanding of what information should be submitted, the structure of the templates and the clarity of the guidance.

SMPs findings

The 10 SMPs submitted generally lacked useful information as none of them were linked to ongoing shortages. As a result, the proposed mitigation measures could not be evaluated in the context of an active shortage, nor their adequacy could be evaluated. However, in many cases, information not specifically linked to potential or ongoing shortages such as manufacturing capacity globally or potential alternative medicines was not sufficiently described.

Upon review, the quality and granularity of the replies received varied significantly. In several cases, the shortage mitigation measures included in the SMP template appeared to be misunderstood. This highlights the need for clearer guidance on the development of SMPs to ensure preparedness when their submission is requested by EMA or NCAs.

3. Survey to participating MAHs

To gather feedback and identify areas for improvement, a survey was conducted among the 15 MAHs who participated in the SPMP pilot. 12 MAHs responded to the survey, providing valuable information which will guide future developments.

The survey consisted of 12 questions and MAHs were asked to rate their experience on a scale from 1 (poor) to 10 (excellent). All participating MAHs rated their experience from average to excellent.

Six companies considered it challenging to provide the requested information while 5 considered the procedure easy or very easy and one rated the procedure as average.

Eight MAHs considered the three-month deadline adequate. One MAH suggested that the timelines should be 4–5 months.

Almost all MAHs considered that the information requested was sufficient for the analysis of potential shortages and supported the proposed pharmaceutical form level for compiling the data.

Half of the MAHs rated the template as too extensive and found the exercise time consuming, particularly the supply chain risk assessment.

Half of the MAHs replied that no additional guidance would be needed while 5 indicated that further clarification on specific points such as classification of the supply risk assessment or other factors to be take into account to reduce interpretation variability.

The full list of questions and responses can be found in Annex 1.

4. Conclusions and next steps

The SPP and SMP pilot has proven to be a highly valuable exercise, offering important insights into the implementation process and highlighting key areas for improvement to support the effective implementation of the new pharmaceutical legislation. In particular, the voluntary feedback received and active participation of MAHs and NCAs enriched the pilot process and will help guide future steps to optimise SPP and SMP templates and guidance.

The SPP and SMP templates will require further review and update to address the findings of the pilot and to ensure the necessary information is captured to inform deployment of the vulnerability assessment methodology. In addition, the guidance will be updated in the first quarter of 2026 considering the findings and the outcome of the co-legislative process.

5. Annex 1 — Survey list of questions and MAHs responses

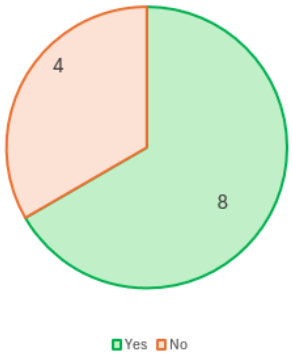
Q1. On a scale from 1–10, how would you rate your overall experience with the pilot project?

Poor								Excellent	
1	2	3	4	5	6	7	8	9	10
0	0	0	0	2	2	2	1	1	4

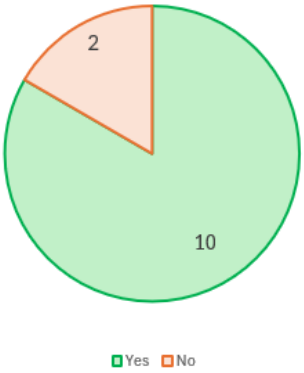
Q2. On a scale from 1–10, how challenging was the provided template for submitting the required information?

Very difficult								Very easy	
1	2	3	4	5	6	7	8	9	10
0	1	3	2	1	0	4	0	1	0

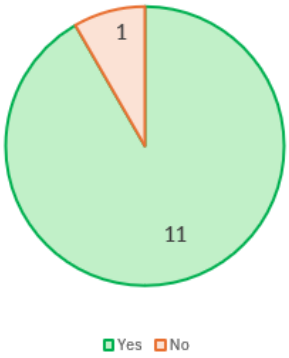
Q3. Do you consider the 3-month deadline for completing the templates adequate?



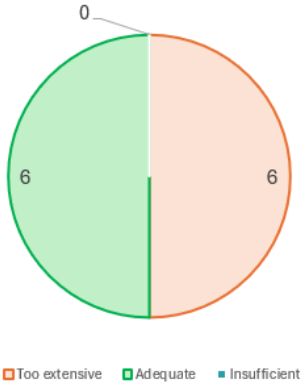
Q4. In your opinion, is the information requested sufficient for the analysis of a potential shortage?



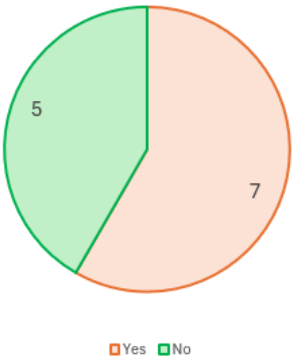
Q5. Do you think that the pharmaceutical form level of the medicinal product is appropriate for compiling the information?



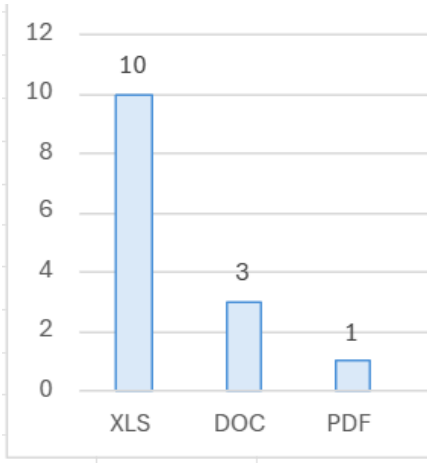
Q6. In your opinion, is the extent of the template



Q7. Would you prefer a preprogrammed template?



Q8. What format do you consider most suitable for the template?

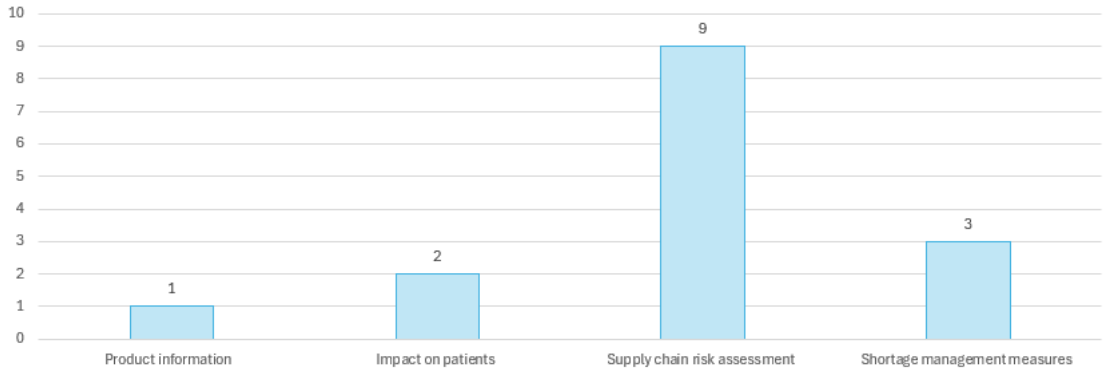


Q9. On a scale from 1–10, how time consuming was the completion of the template?

Very time consuming								**Not time consuming**	
1	2	3	4	5	6	7	8	9	10
2	3		1	3	1	1	1		

Q10. In your opinion, which section of the template was the most time consuming?

- Product information
- Impact on patients
- Supply chain risk assessment
- Shortage management measures



Q11. On a scale from 1–10, how difficult was it to understand the requested information with the provided guidance for industry?

Unclear									**Very clear**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
0	0	0	1	0	2	3	0	2	4

Q12. Regarding the section "classification of the supply vulnerabilities" would you prefer additional guidance or to maintain it as it is?