EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

EMA Shortage Prevention Plan Workshop Report

1. Background and Objectives

On 22 June 2026, EMA organised a workshop to gather technical feedback from industry stakeholders on the updated Shortage Prevention Plan (SPP) template and guidance, which are being revised to align with the requirements of the forthcoming EU pharmaceutical Regulation. SPPs are intended to support the proactive identification, assessment, and mitigation of supply chain risks that could lead to medicine shortages.

The workshop objectives were to:

- present the proposed updates to the SPP template and guidance;
- collect technical feedback from industry stakeholders;
- identify implementation challenges and potential improvements; and
- inform the finalisation of the SPP framework ahead of its anticipated implementation from mid-2027.

2. Participants

The workshop brought together representatives from EMA, the EU Medicines Regulatory Network, and industry associations, including Affordable Medicines Europe, Association Européenne des Spécialités Pharmaceutiques Grand Public (AESGP), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Industrial Gases Association (EIGA), European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Medicines for Europe, Parenteral Drug Association (PDA), Plasma Protein Therapeutics Association PPTA, and Vaccines Europe.

3. Presentations

EMA outlined the development of SPPs prior to their formal introduction under Regulation (EU) 2022/123 through to the proposed requirements under the new Pharmaceutical Regulation. The Agency highlighted the collaborative work undertaken with industry stakeholders and Member State

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

National Competent Authorities to develop a harmonised template and guidance, including a pilot phase conducted in 2025.

EMA presented the proposed updates to the template, which align with the minimum data requirements set out in Annex IV, Part V of the new legislation. An overview was also provided on the planned integration of SPP submissions into the European Shortages Monitoring Platform (ESMP), with the aim of supporting structured data collection, reducing reporting duplication, and improving data analysis capabilities.

4. Breakout Sessions – Key Discussion Points

Session 1: Template Usability and Implementation

Participants generally welcomed the revised SPP template and guidance, recognising it as an improvement on the previous version. However, there was a strong call for greater flexibility and a more risk-based approach, particularly to better distinguish between low-, medium-, and high-risk products. Several stakeholders expressed concern that certain criteria, such as the number of Active Pharmaceutical Ingredient (API)manufacturing sites, could result in products being classified as high risk despite having robust supply arrangements. Discussions also highlighted the need for the template to better accommodate the specific characteristics of plasma-derived medicines, biologics, and other innovative products, as it is currently perceived to be more suited to chemical and generic medicines. Stakeholders further noted significant challenges in obtaining required information from third-party manufacturers and suppliers, especially in the off-patent sector, resulting in a heavy reliance on manual data collection. In addition, participants emphasised the complexity of compiling SPP data from multiple internal systems, including supply chain, regulatory, and quality management platforms, and highlighted the considerable resources required to integrate data across different sites and organisations.

Session 2: Additional Requirements and Implementation Support

Discussion in Session 2 focused on the overall scope of the SPP template and the support needed for implementation. Participants broadly agreed that the template is already comprehensive and that no significant additional data requirements should be introduced. However, stakeholders suggested adding fields to allow justification of risk classifications and ensuring that data elements not required by legislation remain an optional section in the template.

Another main topic was the need for greater regulatory clarity through detailed guidance on:

- when SPPs will be requested,
- expectations during inspections,
- update frequencies, and
- the practical operation of the "submission upon request" process.

Stakeholders also recommended developing mock-up SPP templates, playbooks, and practical guidance documents to illustrate expected levels of detail and regulatory interactions.

To manage implementation burden, participants proposed prioritising medicines included on the Union List of Critical Medicines, particularly for companies managing large product portfolios. However, it was noted that the scope must remain aligned with the new pharmaceutical legislation.

Finally, there was support for increased international regulatory harmonisation.

EMA confirmed that SPPs would not be routinely submitted but would be provided upon request in accordance with the legislative framework. The Agency also indicated that updates would focus on relevant changes rather than requiring complete resubmissions. EMA reiterated that ESMP integration is intended to streamline reporting processes, support structured data analysis, and minimise duplication. The Agency further confirmed its commitment to ongoing engagement with industry throughout the implementation process.

5. Conclusion

The workshop demonstrated broad support for the objectives of the SPP framework while identifying areas requiring further refinement, including risk classification, flexibility for different product types, reporting burden and implementation guidance. EMA will consider the feedback received from the workshop and the written consultation when finalising the updated SPP template and guidance, which will be subsequently adopted by the MSSG. The final documents and workshop report will be published following completion of this process, while development of ESMP functionalities will continue in collaboration with industry stakeholders. Close cooperation between regulators and industry will remain essential to ensure effective and proportionate implementation ahead of the anticipated regulatory deadlines.

Annexes

Agenda - Workshop on Shortage Prevention Plans (SPP)

Guidance for industry on implementing Shortage Prevention Plans