EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guidance and template for industry on implementing Shortage Prevention Plans (SPP)

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1. Introduction

1.1. Background

Improving the availability of medicines authorised in the European Union (EU) is a key priority for the European Medicines Regulatory Network (EMRN comprised of EMA and Member State National Competent Authorities). Since 2016, the EMRN, has been monitoring and managing medicine availability issues, including supply chain disruptions, to improve the continuity of supply of human and veterinary medicines across Europe. The systems and processes that were established, were reinforced in EMA's extended mandate Regulation (EU) 2022/123, including the formal establishment of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Medicines Shortages Single Point of Contact Working Party (SPOC Working Party).

This work will be further reinforced in the new pharmaceutical legislation. The new pharmaceutical Regulation includes provisions aiming to reinforce medicines shortage monitoring and management and strengthen supply chain resilience in the Union, including the obligation for Marketing Authorisation Holders (MAHs) to put in place, and keep up to date, a shortage prevention plan (SPP) for any medicinal product subject to prescription in the EU. The scope may be further extended at the discretion of the European Commission.

In addition to the legal obligation, the recommendation for MAHs to have SPPs in place is included as one of the recommendations (recommendation 4) of the good practices for industry for the prevention of human medicinal product shortages.

The implementation of SPPs will facilitate the MAHs compliance of their obligation to ensure, within the limits of their responsibilities, an adequate and continuous supply to the market (Article 56(3), new pharmaceutical Directive).

This guidance indicates the relevant type and detail of information for shortage prevention plans, according to the different level of risk, including descriptions of the relevant shortage management measures. The degree of effort, formalisation and documentation for each SPP and consequent proposal of shortage mitigating measures should be proportionate to the identified level of risk for each medicine.

1.2. Legal Basis

Regulation (EU) 2022/123: In case of a crisis (public health emergency (PHE) or major event (ME)), the Agency may request SPPs for medicines included in the list of critical medicines for that specific crisis according to Article 9(2) point c and Article 9 (3) point k of Regulation (EU) 2022/123. The Regulation states that, at a minimum, information on production and supply capacity and approved production sites of the finished medicinal product and of active substances, potential alternative production sites and minimum stock levels of the medicinal product should be included. MAHs concerned are required to submit that information to the Agency in accordance with Article 10(2) of that Regulation.

New Pharmaceutical Regulation: Article 117(1) requires MAHs to establish and maintain an up-to-date shortage prevention plan, for any medicinal products subject to medical prescription and for medicinal products identified by the European Commission in accordance with Article 126 (2b) of the Regulation. These plans must include the minimum set of information set out in Part V of Annex IV and take into account the associated guidance drawn up by the Agency, in collaboration with the SPOC WP. The minimum set of information is included as Annex to this guidance.

These plans are only required to be submitted upon request to national competent authorities, the Agency or, in the context of crisis preparedness, the Commission, in accordance with the requirements set out in the text. When requested, the MAH will have two days to submit a copy of the SPP.

SPPs may need to be updated to take MSSG recommendations into account.

1.3. Objective

All MAHs should establish and maintain an up-to-date SPP for any medicinal product for human use with prescription only medicine status in one or more EU/EEA countries.

SPPs may be aggregated/ grouped for medicines that share a common supply chain, at the discretion of the MAH, as long as the minimum set of data, based on the template set out in Annex I, can be made available to National Competent Authorities, EMA or the European Commission within two days of a request to submit the plan.

The main objective of the SPPs is to ensure the MAH has appropriate systems and processes in place to identify potential risks in the supply chain that may impact the supply and availability of medicines, with clear risk minimisation measures to reduce the likelihood of shortages. It is recommended that MAHs high-level hierarchy maintain oversight of the development and update of the SPPs.

The level of detail required to be included in the SPP should be proportionate to the level of risk identified. For this purpose, a risk-based approach is set out in this guidance. In addition, ICH guideline Q9 on quality risk management and ICH Q12 on pharmaceutical product lifecycle management should be applied. The SPP could form part of the annual product quality review and should be updated if relevant changes occur e.g. based on MSSG recommendations, following a critical shortage or due to supply chain changes.

Any additional information requested by the National Competent Authority, EMA or the European Commission should also be provided in accordance with the legislation. The information included in the SPP will be used for the purposes set out in the legislation, by National Competent Authorities, European Medicines Agency or European Commission. The merits of confidentiality claims will be assessed, and commercially confidential information will be protected against unjustified disclosure.

MAHs should provide information based on their knowledge, responsibilities, and contractual access, and where specific data are not available, this should be clearly justified, together with a qualitative assessment of the relevant risks and potential impact on supply.

2. How to establish and update the SPP

2.1. Product details

Product details	Data required
Product name	Specify complete trade name (speciality name)
Active substance(s) name	Specify active substance(s)
Active substance(s) manufacturer(s)	Specify active substance manufacturer(s) (indicate if it is active/ non active)
Finished product manufacturer(s)	Specify finished product manufacturer(s) (indicate if it is active/ non active)

Product details	Data required
[1]*Key input and suppliers*	*Specify key inputs and suppliers* *[While this is not a requirement of the NPL, it is a key element of the new Critical Medicines Act and this data may be requested by competent authorities, alongside the SPP minimum data set.]*
ATC code	Specify ATC code[2]
Therapeutic indication(s)	Specify authorised therapeutic indication
Pharmaceutical form	Specify pharmaceutical form
Strength(s)	Specify strength(s)
Route(s) of administration	Specify route of administration
Pack size(s)	Specify marketed pack size(s) per Member State, with unit of measurement
Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and marketing authorisation number	Specify national procedure, mutual recognition procedure, decentralised procedure or centralised procedure, with Member States involved and associated Marketing Authorisation number(s)
Member State(s) in which the product is placed on the market	Specify EU/ EEA countries
Marketing Authorisation Holder name	Specify MAH name
Marketing Authorisation Holder address	Specify MAH address
Contact person name	Specify contact person name, preferably the iSPOC as registered in EMA's IRIS online platform[3]
Contact person details	Specify email address and contact telephone number of contact person

2.2. Shortage prevention measures and supply chain risk assessment

2.2.1. Patient impact of potential supply disruptions	
(a) Therapeutic indication and alternative marketed medicinal products	Specify: **High** = Inclusion on Union list of critical medicines

[1] 'key input' means input material other than an active substance required in the manufacturing process of a given medicinal product, including primary packaging materials, excipients, solvents and reagents in accordance with the new Critical Medicines Act

[2] The Anatomical Therapeutic Chemical code: a unique code assigned to a medicine according to the organ or system it works on and how it works. The classification system is maintained by the World Health Organization (WHO).

[3] Call for companies to register their Industry Single Point of Contact (i-SPOC) on supply and availability | European Medicines Agency (EMA)

2.2.1. Patient impact of potential supply disruptions

	Medium = Inclusion on Union long list[4] (but not on the Union list) or inclusion on any list of critical medicines in the EU/ EEA (with reference) **Low** = On neither of the above lists
(b) Estimated market share per Member State in the previous 12 months[5]	Specify: **High** = EU level market share > 50% **Medium** = EU level market share 25-50% or > 50% of any individual EU market **Low** = EU level market share <25% Provide breakdown per MS, and overall EU level market share (both over previous 12 calendar months) in %[6].
IMPACT CLASSIFICATION: taking into consideration the two above elements under 2.2.1 (for risk classification):	Based on 2.2.1 (a) and (b) outcomes above, select high, medium or low High (a) / high (b) = **high** High (a) / medium (b) or medium (a) / high (b) = **high** High (a) / low (b) or Low (a) / high (b) = **medium** Medium (a) / low (b) or Low (a) / medium (b) or Medium (a) / medium (b) = **medium** Low (a) / low (b) = **low**

IMPACT CLASSIFICATION		a) Therapeutic indication and alternative marketed medicinal products		
		High (Union list)	Medium (Union long list or national lists)	Low
b) Estimated market share	High (EU market share > 50%)	High impact	High impact	Medium impact
	Medium (EU market share 25-50% or > 50% of any individual EU market)	High impact	Medium impact	Medium impact
	Low (EU level market share <25%	Medium impact	Medium impact	Low impact

2.2.2. Supply chain risk assessment

Supply chain risk assessment to include:	
Supply chain map, including:	Provide visual supply chain map[7] (for all)

2.2.2. Supply chain risk assessment	
• List of manufacturing sites at different steps of manufacturing process • Location of those sites • Share of production volumes per manufacturing site listed • Identified supply chain vulnerabilities and dependencies per site	Details of supply chain map, specifying: • List manufacturing sites at different steps of manufacturing process (for all) • Location of those sites (for all) • Share of production volumes per manufacturing site listed (for all) • Identified supply chain vulnerabilities and dependencies per site[8] (for all)
Record of root causes of resolved shortages and mitigation measures taken for those shortages	Specify shortages [of longer than 1 month duration], that were notified at national level or to EMA [over the past 3 calendar years]. (for all) Include details of root causes and mitigation measures taken for those shortages.
Additional information required for medicines on a critical list during a public health emergency or major event, in accordance with Regulation (EU) 2022/123:	Only for medicines on critical list during a public health emergency or major event, in accordance with Regulation (EU) 2022/123, otherwise leave blank. • Information on production capacity; • Information on supply capacity; • Potential alternative production sites for finished medicinal product; • Potential alternative production sites for active substances; • Minimum stock levels of the medicinal product;
Supply chain risk assessment CLASSIFICATION: (for risk classification):	All: MAH self-assessment of risk, based on **Supply chain risk assessment** information: Select: **High**: Where one or more of the following four criteria is met: • a limited number of manufacturing sites at any step of the manufacturing process; • concentration of those manufacturing sites in a single geographical location;

[4] Once adopted
[5] For the market share calculation the INN and pharmaceutical form should be considered
[6] Reflecting normal supply with no restrictions of supply/controlled distribution (historic demand with no restrictions)
[7] Visual should include at a minimum list manufacturing sites for API and finished product and location of those sites
[8] This should capture vulnerabilities related to single source suppliers, or single site manufacturing locations with no appropriate identified mitigating measures. Other factors could include long lead production time and long lead time for restarting supply, known bottlenecks, history of delays from critical suppliers over the last 3 years (with details) or history of batch rejections, quality defects[18], recalls from the market over the last 3 years in the EU/EEA (with details).

2.2.2. Supply chain risk assessment	
	• a high share of production volume per manufacturing site listed; • identified supply chain vulnerabilities and dependencies[9]; **AND** > 5 shortage notifications[10] of longer than 1 month duration have been notified at national level or to EMA in past 3 years in the EU, with associated root causes. **Medium**: Where one or more of the following three criteria is met: • Where there is a more diversified supply chain, e.g ≥ 2 sites for API/ Finished Product, including sites that are either approved or submitted for approval **AND** ≤ 5 shortage notifications of longer than 1 month duration have been notified in past 3 years in the EU, with associated root causes; • Limited identified supply chain vulnerabilities and dependencies[4]. • Where one or more of the following four criteria is met: – a limited number of manufacturing sites at any step of the manufacturing process; – concentration of those manufacturing sites in a single geographical location; – a high share of production volume per manufacturing site listed; – identified supply chain vulnerabilities and dependencies; **AND** 0-5 shortage notifications of longer than 1 month duration have been notified at national level or to EMA in past 3 years in the EU, with associated root causes. **Low**: No supply chain risk identified, no shortage notified in past 3 years. based on information provided in this section 2.2.2.

[9] vulnerabilities related to single source suppliers, or single site manufacturing locations, including but not limited to those identified via the vulnerability evaluation under the new pharmaceutical legislation. Other factors could include long lead production time and long lead time for restarting supply, known bottlenecks, history of delays from critical suppliers over the last 3 years (with details) or history of batch rejections, quality defects[1], recalls from the market over the last 3 years in the EU/EEA (with details).

[10] Shortage notifications are counted individually per Competent Authority notified.

3. Final risk classification, covering 2.2.1 and 2.2.2 classifications above:

FINAL CLASSIFICATION: Final risk classification (low, medium, high) covering both supply chain vulnerability and public health impact, with separate risk classification if necessary, **covering 2.2.1 and 2.2.2 classifications above**:	**Select high, medium or low, based on outcome classification under 2.2.1 and 2.2.2 above.** High/ high or High/ medium or medium/ high = **high** High/low or Low/high = **medium** Medium/ low or Low/ medium or Medium/ medium = **medium** Low/ low = **low**

FINAL RISK CLASSIFICATION		a) Patient impact of potential shortage disruption		
		High	Medium	Low
b) Supply chain risk assessment	High	High impact	High impact	Medium impact
	Medium	High impact	Medium impact	Medium impact
	Low	Medium impact	Medium impact	Low impact

3.1. Shortage management measures: Risk based approach

As stated above, the level of detail for each SPP and consequent proposed shortage management measures should be proportionate to the identified level of risk for each medicine. Based on the high/ medium/ low classification identified under section 3 above, please complete the following fields as follows:

Shortage management measures	
Risk control strategy in place, to include information on strategies to minimise risks of shortages and how these are implemented	All: In place – yes/ no (for Medium/ High): Describe strategy, including information on strategies to minimise risks of shortages and how these are implemented.[11]

[11] Including but not limited to those specified in the Good practices for industry for the prevention of human medicinal product shortages. The risk control strategy should include information on existence of safety stocks (specifying e.g., buffer stocks held by MAH, safety stocks for national stockpile (national obligation), including minimum stocks at national level); existence of any other *active* manufacturing sites of API, critical raw materials or finished medicinal product registered in the dossier or under evaluation and for non-active sites time to activate, a description of the modalities for the restriction of distribution measures (quantitative quota or qualitative quota/prioritisation of patients), as well as any other measures that could be used or other National specifications requested by competent authorities.

Shortage management measures	
Process for the detection and notification of supply disruptions	All: In place – yes/ no (for Medium/ High): Describe process for the detection and notification of supply disruptions[12]
Process for check of effectiveness, review and update of the shortage prevention plan	All: In place – yes/ no (for Medium/ High): Describe process for check of effectiveness, review and update of the shortage prevention plan[13]
Methodology for establishing the demand forecast	All: In place – yes/ no (for Medium/ High): Provide methodology for establishing the demand forecast[14]

[12] The process description should refer to process to monitor stocks; existence of specific processes for communication on availability issues within different departments of the company and ensuring alignment with national affiliates; existence of specific processes for the reporting of availability issues with the actors in the supply chain to allow early detection (wholesaler distributors, pharmacies); Existence of specific processes for the notification of supply disruptions to regulatory authorities.
A reference to a company-wide procedure for the detection and notification of supply disruptions is acceptable. There is no requirement to develop separate procedures for individual products

[13] Define process for checking of effectiveness, review and update of the SPP.
A reference to a company-wide procedure for the verification of effectiveness and the review and update of the shortage prevention plan is acceptable. There is no requirement to develop separate procedures for individual products.

[14] A clear methodology demonstrating how demand is calculated and monitored and what actions are taken when the demand increases or decreases occur.
A reference to a company-wide procedure or strategy is acceptable. There is no requirement to develop separate procedures for individual products, provided that the procedure adequately addresses demand forecast across the product portfolio, including consideration of seasonal variations where applicable.

Annex to Guidance for industry on implementing Shortage Prevention Plans (SPP)

Annex I – SPP template: minimum set of information

1. Product details

Product details	Reflects section of new pharmaceutical Regulation, Annex IV Part V
Product name	1(a)
Active substance(s) name	1(b)
Active substance(s) manufacturer(s)	1(b)
Finished product manufacturer(s)	1(c)
Key inputs[1] and suppliers	*While this is not a requirement of the new pharmaceutical Regulation, Annex IV Part V, it is a key element of the new Critical Medicines Act and this data may be requested by competent authorities, alongside the SPP minimum data set.*
ATC code	1(d)
Therapeutic indication(s)	1(e)
Pharmaceutical form	1(f)
Strength(s)	1(g)
Route(s) of administration	1(h)
Pack size(s)	1(i)
Details of authorisation: procedure type (national (including Member State(s) involved)/centralised marketing authorisation) and marketing authorisation number	1(j)
Member State(s) in which the product is placed on the market	1(k)
Marketing Authorisation Holder name	3(a)
Marketing Authorisation Holder address	3(a)
Contact person name	3(b)
Contact person details	3(b)

2. Shortage prevention measures and supply chain risk assessment

2(a) Patient impact of potential supply disruptions	
Therapeutic indication and alternative marketed medicinal products	2(a) (criteria for high/ medium/ low as per guidance)
Estimated market share by Member States in the previous 12 months	2(a) (criteria for high/ medium/ low as per guidance)

2(a) Patient impact of potential supply disruptions	
Impact taking into consideration the two above elements:	2(a) (select high/ medium, low, based on outcome of two above)

2(b) Supply chain risk assessment	
Supply chain risk assessment to include:	2(b)
Supply chain map, including: • List of manufacturing sites at different steps of manufacturing process • Location of those sites • Share of production volumes per manufacturing site listed • Identified supply chain vulnerabilities and dependencies per site	2(b)(i)
Record of root causes of resolved shortages and mitigation measures taken for those shortages	2(b)(ii)
Additional information required for medicines on a critical list during a public health emergency or major event, in accordance with Regulation (EU) 2022/123: Information on production capacity: Information on supply capacity: Potential alternative production sites for finished medicinal product: Potential alternative production sites for active substances: Minimum stock levels of the medicinal product:	*This information is only required for medicines on a major event critical medicines list or a public health emergency critical medicines list, in accordance with Regulation (EU) 2022/123, otherwise leave blank.*

3. Final risk classification, covering 2(a) and (b) above:

Final risk classification (low, medium, high) covering both supply chain vulnerability and public health impact, with separate risk classification if necessary:	

The accompanying guidance will indicate the relevant type and detail of information for shortage prevention plans, according to the different level of risk, including descriptions of the relevant shortage management measures. (*Not in legal text but propose to retain:* The degree of effort, formalisation and documentation for each SPP and consequent proposal of shortage mitigating measures should be proportionate to the identified level of risk for each medicine.)

4. Shortage management measures

Shortage management measures	
Risk control strategy in place, to include information on strategies to minimise risks of shortages and how these are implemented	2a(a)
A process for the detection and notification of supply disruptions	2a(b)
Process for check of effectiveness, review and update of the shortage prevention plan	2b
Methodology for establishing the demand forecast	2c