10 September 2024
EMA/65984/2024
European Medicines Agency

Guidance for industry on implementing Shortage Prevention Plans (SPP)

Table of Contents

1. Introduction (background)

Medicine shortages are recognised as a growing issue across the EU and globally, and the COVID-19 pandemic has further increased their impact. They affect medicines of all classes and are increasingly affecting European countries. This may have a significant impact on patient care as they can lead to medicine rationing and delay of critical treatments and can require patients to use alternatives which may be less efficacious or may increase the risk of medication errors due to unfamiliarity with the new regimen.

Improving the availability of medicines authorised in the European Union (EU) is a key priority for the European Medicines Regulatory Network (EMRN). Since 2016, a task force set up by the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA), the HMA / EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TFAAM), has been looking at availability issues, including supply chain disruptions , to improve the continuity of supply of human and veterinary medicines across Europe.

Availability issues with shortages in particular are recognised as a major area to tackle in the European Medicines Agencies Network Strategy to 2025 as well as in the European Commission's roadmap for its Pharmaceutical Strategy which has led to the release of the revision of the pharmaceutical legislation in April 2023. The revised pharmaceutical legislation envisages 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 placed on the market.

The need to have SPPs is also included as one of the recommendations (*recommendation 4*) of the good practices for industry for the prevention of human medicinal product shortages developed by the TFAAM in consultation with industry associations which was published in May 2023. The SPPs are also recognised as one of the recommendations raised by the EC shortage study.

The implementation of SPPs will facilitate the MAH's compliance of their obligations to ensure, within the limits of their responsibilities, an adequate and continuous supply to the market (article 81 Directive 2001/83).

This guidance is intended to support Industry when implementing SPPs.

2. Scope and objective

A stepwise implementation is applicable:

- In case of a crisis (public health emergency (PHE) or major event (ME)) SPPs are **mandatory** for medicines included in the list of critical medicines for that specific crisis according to article 9.3.k of the Regulation 2022/123.
- MAHs should have in place a SPP for any medicinal product for human use they place on the market of the EU/EEA according to the good practices for industry for the prevention of human medicinal product shortages.

The scope can be expanded according to the new pharmaceutical legislation.

The main objective of the SPPs is to identify potential risks in the supply chain (likelihood of shortages) and the impact on patients of shortages in order to reduce the likelihood of shortages.
The formalization of the shortage management measures (see point 4.4.) should be proportionate to the identified level of risk identified. For this purpose, ICH guideline Q9 on quality risk management should be applied.

3. How to implement a SPP

The implementation will remain voluntary, unless a PHE or ME arises or until the new pharmaceutical legislation comes into force and a broader scope is foreseen.

It is key that the company considers the SPPs not as an administrative document but as a useful tool that is beneficial, first and foremost for them to identify any potential risk and be prepared if shortages occur. It is highly recommended that the high-level hierarchy of the company (personnel with power and resources to solve the detected deficiencies in the supply chain) is involved in the development of the SPP.

The SPP should be part of the annual product quality review and updated accordingly on an annual basis or if relevant changes occur such as critical shortage occurrence or a variation of the supply chain.

The document should be written in English and translated into the language of the Member State when requested by the NCA. National specifications, if any, should be indicated in the risk assessment (variations of markets, production cycle) if requested by the NCA.

The information included in the SPP will be used only by Competent Authorities. Information will not be disclosed with third parties.

4. How to complete the SPP template

4.1. Product information

The SPP should be completed at the level of pharmaceutical form.

Product information	
Product name(*) Pharmaceutical form(*) Strength(s) (*)	*Please note the complete trade name (speciality name), pharmaceutical form and strength(s)*
Active substance(s) name(*)	*Please note the active substance(s)*
Active substance(s) manufacturer(s) (*)	*Please note the active substance(s) manufacturer(s) (active sites)*
Finished product manufacturer(s) (*)	*Please note the finished product manufacturer(s) (active sites)*
ATC code(*)	*Please note the ATC code*
Therapeutic indication(s) (*)	*Please note the authorized therapeutic indication(s)*
Route(s) of administration(*)	*Please note the route(s) of administration*
Pack size(s) (*)	*Please note the marketed pack size(s) per Member State. If helpful, this information can be submitted as an annex.*
Details of authorisation (procedure type (national (including Member State(s) involved)/ centralised	*Please note the procedure type (e.g., MRP, DCP, CAP) and reference (e.g., CAP number or MRP procedure number): if it concerns a national procedure, please include the Member State(s) involved*

Product information	
marketing authorisation) and reference(*)	
Member States in which the product is marketed(*)	*Please list the Member States in which the product is marketed*
MAH (name and address) (*)	*Please note the name and address of the Marketing Authorisation Holder. In case of NAP, MRP or DCP, the details of MAH can be included as an annex if needed.*
Contact person's details(*)	*Please note the contact details of the contact person, e.g. e-mail address, telephone*

4.2. Risk assessment

Impact on patient (3 different risk levels: high, medium, low)	
Classification of the therapeutic indication (**)	*Please indicate if the therapeutic importance of the medicine is high, medium or low, based on the methodology used to develop the Union list of critical medicines (see annex 1).* *If the medicine is included in the Union list of critical medicines, the final impact on patients can be considered as high.*
Classification of the medicine based on marketed alternative medicinal products per Member State(*) (**) (***)	*Please indicate if the availability of alternatives to treat the authorized indications of the medicine poses a high, medium or low risk for shortages and impact on patients, based on the methodology used to develop the Union list of critical medicines (see annex 1) and this per Member State.* *If the medicine is included in the Union list of critical medicines, the final impact on patients can be considered as high.*
Annual sales data over the last year in the EU (number of units, monthly sales)	*Please list the monthly sales data over the last 12 months per Member State in number of units, e.g.,*

MS	***Month***	***Sales data***
AT	*January*	*6 kg*
AT	*February*	*5 kg*
BE	*January*	*2 kg*

Impact on patient (3 different risk levels: high, medium, low)	
Final impact on patients classification:	*Please provide the final impact on patients, expressed as either high, medium or low impact. To that end, please use the following matrix, based on the first two criteria of this section (classification of the therapeutic indication and classification of the medicine based on marketed alternative medicinal products).*

		Classification of the therapeutic indication		
		High	Medium	Low
Classification of the medicine based on marketed alternative medicinal products	High	High impact	High impact	Medium impact
	Medium	High impact	Medium impact	Low impact
	Low	Medium impact	Low impact	Low impact

In case of different outcome for different Member States, please list the most restrictive option.

NOTE: for products included in the Union list of critical medicines select high.

Supply chain risk assessment. Risk level of likelihood of shortages: high, medium, low	
Supply chain map with risk identification and analysis with particular attention to supply chain vulnerabilities(*)	
• Active substance(s): risk assessment on the manufacture and supply	*Indicate if the level of likelihood of shortage in relation with the active substance is high, medium or low based on worst case scenario and explain the chosen risk classification.* *Possible factors to take into account: number of suppliers, dependency on third countries, complexity of the process*
• Critical raw materials: risk assessment on the manufacture and supply	*Indicate if the level of likelihood of shortage in relation with critical raw materials is high, medium or low based on worst case scenario and explain the chosen risk classification.* *Possible factors to take into account: number of suppliers, dependency on third countries, complexity of the process*
• Finished product: risk assessment of the manufacture, control and supply	*Indicate if the level of likelihood of shortage in relation with the finished product manufacturer is high, medium or low based on worst case scenario and explain the chosen risk classification.*

<table>
<tr><th colspan="3">Supply chain risk assessment. Risk level of likelihood of shortages: high, medium, low</th></tr>
<tr><td></td><td colspan="2">Possible factors to take into account: number of suppliers, dependency on third countries, complexity of the process</td></tr>
<tr><td>History details of batch rejections, quality defects[1] [1], recalls from the market over the last 3 years in the EU/EEA</td><td colspan="2">Please list all batch rejections, quality defects and recalls from the EU/EEA market over the last 3 years, e.g.,
<table>
<tr><th>Quality event</th><th>Affected MSs</th><th>Timing</th><th>Reason</th></tr>
<tr><td>Batch rejection 1</td><td>BE/ES</td><td>2021</td><td>Impurity</td></tr>
<tr><td>Batch rejection 2</td><td>all</td><td>2023</td><td>…</td></tr>
<tr><td>Recall 1</td><td>AT</td><td>2022</td><td>Particles</td></tr>
<tr><td>Quality defect 1</td><td>FR/DE</td><td>2022</td><td>…</td></tr>
<tr><td>Quality defect 2</td><td>ES/PT/MT</td><td>2022</td><td>…</td></tr>
</table></td></tr>
<tr><td>History details of delays from critical suppliers over the last 3 years</td><td colspan="2">Please list the delays from critical suppliers (API, critical raw material/excipients/packaging material) in the past 3 years, e.g.,
<table>
<tr><th>Timing</th><th>Critical supplier</th><th>Duration of delay</th></tr>
<tr><td>2021</td><td>API</td><td>3 months</td></tr>
<tr><td>2021</td><td>Critical excipient</td><td>6 months</td></tr>
<tr><td>2022</td><td>Packaging material</td><td>6 weeks</td></tr>
<tr><td>2023</td><td>Raw material</td><td>12 months, ongoing</td></tr>
</table></td></tr>
<tr><td>Average lead production time and lead time for restarting supply</td><td colspan="2">Please note the time needed to manufacture and release a batch, as well as the time needed to restart supply</td></tr>
<tr><td>History details of shortages of the product over the last three years including record of root causes and any mitigation measures taken for those shortages(*)</td><td colspan="2">Please list all shortages of the product over the last 3 years and include the root cause and mitigation measures per shortage, e.g.,
<table>
<tr><th>Start date</th><th>End date</th><th>MSs affected</th><th>Root cause</th><th>Mitigation measures taken</th></tr>
<tr><td>02/02/2022</td><td>02/03/2023</td><td>BE, ES, PT,GR</td><td>API shortage</td><td>Short-term: moved stocks amongst MSs
Mid-term: extra API manufacturer</td></tr>
</table></td></tr>
</table>

[1] According to the Compilation of Union Procedures on Inspections and Exchange of Information a Quality defects is 'any defect in a medicinal product within the scope of their authorisation that could result in a recall or abnormal restriction in supply'

Supply chain risk assessment. Risk level of likelihood of shortages: high, medium, low	
Bottlenecks in the supply and manufacturing process	*Please list the identified bottlenecks in the supply and manufacturing process*
Seasonality	*Please indicate if the medicine in scope is subject to seasonality (yes or no)*
Other factors to be taken into account	*Please list any other factors that need to be taken into account*
National specifications, when requested by NCAs	
Final supply chain risk assessment classification	*Please note the final supply chain risk assessment classification as low, medium or high probability of shortages by taking into account the above mentioned information.*

4.3. Risk classification

The final risk level is the result of the combination of the impact on patients and the likelihood of disruption in the supply chain. There are three categories of risk:

- Low risk
- Medium risk
- High risk

		Impact on patients		
		High impact	Medium impact	Low impact
Likelihood of shortages	High probability	High risk	High risk	Medium risk
	Medium probability	High risk	Medium risk	Low risk
	Low probability	Medium risk	Low risk	Low risk

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.

- If low risk: no further actions are needed; please be reminded that SPPs need to be annually reviewed or if relevant changes occur such as critical shortage occurrence or a variation of the supply chain.

- If medium or high risk: please complete the section below and include proposals to decrease the risk of shortage

4.4. Shortage management measures

Measures	
Risk control strategy in place, i.e. strategies to minimise risks of shortages and how these are implemented(*)	
• Existence of safety stocks, including minimum stocks at national level	*Please list any existence of safety stock per MS, including the minimum required stock. Please differentiate different kinds of stock, e.g., buffer stocks held by MAH, safety stocks for national stockpile (national obligation)* *If this does not exist, please indicate if this is considered as a possible management measure.*
• Existence of any other *active* manufacturing sites of critical raw materials registered in the dossier or under evaluation. For non-active sites, time to activate	*Please indicate (yes or no) if there is any other site registered or under evaluation. In case of a non-active site, please provide the time needed to activate.* *If this does not exist, please indicate if this is considered as a possible management measure*
• Existence of any other active manufacturing sites of API registered in the dossier or under evaluation. For non-active sites, time to activate	*Please indicate (yes or no) if there is any other site registered or under evaluation. In case of a non-active site, please provide the time needed to activate.* *If this does not exist, please indicate if this is considered as a possible management measure*
• Existence of any other active manufacturing sites of finished medicinal product registered in the dossier or under evaluation. For non-active sites, time to activate	*Please indicate (yes or no) if there is any other site registered or under evaluation. In case of a non-active site, please provide the time needed to activate.* *If this does not exist, please indicate if this is considered as a possible management measure*
• Other measures	*Please note any other strategy that is in place, under development or considered to minimise the risk of shortage*
Existence of any specific processes for the detection of supply disruptions	
• Monitoring of stocks	*Please indicate (yes or no) if you have a system in place to monitor stock levels and if yes, what actions are being taken when those levels are low.* *If no such system is in place, please indicate if this is considered as a possible management measure*

Measures	
• Monitoring of demand	*Please indicate (yes or no) if you have a system in place to monitor demand and if yes, what actions are being taken when the demand changes (either increase or decrease).* *If no such system is in place, please indicate if this is considered as a possible management measure*
• …….	*Please note any other process in place, under development or considered for the detection of supply disruptions*
Company's internal procedures for communication/reporting	
• Existence of specific processes for communication of availability issues within different departments of the company	*Please indicate (yes or no) if you have a specific process in place to communicate on availability issues withing different departments of your company and if yes, please explain.* *If no such process is in place, please indicate if this is considered as a possible management measure.*
• Existence of specific processes for the reporting of availability issues with the actors in the supply chain to allow early detection (wholesaler distributors, pharmacies)	*Please indicate (yes or no) if you have a specific process in place for reporting on availability issues with actors in the supply chain to allow early detection and if yes, please explain.* *If no such process is in place, please indicate if this is considered as a possible management measure*
• Existence of specific processes for the notification of supply disruptions to regulatory authorities	*Please indicate (yes or no) if you have a specific process in place for the notification of supply disruptions to regulatory authorities and if yes, please explain.* *If no such process is in place, please indicate if this is considered as a possible management measure*
Process for checking of effectiveness, review and update of the SPP (*)	*Please indicate (yes or no) if you have a specific process in place to check the effectiveness of the SPP and to review and update the SPP and if yes, please explain.* *If no such process is in place, please indicate if this is considered as a possible management measure*

[1](*) Data required in Annex IV-part V- the shortage prevention plan of the proposal of Regulation.
[1](**) risk levels according to the methodology published for the development of the Union list of critical medicines.

[1](**) Alternatives marketed by the same and different MAHs.

Annex 1: Methodology to identify critical medicines for the "Union list of critical medicines"

Full document can be found here.

Critical medicines will be selected based on a risk assessment considering their relevance to public health, the so-called medicinal product criticality[2].

Assessment and risk assignment of medicinal product criticality

Medicinal product criticality will be based on the following two criteria:

- The **therapeutic indication (criterion 1)** of the medicine and
- the **availability of appropriate alternatives (criterion 2)**.

For criterion 1, all authorised medicines in a Member State should be classified, irrespective of their marketing status. For criterion 2, only authorised medicines marketed in the respective Member State should be classified.

For each criterion, **3 risk levels (low, medium and high)** exist. Once a risk level has been assigned for each criterion, a risk matrix is applied to assign the medicine to either of the following categories:

- "critical medicines"
- "medicines at risk" and,
- "other medicines".

Criterion 1: Therapeutic indication

For **criterion 1** (therapeutic indication), the importance of the therapeutic indication will be assessed.

If a product has multiple therapeutic indications, the indication with the most serious implications for patients should determine the risk level.

High risk	Indications with **very serious implications** for the health of **individual patients or public health**: medicines or classes of medicines used to treat patients with **general life-threatening acute conditions, specific life-threatening acute conditions, or irreversibly progressive conditions[2]**
	A medicinal product should be allocated to the "high-risk" level if one or more of the following conditions are met: • Indications with **very serious implications** for the health of **individual patients or public health**: medicines or classes of medicines used to treat patients with **general life-threatening acute conditions, specific life-threatening acute conditions, or irreversibly progressive conditions[3]** • The disease to be treated is potentially fatal, irreversibly progressive or, if left untreated, will pose an immediate threat, or cause severe impairment to the patient.

[2] U.M. Musazzi, et al.; International Journal of Pharmaceutics 579 (2020)
[3] For the purpose of this sub-criteria "to treat" should be interpreted as to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, in line with the EU definition of medicinal product.

	This applies similarly to acute situations (emergencies), chronic situations or situations with potentially fatal outcomes. • If the treatment is unavailable or interrupted, it will jeopardise the vital prognosis of patients in the short or medium term or represent a significant loss of opportunity for patients regarding the severity or potential evolution of the disease. • The treatment **must be administered immediately or within regular dosing intervals.**[4] • The product is part of a national disease control program (e.g., vaccination campaign)[5]
Medium risk	Indications with **serious implications** for the health of **individual patients or public health**
	A medicinal product should be allocated to the medium-risk level if one or more of the following conditions are met: • Medicines indicated for treatment of chronic, severely limiting diseases. • Medicines for the treatment of vulnerable patient groups (such as paediatric medicines). • Medicines for the treatment of patient groups or diseases where a switch in medication is associated with particular difficulties. • Medicines indicated for prevention or treatment of notifiable diseases. • If the disease is left untreated, it may induce potentially irreversible disease progression, hospitalisation or intensified treatment, but no fatality is expected. • A product which prevents relapses of a condition, but, if suspended, would not immediately expose relapses; maybe the relapse will only occur weeks or months after treatment interruption (e.g. multiple sclerosis), or the disease progression is slow (Duchenne muscular dystrophy or cystic fibrosis).
Low risk	Other indications.
	• A medicinal product should be allocated to the low-risk level if it does not fulfil the above-mentioned high- or medium-risk conditions.

Criterion 2: Availability of appropriate alternatives

This risk classification aims to estimate if a potential shortage can be managed with **appropriate alternatives**, i.e. medicines that can be substituted without any negative impact on the patient's health by providing the same quality of care standard.

An alternative is appropriate if it fulfils the following criteria:

4 This requirement originates from the recommendations of the Jour Fixe on Delivery and Supply shortages. The opinion of the WS2 was, that the requirement is appropriately defined without a specific time limit. However, if during the risk assessment for medicines, the need to define a specific time period is identified, it should be defined, but should not exceed 24 hours.

5 The "national disease control programme" does not refer to lists of essential or critical medicines established by the WHO or available at national level.

- The alternative medicine is authorised for the same therapeutic indication in the respective Member State (i.e. no off-label use);
- The alternative medicine is available on the market of the respective Member State;
- Alternative treatment is clinically possible;
- The use of alternative treatment does not have a negative impact on the patient's health and provides the same quality of care standard.

Appropriate alternatives should be identified in line with the clinical considerations stated below in the table (please refer to explanatory notes).

The medicinal product will be allocated to the respective risk level based on the number of identified appropriate alternatives.

High risk	Quantitative risk-classification: No appropriate alternative is available; OR Only one appropriate alternative (product) on ATC level 4 or 5 (same active substance or alternative is within the same ATC level 4 group or in another ATC level 4 group) is available --- Qualitative risk classification: *(Clinical considerations and explanatory notes)* High-risk treatments are those treatments for which no appropriate alternative treatment exists or is available, or switching to the alternative treatment would require extensive clinical consultations not applicable for specific indications. Substitution of treatment is expected to affect patient safety or disease prognosis. Alternative treatment is not clinically possible: The active substance or combination of active substances (e.g., combination of ethambutol, rifampicin and isoniazid used to treat tuberculosis, combination treatment for HIV) has unique pharmacology and no alternative treatment options exist. **Alternative treatment would require extensive clinical consultations, not applicable for high-risk indications:** • The alternative treatment has a lower therapeutic index than the initial treatment. • Switching to alternative treatment cannot be accomplished in a short time due to clinical reasons related to poor clinical outcomes, therapeutic failures, delayed onset of treatment, compromised disease control (e.g., psychiatric drugs), decreased efficacy (i. e., antibiotic resistance) or requires additional monitoring (e.g., renal or hepatic parameters). • Switching to an alternative treatment cannot be accomplished in a short time due to the organisation of care (e.g., to receive the alternative treatment, the patient may require an appointment with a different specialist who can prescribe the alternative treatment), or requires switching from self-administration to in-patient / hospital administration (e.g. switch from subcutaneous to intravenous administration).

	• The alternative treatment is only available for compassionate use. • The alternative treatment does not meet the clinical needs of the entire target patient population: a subgroup of patients cannot use the alternative treatment / the alternative treatment is contra-indicated (including patients with specific needs, target population commonly served by off-label use, elderly, paediatric, disabled patients, etc.). • The alternative treatment has additional serious, irreversible or incurable adverse events compared to the initial treatment. Due to the use of the alternative treatment, the target patient population may experience life-threatening complications (e.g., greater toxicity). **Alternative treatment is not available:** • Alternative treatment is possible, but the alternative treatment is not available (the alternative treatment is not marketed, or the alternative product has been withdrawn from the market).
Medium risk	**Quantitative risk-classification:** • At least two appropriate alternatives (products) on ATC level 4 or 5 (same active substance or alternative is within the same ATC level 4 group) are available? --- **Qualitative risk classification:** *(Clinical considerations and explanatory notes)* Medium-risk treatments are those treatments for which alternative treatment requires additional input from medical personnel but is not expected to affect patient safety or disease prognosis , or the availability of alternative treatment may be limited. **Alternative treatment is clinically possible but requires input from medical personnel:** • Alternative treatment has the same or equal / similar therapeutic effect and may be achieved by using alternative active substances (from the same therapeutic or ATC or pharmacological group). • Alternative treatment may be achieved by using alternative pharmaceutical forms or different routes of administration or extemporaneous preparations / in-house compounding, alternative strengths, or alternative dosing regimens. Using the alternative pharmaceutical form does not require switching from self-administration to in-patient administration. **Alternative treatment is available in limited quantities:** • The alternative product is available in limited quantities, and a potential shortage is expected due to increased demand.
Low risk	**Quantitative risk-classification:** • More than two appropriate alternatives (products) are available on ATC level 4 or 5 --- **Qualitative risk classification:** *(Clinical considerations and explanatory notes)*

	Lowrisk treatments are those treatments for which alternative treatment exists, or the availability of alternative treatment is manageable. Products can freely be substituted, and little or no input from medical personnel is required. **Alternative treatment is clinically possible and requires little or no input from medical personnel:** • Alternative treatment is possible by using the same active substance, the same strength in the same pharmaceutical form or a different pharmaceutical form with the same route of administration (e.g. generic substitution, substitution of formulations) • Alternative treatment is possible using a well-established alternative active substance (e.g. OTC dispensing of pain medication). • Alternative treatment is possible and does not affect patient safety. **Alternative treatment is readily available, and no supply issues are expected due to increased demand.**

Overall risk categorisation

Once a medicine has been assigned a risk level for the two criteria, criticality will be set using the risk matrix (below), and the medicine will be assigned one of the following three categories:

- "critical medicines"
- "medicines at risk" and,
- "other medicines".

		Criterion 1 (Therapeutic indication/ importance)		
		High risk	Medium risk	Low risk
Criterion 2 (Availability of alternatives	High risk	**Critical medicine**	**Critical medicine**	**At-risk medicine**
	Medium risk	**Critical medicine**	**At-risk medicine**	**Other medicines**
	Low risk	**At-risk medicine**	**Other medicines**	**Other medicines**

The Union list will then be drafted based on the "critical medicines" assigned.

Annex 2: Flow of risk assessment

Step 1. Impact on patients:

- Methodology: cfr methodology Union list of critical medicines
- Outcome is "low impact", "medium impact" or "high impact"

		Classification of the therapeutic indication		
		High	Medium	Low
Classification of the medicine based on marketed alternative medicinal products	High	High impact	High impact	Medium impact
	Medium	High impact	Medium impact	Low impact
	Low	Medium impact	Low impact	Low impact

Step 2. Likelihood of shortages

- Methodology: industry assesses impact based on their experience
- Outcome is "low probability", "medium probability" or "high probability"

Step 3. All together:

- Methodology: apply risk matrix
- Outcome is "low risk", "medium risk" or "high risk"

		Impact on patients		
		High impact	Medium impact	Low impact
Likelihood of shortages	High probability	High risk	High risk	Medium risk
	Medium probability	High risk	Medium risk	Low risk
	Low probability	Medium risk	Low risk	Low risk

Step 4. final risk classification – consequence

- If "low risk": no further actions are needed; please be reminded that SPPs need to be annually reviewed or if relevant changes occur such as critical shortage occurrence or a variation of the supply chain.
- If "medium risk" or "high risk": please complete the section on shortage management measures and include proposals to decrease the risk of shortage.