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European Medicines Agency

Shortage Prevention Plans (SPP) template

Minimum set of information

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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