EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Shortage Mitigation Plan (SMP)

1. Introduction

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 all 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 prepare a shortage mitigation plan.

The need to have a shortage management plan to respond to shortages is also included as one of the recommendations (*recommendation 5*) 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 shortage mitigation plans are also recognised as one of the recommendations raised by the EC shortage study.

The implementation of shortage mitigation plans (SMP) 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).

2. Scope

Concerned MAHs should develop a SMP to address potential or actual shortages of medicines marketed by them with the aim to minimise any possible impact on patients in a timely and proportionate manner.

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A SMP formally identifies signals and risks for the continued availability of the product and implements a procedure for their mitigation. The effectiveness of such mitigation plans and the controls intended to prevent supply interruptions should be formally evaluated for effectiveness.

The degree of effort, formalisation and documentation for each SMP should be proportionate to the identified level of risk for each medicine, for this purpose, ICH guideline Q9 on quality risk management should be applied.

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 SMP.

3. Shortage Mitigation Plan

3.1. Minimum requirements

MAHs should implement procedures describing the steps to manage a specific shortage, from the time a shortage (or potential shortage) is identified to its resolution, including measures taken to mitigate the impact of the shortage, notification to regulatory Authorities and follow up.

The specific processes should contain roles and responsibilities and the escalation process.

A record of root causes and mitigation measures taken should be kept after the resolution of shortages.

A template for the proposed mitigation measures is included as Annex I.

3.2. Submission

SMPs will be submitted to the Competent Authorities concerned (Competent Authority of the Member State where the medicinal product is marketed and, in addition, the EMA for a medicinal product covered by a centralised marketing authorisation) upon request according to timelines laid down in the pharmaceutical legislation and national regulations. SMPs may also be submitted directly to Competent Authorities when MAHs become aware of a shortage, in such case the shortage report and SMP might be merged in a single document.

The MAH shall provide the information required and ensure that data provided are correct, accurate, not misleading and complete. The MAH shall update the information where necessary.

Annex I – SMP template (some of the information listed below is extracted from the shortage reporting template and it is included for ease of reference)

Product information

Product information	
Product name (*i)	
Active substance(s) name(*)	
Active substance(s) manufacturer(s) (*)	
Finished product manufacturer(s) (*)	
ATC code (*)	
Therapeutic indication(s) (*)	
Pharmaceutical form (*)	
Strength(s) (*)	
Route(s) of administration (*)	
Affected pack size(s) (*)	
Pharmaceutical form, strength, route of administration or pack size, not affected by the supply disruption(*)	
Details of authorisation (procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference (*)	
Member States in which the product is marketed (*)	
MAH (name and address) [1](*)	
Contact person's details (*)	

Shortage details

Shortage details	
Shortage status (actual or potential) (*)	
Impacted EU/EEA countries(*)	
Other impacted countries - non EU/EEA countries (*)	
Full description of the root cause (*)	

[1] In case of NAP, MRP, or DCP, the details of MAH might be included as an Annex if needed

Shortage details	
History of shortages of the product in the EU over the last three years including the record of root causes and mitigation measures taken to address the shortages	
Expected start date of shortage (*)	
Expected end date of shortage (*)	
Monthly sales (*)	
Actual demand at national level in previous 12 months[2](*)	
Quantities delivered per month per Member State, in previous 12 months (*)	
Manufacturing capacity globally per manufacturing site (*)	
Forecast of supply per month and per Member State for the duration of the shortage (*)	
Forecast of demand per month and per Member State for the duration of the shortage (*)	
Potential alternative products (*)	
Impact on the supply of other medicinal products from the same marketing authorisation holder (*)	
Potential impact on the consumption of or demand for other medicinal products (*)	

Shortage mitigating proposals

Any mitigating measures taken or planned by the marketing authorisation holder to address the shortage(*)

Proposals	
Availability of alternatives:	
• Therapeutic alternative(s) marketed in the impacted country[3][4](1)	

[2] When relevant please provide separate rows containing information for hospital and community pharmacies
[3] From the same MAH and different MAHs
[4] The methodology published for the development of the Union list of critical medicines should be followed

Proposals	
• Therapeutic alternatives marketed in the EU/EEA(1)	
• Therapeutic alternatives marketed outside the EU/EEA (that could be imported from abroad)(1)	
Allocation of orders. If applicable, please provide details of criteria used to prioritise supply to countries and the clinical justification.	
Request for support from Competent Authorities to solve/mitigate the impact of the shortage	
Reallocation of stock between markets. If applicable, please provide details on the justification for the reallocation of stock from one Member State to another and the mitigation measures if this results in a shortage.	
Marketing of product in different language[5]	
Marketing of product with less than 6 months of expiry date[6]	
Controlled distribution by the MAH[7]	
Alternative distribution routes to expedite supply (site to country)	
Other	
• Supply plan proposal for member states including specific final presentations to maximize patient supply	
Communication in collaboration with EMA/NCAs[8]	

(*) Data required in Annex IV-part III information to be provided in case of a temporary disruption of supply and part IV-the shortage mitigation plan of the proposal of Regulation.

[5] The MAH has to submit the request to the concerned NCA according to relevant national regulations
[6] The MAH has to submit the request to the concerned NCA according to relevant national regulations
[7] The MAH has to submit the request to the concerned NCA according to relevant national regulations
[8] Including details of planned information for HCP, patients and press release if needed