



6 October 2023  
EMA/323316/2023  
Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

## MSSG Solidarity Mechanism

### 1. Introduction

A non-paper on security of medicines supply in Europe was developed in early 2023 by Belgium and signed by 23 Member States. The non-paper made a number of recommendations, including a recommendation to develop an EU solidarity mechanism for MSs experiencing critical shortages of important medicines where all other available options have been exhausted. This proposal foresees the development of this new mechanism at the level of the MSSG; a notification would be circulated by the MS experiencing the critical shortage to which other MSs may respond to provide some temporary relief by making stocks of the medicine available.

The proposal to set up a voluntary solidarity mechanism was discussed and agreed by the MSSG during the meeting held on 19 June 2023.

Following this agreement, a Working Group was set up to further develop the proposal and was composed of representatives from MS which are MSSG representatives or delegates, European Commission (DG SANTE, HERA and the Secretariat General), Medicine Shortages SPOC WP and EMA Secretariat.

### 2. Scope

The solidarity mechanism is a voluntary mechanism which allows a MS to request assistance from the MSSG in obtaining stocks of a medicine during critical shortages. This mechanism should be used as the last resort when the MSs have exhausted other possibilities, and the following conditions must be met:

1. EMA has already been notified of the critical shortage. The shortage must have been brought to the attention of the Medicine Shortages SPOC WP and escalated to the MSSG for further EU coordinated actions.
2. There are no or insufficient therapeutic alternatives available in the MS.
3. There are insufficient quantities to treat critical indications.
4. Importation of foreign stock or other short-term measures do not provide a solution in a timely manner or in sufficient quantities to address the shortage;
5. Urgent situation (stockout within e.g. 1 month or less).



## **3. Procedure**

### **3.1. Submission of the request**

Member States should send their request to the MSSG Secretariat as soon as possible.

The request should be sent by email to the MSSG Secretariat mailbox [MSSGSecretariat@ema.europa.eu](mailto:MSSGSecretariat@ema.europa.eu) using the request template in Annex 1. The email subject should include "Solidarity Mechanism Request" and the name of the medicine involved.

### **3.2. Validation by EMA**

The MSSG secretariat will acknowledge receipt of the notification and validate the request within 2 working days to confirm that all conditions are met and the information provided is complete.

If the conditions are not met, the MSSG Secretariat will inform the issuing MS that conditions are not met and the request cannot be pursued.

If the information is incomplete, the MSSG Secretariat will contact the issuing MS to provide the missing information.

If conditions are met and the information is complete, EMA will launch the voluntary solidarity mechanism.

### **3.3. Launch of the procedure**

If conditions are met and the information is complete, EMA will start the procedure for the solidarity mechanism and notify the members of the MSSG, and will inform the European Commission in parallel.

MSs are requested to send an acknowledgement of receipt and to provide feedback by completing the response template in Annex 2. EMA will compile the information received.

Although the solidarity mechanism is a voluntary exercise, MSs will be requested to respond to the requests, regardless of their ability to provide assistance. The deadline for replies will be 5 working days. In case more time is needed to gather information from the concerned parties (e.g., industry or Ministry of Health), a request for an extension of the timeline for an additional maximum of 5 working days should be sent to the MSSG Secretariat.

### **3.4. Compilation and sharing of information**

EMA will review the compiled information and confirm whether any MS is able to support the issuing MS.

If this is the case, EMA will put the issuing country in contact with those MS able to support them. EMA will set up meetings with the issuing MS, the donating party and other relevant concerned parties (e.g., pharmaceutical company, wholesaler or Ministry of Health) to discuss operational requirements.

If no MS is able to support, the issuing MS will explore further options and will lead the discussions at the MSSG. The MSSG secretariat will include the topic in the agenda of the next meeting to explore together additional measures. The Commission will be kept informed.

## **4. Interaction with companies**

In the event that a MS is able to provide assistance, EMA will set up meetings with the issuing Member State, the donating party, and other relevant concerned parties (e.g., pharmaceutical company, wholesaler or Ministry of Health) to discuss operational requirements.

## **5. Communication**

Information on the solidarity mechanism will be published as part of the minutes of the MSSG meetings. However, only information on the active substance and the outcome of the solidarity mechanism will be published, with no details of which MSs are requesting or providing assistance.

# Annex 1 - Template for submission of request

(please see the Excel template attached separately)



## Request Template - Solidarity Mechanism

Template to be filled in and sent to the MSSG Secretariat mailbox via <[MSSGSecretariat@ema.europa.eu](mailto:MSSGSecretariat@ema.europa.eu)>. Add " Solidarity Mechanism Request" in the e-mail subject and the name of the product(s) involved.

### All 5 conditions need to be met to launch a request for solidarity mechanism (please confirm below by ticking the boxes, as appropriate)

- EMA has already been notified on the critical shortage. The shortage must have been brought to the attention of the Medicine Shortages SPOC WP and escalated to the MSSG for further EU coordinated actions.
- There are no or insufficient therapeutic alternatives available in the MS
- There are insufficient quantities to treat critical indications.
- Importation of foreign stock or other short-term measures do not provide a solution in a timely manner or in sufficient quantities to address the shortage
- Urgent situation (stock out within e.g. 1 month or less)

Please ensure that all mandatory fields are completed prior to submission.

Solidarity Mechanism Request Template 2023																			
Identification		Product/MAH details					Shortage Information								Shortage Management				
Member State in need mandatory	Medicinal Product Name mandatory	INN mandatory	Pharmaceutical Form mandatory	Strength mandatory	MAH name mandatory	Date of beginning of the market disruption	Date of ending market disruption (expected)	Reason	Availability (marketed + no ongoing supply problem) of alternative medicinal products (yes/no) mandatory		Current stock at national level (number of packs)	Monthly sales volume at national level (number of packs)	Date of expected next delivery	Volume of next delivery (number of packs)	Motivation why situation is urgent mandatory	Steps already undertaken	is shortage notified via EMA SPOC WP? (yes/no) mandatory	How did you deal with input received from EMA?	Is importation possible? (yes/no) mandatory
									With the same active substance if yes, please provide product details	Therapeutic alternatives if yes, please provide product details									

## Annex 2 – Template for collecting feedback from other MS

(please see the Excel template attached separately)



### Response template - Solidarity Mechanism

Template to be filled in within 5 working days when the Solidarity Mechanism is launched. If more time is needed to provide a final response, please indicate that you request an extension for an additional 5 working days to provide your response.

**Please ensure that all mandatory fields are completed prior to submission.**

Identification Member State <i>mandatory</i>	Are you able to provide assistance to the MS issuing the request for solidarity by supplying stocks of the requested medicinal product? (Yes/no) <i>mandatory</i>	If yes, please provide the following details of the medicinal product that can be supplied										If no, please explain	
		Medicinal Product Name (Full medicinal product name)	INN	Strength	Pharmaceutical form	MAH	MAH Contact details	Amount that can be provided	Unit of measurement for the amount (vials/grams/packs)	Please indicate if national safety stock or MAH/wholesaler stock will be used	Other relevant information (e.g. cost)		