

7 November 2025
EMA/323316/2023, Rev.1
Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

MSSG Voluntary 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 (MSs). The non-paper made a number of recommendations, including a recommendation to develop an EU voluntary solidarity mechanism (VSM) 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 (issuing MS) to which other MSs may respond to provide some temporary relief by making stocks of the medicine available.

The proposal to set up a VSM 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, DG ECHO and the Secretariat General), Medicine Shortages SPOC WP and EMA Secretariat.

2. Scope

The VSM 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.
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

The issuing MS 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 using the request template in Annex 1. The email subject should include "Voluntary 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.

3.3. Pre-launch VSM activities

If conditions are met and the information is complete, EMA will start "pre-launch" VSM activities. As part of this process, EMA will contact the involved and alternative MAHs to better understand the issue, timelines and if they could support the issuing country immediately. EMA could also set up trilateral meetings (issuing country, EMA and MAH) if needed.

If immediate support to cover the quantities required, and provided that the issuing country is in agreement, the VSM with MSs will not be launched.

The "pre-launch" VSM activities will be conducted within 2 working days with the possibility of extension of an additional day to compile the information, if required.

If the "pre-launch" VSM activities are not successful and no immediate support is identified from MAHs, the EMA will launch the VSM procedure with all MSs.

3.4. Launch of the procedure

If conditions are met and the information is complete, EMA will start the procedure and launch the VSM.

MSs response to notification

- MSs are requested to provide feedback by completing the response template in Annex 2 within 5 working days.
- Although the VSM is a voluntary exercise, MSs are requested to respond to the requests, even if they are not able to provide assistance. The deadline for replies will be 5 working days. If 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.

European Commission response to notification

- In parallel, EMA will reach out informally to the European Commission, DG ECHO1 ECHO1 - [European Response Coordination Centre \(ERCC\)](#) - to determine if there are available stocks in rescEU. The

¹ Such requests for assistance will be made via the ERCC (IT system CECIS) by EMA.

deadline for replies will be 5 working days. For this purpose, EMA will send an email to ECHO-rescEU@ec.europa.eu; ECHO-ERCC@ec.europa.eu

- Where stocks are identified, and no MAHs nor MS has responded positively to the notification set out above, EMA will contact the issuing MS and invite them to consider submitting a formal request through the UCPM civil protection contact points (in CECIS). Coordination between health authorities and civil protection authorities is therefore key. In case of deployment of rescEU, 100% of transport costs can be covered by the Union Civil Protection Mechanism.
- These exchanges are without prejudice to the possibility for the MS to introduce a request for assistance to the UCPM at any time in case of an emergency that overwhelms national response capacities.

4. Compilation 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. If needed, 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 same steps will be taken if further coordinated actions are needed despite a positive outcome of the VSM. This could be the case when the quantities of stocks shared by MSs are not sufficient to meet the needs of the issuing MS, or if the supply situation is critical in multiple countries in the EU/EEA. The Commission will be kept informed.

When during the compilation of information critical situations are identified in other countries, EMA will identify if they would need support as part of the VSM procedure. In this case, EMA will seek information about the quantities needed and put those countries in contact with the supportive MAHs/MS when surplus stock is identified within the VSM procedure.

5. Interaction with companies

As mentioned under section 3.2 EMA will contact the involved and alternative MAHs as part of the “pre-launch” VSM activities and set up trilateral meetings, if needed.

6. Interaction with international partners

In case of a critical situation where support from other MSs or alternative MAHs is not possible or not sufficient, EMA will contact international partners, to understand the supply situation in their jurisdictions. If they do not have ongoing shortages, EMA will request their support to address the critical shortage in the EU.

As a next step, EMA will contact MAHs in those countries to request support but without causing shortages.

If a positive reply is received, the information will be shared immediately with the issuing country.

7. Communication

Information on the VSM will be published as part of the minutes of the MSSG meetings. Information on the name of the issuing country, active substance and high-level information about the outcome of the VSM will be published in the MSSG annual activity report.

Annex 1 - Template for submission of request



Request Template - Voluntary Solidarity Mechanism (VSM)

Template to be filled in and sent to the MSSG Secretariat mailbox via <MSSGSecretariat@ema.europa.eu>.

Add "Voluntary 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 voluntary 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 Working Party
☐	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 insufficient quantities to address the shortage
☐	Urgent situation (stock out within e.g. 1 month or less)

Please ensure that all fields are completed prior to submission.

Voluntary Solidarity Mechanism Request Template 2025

Identification	Product/MAH details					
	Medicinal Product Name	INN	Pharmaceutical Form	Strength	MAH name	Manufacturer name and country
Member State in need						

Information									
Date of beginning of the market disruption	Date of ending market disruption (expected)	Reason	Availability (marketed + no ongoing supply problem) of alternative medicinal products		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)	Amount required (units)
			With the same active substance <i>if yes, please provide product details</i>	Therapeutic alternatives <i>if yes, please provide product details</i>					

Shortage Management			
Steps already undertaken	Is the shortage notified via EMA SPOC WP? (yes/no)	How did you deal with input received from EMA?	Is importation possible? (yes/no)

Annex 2 – Template for collecting feedback from other MS



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 "no" for the time being and provide your final response after another 5 working days.

Fields to be filled in by the supportive countries													Fields to be filled in by the issuing country		
Member State	Date of answer/update	Are you able to provide assistance to the MS issuing the request for solidarity by supplying stocks of the requested medicinal product? (YES/NO)	If yes, please provide the following details of the medicinal product that can be supplied										If no, please explain the reason	Do you accept the offer?	Stock Date of arrival in your country
			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)	Origin of stock (national stockpile or MAH)?	Other relevant information			
AT															
BE															
BG															
CY															
CZ															
DE															
DK															
EE															
ES															
FI															
FR															
GR															
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NO															
PL															
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RO															
SE															
SI															
SK															