EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

European Shortages Monitoring Platform (ESMP) Implementation Guide for National Competent Authorities

Version 1.5

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Revision history

Date	Description
24/07/2024	ESMP Implementation guide for NCAs - v1.0
07/11/2024	V1.1 • Improvement of the order of the rows in the data element table • Correction in the Unit of presentation definition • Correction of the error in the pack medicinal product level in MSSG-led preparedness"
29/01/2025	V1.2 Update of PMS ID fields: • Renamed PMS ID (Medicinal product) to PMS ID • Renamed PMS ID (Packaged medicinal product) to Package PMS ID • Highlight PMS guide link is only for reference and not mandatory to consult
07/03/2025	V1.3 • Clarification of the forecasting period definition in concerned chapters • Highlight where conditions in conditional data elements are listed
13/05/2025	V1.4 Update of Stock and supply data elements: • Changed the data element P1.7.3 "Packaging" to "Package description" • Renamed the data elements E2.2.1-6 "Historical consumption non-PHE/ME need" to "Non-PHE/ME need" for all months (1 to 6) • Renamed the data elements E2.3.1-6 "Historical volume of prescriptions" to "Volume of prescriptions" for all months (1 to 6)
28/04/2026	V1.5 • Addition of chapter 4 on Critical shortages, and chapter 4.1 Voluntary Solidarity Mechanism • Update of the description of data elements T1.1.1- T1.1.6 Estimated total number of patients to provide further clarification

Table of abbreviations

Abbreviation	Explanation
EEA	European Economic Area
EMA	European Medicines Agency
ESMP	European Shortages Monitoring Platform
EU	European Union
ICU	Intensive Care Unit
ID	Identification
INN	International Non-proprietary Name
ME	Major Event
MAH	Marketing authorisation holder
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products (Medicines Shortages Steering Group)
MS	EU Member State
NCA	National competent authority
OMS	Organisation Management Services
PHE	Public Health Emergency
PMS	Product Management Services
RMS	Referentials Management Services[1]
SmPC	Summary of product characteristics
SMS	Substance Management Services
SPOR	Substance, Product, Organisation, and Referentials

[1] RMS provides referentials lists and terms. RMS supports the continuous exchange of data between information systems across the European medicines regulatory network and the pharmaceutical industry. ESMP uses RMS lists and IDs to ensure correct data submission. For further information about RMS please consult additional resources as Referentials Management Service (RMS) | European Medicines Agency (EMA) and RMS Web UI.

1. Scope of this guidance

This European Shortages Monitoring Platform (ESMP) implementation guide for national competent authorities (NCAs) describes technical details and rules that NCAs must follow to ensure the successful completion of electronic submissions to the European Medicines Agency (EMA) through the ESMP.

The focus of this guide is to deliver detailed guidance and instructions on technical specifications, clarifying data sets and data elements in scope of reporting requirements to the EMA. Each data element is listed in a dedicated table which describes the information to be provided: ID, name, description, example, conformance, data type, validation rules and destination reference. Further details are presented in the following sections of the guide.

The implementation guide will be complementary to the ESMP User guide for NCAs and aims to support NCAs to fulfil reporting obligations to the EMA on information on crisis and crisis preparedness reporting as defined by Regulation (EU) 2022/123, including stock and supply, patient estimation, medicine usage, and other.

1.1 How to read this guide

This section defines the attributes' schema, used throughout the whole document for each data element, and provides business guidance and conventions for the electronic submission of data on the availability and supply of medicines for human use into the ESMP.

The requirements for each data set and data element are described in the following tabular format:

Tag	Explanation
ID	Unique identification code of the corresponding data element.
Name	Common name used to refer to the data element.
Description	The definition of the data element, the convention, and the condition under which the information should be provided in the context of submission of data on the availability of medicines for human use into the ESMP.
Example	The examples provided in this guide are purely fictional and included for illustrative purposes only. They do not represent real individuals, organisations, or actual cases, and should not be interpreted as accurate or authoritative data.

Tag	Explanation
Conformance	Whether the information should be provided on a mandatory, conditional, or optional basis. It is possible for a class to be conditional yet include mandatory data fields. Once the conditions for the class are fulfilled, all mandatory data fields shall be populated. If the conditions are not fulfilled, none of the data fields belonging to the class shall be provided. • **Mandatory**: the provision of the data is compulsory; therefore, the field(s) shall be populated with the available information. • **Conditional**: the provision of the data is compulsory only if a condition is met. Therefore, the field(s) shall be populated accordingly. • **Optional:** the provision of the data is not mandatory; however, the field(s) can be populated if the information is available.
Data type	The type of data is specified as: • string: sequence of characters, digits, or symbols—always treated as text; • date: date in the DD-MM-YYYY format; • decimal: numeric data type for numbers with fractions (decimal separator is .); • integer: numeric data type for numbers without fractions;
Validation rule	Values applicable to the data element (e.g., reference to the SMS, OMS or relevant RMS lists).
Destination reference	Reference to the data submission template and specific location in which to insert the required information.

For data elements that require to insert a reference to Referentials Management Services (RMS) identifiers, which are 12-digit IDs that codify data, used to insert information in the system, you can consult RMS lists in the SPOR platform[2]. The relevant RMS lists are linked within each relevant data element table, in the validation rule row.

[2] https://spor.ema.europa.eu/rmswi/#/lists

2. Crisis submissions

In times of crisis (i.e., during a public health emergency or major event), you are required to report information on centrally and nationally authorised products in scope of a list of critical medicines for a specific public health emergency or major event, which are authorised in your country. You will have to submit the following information about medicinal products in scope of reporting requirements:

- Stock and supply;
- Patient estimation;
- Medicine usage.

The following chapters describe in depth the different data elements and related details that NCAs will need to submit to fulfil the reporting requirements.

2.1 Stock and supply

2.1.1 Product information

To collect information on medicinal products in scope of reporting requirements through the ESMP, the platform will generate templates which you can download, compile, and upload, which will be tailored to the user's affiliation and include the specific products in scope of reporting requirements for a particular crisis. The templates will be pre-populated with information previously submitted to the EMA through different systems.

Please **do not change the fields which have been retrieved from other EMA systems** while completing the submission procedure. Any changes to product information through the ESMP will not be processed by the system, hence will not generate any changes in the PMS database.

Data elements for product information								
Package PMS ID	Full product name	Short product name	MAH	Active substance	Strength	Pharmaceutical form	Pack size	Package description
P1.1.2	P1.2.1	P1.2.2	P1.10	P1.3.2	P1.4	P1.6.2	P1.7.2	P1.7.3

Please consult the box and tables below for further details about each data element and relative conformance.

Product information fields with "optional" conformance are included in the dataset only to support users to refer to the correct product while inserting stock and supply information.

Tag	Explanation
ID	P1.1.2
Name	Package PMS ID
Description	Unique identifier assigned to a packaged medicinal product throughout its lifecycle. It is an essential identifier that will ensure that the information inserted in the template is associated with the correct product. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Package PMS ID" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*96781*
Conformance	Mandatory
Data type	String
Validation rule	Must exist in the list of critical medicinal product records authorised in the user's country of affiliation.
Destination reference	NCA stock and supply template / column A

Tag	Explanation
ID	P1.2.1
Name	Full product name
Description	Full medicinal product name as indicated in *Section 1: Name of the Medicinal Product* of the Summary of Product Characteristics (SmPC) or other regulatory documents, in line with the local language of the country where the product is authorised. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Full name", in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*Esempin 500 mg - Film-coated tablet*
Conformance	Optional, will not be processed[3]

[3] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column B

Tag	Explanation
ID	P1.2.2
Name	Short product name
Description	Invented name as specified within the full product name. If the product has no invented name, the data element will instead combine the International Non-proprietary Name (INN) and the company name from the full product name. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Invented name part" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*Esempin*
Conformance	Optional, will not be processed[4]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column C

Tag	Explanation
ID	P1.10
Name	MAH

[4] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
Description	Company or other legal entity that has the authorisation to market a medicine in one, several or all EU/EEA Member States (MS). This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Marketing authorisation holder (organisation)" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*Esempex Ltd*
Conformance	Optional, will not be processed[4]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column D

Tag	Explanation
ID	P1.3.2
Name	Active substance
Description	Active substance(s) contained in the medicinal product. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Ingredient" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*paracetamol*
Conformance	Optional, will not be processed[5]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column E

[5] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
ID	P1.4
Name	Strength
Description	Quantity of the active substance contained in a pharmaceutical product including the unit of measurement. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Ingredient" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*500 mg*
Conformance	Optional, will not be processed[6]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column F

Tag	Explanation
ID	P1.6.2
Name	Pharmaceutical form
Description	Pharmaceutical form as authorised by regulatory authorities and as reflected in regulatory documents. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "(Authorised) pharmaceutical form" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*Film-coated tablet*
Conformance	Optional, will not be processed[6]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column G

[6] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
ID	P1.7.2
Name	Pack size
Description	Total number of units of the manufactured item or package item and represented per unit of presentation. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Packaged medicinal product" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*100 tablets*
Conformance	Optional, will not be processed**Error! Bookmark not defined.**
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column H

Tag	Explanation
ID	P1.7.3
Name	Package description
Description	The packaging/container(s) information of a medicinal product and any associated device(s) which are an integral part or provided in combination with a medicinal product, as supplied for sale or distribution/supply. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Packaged medicinal product" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*100 tablets in an amber glass bottle*
Conformance	Optional, will not be processed[7]
Data type	String
Validation rule	Not applicable

[7] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
Destination reference	NCA stock and supply template / column I

2.1.2 Member state available stock

The member state available stock section reports details about current hospital stock, current community pharmacy stock, current wholesale distributors stock, and current strategic reserve.

Data elements for member state available stock			
Current hospital stock	Current community pharmacy stock	Current wholesale distributors stock	Current strategic reserve
E1.1	E1.2	E1.3	E1.4

Please consult the tables below for further details about the data elements and relative conformances.

Tag	Explanation
ID	E1.1
Name	Current hospital stock
Description	Amount of packs of the relevant medicinal product in stock at the hospital level in a specific EU/EEA Member state at the time of submission.
Example	*7500*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column J

Tag	Explanation
ID	E1.2
Name	Current community pharmacy stock
Description	Amount of packs of the relevant medicinal product in stock at the community pharmacy level in a specific EU/EEA Member state the time of submission.
Example	*8300*
Conformance	Mandatory
Data type	Integer

Tag	Explanation
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column K

Tag	Explanation
ID	E1.3
Name	Current wholesale distributors stock
Description	Amount of packs of the relevant medicinal product in stock at the wholesale distributors level intended for a specific EU/EEA member state the time of submission.
Example	*6300*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column L

Tag	Explanation
ID	E1.4
Name	Current strategic reserve
Description	Amount of packs of the relevant medicinal product in stock at the time of submission that have been acquired and are managed by the member state regardless where the stock is stored. This is different from stockpiling requirements applied to wholesale distributors or MAHs which are a part of MS need and need to be captured under planned minimum stock.
Example	*9200*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column M

2.1.3 Planned minimum stock

The planned minimum stock is the minimum amount of packs of the relevant medicinal product that should be present in the supply chain of a specific EU/EEA member state to assure continuity of availability to patients from the beginning until the end of the forecast period. This amount refers to the buffer that each member state wants to implement on top of the PHE/ME needs and the non-PHE/ME needs.

It can be derived from existing stockpiling requirements that are present during non-PHE/ME periods or from the PHE/ME patient estimation, calculated based on consumption during a previous wave of a pandemic or derived from the PHE/ME patient estimation.

Data elements for planned minimum stock
Planned minimum stock
E1.5

Please consult the table below for further details about the data elements and relative conformances.

Tag	Explanation
ID	E1.5
Name	Planned minimum stock
Description	Minimum amount of packs of the relevant medicinal product that should be present in the supply chain of a specific EU/EEA member state to assure continuity of availability to patients from the beginning until the end of the forecast period.
Example	7500
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column N

2.1.4 Planned strategic reserve

The planned strategic reserve section reports details about stocks of medicinal products held back from normal use by each member state to cope with unexpected events. It refers to the amount of packs of the relevant medicinal product planned to be acquired by each member state to be included in your country's national strategic reserve during six months of the forecasting period.

It refers to the planned supply that is expected to become available during each month of the forecasting period that is not part of the MAHs' supply forecast or EU centrally procured supply forecast.

The forecasting period will be defined and communicated by MSSG with the announcement of reporting obligations in a crisis. The forecasting period covers the interval of 6 months. For example, if a crisis is recognised in May 2026 and reporting obligation starts from 1 June, month 1 of the forecasting period will be June 2026. In this case, the forecasting period will be from June 2026 (month 1) - November 2026 (month 6).

Data elements for planned strategic reserve					
Planned strategic reserve - month 1	Planned strategic reserve - month 2	Planned strategic reserve - month 3	Planned strategic reserve - month 4	Planned strategic reserve - month 5	Planned strategic reserve - month 6
E2.1.1	E2.1.2	E2.1.3	E2.1.4	E2.1.5	E2.1.6

Please consult the tables below for further details about data elements and relative conformances.

Tag	Explanation
ID	E2.1.1
Name	Planned strategic reserve - month 1
Description	Amount of packs of the relevant medicinal product planned to be acquired by the member state to be included in the national strategic reserve in that specific EU/EEA member state during the first month of the forecasting period.
Example	*7500*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column O

Tag	Explanation
ID	E2.1.2
Name	Planned strategic reserve - month 2
Description	Amount of packs of the relevant medicinal product planned to be acquired by the member state to be included in the national strategic reserve in that specific EU/EEA member state during the second month of the forecasting period.
Example	*6500*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999

Tag	Explanation
Destination reference	NCA stock and supply template / column P

Tag	Explanation
ID	E2.1.3
Name	Planned strategic reserve - month 3
Description	Amount of packs of the relevant medicinal product planned to be acquired by the member state to be included in the national strategic reserve in that specific EU/EEA member state during the third month of the forecasting period.
Example	*8500*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column Q

Tag	Explanation
ID	E2.1.4
Name	Planned strategic reserve - month 4
Description	Amount of packs of the relevant medicinal product planned to be acquired by the member state to be included in the national strategic reserve in that specific EU/EEA member state during the fourth month of the forecasting period.
Example	*3500*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column R

Tag	Explanation
ID	E2.1.5
Name	Planned strategic reserve - month 5

Tag	Explanation
Description	Amount of packs of the relevant medicinal product planned to be acquired by the member state to be included in the national strategic reserve in that specific EU/EEA Member state during the fifth month of the forecasting period.
Example	*9200*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column S

Tag	Explanation
ID	E2.1.6
Name	Planned strategic reserve - month 6
Description	Amount of packs of the relevant medicinal product planned to be acquired by the member state to be included in the national strategic reserve in that specific EU/EEA member state during the sixth month of the forecasting period.
Example	*8100*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column T

2.1.5 Non-PHE/ME need

The non-PHE/ME need refers to the amount of packs of the relevant medicinal product in a specific EU/EEA Member state that are estimated to be used for procedures not related to the PHE/ME in question during the six months of the forecasting period.

The non-PHE/ME need can be based on historical consumption pre-PHE/ME, preferably matched for the same month of the year, to account for seasonal patterns and adjusted for any (expected) changes to regular procedures stemming from preventive measures (e.g., lockdown situations). If not possible, the monthly average derived from the yearly need can be used as a constant across the forecasting period.

The forecasting period will be defined and communicated by MSSG with the announcement of reporting obligations in a crisis. The forecasting period covers the interval of 6 months. For example, if a crisis is recognised in May 2026 and reporting obligation starts from 1 June, month 1 of the forecasting period

will be June 2026. In this case, the forecasting period will be from June 2026 (month 1) - November 2026 (month 6).

Data elements for non-PHE/ME need					
Non-PHE/ME need - month 1	Non-PHE/ME need - month 2	Non-PHE/ME need - month 3	Non-PHE/ME need - month 4	Non-PHE/ME need - month 5	Non-PHE/ME need - month 6
E2.2.1	E2.2.2	E2.2.3	E2.2.4	E2.2.5	E2.2.6

Please consult the tables below for further details about data elements and relative conformances.

Tag	Explanation
ID	E2.2.1
Name	Non-PHE/ME need - month 1
Description	Amount of packs of the relevant medicinal product expected to be needed in procedures not related to the PHE/ME in a specific EU/EEA member state during the first month of the forecasting period.
Example	*9150*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column U

Tag	Explanation
ID	E2.2.2
Name	Non-PHE/ME need - month 2
Description	Amount of packs of the relevant medicinal product expected to be needed in procedures not related to the PHE/ME in a specific EU/EEA member state during the second month of the forecasting period.
Example	*3500*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column V

Tag	Explanation
ID	E2.2.3
Name	Non-PHE/ME need - month 3
Description	Amount of packs of the relevant medicinal product expected to be needed in procedures not related to the PHE/ME in a specific EU/EEA member state during the third month of the forecasting period.
Example	*2500*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column W

Tag	Explanation
ID	E2.2.4
Name	Historical consumption non-PHE/ME need - month 4
Description	Amount of packs of the relevant medicinal product expected to be needed in procedures not related to the PHE/ME in a specific EU/EEA member state during the fourth month of the forecasting period.
Example	*9200*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column X

Tag	Explanation
ID	E2.2.5
Name	Historical consumption non-PHE/ME need - month 5
Description	Amount of packs of the relevant medicinal product expected to be needed in procedures not related to the PHE/ME in a specific EU/EEA member state during the fifth month of the forecasting period.
Example	*4200*
Conformance	Mandatory

Tag	Explanation
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column Y

Tag	Explanation
ID	E2.2.6
Name	Historical consumption non-PHE/ME need - month 6
Description	Amount of packs of the relevant medicinal product expected to be needed in procedures not related to the PHE/ME in a specific EU/EEA member state during the sixth month of the forecasting period.
Example	*3100*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column Z

2.1.6 Volume of prescriptions

The volume of prescriptions refers to the total amount of packs of the relevant medicinal product that are expected to be prescribed in a specific EU/EEA member state during the six months of the forecasting period.

This volume can be based on the total amount of monthly packs prescribed the year before the declaration of a given PHE/ME, preferably matched for the same month of the year, to account for seasonal patterns. If not possible, a monthly average derived from the yearly volume can be used as a constant across the forecasting period.

The volume of prescriptions is a similar data element as the non-PHE/ME consumption yet derived from a different source. Either data element can be used to estimate the non-PHE/ME need during the forecast period.

The forecasting period will be defined and communicated by MSSG with the announcement of reporting obligations in a crisis. The forecasting period covers the interval of 6 months. For example, if a crisis is recognised in May 2026 and reporting obligation starts from 1 June, month 1 of the forecasting period will be June 2026. In this case, the forecasting period will be from June 2026 (month 1) - November 2026 (month 6).

Data elements for volume of prescriptions					
Volume of prescriptions - month 1	Volume of prescriptions - month 2	Volume of prescriptions - month 3	Volume of prescriptions - month 4	Volume of prescriptions - month 5	Volume of prescriptions - month 6
E2.3.1	E2.3.2	E2.3.3	E2.3.4	E2.3.5	E2.3.6

Please consult the tables below for further details about data elements and relative conformances.

Tag	Explanation
ID	E2.3.1
Name	Volume of prescriptions - month 1
Description	Total amount of packs of the relevant medicinal product that are expected to be prescribed in a specific EU/EEA member state during the first month of the forecasting period.
Example	*9150*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column AA

Tag	Explanation
ID	E2.3.2
Name	Volume of prescriptions - month 2
Description	Total amount of packs of the relevant medicinal product that are expected to be prescribed in a specific EU/EEA member state during the second month of the forecasting period.
Example	*3500*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column AB

Tag	Explanation
ID	E2.3.3
Name	Volume of prescriptions - month 3
Description	Total amount of packs of the relevant medicinal product that are expected to be prescribed in a specific EU/EEA member state during the third month of the forecasting period.
Example	*2500*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column AC

Tag	Explanation
ID	E2.3.4
Name	Volume of prescriptions - month 4
Description	Total amount of packs of the relevant medicinal product that are expected to be prescribed in a specific EU/EEA member state during the fourth month of the forecasting period.
Example	*9200*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column AD

Tag	Explanation
ID	E2.3.5
Name	Volume of prescriptions - month 5
Description	Total amount of packs of the relevant medicinal product that are expected to be prescribed in a specific EU/EEA member state during the fifth month of the forecasting period.
Example	*4200*
Conformance	Optional

Tag	Explanation
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column AE

Tag	Explanation
ID	E2.3.6
Name	Volume of prescriptions - month 6
Description	Total amount of packs of the relevant medicinal product that are expected to be prescribed in a specific EU/EEA member state during the sixth month of the forecasting period.
Example	*3100*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA stock and supply template / column AF

2.2 Patient estimation

2.2.1 Patient estimation

The patient estimation data submission collects details about the estimated number of patients to be vaccinated, estimated number of expected hospitalised, and intensive care unit (ICU) patients-days, forecasted for the period of six months in the period after the start of reporting requirements.

Patient-days are defined as the sum of the number of days where beds (hospital or ICU) are occupied by PHE/ME patients, regardless of the number of individual PHE/ME patients or the hospital/ICU stay of an individual PHE/ME patient. E.g., one patient staying in the hospital for 30 days amounts to 30 patient-days and 30 patients staying in the hospital for one day amounts to 30 patient-days, as well.

When information on predicted patient-days is not available in your Member State, an estimate can be based on the total capacity available (hospital or ICU) for the PHE/ME patients adjusted for the proportion of the expected occupancy. This should include the currently existing capacity as well as any additional capacity planned or to be deployed during future progression of the PHE/ME.

The forecasting period will be defined and communicated by MSSG with the announcement of reporting obligations in a crisis. The forecasting period covers the interval of 6 months. For example, if a crisis is recognised in May 2026 and reporting obligation starts from 1 June, month 1 of the forecasting period

will be June 2026. In this case, the forecasting period will be from June 2026 (month 1) - November 2026 (month 6).

Data elements for patient estimation			
Estimated total number of patients	Estimated total number of hospitalised patient-days	Estimated total number of ICU patient-days	PHE/ME RMS ID
T1.1.1 T1.1.2 T1.1.3 T1.1.4 T1.1.5 T1.1.6	T2.1.1 T2.1.2 T2.1.3 T2.1.4 T2.1.5 T2.1.6	T3.1.1 T3.1.2 T3.1.3 T3.1.4 T3.1.5 T3.1.6	T1.2

Please consult the tables below for further details about data elements and relative conformances.

Tag	Explanation
ID	T1.1.1, T1.1.2, T1.1.3, T1.1.4, T1.1.5, T1.1.6
Name	Estimated total number of patients
Description	Estimated number of patients which the MS foresees to vaccinate during the forecast period, regardless of the medicinal product used, estimated for the six months of the forecasting period. This data element refers exclusively to the number of patients to be vaccinated and therefore if there is no national vaccination strategy foreseen these data elements should be populated with the value "0".
Example	*500*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA patient estimation template / column row 2

Tag	Explanation
ID	T2.1.1, T2.1.2, T2.1.3, T2.1.4, T2.1.5, T2.1.6
Name	Estimated total number of hospitalised patient-days
Description	Estimated number of days a hospital bed is occupied by a PHE/ME patient regardless of the total number of new PHE/ME patients admitted to the hospital. This is estimated per month for the six months of the forecasting period.
Example	*440*
Conformance	Mandatory
Data type	Integer

Tag	Explanation
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA patient estimation template / row 3

Tag	Explanation
ID	T3.1.1, T3.1.2, T3.1.3, T3.1.4, T3.1.5, T3.1.6
Name	Estimated total number of ICU patient-days
Description	Estimated number of days an Intensive Care Unit (ICU) bed is occupied by a PHE/ME patient regardless of the total number of new PHE/ME patients admitted to the hospital. This is estimated per month for the six months of the forecasting period.
Example	*380*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA patient estimation template / row 4

Tag	Explanation
ID	T1.2
Name	PHE/ME RMS ID
Description	Identifier that links the patient estimation to a particular Public Health Emergency or Major Event.
Example	*200000026053*
Conformance	Mandatory
Data type	String
Validation rule	Must be a valid PHE/ME RMS ID, with a term to be defined/included in the RMS list "Declared Public Health Emergency or Major Event" with list ID "200000026052".
Destination reference	NCA patient estimation template / column N

2.3 Medicines usage

2.3.1 Medicine information

The "medicine information" data submission flow lists all the critical medicines for a PHE/ME, presented by their active substances and pharmaceutical forms. This product information will be pre-populated in the template when downloaded from the ESMP and will be tailored to the scope of a specific PHE/ME.

Data elements for medicine information			
Active substance (SMS ID)	Active substance	Pharmaceutical dose form (RMS ID)	Pharmaceutical dose form
P1.3.1	P1.3.2	P1.6.1	P1.6.2

Please consult the tables below for further details about data elements and relative conformances.

Tag	Explanation
ID	P1.3.1
Name	Active substance (SMS ID)
Description	SMS ID(s) that identify the active substance(s) contained in the medicinal product. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*76708*
Conformance	Mandatory
Data type	String
Validation rule	Must exist in the list of active substance records in SMS
Destination reference	NCA medicine usage template / column A

Tag	Explanation
ID	P1.3.2
Name	Active substance
Description	Active substance(s) contained in the medicinal product. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*paracetamol*

Tag	Explanation
Conformance	Optional, will not be processed[8]
Data type	String
Validation rule	Not applicable
Destination reference	NCA medicine usage template / column B

Tag	Explanation
ID	P1.6.1
Name	Pharmaceutical dose form (RMS ID)
Description	RMS ID(s) that identify the pharmaceutical dose form(s) as authorised by regulatory authorities and as reflected in regulatory documents. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*100000073665*
Conformance	Mandatory
Data type	String
Validation rule	Must exist in the list of Pharmaceutical dose form records
Destination reference	NCA medicine usage template / column C

Tag	Explanation
ID	P1.6.2
Name	Pharmaceutical dose form
Description	Pharmaceutical dose form(s) as authorised by regulatory authorities and as reflected in regulatory documents. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*Film-coated tablet*
Conformance	Optional will not be processed[9]

[8] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.
[9] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
Data type	String
Validation rule	Not applicable
Destination reference	NCA medicine usage template / column D

2.3.2 Hospital medicine usage

The hospital medicine usage section collects details about the average daily medicine dose used to treat a PHE/ME hospitalised patient and proportion of the total PHE/ME hospitalised patients expected to be treated with that medicine, displayed as the combination of its active substances and pharmaceutical form.

Historical data on medicines usage can be used to estimate average use per combination of active substance and pharmaceutical form per patient-day after consultation with clinical experts and, where applicable, adjusting according to the latest scientific knowledge on the use of the medicine in the PHE/ME or the average daily use can be estimated using recent consumption data.

The estimates of medicines use should preferably be made at national level, as clinical practices often vary between the countries. However, in case it is not possible to obtain this information, the estimates developed for other countries with similar clinical practices or estimates provided by experts could be used.

Data elements for hospital medicine usage	
Average daily dose of medicine per adult patient - hospital (mg/patient-day)	Proportion of estimated patients receiving the medicine - hospital
U1.1	U1.2

Please consult the tables below for further details about data elements and relative conformances.

Tag	Explanation
ID	U1.1
Name	Average daily dose of medicine per adult patient - hospital (mg/patient-day)
Description	Quantity of medicine required to treat an average adult in a hospital per patient-day.
Example	*3000*
Conformance	Mandatory
Data type	Decimal

Tag	Explanation
Validation rule	• Must be a number between 0 and 99999999.99 • Either hospital-related fields - the Average daily dose of medicine per adult patient - hospital (mg/patient-day) (this field) and the Proportion of estimated patients receiving the medicine - hospital (U1.2) – or ICU-related fields - Average daily dose of medicine per adult patient - ICU (mg/patient-day) (U2.1) and the Proportion of estimated patients receiving the medicine – ICU (U2.2) - must be filled in, but not both.
Destination reference	NCA medicine usage template / column E

Tag	Explanation
ID	U1.2
Name	Proportion of estimated patients receiving the medicine - hospital
Description	Proportion of the PHE/ME hospitalised patients expected to be treated with that medicine.
Example	*23.55*
Conformance	Mandatory
Data type	Decimal
Validation rule	• Must be a number between 0 and 100 • Must not include the "%" sign • Either hospital-related fields - the Proportion of estimated patients receiving the medicine - hospital (this field) and the Average daily dose of medicine per adult patient - hospital (mg/patient-day) (U1.1) – or ICU-related fields - Average daily dose of medicine per adult patient - ICU (mg/patient-day) (U2.1) and the Proportion of estimated patients receiving the medicine – ICU (U2.2) - must be filled in, but not both.
Destination reference	NCA medicine usage template / column F

2.3.3 ICU medicine usage

The ICU medicine usage section collects details about the average daily medicine dose used to treat a PHE/ME ICU patient and proportion of PHE/ME ICU patients expected to be treated with that medicine, displayed as the combination of its active substances and pharmaceutical form.

Historical data on medicines usage can be used to estimate average use per combination of active substance and pharmaceutical form per patient-day after consultation with clinical experts and where applicable, adjusting according to the latest scientific knowledge on the use of the medicine in the PHE/ME or the average daily use can be estimated using recent consumption data.

The estimates of medicines use should preferably be made at national level, as clinical practices often vary between the countries. However, in case it is not possible to obtain this information, the

estimates developed for other countries with similar clinical practices or estimates provided by experts could be used.

Data elements for ICU medicine usage	
Average daily dose of medicine per adult patient - ICU (mg/patient-day)	Proportion of estimated patients receiving the medicine - ICU
U2.1	U2.2

Please consult the tables below for further details about data elements and relative conformances.

Tag	Explanation
ID	U2.1
Name	Average daily dose of medicine per adult patient - ICU (mg/patient-day)
Description	Quantity of medicine required to treat an average adult in the ICU per patient-day.
Example	*3000*
Conformance	Mandatory
Data type	Decimal
Validation rule	• Must be a number between 0 and 99999999.99 • Either ICU-related fields - the Average daily dose of medicine per adult patient - ICU (mg/patient-day) (this field) and the Proportion of estimated patients receiving the medicine – ICU (U2.2) - or hospital-related fields - the Average daily dose of medicine per adult patient - hospital (mg/patient-day) (U1.1) and the Proportion of estimated patients receiving the medicine - hospital (U1.2) – must be filled in, but not both.
Destination reference	NCA medicine usage template / column G

Tag	Explanation
ID	U2.2
Name	Proportion of estimated patients receiving the medicine - ICU
Description	Proportion of the PHE/ME ICU patients expected to be treated with that medicine.
Example	*23.55*
Conformance	Mandatory
Data type	Decimal

Tag	Explanation
Validation rule	• Must be a whole number between 0 and 100 • Must not include the "%" sign • Either ICU-related fields – the Proportion of estimated patients receiving the medicine – ICU (this field) and the Average daily dose of medicine per adult patient - ICU (mg/patient-day) (U2.1) - or hospital-related fields - the Average daily dose of medicine per adult patient - hospital (mg/patient-day) (U1.1) and the Proportion of estimated patients receiving the medicine - hospital (U1.2) – must be filled in, but not both.
Destination reference	NCA medicine usage template / column H

3. MSSG-led preparedness submissions

Following the announcement of an MSSG-led preparedness action, aimed to address events that might lead to a public health emergency or major event, you are required to report information on centrally and nationally authorised products in scope of a list of medicines to be monitored for MSSG-led crisis preparedness. You will have to submit information on national demand of medicinal products in scope of reporting requirements.

The following chapters describe in depth the different data elements and related details, that NCAs will need to submit to fulfil reporting requirements.

3.1 National demand

3.1.1 Product information

To collect information on medicinal products in scope of reporting requirements through the ESMP, the platform will generate templates which you can download, compile, and upload, which will be tailored to the user's affiliation and include the specific products in scope of reporting requirements for a particular MSSG-led preparedness action. The templates will be pre-populated with information previously submitted to the EMA through different systems.

Please **do not change the fields which have been retrieved from other EMA systems** while completing the submission procedure. Any changes to product information through the ESMP will not be processed by the system, hence will not generate any changes in the PMS database.

Data elements for product information							
PMS ID	Full product name	Short product name	MAH	Active substance	Active substance strength	Pharmaceutical form	Unit of presentation
P1.1.1	P1.2.1	P1.2.2	P1.10	P1.3.2	P1.4	P1.6.2	P1.5

Please consult the box and tables below for further details about the data element and relative conformance.

Tag	Explanation
ID	P1.1.1
Name	PMS ID
Description	Unique identifier assigned to a medicinal product throughout its lifecycle.[10] It is an essential identifier that will ensure that the information inserted in the template is associated with the correct product. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.

[10] The PMS ID is a supplementary stable ID to any existing authorisation number or equivalent identifier as assigned by an authorising body.

Tag	Explanation
	This data element corresponds to the entity "Product Management Service Identifier" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*96781*
Conformance	Mandatory
Data type	String
Validation rule	Must exist in the list of critical medicinal product records authorised in the user's country of affiliation.
Destination reference	NCA national demand template / column A

Tag	Explanation
ID	P1.2.1
Name	Full product name
Description	Full medicinal product name as indicated in *Section 1: Name of the Medicinal Product* of the corresponding Summary of Product Characteristics (SmPC) or other regulatory documents, in line with the local language of the country where the product is authorised. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Full name" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*Esempin 500 mg - Film-coated tablet*
Conformance	Optional, will not be processed[11]
Data type	String
Validation rule	Not applicable
Destination reference	NCA national demand template / column B

Tag	Explanation
ID	P1.2.2

[11] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
Name	Short product name
Description	Invented name as specified within the full product name. If the product has no invented name, the data element will instead combine the International Non-proprietary Name (INN) and the company name from the full product name. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Invented name part" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*Esempin*
Conformance	Optional, will not be processed[12]
Data type	String
Validation rule	Not applicable
Destination reference	NCA national demand template / column C

Tag	Explanation
ID	P1.10
Name	MAH
Description	Company or other legal entity that has the authorisation to market a medicine in one, several or all EU/EEA Member States. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Marketing authorisation holder (organisation)" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*Esempex Ltd*
Conformance	Optional, will not be processed[12]
Data type	String
Validation rule	Not applicable
Destination reference	NCA national demand template / column D

[12] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
ID	P1.3.2
Name	Active substance
Description	Active substance(s) contained in the medicinal product. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Ingredient" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*paracetamol*
Conformance	Optional, will not be processed[13]
Data type	String
Validation rule	Not applicable
Destination reference	NCA national demand template / column E

Tag	Explanation
ID	P1.4
Name	Active substance strength
Description	Quantity of the active substance contained in the pharmaceutical product including the unit of measurement. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "Ingredient" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*500 mg*
Conformance	Optional, will not be processed[13]
Data type	String
Validation rule	Not applicable

[13] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
Destination reference	NCA national demand template / column F

Tag	Explanation
ID	P1.6.2
Name	Pharmaceutical form
Description	Pharmaceutical form as authorised by regulatory authorities and as reflected in regulatory documents. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. This data element corresponds to the entity "(Authorised) pharmaceutical form" in PMS - ISO IDMP, Chapter 2. Please note that the PMS guide is linked only for reference and it is not a mandatory resource to consult.
Example	*Film-coated tablet*
Conformance	Optional, will not be processed[14]
Data type	String
Validation rule	Not applicable
Destination reference	NCA national demand template / column G

Tag	Explanation
ID	P1.5
Name	Unit of presentation
Description	The unit of presentation is a qualitative term describing the discrete unit in which a manufactured item is presented. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*Vial, tablet, bottle, capsule*
Conformance	Optional, will not be processed[14]
Data type	String
Validation rule	Not applicable

[14] This data field is included in the dataset only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to this data element will not be processed by the ESMP. If changes need to be applied to this data element, they must be done in directly in PMS by the respective MAH.

Tag	Explanation
Destination reference	NCA national demand template / column H

3.1.2 Demand forecast

The demand forecast information section collects details about the estimated national demand for the six months of the forecasting period.

The forecasting period will be defined and communicated by MSSG with the announcement of reporting obligations in a MSSG-led preparedness action. The forecasting period covers the interval of 6 months. For example, if a MSSG-led preparedness action is announced in May 2026 and reporting obligation starts from 1 June, month 1 of the forecasting period will be June 2026. In this case, the forecasting period will be from June 2026 (month 1) - November 2026 (month 6).

Data elements for demand forecast					
Demand forecast - month 1	Demand forecast - month 2	Demand forecast - month 3	Demand forecast - month 4	Demand forecast - month 5	Demand forecast - month 6
D1.1.1	D1.1.2	D1.1.3	D1.1.4	D1.1.5	D1.1.6

Please consult the tables below for further details about data elements and relative conformances.

Tag	Explanation
ID	D1.1.1
Name	Demand forecast - month 1
Description	Estimated number of units of the relevant medicinal product that have to be available for patients in a specific EU/EEA member state during the first month of the forecast period.
Example	*7500*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA national demand template / column I

Tag	Explanation
ID	D1.1.2
Name	Demand forecast - month 2

Tag	Explanation
Description	Estimated number of units of the relevant medicinal product that have to be available for patients in a specific EU/EEA member state during the second month of the forecast period.
Example	*7500*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA national demand template / column J

Tag	Explanation
ID	D1.1.3
Name	Demand forecast - month 3
Description	Estimated number of units of the relevant medicinal product that have to be available for patients in a specific EU/EEA member state during the third month of the forecast period.
Example	*7500*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA national demand template / column K

Tag	Explanation
ID	D1.1.4
Name	Demand forecast - month 4
Description	Estimated number of units of the relevant medicinal product that have to be available for patients in a specific EU/EEA member state during the fourth month of the forecast period.
Example	*7500*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999

Tag	Explanation
Destination reference	NCA national demand template / column L

Tag	Explanation
ID	D1.1.5
Name	Demand forecast - month 5
Description	Estimated number of units of the relevant medicinal product that have to be available for patients in a specific EU/EEA member state during the fifth month of the forecast period.
Example	*7500*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA national demand template / column M

Tag	Explanation
ID	D1.1.6
Name	Demand forecast - month 6
Description	Estimated number of units of the relevant medicinal product that have to be available for patients in a specific EU/EEA member state during the sixth month of the forecast period.
Example	*7500*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA national demand template / column N

4. Critical shortages

4.1 Voluntary solidarity mechanism

The Voluntary solidarity mechanism (VSM) is a procedure which allows a Member State (MS) to request assistance from other MSs in obtaining stocks of a medicine during a critical shortage. This procedure should be used as the last resort when the MS have exhausted other possibilities, and the main conditions for launching a VSM must be met.

The following chapters describe in depth the different data elements and related details, that NCAs will need to submit to fulfil reporting requirements.

⚠ **All data elements are mandatory** and must be provided to successfully upload the file. If any information **is not known or cannot be provided** at the time of submission, users must enter a value such as "**Unknown**", or in the case where a date must be inserted, a default date such as "**01/01/9999**" should be entered.

4.1.1 Product information

To submit information on products for which a voluntary solidarity mechanism needs to be requested through the ESMP, the platform will generate empty templates which you can download, compile, and upload.

Data elements for Product information					
Medicinal product name	Active substance	Pharmaceutical form	Strength	MAH name	Manufacturer name and country
P2.1	P2.2	P2.3	P2.4	P2.5	P2.6

Please consult the box and tables below for further details about each data element and relative conformance.

Tag	Explanation
ID	P2.1
Name	Medicinal product name
Description	Medicinal product name as indicated in *Section 1: Name of the Medicinal Product* of the Summary of Product Characteristics (SmPC) or other regulatory documents, in line with the local language of the country where the product is authorised.
Example	*Esempin*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in

Tag	Explanation
Destination reference	NCA VSM template / column A

Tag	Explanation
ID	P2.2
Name	Active substance
Description	Active substance(s) contained in the medicinal product. Multiple active substance may be entered, separated by a comma.
Example	*paracetamol*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column B

Tag	Explanation
ID	P2.3
Name	Pharmaceutical form
Description	Pharmaceutical form as authorised by regulatory authorities and as reflected in regulatory documents.
Example	*film-coated tablet*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column C

Tag	Explanation
ID	P2.4
Name	Strength
Description	Quantity of the active substance contained in the pharmaceutical product including the unit of measurement.

Tag	Explanation
Example	*500 mg*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column D

Tag	Explanation
ID	P2.5
Name	MAH name
Description	Company or other legal entity that has the authorisation to market a medicine in one, several or all EU/EEA Member States.
Example	*Esempex Ltd*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column E

Tag	Explanation
ID	P2.6
Name	Manufacturer name and country
Description	Indicates the name of the manufacturer and the country where the manufacturing site is located.
Example	*Esempex Labs, Portugal*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column F

4.1.2 Shortage information

The "shortage information" section aims to gather insight on shortages in the supply chain, capturing aspects related to timelines, disruptions, and the underlying causes of shortages of a particular product.

Data elements for Shortage information								
Start date of the market disruption (dd/mm/yyyy)	(Expected) end date of market disruption (dd/mm/yyyy)	Root cause of shortage	Availability of alternatives with the same active substance	Therapeutic alternatives	Current stock at national level (number of units)	Monthly sales volume at national level (number of units)	Date of (expected) next delivery	Volume of next delivery (number of units)
S2.1	S2.2	S2.3	S2.4	S2.5	S2.6	S2.7	S2.8	S2.9

Please consult the tables below for further details about each data element and relative conformance.

Tag	Explanation
ID	S2.1
Name	Start date of the market disruption (dd/mm/yyyy)
Description	Specifies the date on which the market disruption began.
Example	01/04/2026
Conformance	Mandatory
Data type	String
Validation rule	• Must be in format dd/mm/yyyy • If not known, a default date such as "01/01/1900" should be entered
Destination reference	NCA VSM template / column G

Tag	Explanation
ID	S2.2
Name	(Expected) end date of market disruption (dd/mm/yyyy)
Description	Specifies the date on which the market disruption is expected to ending or is expected to end.
Example	01/06/2026
Conformance	Mandatory
Data type	String
Validation rule	• Must be in format dd/mm/yyyy • Must be after the start date of the market disruption • If not known, a default date such as "01/01/9999" should be entered

Destination reference	NCA VSM template / column H

Tag	Explanation
ID	S2.3
Name	Root cause of the shortage
Description	Primary reason(s) for the shortage. If applicable, multiple reasons may be entered
Example	*Manufacturing issues*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column I

Tag	Explanation
ID	S2.4
Name	Availability of alternatives with the same active substance
Description	Indicates whether other products containing the same active substance are available on the market to mitigate the impact of the disruption.
Example	*No, stocks at other MAHs are only sufficient to cover the need for one more week*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column J

Tag	Explanation
ID	S2.5
Name	Therapeutic alternatives
Description	Indicates whether different therapeutic alternatives are available on the market to help mitigate the impact of the disruption.

Tag	Explanation
Example	*Yes, two authorised products with ibuprofen remain available*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column K

Tag	Explanation
ID	S2.6
Name	Current stock at national level (number of units)
Description	Indicates the total number of units currently available in national stock.
Example	*140.000 packs*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column L

Tag	Explanation
ID	S2.7
Name	Monthly sales volume at national level (number of units)
Description	Indicates the total number of units sold per month at national level.
Example	*180.000 packs*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column M

Tag	Explanation
ID	S2.8

Tag	Explanation
Name	Date of (expected) next delivery
Description	Indicates the expected date of the next delivery of the product.
Example	*01/06/2026*
Conformance	Mandatory
Data type	String
Validation rule	• Must be in format dd/mm/yyyy • Must be after the start date of the market disruption • If not known, a default date such as "01/01/9999" should be entered
Destination reference	NCA VSM template / column N

Tag	Explanation
ID	S2.9
Name	Volume of next delivery (number of units)
Description	Indicates the number of units included in the next scheduled delivery.
Example	*150.000 packs*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column O

Request details

The "request details" section refers to other relevant key information for the shortage in question, the amounts required, possibility for import, as well as context on previously taken actions and discussions held at SPOC WP.

Please consult the tables below for further details about each data element and relative conformance.

Data elements for Request details				
Amount required (number of units)	Reason for urgency	Steps already undertaken to mitigate the critical shortage at national level	Outcome of SPOC WP discussion/survey and resulting actions taken at national level	Is importation possible? (yes/no)
R2.1	R2.2	R2.3	R2.4	R2.5

Please consult the tables below for further details about each data element and relative conformance.

Tag	Explanation
ID	R2.1
Name	Amount required (number of units)
Description	Indicates the number of units required to meet the national demand.
Example	*360.000 packs*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column P

Tag	Explanation
ID	R2.2
Name	Reason for urgency
Description	Indicates the justification for why the request or action must be addressed urgently.
Example	*Monthly demand exceeds available supply, with current stocks projected to run out within a week*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column Q

Tag	Explanation
ID	R2.3
Name	Steps already undertaken to mitigate the critical shortage at national level
Description	Summarises the actions already taken at national level to reduce or manage the impact of the critical shortage.
Example	*Applied rationing measures, explored limited import options and identified suitable therapeutic alternatives*
Conformance	Mandatory

Tag	Explanation
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column R

Tag	Explanation
ID	R2.4
Name	Outcome of SPOC WP discussion/survey and resulting actions taken at national level
Description	Summarises the outcome of the SPOC WP discussion or survey and any resulting actions implemented at national level in response
Example	*SPOC WP noted supply strain, prompting strengthened monitoring and targeted national actions*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column S

Tag	Explanation
ID	R2.5
Name	Is importation possible? (yes/no)
Description	Indicates whether importing the product from other countries is feasible as part of the shortage mitigation measures.
Example	*no*
Conformance	Mandatory
Data type	String
Validation rule	Must be filled in
Destination reference	NCA VSM template / column T