EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

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

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EUROPEAN MEDICINES AGENCY
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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
SmPC	Summary of product characteristics
SMS	Substance Management Services
SPOR	Substance, Product, Organisation, and Referentials

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 (once published) 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	Format of the of the value to be inserted.
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.

Tag	Explanation
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[1]. The relevant RMS lists are linked within each relevant data element table, in the validation rule row.

[1] 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 the list of critical medicines for a specific public health emergency (PHE) or major event (ME), 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 via 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 via 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 via 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 (Packaged medicinal product)	Full product name	Short product name	MAH	Active substance	Strength	Pharmaceutical form	Pack size	Packaging
P1.1.1	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	P1.1.1
Name	PMS ID (Packaged medicinal product ID[2])

[2] More information on Packaged medicinal product ID will be provided once this data element will be described in the PMS Implementation Guide.

Tag	Explanation
Description	Unique identifier assigned to a packaged medicinal product throughout its lifecycle.[3] 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.
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.
Example	*Esempin 500 mg - Film-coated tablet*
Conformance	Optional, will not be processed[4]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column B

[3] The PMS ID is a supplementary stable ID to any existing authorisation number or equivalent identifier as assigned by an authorising body.
[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
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.
Example	*Esempin*
Conformance	Optional, will not be processed[5]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply 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 (MS). This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*Esempex Ltd*
Conformance	Optional, will not be processed[5]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column D

Tag	Explanation
ID	P1.3.2

[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
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*
Conformance	Optional, will not be processed[6]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column E

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.
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

[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
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.
Example	*Film-coated tablet*
Conformance	Optional, will not be processed[7]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column G

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.
Example	*100 tablets*
Conformance	Optional, will not be processed[7]
Data type	String
Validation rule	Not applicable
Destination reference	NCA stock and supply template / column H

Tag	Explanation
ID	P1.7.3
Name	Packaging

[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
Description	Physical type of the container of the 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.
Example	*Blister*
Conformance	Optional, will not be processed[8]
Data type	String
Validation rule	Not applicable
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

[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.

Tag	Explanation
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
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

Tag	Explanation
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

Tag	Explanation
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.

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
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

Tag	Explanation
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
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 Historical consumption (non-PHE/ME need)

The "historical consumption" (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.

Data elements for historical consumption					
Historical consumption non-PHE/ME need - month 1	Historical consumption non-PHE/ME need - month 2	Historical consumption non-PHE/ME need - month 3	Historical consumption non-PHE/ME need - month 4	Historical consumption non-PHE/ME need - month 5	Historical consumption 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	Historical consumption 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	Historical consumption 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*

Tag	Explanation
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	Historical consumption 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
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 Historical 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 historical consumption yet derived from a different source. Either data element can be used to estimate the non-PHE/ME need during the forecast period.

Data elements for historical volume of prescriptions					
Historical volume of prescriptions - month 1	Historical volume of prescriptions - month 2	Historical volume of prescriptions - month 3	Historical volume of prescriptions - month 4	Historical volume of prescriptions - month 5	Historical 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	Historical 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	Historical 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	Historical 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	Historical 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	Historical 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*

Tag	Explanation
Conformance	Optional
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	Historical 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.

Data elements for patient estimation			
Estimated total number of	Estimated total number of	Estimated total number of	PHE/ME RMS ID

Data elements for patient estimation			
patients	hospitalised patient-days	ICU patient-days	
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.
Example	*500*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA patients 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
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA patients 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 patients 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 patients 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 information 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*
Conformance	Optional, will not be processed[9]
Data type	String
Validation rule	Not applicable
Destination reference	NCA medicine information template / column B

[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
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 information 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[10]
Data type	String
Validation rule	Not applicable
Destination reference	NCA medicine information template / column D

[10] 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.

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
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 information 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 information template / column F

2.3.3 Intensive care unit 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 information 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
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 information template / column H

3. MSSG-led preparedness submissions

Following an Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) announcement of a specific preparedness exercise, 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 via 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 exercise. The templates will be pre-populated with information previously submitted to the EMA via 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 via 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 (Packaged medicinal product)	Full product name	Short product name	MAH	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 (Packaged medicinal product ID[11])
Description	Unique identifier assigned to a packaged medicinal product throughout its lifecycle.[12] It is an essential identifier that will ensure that the information inserted in the template is associated with the correct product.

[11] More information on Packaged medicinal product ID will be provided once this data element will be described in the PMS Implementation Guide.
[12] 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 is pre-populated in the data submission template if the file is downloaded from the ESMP.
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.
Example	*Esempin 500 mg - Film-coated tablet*
Conformance	Optional, will not be processed[13]
Data type	String
Validation rule	Not applicable
Destination reference	NCA National demand template / column B

Tag	Explanation
ID	P1.2.2
Name	Short product name

[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
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.
Example	*Esempin*
Conformance	Optional, will not be processed[1413]
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.
Example	*Esempex Ltd*
Conformance	Optional, will not be processed[14]
Data type	String
Validation rule	Not applicable
Destination reference	NCA National demand template / column D

Tag	Explanation
ID	P1.3.2
Name	Active substance

[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
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*
Conformance	Optional, will not be processed[1513]
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.
Example	*500 mg*
Conformance	Optional, will not be processed[154]
Data type	String
Validation rule	Not applicable
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.

[15] 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
Example	*Film-coated tablet*
Conformance	Optional, will not be processed[164]
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	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.
Example	*100 tablets*
Conformance	Optional, will not be processed[161313]
Data type	String
Validation rule	Not applicable
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.

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.

[16] 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	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	Mandatory
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
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	Mandatory
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	Mandatory

Tag	Explanation
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	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
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	Mandatory
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	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	NCA National demand template / column N