EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 July 2024

European Medicines Agency

European Shortages Monitoring Platform (ESMP) Implementation Guide for Marketing Authorisation Holders

Version 1.0

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

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Table of abbreviations

Abbreviation	Full name
API	Active Pharmaceutical Ingredient
CAP	Centrally Authorised Product
EEA	European Economic Area
EMA	European Medicines Agency
ESMP	European Shortages Monitoring Platform
EU	European Union
INN	International Non - proprietary Name
IRIS	Integrated Regulatory Information System
ISO	International Organization for Standardization
MAH	Marketing Authorisation Holder
MPID	Medical Product Identifier
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products (Medicines Shortages Steering Group)
NAP	Nationally Authorised Product
OMS	Organisation Management Services
PCID	Packaged Medicinal Product Identifier
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 marketing authorisation holders (MAHs) describes technical details and rules that MAHs must follow to ensure the successful completion of electronic submissions to 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 relevant details are also presented in the dedicated sections of the guide.

The implementation guide will be complementary to the EMSP User guide for MAHs (once published) and aims to support MAHs to fulfil reporting obligations to the EMA on information on shortages and supply of medicinal products as defined by Regulation (EU) 2022/123.

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 description 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; • 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 the insertion of Referentials Management Services (RMS) identifiers, which are 12 - digit IDs that codify data used to insert information in the system, you can consult two resources:

- RMS lists in the SPOR platform[1], which are linked within each relevant data element table, in the validation rule row;
- The RMS identifiers annex, which collects and catalogues all RMS lists used in the ESMP, RMS IDs, corresponding terms, and their meaning.

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

2. Routine shortage submissions

In normal circumstances, MAHs are required to report shortages of centrally authorised products (CAPs) when the MAH is made aware of a potential or actual shortage.

Once the functionalities for routine shortage reporting are made available in the ESMP, you will have to submit the following information for the medicinal products for which you notify a shortage, and keep those entries up to date:

- Shortage information;
- Shortage prevention and mitigation plans;
- Shortage impact assessment;
- Alternative therapies.

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

2.1. Preliminary requirements

The ESMP is integrated with the EMA data management services to ensure a reliable exchange of information. By providing master data and a common language across the EU/EEA, this integration facilitates data management and regulatory compliance. The ESMP will retrieve the following data from EMA systems to pre-populate reporting templates:

- Product information from the Product Management Service (PMS);
- Marketing status for CAPs from IRIS.

Data retrieved from PMS and IRIS cannot be modified through the ESMP.

Please ensure that marketing status information of all your CAPs is inserted correctly and is up to date within the IRIS platform. Data from IRIS will be retrieved only for products in scope of reporting requirements which have been indicated as "marketed" or "temporarily unavailable" in specific EU/EEA countries. Products for which marketing status information has not been inserted in IRIS, and products for which marketing status has been indicated as "not marketed" or "never marketed", will not be retrieved from IRIS; hence, entries for such product and country combinations will not be pre - populated in the data submission templates in the ESMP.

If marketing status details for CAPs in IRIS are out of date or incorrect, changes need to be entered directly in the IRIS platform, after which they will be automatically reflected in the ESMP. For more information regarding how to modify marketing status information in IRIS, please refer to the IRIS guide for applicants[2], section 6, and to the relevant sections of the EMA website[3].

[2] https://www.ema.europa.eu/en/documents/other/iris - guide - applicants - how - create - and - submit - scientific - applications - industry - and - individual - applicants - en.pdf
[3] https://www.ema.europa.eu/en/human - regulatory - overview/post - authorisation/notifying - change - marketing - status

2.2. Routine shortage reporting

2.2.1. Product information

To collect information on medicinal products in scope of reporting requirements via the ESMP (i.e., CAPs experiencing potential or actual shortages), the platform will generate templates which you can download, compile, and upload. Where possible, the templates will be pre-populated with information previously submitted to the EMA through different systems and previously through the ESMP.

Please **do not change the fields which have been retrieved from other EMA systems** while completing the submission procedure. Any changes to product information in the pre-filled templates will not be processed by the system, hence will not generate any changes in the PMS or IRIS databases.

Data elements for product information										
PMS ID (Packaged medicinal product)	Full product name	Short product name	Active substance	Strength	Pharmaceutical form	Pack size	Packaging	PCID	Country of authorisation	Marketing status
P1.1.1	P1.2.1	P1.2.2	P1.3.2	P1.4	P1.6.2	P1.7.2	P1.7.3	P1.7.1	P1.8	P1.9

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

Tag	Explanation
ID	P1.1.1
Name	PMS ID (Packaged medicinal product ID[4])
Description	Unique identifier assigned to a packaged medicinal product throughout its lifecycle.[5] 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 to which the user has an affiliation.

[4] More information on Packaged medicinal product ID will be provided once this data element will be described in the PMS Implementation Guide.
[5] The PMS ID is a supplementary stable ID to any existing authorisation number or equivalent identifier as assigned by an authorising body.

Tag	Explanation
Destination reference	MAH Routine shortage reporting 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[6]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Routine shortage reporting 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.
Example	*Esempin*
Conformance	Optional, will not be processed[66]
Data type	String
Validation rule	Not applicable

[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.

Tag	Explanation
Destination reference	MAH Routine shortage reporting template / column C

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[76]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Routine shortage reporting template / column D

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[76]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Routine shortage reporting template / column E

[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.

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.
Example	*Film-coated tablet*
Conformance	Optional, will not be processed[86]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Routine shortage reporting template / column F

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[866]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Routine shortage reporting template / column G

Tag	Explanation
ID	P1.7.3
Name	Packaging

[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.

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[69]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Routine shortage reporting template / column H

Tag	Explanation
ID	P1.7.1
Name	PCID
Description	Unique Packaged Medicinal Product Identifier (PCID) assigned to each packaged medicinal product by PMS based on the data submitted. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*EU-100000396-00020080-0001*
Conformance	Optional, will not be processed[96]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Routine shortage reporting template / column I

Tag	Explanation
ID	P1.8
Name	Country of authorisation

[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.

Tag	Explanation
Description	Country where the medicinal product has been authorised, as approved by the regulatory authority, and indicated in the corresponding regulatory document(s). **Note:** In the ESMP, all centrally authorised products will be listed once per each EU/EEA country, so availability information can be inserted separately for each country. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*BE*
Conformance	Mandatory[10]
Data type	String
Validation rule	• Must comply with the standard ISO 3166 Alpha - 2 code • Must be an EU/EEA member state
Destination reference	MAH Routine shortage reporting template / column J

Tag	Explanation
ID	P1.9
Name	Marketing status
Description	Marketing status of the product, indicating whether a product is placed on the market. For more information on marketing status for CAPs, please refer to section 2.1 Preliminary Requirements.
Example	*Marketed*
Conformance	Optional[11]
Data type	String
Validation rule	Must reflect the existing marketing status as present in IRIS.
Destination reference	MAH Routine shortage reporting template / column K

[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.
[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 IRIS.

2.2.2. Shortage information

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

Data elements for shortage information								
Shortage status	Shortage start date or expected start date	Shortage end date or expected end date	Point in supply chain at which disruption occurs	Root cause of the shortage	Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Root cause of the shortage - additional information
S1.1	S1.2	S1.3	S1.4	S1.5	S1.6.1	S1.6.2	S1.6.3	S1.7

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

Tag	Explanation
ID	S1.1
Name	Shortage status
Description	Current state of a shortage situation of a medicinal product in a specific EU/EEA Member State, which can be categorised as "Potential", "Actual", "Resolved", or "No Shortage". It is based on the most reliable information at the time of reporting. Any change in the status, such as from potential to actual or from actual to resolved, must be reported immediately by submitting the updated information.
Example	Potential
Conformance	Mandatory
Data type	String
Validation rule	Must be one of the following options: • Potential • Actual • Resolved • No shortage
Destination reference	MAH Routine shortage reporting template / column L

Tag	Explanation
ID	S1.2
Name	Shortage start date or expected start date

Tag	Explanation
Description	Date when a shortage begins or is anticipated to begin. For a shortage with an "Actual" or "Resolved" status, indicate the shortage start date. For a "Potential" status, indicate the expected shortage start date.
Example	20/05/2024
Conformance	Conditional
Data type	Date

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential" or "Resolved":
	  ○ Must be filled in (mandatory);
	  ○ Must be format dd/mm/yyyy;
	  ○ Must be no more than 2 years prior to the current date;
	  ○ Must be within 10 years of the current date.

Destination reference	MAH Routine shortage reporting template / column M

Tag	Explanation
ID	S1.3
Name	Shortage end date or expected end date
Description	Date when a shortage is expected to or actually ends. For "Actual" and "Potential" shortages, it indicates an estimated end date. For "Resolved" shortages, it indicates the actual shortage end date.
Example	*13/09/2029*
Conformance	Conditional
Data type	Date

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential":
	  ○ Must be filled in (mandatory);
	  ○ Must be format dd/mm/yyyy;
	  ○ Must be the current date or within 10 years after the current date;
	  ○ Must not be earlier than the Shortage start date or expected start date;
	• If the Shortage status is reported as "Resolved":
	  ○ Must be filled in (mandatory);
	  ○ Must be format dd/mm/yyyy;
	  ○ Must be no more than 2 years prior to the current date;
	  ○ Must be within 10 years of the current date;
	  ○ Must not be earlier than the Shortage start date or expected start date.

Destination	MAH Routine shortage reporting template / column N

Tag	Explanation
reference	

Tag	Explanation
ID	S1.4
Name	Point in supply chain at which disruption occurs
Description	Specific stages of the medicine manufacturing and distribution where issues are occurring. If applicable, multiple values may be entered.
Example	*200000028583;200000028585*
Conformance	Conditional
Data type	String

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential" or "Resolved":
	  ○ Must be filled in (mandatory);
	  ○ Must be the RMS term ID of a term in the RMS list "Supply chain disruption shortage" with list ID "200000028549", consult possible values in the Annex 1 – RMS IDs list, Shortage chain distribution shortage;
	  ○ Multiple values must be separated by a ";";
	  ○ Must not contain duplicate values.

Destination reference	MAH Routine shortage reporting template / column O

Tag	Explanation
ID	S1.5
Name	Root cause of the shortage
Description	Primary reason(s) for the market disruption. If applicable, multiple values may be entered.
Example	200000028683;200000028684
Conformance	Conditional
Data type	String

Tag	Explanation

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential" or "Resolved":
	  ○ Must be filled in (mandatory);
	  ○ Must be the RMS term ID of a term in the RMS list "Shortage root cause" with list ID "200000028648", consult possible values in the Annex 1 – RMS IDs list, Shortage root cause;
	  ○ Multiple values must be separated by a ";";
	  ○ Must not contain duplicate values.

Destination reference	MAH Routine shortage reporting template / column P

Tag	Explanation
ID	S1.6.1
Name	Countries in which manufacturing issues occur
Description	Countries where the production problems are happening. If the shortage is due to manufacturing issues, you should indicate the specific countries affected, such as the country of the production line experiencing the issue. If applicable, multiple values may be entered.
Example	*CN;CO*
Conformance	Conditional
Data type	String

Validation rule	• If the reported Root cause of shortage does **not** refer to Manufacturing issues ('200000028689', '200000028690', '200000028691', or, '200000028692'):
	  ○ Must not be filled in (to be left empty)
	• If the reported Root cause of shortage refers to Manufacturing issues ('200000028689', '200000028690', '200000028691', or, '200000028692'):
	  ○ Must be filled in (mandatory);
	  ○ Must comply with the standard ISO 3166 Alpha - 2 code;
	  ○ Multiple values must be separated by a ";";
	  ○ Must not contain duplicate values.

Destination reference	MAH Routine shortage reporting template / column Q

Tag	Explanation
ID	S1.6.2
Name	Countries in which unexpected increased demand occurs

Tag	Explanation
Description	Countries where there is an unexpected rise in the need for the product. If the shortage is due to unexpected increased demand, you should indicate the specific countries experiencing this surge, such as those affected by changes in epidemiology. If applicable, multiple values may be entered.
Example	*CN;CO*
Conformance	Conditional
Data type	String

Validation rule	• If the reported Root cause of shortage does **not** refer to Unexpected increased demand ("200000028700", "200000028701", "200000028702", "200000028703", or, "200000028704"):
	  ○ Must not be filled in (to be left empty)
	• If the reported Root cause of shortage refers to Unexpected increased demand ("200000028700", "200000028701", "200000028702", "200000028703", or, "200000028704"):
	  ○ Must be filled in (mandatory);
	  ○ Must comply with the standard ISO 3166 Alpha - 2 code;
	  ○ Multiple values must be separated by a ";";
	  ○ Must not contain duplicate values.

Destination reference	MAH Routine shortage reporting template / column R

Tag	Explanation
ID	S1.6.3
Name	Countries in which distribution issues occur
Description	Countries where there are problems in distributing the product. If the shortage is due to distribution issues, you should indicate the specific countries experiencing these problems. If applicable, multiple values may be entered.
Example	*CN;CO*
Conformance	Conditional
Data type	String

Tag	Explanation
Validation rule	• If the reported Root cause of shortage does **not** refer to Distribution issues ("200000028706", "200000028707", "200000028708", "200000028709", or "200000028710"): ○ Must not be filled in (to be left empty) • If the reported Root cause of shortage refers to Distribution issues ("200000028706", "200000028707", "200000028708", "200000028709", or "200000028710"): ○ Must be filled in (mandatory); ○ Must comply with the standard ISO 3166 Alpha - 2 code; ○ Multiple values must be separated by a ";"; ○ Must not contain duplicate values.
Destination reference	MAH Routine shortage reporting template / column S

Tag	Explanation
ID	S1.7
Name	Root cause of the shortage - additional information
Description	Further information and details on the root cause of the shortage that are not already covered by the "Root cause of shortage" data field.
Example	*Reprioritisation of product portfolio*
Conformance	Optional
Data type	String, free text
Validation rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Routine shortage reporting template / column T

2.2.3. Shortage prevention and mitigation

The "shortage prevention and mitigation" section collects information about possible measures that could potentially overcome the shortages of medicinal products in scope of reporting.

Data elements for prevention and mitigation	
Shortage prevention and mitigation plans	Shortage prevention and mitigation plans - ongoing and planned steps
S2.1	S2.2

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

Tag	Explanation
ID	S2.1
Name	Shortage prevention and mitigation plans

Tag	Explanation
Description	Strategies implemented to prevent or address supply shortages to mitigate their impact on patients. One or more actual or intended mitigation measures for the shortage should be reported. If applicable, multiple values may be entered. • If "potential alternative active substance manufacturer/production site" or "potential alternative finished product manufacturer/production site" are selected as mitigating measures, please identify the site in the free text field ID S2.2. • If "resolve manufacturing or quality issue(s)" is selected, please elaborate in detail in the free text field ID S2.2.
Example	*200000028633;200000028640*
Conformance	Conditional
Data type	String
Validation rule	• If the Shortage status is reported as "No Shortage": ○ Must not be filled in (to be left empty) • If the Shortage status is reported as "Actual", "Potential" or "Resolved": ○ Must be filled in (mandatory); ○ Must be the RMS term ID of a term in the RMS list "mitigation plan prevention plan" with list ID "200000028617", consult possible values in the Annex 1 – RMS IDs list, Mitigation plan prevention plan; ○ Multiple values must be separated by a ";"; ○ Must not contain duplicate values.
Destination reference	MAH Routine shortage reporting template / column U

Tag	Explanation
ID	S2.2
Name	Shortage prevention and mitigation plans - ongoing and planned steps
Description	Complementary description of the mitigation and prevention plans, in addition to the tag "Shortage prevention and mitigation plans". Any relevant additional information on the proposed shortage prevention and mitigation measures must be reported. • If "potential alternative active substance manufacturer/production site" or "potential alternative finished product manufacturer/production site" are selected as mitigating measures, please identify the site here. • If "resolve manufacturing or quality issue(s)" is selected, please elaborate in detail here.
Example	*Manufacturing of finished product/active substance commissioned to alternative manufacturer; Batch testing taking place at alternative testing site*
Conformance	Optional
Data type	String, free text

Tag	Explanation
Validation rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Routine shortage reporting template / column V

2.2.4. Impact assessment

The "impact assessment" section gathers information about the effects the shortage of a particular medicine in scope of reporting requirements on patients.

Data elements for impact assessment			
Affected population estimate	Market share	Shortage impact risk assessment	Shortage impact risk assessment - additional information
S3.1	S3.2	S3.4	S3.5

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

Tag	Explanation
ID	S3.1
Name	Affected population estimate
Description	Estimated number of patients or population affected in the relevant EU/EEA country.
Example	*15590*
Conformance	Optional
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Routine shortage reporting template / column W

Tag	Explanation
ID	S3.2
Name	Market share

Tag	Explanation
Description	Latest available data on the market share from the beginning of year to the latest period (year to date), in percentage, at pack level for the relevant medicinal product in a specific EU/EEA member state in relation to other authorised medicinal products on this particular market. Market share data should address both hospital and non-hospital markets. This data must be provided if available.
Example	*15*
Conformance	Optional
Data type	Integer
Validation rule	• Must be a whole number between 0 and 100 • Must not include the "%" sign
Destination reference	MAH Routine shortage reporting template / column X

Tag	Explanation
ID	S3.4
Name	Shortage impact risk assessment
Description	Company assessment of the risk level of the shortage situation and its impact on patients. Indicate as: low, medium, or high.
Example	*200000033600*
Conformance	Conditional
Data type	String

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential" or "Resolved":
	  ○ Must be filled in (mandatory);
	  ○ Must be the RMS term ID of a term in the RMS list "shortage impact risk assessment" with list ID "200000033599", consult possible values in the Annex 1 – RMS IDs list, Shortage impact risk assessment.

Destination reference	MAH Routine shortage reporting template / column Y

Tag	Explanation
ID	S3.5
Name	Shortage impact risk assessment – additional information
Description	Further information on the reason for the rating in the tag "shortage impact risk assessment".

Tag	Explanation
Example	*Risk level high due to high market share and few or no suitable alternative products*
Conformance	Optional
Data type	String, free text
Validation rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Routine shortage reporting template / column Z

2.2.5. Alternative therapies

The "alternative therapies" section collects information about alternative therapies or substances available which could be used to mitigate the lack of the product in shortage.

Data elements for alternative substances	
Alternatives therapies available?	Alternative substances
S4.1	S4.2

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

Tag	Explanation
ID	S4.1
Name	Alternative therapies available?
Description	Indicate if there are treatments available on the market that can be used instead of the primary medication for the respective condition.
Example	*No*
Conformance	Conditional
Data type	String

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential" or "Resolved":
	  ○ Must be filled in (mandatory);
	  ○ Values must be only "yes" or "no" (not case sensitive).

Destination reference	MAH Routine shortage reporting template / column AA

Tag	Explanation
ID	S4.2

Tag	Explanation
Name	Alternative therapies
Description	Substitute medicinal products or active substances that can be used when the primary medication is unavailable. Details on these therapeutic alternatives, according to the company's best knowledge, including products from the same MAH and other MAHs, should be provided if available.
Example	*Products with same API from other MAH available and also marketed in this member state. Ibuprofen can also be used as an alternative.*
Conformance	Conditional
Data type	String, free text

Validation rule	• If the Alternative therapies available? is reported as "No":
	  ○ Must not be filled in (to be left empty)
	• If the Alternative therapies available? is reported as "Yes":
	  ○ Must be filled in (mandatory);
	  ○ Must not exceed the maximum length of 2000 characters.

Destination reference	MAH Routine shortage reporting template / column AB

2.2.6. Additional information

The "additional information" section refers to other regulatory processes initiated for the situation in question, as well as information on the assistance required from relevant NCAs.

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

Data elements for additional information			
Rapid Alert reference number	Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report	Reference to related pending regulatory action	Required NCA actions, if any
S5.1	S5.2	S5.3	S5.4

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

Tag	Explanation
ID	S5.1
Name	Rapid Alert reference number
Description	Reference number of the rapid alert for a quality defect/recall action of the product to be indicated in case it was reported through the Rapid Alert System.
Example	*ES/II/2019/05/02*
Conformance	Optional
Data type	String, free text
Validation rule	Must not exceed the maximum length of 2000 characters

Tag	Explanation
Destination reference	MAH Routine shortage reporting template / column AC

Tag	Explanation
ID	S5.2
Name	Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report.
Description	List of all notified authorities that were notified of the quality defect including the reference numbers to the respective quality defect report.
Example	*EMA; BfArM/All EU National Authorities; Reference: QDYYYY - 123*
Conformance	Optional
Data type	String, free text
Validation rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Routine shortage reporting template / column AD

Tag	Explanation
ID	S5.3
Name	Reference to related pending regulatory action
Description	Indicate the reference to related pending regulatory action, if applicable.
Example	*EMEA/H/B/919*
Conformance	Optional
Data type	String, free text
Validation rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Routine shortage reporting template / column AE

Tag	Explanation
ID	S5.4
Name	Required NCA actions, if any
Description	Actions required from any national competent authority to prevent or mitigate the shortage. Indicate if applicable.
Example	*Explore potential regulatory flexibilities to address the shortage, (e.g. possible labelling exemption).*
Conformance	Optional

Tag	Explanation
Data type	String, free text
Validation rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Routine shortage reporting template / column AF

3. Crisis and MSSG - led preparedness submissions

In times of crisis (i.e., during a public health emergency or major event) or an Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) announcement of a specific preparedness exercise, you are required to report information on centrally and nationally authorised products. In the first case, reporting requirements refer to products included in the list of critical medicines for a specific public health emergency (PHE) or major event (ME); in the second, you are required to report information on products included in a list of medicines to be monitored for MSSG - led crisis preparedness. In both cases, you will have to submit the following information for medicinal products in scope of reporting requirements:[i]

- Marketing status for CAPs;
- Marketing status for NAPs;
- Availability information;
- Manufacturing information;
- Alternative therapies.

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

3.1. Preliminary requirements

The ESMP is integrated with the EMA data management services to ensure a reliable exchange of information. By providing master data and a common language across the EU/EEA, this integration facilitates data management and regulatory compliance. The ESMP will retrieve the following data from EMA systems to pre - populate reporting templates:

- Product information at pack size medicinal product level from the Product Management Service (PMS);
- Organisation details from the Organisation Management Services (OMS);
- Marketing status for **centrally authorised products (CAPs)** from IRIS.

Data retrieved from PMS, OMS, and IRIS cannot be modified through the ESMP.

Please ensure that marketing status information of all your CAPs is inserted correctly and is up to date within the IRIS platform. Data from IRIS will be retrieved only for products in scope of reporting requirements which have been indicated as "marketed" or "temporarily unavailable" in specific EU/EEA countries. Products for which marketing status information has not been inserted in IRIS, and products for which marketing status has been indicated as "not marketed" or "never marketed", will not be retrieved from IRIS. Entries for such product and country combinations will not be pre - populated in the data submission templates in the ESMP.

If marketing status details for CAPs in IRIS are out of date or incorrect changes need to be implemented directly in the IRIS platform which then will be automatically reflected in the ESMP. For

more information regarding how to modify marketing status information in IRIS, please refer to the IRIS guide for applicants[12], section 6, and to the relevant sections of the EMA website[13].

On the other hand, marketing status information for **nationally authorised products (NAPs)** in scope of crisis or MSSG - led preparedness reporting will be requested in the ESMP and submitted through a standalone reporting data flow. Please consult chapter 3.3 Marketing status for NAPs, for further information about the submission details.

3.2. Marketing status for CAPs

Information on marketing status for CAPs, which constitutes a preliminary requirement for data submissions in the ESMP, is maintained in IRIS. To review or modify marketing status information for products in scope of reporting requirements to ESMP you will be re - directed to IRIS.

3.3. Marketing status for NAPs

Data on the marketing status of nationally authorised products (NAPs; including products authorised via the national procedure (NP), decentralised procedure (DCP) or the mutual recognition procedure (MRP)) in scope of crisis or MSSG-led preparedness reporting will be requested directly in the ESMP and submitted through this reporting data flow. You will be required to keep this data up to date when changes to the marketing status of your products occur. Once the data is submitted, products which are indicated as "marketed" or "temporarily unavailable" will be reflected in the "Availability information" reporting template in the ESMP.

3.3.1. Product information

To collect marketing status information on NAPs in scope of reporting requirements in 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 or MSSG-led preparedness exercise. 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 in the pre-filled template 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	Active substance	Strength	Pharmaceutical form	Pack size	Packaging	PCID	Country of authorisation
P1.1.1	P1.2.1	P1.2.2	P1.3.2	P1.4	P1.6.2	P1.7.2	P1.7.3	P1.7.1	P1.8

[12] https://www.ema.europa.eu/en/documents/other/iris - guide - applicants - how - create - and - submit - scientific - applications - industry - and - individual - applicants - en.pdf
[13] https://www.ema.europa.eu/en/human - regulatory - overview/post - authorisation/notifying - change - marketing - status

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

Tag	Explanation
ID	P1.1.1
Name	PMS ID (Packaged medicinal product ID[14])
Description	Unique identifier assigned to a packaged medicinal product throughout its lifecycle.[15] 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 to which the user has an affiliation.
Destination reference	Marketing status for NAPs template / column A

Tag	Explanation
ID	P1.2.1
Name	Full product name
Description	Full product name as specified 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*

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

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

Tag	Explanation
Conformance	Optional, will not be processed[16]
Data type	String
Validation rule	Not applicable
Destination reference	Marketing status for NAPs 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.
Example	*Esempin*
Conformance	Optional, will not be processed[16][16]
Data type	String
Validation rule	Not applicable
Destination reference	Marketing status for NAPs template / column C

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*

[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.

Tag	Explanation
Conformance	Optional, will not be processed[1716]
Data type	String
Validation rule	Not applicable
Destination reference	Marketing status for NAPs template / column D

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[1716]
Data type	String
Validation rule	Not applicable
Destination reference	Marketing status for NAPs template / column E

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.
Example	*Film-coated tablet*

[17] 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.

Tag	Explanation
Conformance	Optional, will not be processed[1816]
Data type	String
Validation rule	Not applicable
Destination reference	Marketing status for NAPs template / column F

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[1816]
Data type	String
Validation rule	Not applicable
Destination reference	Marketing status for NAPs template / column G

Tag	Explanation
ID	P1.7.3
Name	Packaging
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*

[18] 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.

Tag	Explanation
Conformance	Optional, will not be processed[1916]
Data type	String
Validation rule	Not applicable
Destination reference	Marketing status for NAPs template / column H

Tag	Explanation
ID	P1.7.1
Name	PCID
Description	Unique Packaged Medicinal Product Identifier (PCID) assigned to each packaged medicinal product by PMS based on the data submitted. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*EU-100000396-00020080-0001*
Conformance	Optional, will not be processed[1916]
Data type	String
Validation rule	Not applicable
Destination reference	Marketing status for NAPs template / column I

Tag	Explanation
ID	P1.8
Name	Country of authorisation
Description	Country where the medicinal product has been authorised, as approved by the regulatory authority, and indicated in the corresponding regulatory document(s). This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*BE*
Conformance	Optional, will not be processed[16]

[19] 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.

Tag	Explanation
Data type	String
Validation rule	Not applicable
Destination reference	Marketing status for NAPs template / column J

3.3.2. Marketing status details

The "marketing status details" section is intended to gather information about whether a particular product is placed on the market, and if applicable, the date of planned permanent withdrawal and any related information.

Data elements for marketing status details		
Marketing status	Date of planned permanent withdrawal	Planned withdrawal comment
P1.9	W1.1	W1.2

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

Tag	Explanation
ID	P1.9
Name	Marketing status
Description	Marketing status indicating whether a product is placed on the market.
Example	100000072083
Conformance	Mandatory
Data type	String
Validation rule	Must be the RMS term ID of a term in the RMS list "Marketing status" with list ID "100000072052", consult the possible RMS term IDs in the Annex 1 – RMS IDs list, Marketing status.
Destination reference	Marketing status for NAPs template / column K

Tag	Explanation
ID	W1.1
Name	Date of planned permanent withdrawal
Description	Date in the future when the MAH plans to permanently withdraw the marketing authorisation of the product, if applicable.

Tag	Explanation
Example	*15/05/2028*
Conformance	Conditional
Data type	Date
Validation rule	• If the Marketing status is reported as "Marketed", "Temporarily Unavailable", or "Never Marketed": ○ Must not be filled in (to be left empty) • If the Marketing status is reported as "Not marketed": ○ Must be filled in (mandatory); ○ Must be format dd/mm/yyyy; ○ Must be in the future.
Destination reference	Marketing status for NAPs template / column L

Tag	Explanation
ID	W1.2
Name	Planned withdrawal comment
Description	Reason for the permanent withdrawal of the marketing authorisation of the product, or any other information deemed relevant.
Example	Withdrawal due to commercial reasons
Conformance	Conditional
Data type	String, free text
Validation rule	• If the Date of planned permanent withdrawal is not reported: ○ Must not be filled in (to be left empty) • If the Date of planned permanent withdrawal is reported: ○ Must be filled in (mandatory); ○ Must not exceed the maximum length of 2000 characters.
Destination reference	Marketing status for NAPs template / column M

3.4. Availability information

3.4.1. Product information

To collect availability information on medicinal products in scope of reporting requirements in 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 or MSSG-led preparedness exercise. 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 in the pre-filled template will not be processed by the system, hence will not generate any changes in the PMS or IRIS database.

Data elements for product information										
PMS ID (Packaged medicinal product)	Full product name	Short product name	Active substance	Strength	Pharmaceutical form	Pack size	Packaging	PCID	Country of authorisation	Marketing status
P1.1.1	P1.2.1	P1.2.2	P1.3.2	P1.4	P1.6.2	P1.7.2	P1.7.3	P1.7.1	P1.8	P1.9

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

Tag	Explanation
ID	P1.1.1
Name	PMS ID (Packaged medicinal product ID[20])
Description	Unique identifier assigned to a packaged medicinal product throughout its lifecycle.[21] 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 to which the user has an affiliation.
Destination reference	MAH Availability information 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

[20] More information on Packaged medicinal product ID will be provided once this data element will be described in the PMS Implementation Guide.
[21] The PMS ID is a supplementary stable ID to any existing authorisation number or equivalent identifier as assigned by an authorising body.

Tag	Explanation
	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[22]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Availability information 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.
Example	*Esempin*
Conformance	Optional, will not be processed[2222]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Availability information template / column C

Tag	Explanation
ID	P1.3.2
Name	Active substance
Description	Active substance(s) contained in the medicinal product.

[22] 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.

Tag	Explanation
	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[2322]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Availability information template / column D

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[232222]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Availability information template / column E

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.
Example	Film-coated tablet

[23] 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.

Tag	Explanation
Conformance	Optional, will not be processed[23]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Availability information template / column F

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[2422]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Availability information template / column G

Tag	Explanation
ID	P1.7.3
Name	Packaging
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[2422]

[24] 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.

Tag	Explanation
Data type	String
Validation rule	Not applicable
Destination reference	MAH Availability information template / column H

Tag	Explanation
ID	P1.7.1
Name	PCID
Description	Unique Packaged Medicinal Product Identifier (PCID) assigned to each packaged medicinal product by PMS based on the data submitted. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*EU-100000396-00020080-0001*
Conformance	Optional, will not be processed[252222]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Availability information template / column I

Tag	Explanation
ID	P1.8
Name	Country of authorisation
Description	Country where the medicinal product has been authorised, as approved by the regulatory authority, and indicated in the corresponding regulatory document(s). **Note**: In the ESMP, all centrally authorised products will be listed once per each EU/EEA country, so availability and supply information can be inserted separately for each country. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*BE*

[25] 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.

Tag	Explanation
Conformance	Mandatory[26]
Data type	String
Validation rule	• Must comply with the standard ISO 3166 Alpha - 2 code • Must be an EU/EEA member state
Destination reference	MAH Availability information template / column J

Tag	Explanation
ID	P1.9
Name	Marketing status
Description	Marketing status indicating whether a product is placed on the market. **Note**: marketing status for CAPs will be retrieved from IRIS, whereas marketing status for NAPs will be retrieved from previous submissions to the ESMP. For more information on marketing status, including how to update data, please consult section 3.1 Preliminary Requirements. For more information on marketing status for CAPs, please refer to section 3.2 Marketing status for CAPs. For more information on marketing status for NAPs, please refer to section 3.3 Marketing status for NAPs.
Example	*Marketed*
Conformance	Optional[27]
Data type	String
Validation rule	Must reflect the existing marketing status as inserted in IRIS for CAPs or through the dedicated data submission flow in the ESMP for marketing status for NAPs.
Destination reference	MAH Availability information template / column K

3.4.2. 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.

[26] This data element is retrieved from PMS and pre - populated within the template, it is essential to ensure that the inserted shortage details are associated with the correct country of authorisation.
[27] This data element is pre - populated within the template, it reflects the marketing status for the specific medicinal product in the country of authorisation. Changes or addition to this data field will not be processed by the ESMP via this reporting flow.

Data elements for Shortage information								
Shortage status	Shortage start date or expected start date	Shortage end date or expected end date	Point in supply chain at which disruption occurs	Root cause of the shortage	Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Root cause of the shortage - additional information
S1.1	S1.2	S1.3	S1.4	S1.5	S1.6.1	S1.6.2	S1.6.3	S1.7

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

Tag	Explanation
ID	S1.1
Name	Shortage status
Description	Current state of a shortage situation of a medicinal product in a specific EU/EEA member state, which can be categorised as "Potential", "Actual", "Resolved", or "No Shortage". It is based on the most reliable information at the time of reporting. Any change in the status, such as from potential to actual or from actual to resolved, must be reported immediately by submitting the updated information.
Example	*Potential*
Conformance	Mandatory
Data type	String
Validation rule	Must be one of the following options: • Potential • Actual • Resolved • No shortage
Destination reference	MAH Availability information template / column L

Tag	Explanation
ID	S1.2
Name	Shortage start date or expected start date
Description	Date or expected start date when a shortage begins or is anticipated to begin. For a shortage with an "Actual" or "Resolved" status, it indicates the shortage start date. For a "Potential" shortage status, it indicates the expected shortage start date.
Example	*20/05/2024*
Conformance	Conditional

Tag	Explanation
Data type	Date
Validation rule	• If the Shortage status is reported as "No Shortage": o Must not be filled in (to be left empty) • If the Shortage status is reported as "Actual", "Potential" or "Resolved": o Must be filled in (mandatory); o Must be format dd/mm/yyyy; o Must be no more than 2 years prior to the current date; o Must be within 10 years of the current date.
Destination reference	MAH Availability information template / column M

Tag	Explanation
ID	S1.3
Name	Shortage end date or expected end date
Description	Date or expected end date when a shortage is expected to or actually ends. For "Actual" and "Potential" shortages, it indicates an estimated end date. For "Resolved" shortages, it indicates the actual shortage end date.
Example	*13/09/2029*
Conformance	Conditional
Data type	Date
Validation rule	• If the Shortage status is reported as "No Shortage": o Must not be filled in (to be left empty) • If the Shortage status is reported as "Actual", "Potential": o Must be filled in (mandatory); o Must be format dd/mm/yyyy; o Must be the current date or within 10 years of the current date; o Must not be earlier than the Shortage start date or expected start date • If the Shortage status is reported as "Resolved": o Must be filled in (mandatory); o Must be format dd/mm/yyyy; o Must be no more than 2 years prior to the current date; o Must be within 10 years of the current date; o Must not be earlier than the Shortage start date or expected start date.
Destination reference	MAH Availability information template / column N

Tag	Explanation
ID	S1.4
Name	Point in supply chain at which disruption occurs

Tag	Explanation
Description	Specific stages of the medicine manufacturing and distribution where issues are occurring. If applicable, multiple values may be entered.
Example	*200000028583;200000028585*
Conformance	Conditional
Data type	String

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential" or "Resolved":
	  ○ Must be filled in (mandatory);
	  ○ Must be the RMS term ID of a term in the RMS list "Supply chain disruption shortage" with list ID "200000028549", consult possible values in the Annex 1 – RMS IDs list, Shortage chain distribution shortage;
	  ○ Multiple values must be separated by a ";";
	  ○ Must not contain duplicate values.

Destination reference	MAH Availability information template / column O

Tag	Explanation
ID	S1.5
Name	Root cause of the shortage
Description	Primary reason behind the disruption.
Example	*200000028683;200000028684*
Conformance	Conditional
Data type	String

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential" or "Resolved":
	  ○ Must be filled in (mandatory);
	  ○ Must be the RMS term ID of a term in the RMS list "Shortage root cause" with list ID "200000028648", consult possible values in the Annex 1 – RMS IDs list, Shortage root cause;
	  ○ Must not contain duplicate values.

Destination reference	MAH Availability information template / column P

Tag	Explanation
ID	S1.6.1

Tag	Explanation
Name	Countries in which manufacturing issues occur
Description	Countries where the production problems are happening. If the shortage is due to manufacturing issues, you should indicate the specific countries affected, such as the country of the production line experiencing the issue. If applicable, multiple values may be entered.
Example	*CN;CO*
Conformance	Conditional
Data type	String
Validation rule	• If the reported Root cause of shortage does **not** refer to Manufacturing issues ("200000028689", "200000028690", "200000028691", or, "200000028692"): ○ Must not be filled in (to be left empty) • If the reported Root cause of shortage refers to Manufacturing issues ("200000028689", "200000028690", "200000028691", or, "200000028692"): ○ Must be filled in (mandatory); ○ Must comply with the standard ISO 3166 Alpha - 2 code; ○ Multiple values must be separated by a ";"; ○ Must not contain duplicate values.
Destination reference	MAH Availability information template / column Q

Tag	Explanation
ID	S1.6.2
Name	Countries in which increased demand occurs
Description	Countries where there is a sudden rise in the need for the product. If the shortage is due to unexpected increased demand, you should indicate the specific countries experiencing this surge, such as those affected by changes in epidemiology. If applicable, multiple values may be entered.
Example	*CN;CO*
Conformance	Conditional
Data type	String

Tag	Explanation

Validation rule	• If the reported Root cause of shortage does **not** refer to Unexpected increased demand ("200000028700", "200000028701", "200000028702", "200000028703", or, "200000028704"):
	  ○ Must not be filled in (to be left empty)
	• If the reported Root cause of shortage refers to Unexpected increased demand ("200000028700", "200000028701", "200000028702", "200000028703", or, "200000028704"):
	  ○ Must be filled in (mandatory);
	  ○ Must comply with the standard ISO 3166 Alpha - 2 code;
	  ○ Multiple values must be separated by a ";";
	  ○ Must not contain duplicate values.

Destination reference	MAH Availability information template / column R

Tag	Explanation
ID	S1.6.3
Name	Countries in which distribution issues occur
Description	Countries where there are problems in delivering the product. If the shortage is due to distribution issues, you should indicate the specific countries experiencing these problems. If applicable, multiple values may be entered.
Example	*CN;CO*
Conformance	Conditional
Data type	String

Validation rule	• If the reported Root cause of shortage does not refer to Distribution issues ("200000028706", "200000028707", "200000028708", "200000028709", or "200000028710"):
	  ○ Must not be filled in (to be left empty)
	• If the reported Root cause of shortage refers to Distribution issues ("200000028706", "200000028707", "200000028708", "200000028709", or "200000028710"):
	  ○ Must be filled in (mandatory);
	  ○ Must comply with the standard ISO 3166 Alpha - 2 code;
	  ○ Multiple values must be separated by a ";";
	  ○ Must not contain duplicate values.

Destination reference	MAH Availability information template / column S

Tag	Explanation
ID	S1.7
Name	Root cause of the shortage - additional information

Tag	Explanation
Description	Further information on the root cause of the shortage that are not already covered by the "Root cause of shortage" data field.
Example	*Reprioritisation of product portfolio*
Conformance	Optional
Data type	String
Validation rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Availability information template / column T

3.4.3. Shortage prevention and mitigation plans

The "shortage prevention and mitigation plans" section collects information about measures planned to be put in place to overcome the shortages of medicinal products in scope of reporting.

Data elements for shortage prevention and mitigation plans	
Shortage prevention and mitigation plans	Shortage prevention and mitigation plans - ongoing and planned steps
S2.1	S2.2

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

Tag	Explanation
ID	S2.1
Name	Shortage prevention and mitigation plans
Description	Strategies implemented to address or prevent supply shortages to mitigate their impact on patients. One or more actual or intended mitigation measures for the shortage should be reported. If applicable, multiple values may be entered. • If "potential alternative active substance manufacturer/production site" or "potential alternative finished product manufacturer/production site" are selected as mitigating measures, please identify the site in the free text field ID S2.2. • If "resolve manufacturing or quality issue(s)" is selected, please elaborate in detail in the free text field ID S2.2.
Example	*200000028633;200000028640*
Conformance	Conditional
Data type	String

Tag	Explanation

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential" or "Resolved":
	  ○ Must be filled in (mandatory);
	  ○ Must be the RMS term ID of a term in the RMS list "mitigation plan prevention plan" with list ID "200000028617", consult possible values in the Annex 1 – RMS IDs list, Mitigation plan prevention plan;
	  ○ Multiple values must be separated by a ";";
	  ○ Must not contain duplicate values.

Destination reference	MAH Availability information template / column U

Tag	Explanation
ID	S2.2
Name	Shortage prevention and mitigation plans - ongoing and planned steps
Description	Complementary description of the mitigation and prevention plans, in addition to the tag "Shortage prevention and mitigation plans". Any relevant additional information on the proposed shortage prevention and mitigation measures must be reported. • If "potential alternative active substance manufacturer/production site" or "potential alternative finished product manufacturer/production site" are selected as mitigating measures, please identify the site here. • If "resolve manufacturing or quality issue(s)" is selected, please elaborate in detail here.
Example	*Manufacturing of finished product/active substance commissioned to alternative manufacturer in India; Batch testing taking place at alternative testing site in Belgium*
Conformance	Optional
Data type	String, free text
Validation rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Availability information template / column V

3.4.4. Market share

The "market share" section aims to collect information of a product's market presence.

Data elements for market share	
Market share	Market share – additional information
S3.2	S3.3

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

Tag	Explanation
ID	S3.2
Name	Market share
Description	Latest available data on the market share from the beginning of year to the latest period (year to date), in percentage, at pack level for the relevant medicinal product in a specific EU/EEA member state in relation to other authorised medicinal products on this particular market. Market share data should address both hospital and non-hospital markets. This data must be provided if available.
Example	*15*
Conformance	Optional
Data type	Integer
Validation Rule	• Must be a whole number between 0 and 100 • Must not include the "%" sign
Destination reference	MAH Availability information template / column W

Tag	Explanation
ID	S3.3
Name	Market share – additional information
Description	Further information on the market share.
Example	*Data with delay of 2 months*
Conformance	Optional
Data type	String, free text
Validation Rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Availability information template / column X

3.4.5. Sales volume and forecast

The "sales volume and forecast" section aims to collect the information on the units of a product sold in regular circumstances, the current state and the projected estimates for the forecasting period.

Data elements for sales volume and forecast	
Sales volume pr	Sales volume current
S6.1	S6.2

Sales volume forecast - month 1	Sales volume forecast - month 2	Sales volume forecast - month 3	Sales volume forecast - month 4	Sales volume forecast - month 5	Sales volume forecast - month 6	Sales volume - additional information
S7.1.1	S7.1.2	S7.1.3	S7.1.4	S7.1.5	S7.1.6	S7.2

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

Tag	Explanation
ID	S6.1
Name	Sales volume pre-PHE/ME
Description	Full year average of monthly packs of the relevant medicinal product sold in a specific EU/EEA member state for the period before the PHE/ME in scope (e.g. 2019 for COVID-19).
Example	*25000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column Y

Tag	Explanation
ID	S6.2
Name	Sales volume current
Description	Amount of packs of the relevant medicinal product sold in the last 4 weeks in a specific EU/EEA member state.
Example	*128900*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column Z

Tag	Explanation
ID	S7.1.1
Name	Sales volume forecast - month 1

Tag	Explanation
Description	Amount of packs of the relevant medicinal product expected to be sold in a specific EU/EEA member state in the first month of the forecasting period.
Example	*29000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AA

Tag	Explanation
ID	S7.1.2
Name	Sales volume forecast - month 2
Description	Amount of packs of the relevant medicinal product expected to be sold in a specific EU/EEA member state in the second month of the forecasting period.
Example	*30000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AB

Tag	Explanation
ID	S7.1.3
Name	Sales volume forecast - month 3
Description	Amount of packs of the relevant medicinal product expected to be sold in a specific EU/EEA member state in the third month of the forecasting period.
Example	*32000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AC

Tag	Explanation
ID	S7.1.4
Name	Sales volume forecast - month 4
Description	Amount of packs of the relevant medicinal product expected to be sold in a specific EU/EEA member state in the fourth month of the forecasting period.
Example	*31000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AD

Tag	Explanation
ID	S7.1.5
Name	Sales volume forecast - month 5
Description	Amount of packs of the relevant medicinal product expected to be sold in a specific EU/EEA member state in the fifth month of the forecasting period.
Example	*30000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AE

Tag	Explanation
ID	S7.1.6
Name	Sales volume forecast - month 6
Description	Amount of packs of the relevant medicinal product expected to be sold in a specific EU/EEA member state in the sixth month of the forecasting period.
Example	*28000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AF

Tag	Explanation
ID	S7.2
Name	Sales volume – additional information
Description	Further information about the sales volume.
Example	*Sales forecast reflecting moderate spikes of respiratory diseases in the upcoming autumn/winter months*
Conformance	Optional
Data type	String, free text
Validation Rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Availability information template / column AG

3.4.6. Supply forecast and stock information

The "supply forecast and stock information" section displays insights into a product's projected supply for the duration of the forecasting period, as well as its stock levels.

Data elements for supply forecast						
Supply forecast - month 1	Supply forecast - month 2	Supply forecast - month 3	Supply forecast - month 4	Supply forecast - month 5	Supply forecast - month 6	Supply forecast – additional information
S8.1.1	S8.1.2	S8.1.3	S8.1.4	S8.1.5	S8.1.6	S8.2

Data elements for stock information		
Available stocks	Desired safety stock	Stocks – additional information
S9.1	S9.2	S9.3

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

Tag	Explanation
ID	S8.1.1
Name	Supply forecast - month 1
Description	Amount of packs of the relevant medicinal product expected to become available on the market in a specific EU/EEA member state in the first month of the forecasting period.
Example	*3500000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999

Tag	Explanation
Destination reference	MAH Availability information template / column AH

Tag	Explanation
ID	S8.1.2
Name	Supply forecast - month 2
Description	Amount of packs of the relevant medicinal product expected to become available on the market in a specific EU/EEA member state in the second month of the forecasting period.
Example	*3500000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AI

Tag	Explanation
ID	S8.1.3
Name	Supply forecast - month 3
Description	Amount of packs of the relevant medicinal product expected to become available on the market in a specific EU/EEA member state in the third month of the forecasting period.
Example	*2000000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AJ

Tag	Explanation
ID	S8.1.4
Name	Supply forecast - month 4

Tag	Explanation
Description	Amount of packs of the relevant medicinal product expected to become available on the market in a specific EU/EEA member state in the fourth month of the forecasting period.
Example	*3500000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AK

Tag	Explanation
ID	S8.1.5
Name	Supply forecast - month 5
Description	Amount of packs of the relevant medicinal product expected to become available on the market in a specific EU/EEA member state in the fifth month of the forecasting period.
Example	*3500000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AL

Tag	Explanation
ID	S8.1.6
Name	Supply forecast - month 6
Description	Amount of packs of the relevant medicinal product expected to become available on the market in a specific EU/EEA member state in the sixth month of the forecasting period.
Example	*4000000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999

Tag	Explanation
Destination reference	MAH Availability information template / column AM

Tag	Explanation
ID	S8.2
Name	Supply forecast – additional information
Description	Any further information on the supply forecast.
Example	*Supply forecast currently not certain due to manufacturing incident.*
Conformance	Optional
Data type	String, free text
Validation Rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Availability information template / column AN

Tag	Explanation
ID	S9.1
Name	Available stocks
Description	The amount of packs of the relevant medicinal product in stock at the level of the marketing authorisation holder (physically available and in the MAH's ownership) at the time of submission, intended to be distributed to a specific EU/EEA member state.
Example	*1073*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AO

Tag	Explanation
ID	S9.2
Name	Desired safety stock
Description	The amount of packs of the relevant medicinal product that the MAH always strives to have available as a buffer for a specific EU/EEA member state to

Tag	Explanation
	account for unexpected fluctuations in demand and assure continuity of supply to patients.
Example	*1000*
Conformance	Mandatory
Data type	Integer
Validation rule	Must be a whole number between 0 and 99999999
Destination reference	MAH Availability information template / column AP

Tag	Explanation
ID	S9.3
Name	Stocks – additional information
Description	Further information on stocks (e.g. on projected resupply).
Example	*Low stock expected in second half of the year due to possible spikes in demand; 10000 units will be made available at the expected end date of the shortage.*
Conformance	Optional
Data type	String, free text
Validation Rule	Must not exceed the maximum length of 2000 characters
Destination reference	MAH Availability information template / column AQ

3.5. Manufacturing information

3.5.1. Product information

To collect manufacturing information on medicinal products in scope of reporting requirements in 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 or MSSG-led preparedness exercise. 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 or organisation information in the pre-filled template will not be processed by the system, hence will not generate any changes in the PMS or OMS database.

Data elements for product information		
PMS ID (Medicinal product)	Full product name	Active substance
P1.1.2	P1.2.1	P1.3.2

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

Tag	Explanation
ID	P1.1.2
Name	PMS ID (Medicinal product)[28]
Description	Unique identifier assigned to a medicinal product throughout its lifecycle.[29] 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 to which the user has an affiliation.
Destination reference	MAH Manufacturing information 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*

[28] More information on Medicinal product ID will be provided once this data element will be described in the PMS Implementation Guide.
[29] The PMS ID is a supplementary stable ID to any existing authorisation number or equivalent identifier as assigned by an authorising body.

Tag	Explanation
Conformance	Optional, will not be processed[30]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Manufacturing information template / column B

Tag	Explanation
ID	P1.3.2
Name	Active substance
Description	Active substance(s) contained in the medicinal product. They will be displayed as standalone substances where the operation type corresponds to "Manufacturer of active substance", and, if the product has multiple active substances, as compositions of active substances for all other steps of manufacturing. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.
Example	*paracetamol*
Conformance	Mandatory
Data type	String
Validation rule	Must be an active substance or multiple active substances assigned to the Medicinal product as specified in field P1.1.2, as retrieved from PMS
Destination reference	MAH Manufacturing information template / column C

3.5.2. Representative product

Information on the "representative product" can be populated to indicate that the manufacturing details, production plan and capacity of a specific product are already included in the information and figures provided for another entry.

Data elements for representative product
Representative product
X1.1

[30] 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

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

Tag	Explanation
ID	X1.1
Name	Representative product
Description	PMS identifier of the representative medicinal product for which the manufacturing information will be populated and includes the production of the relevant medicinal product which is considered to be an equivalent manufactured item. The PMS identifier needs to be filled in if the manufacturing process of the representative product and this medicinal product is identical up to the point of packaging and labelling (i.e. they are both produced in the same manufacturing sites, have the same alternative sites, are part of the same global monthly production plan and average and peak global monthly production output of previous year). Inserting this identifier allows the MAH to only complete the manufacturing information once for the representative product while referring to it in the entries of equivalent medicinal products. Therefore, if the Representative product field is populated for the particular medicinal product, no other information in this data submission template needs to be provided.
Example	*96781*
Conformance	Optional
Data type	String
Validation rule	Must be a valid PMS ID (Medicinal product)
Destination reference	MAH Manufacturing information template / column D

3.5.3. Organisation information

The "organisation information" section displays information on the manufacturing countries where specific parts of the manufacturing process are carried out. Where possible, 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 or organisation information via ESMP will not be processed by the system, hence will not generate any changes in the PMS or OMS databases.

Data elements for organisation information						
Operation type ID	Operation type	ORG - ID (Manufacturer)	Manufacturer	LOC - ID (Manufacturer)	City (Manufacturer)	Country (Manufacturer)

Data elements for organisation information						
O1.1	O1.2	O1.3	O1.4	O1.5	O1.6	O1.7

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

Tag	Explanation
ID	O1.1
Name	Operation type ID
Description	Identifier for the particular stage of manufacturing of the product performed by the specific manufacturer (field O1.2). This data element is pre-populated in the template for centrally authorised products with the operation type ID for each respective manufacturing location from PMS if the file is downloaded from the ESMP. For nationally authorised products it will contain IDs for values "Manufacturing of active substance" and "Processing operations for the medicinal product" (the operation type name for the production of the manufactured item as bulk without packaging and labelling) if the file is downloaded from the ESMP.
Example	*100000160408*
Conformance	Mandatory[31]
Data type	String
Validation rule	• For CAPs, must be the operation type ID of each respective manufacturing location, with terms from the RMS list "Manufacturing activity" with list ID "100000160406", assigned to the Medicinal product, as retrieved from PMS. Consult the possible RMS term IDs in the Annex 1 – RMS IDs list, Manufacturing activity • For NAPs, must be the RMS term ID of either "Manufacturing of active substance" (100000160466) or "Processing operations for the medicinal product" (100000160413)
Destination reference	MAH Manufacturing information template / column E

Tag	Explanation
ID	O1.2
Name	Operation type

[31] 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.

Tag	Explanation
Description	Term name of the operation type (RMS list) for the particular stage of manufacturing of the product performed by the specific manufacturer (field O1.1). This data element is pre-populated in the template for centrally authorised products with the operation type for each respective manufacturing location if the file is downloaded from the ESMP. For nationally authorised products it will contain values "Manufacturer of active substance" and "Processing operations for the medicinal product" (the operation type name for the production of the manufactured item as bulk without packaging and labelling) if the file is downloaded from the ESMP. Consult the possible terms corresponding to RMS term IDs in the Annex 1 – RMS IDs list, Manufacturing activity.
Example	*Quality control testing of medicinal product*
Conformance	Optional, will not be processed[32]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Manufacturing information template / column F

Tag	Explanation
ID	O1.3
Name	ORG-ID (Manufacturer)
Description	Organisation ID from OMS referring to the manufacturer's organisation as a legal entity (e.g. organisation name). This data element is pre-populated in the template for centrally authorised products with the organisation ID for each respective manufacturing location from PMS if the file is downloaded from the ESMP. This data element will be empty for NAPs as PMS currently does not hold manufacturing information for NAPs.
Example	*ORG-105011779*
Conformance	Conditional[33]

[32] 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.
[33] 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.

Tag	Explanation
Data type	String
Validation rule	• For CAPs, must be a valid ORG-ID assigned to the Medicinal product as specified in field P1.1.2, as retrieved from PMS • For NAPs, must not be filled in (to be left empty)
Destination reference	MAH Manufacturing information template / column G

Tag	Explanation
ID	O1.4
Name	Manufacturer
Description	Name of the holder of a manufacturing authorisation as described in Article 40 of Directive 2001/83/EC1. This data element is pre-populated in the template for centrally authorised products with the manufacturer for each respective stage of manufacturing from PMS if the file is downloaded from the ESMP. This data element will be kept empty for NAPs as PMS currently does not hold manufacturing information for NAPs.
Example	*ESMP Laboratories Limited IE*
Conformance	Optional, will not be processed[34]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Manufacturing information template / column H

Tag	Explanation
ID	O1.5
Name	LOC-ID (Manufacturer)

[34] 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 OMS.

Tag	Explanation
Description	ID for the physical location (address) of a manufacturer organisation. This data element is pre-populated in the template for centrally authorised products with the location ID for each respective manufacturing location from PMS if the file is downloaded from the ESMP. This data element will be kept empty for NAPs as PMS currently does not hold manufacturing information for NAPs.
Example	*LOC-105030267*
Conformance	Conditional[35]
Data type	String
Validation rule	• For CAPs, must be a valid LOC-ID assigned to the ORG-ID as specified in field O1.3, as retrieved from PMS • For NAPs, must not be filled in (to be left empty)
Destination reference	MAH Manufacturing information template / column I

Tag	Explanation
ID	O1.6
Name	City (Manufacturer)
Description	Name of the city in which the physical location of the organisation lies. This data element is pre-populated in the template for centrally authorised products with the city of each respective manufacturing location from PMS if the file is downloaded from the ESMP. This data element will be kept empty for NAPs as PMS currently does not hold manufacturing information for NAPs.
Example	Parma
Conformance	Optional, will not be processed[3632]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Manufacturing information template / column J

[35] 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.
[36] 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 OMS.

Tag	Explanation
ID	O1.7
Name	Country (Manufacturer)
Description	Name of the country or region in which the physical location of the organisation lies. This data element is pre-populated in the template for centrally authorised products with the country or region for each respective manufacturing location from PMS if the file is downloaded from the ESMP. This data element will be kept empty for NAPs as PMS currently does not hold manufacturing information for NAPs.
Example	Italy
Conformance	Optional, will not be processed[36] [32]
Data type	String
Validation rule	Not applicable
Destination reference	MAH Manufacturing information template / column K

3.5.4. Manufacturing details

The "manufacturing details" section displays information on whether the manufacturing site is currently in use and if the site is owned by the MAH or operated by a contract manufacturer.

Data elements for manufacturing details	
Manufacturing sites status	Is the site a contract manufacturer?
M1.1	M1.2

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

Tag	Explanation
ID	M1.1
Name	Manufacturing sites status

Tag	Explanation
Description	Status of the manufacturing site, that can be either "Active" or "Backup". An active site is an authorised and registered manufacturing site that is currently involved in the manufacturing of the product. A backup site is an authorised and registered manufacturing site that is currently not involved in the manufacturing of the product. For backup manufacturing sites some time is needed before this site could re-enter the production supply line (e.g., qualifications, validations, variations etc.).
Example	*Active*
Conformance	Conditional
Data type	String

Validation rule	• If the Representative product is reported:
	  ○ Must not be filled in (to be left empty)
	• If the Representative product is not reported:
	  ○ Must be filled in (mandatory);
	  ○ Must be a valid option between "Active" or "Backup" (not case sensitive).

Destination reference	MAH Manufacturing information template / column L

Tag	Explanation
ID	M1.2
Name	Is the site a contract manufacturer?
Description	Specification of the affiliation of the manufacturer as a contract manufacturer or a site owned by the MAH.
Example	*Yes*
Conformance	Conditional
Data type	String

Validation rule	• If the Representative product is reported:
	  ○ Must not be filled in (to be left empty)
	• If the Representative product is not reported:
	  ○ Must be filled in (mandatory);
	  ○ Must be a valid option between "yes" or "no" (not case sensitive).

Destination reference	MAH Manufacturing information template / column M

3.5.5. Alternatives sites

The "alternative sites" section aims to gather information about the existence of alternative manufacturing sites and their details. Alternative sites are manufacturing sites that are not listed in the currently valid Marketing Authorisation of the medicinal product in question, but that have the necessary technology and could, after appropriate authorisations, be used to (partially) manufacture the relevant active substance or finished product to address the supply issues or increase in demand (e.g., the alternative manufacturing site has the technology to manufacture tablets but has not been in involved in manufacturing of tablets of the product in question so far).

Data elements for alternative sites	
Alternative site LOC-ID	Alternative site Country
M2.1	M2.2

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

Tag	Explanation
ID	M2.1
Name	Alternative site LOC-ID
Description	Location ID of an alternative site refers to the identifier of the physical location (address) of it as present in OMS, if the alternative site is registered in OMS. If it is not registered in OMS and therefore does not have a Location ID, must be left blank and the country of the alternative site is to be entered in the following field. If applicable, multiple values may be entered.
Example	*LOC-105030268*
Conformance	Conditional
Data type	String
Validation rule	• If: - the Representative product is not reported, and, - Is the site a contract manufacturer? is reported as "No": ○ Must be filled in (mandatory); ○ Must be a valid Location-ID; ○ Multiple values must be separated by a ";"; ○ Must not contain duplicate values; ○ Either the Alternative site LOC-ID (this field) or the Alternative site Country (M2.2) must be filled in, but not both. • Else, must not be filled in (to be left empty)
Destination reference	MAH Manufacturing information template / column N

Tag	Explanation
ID	M2.2
Name	Alternative site Country
Description	Name of the country or region in which the physical location of the alternative site lies, if the alternative location is not registered in OMS and therefore does not have a Location ID. If applicable, multiple values may be entered.
Example	*SK*
Conformance	Conditional
Data type	String
Validation rule	• If: - the Representative product is not reported, and, - Is the site a contract manufacturer? is reported as "No": ○ Must be filled in (mandatory); ○ Must comply with the standard ISO 3166 Alpha-2 code; ○ Multiple values must be separated by a ";"; ○ Must not contain duplicate values; ○ Either the Alternative site Country (this field) or the Alternative site LOC-ID (M2.1) must be filled in, but not both. • Else, must not be filled in (to be left empty)
Destination reference	MAH Manufacturing information template / column O

3.5.6. Production plan and capacity

The "product plan and capacity" section aims to gather information about the global production plan in the future and the baseline and peak production outputs of the previous year for the active pharmaceutical ingredients (APIs) and the manufactured item (as bulk without packaging and labelling).

Data elements for production capacity									
Unit of measurement	Global Monthly Production plan - month 1	Global Monthly Production plan - month 2	Global Monthly Production plan - month 3	Global Monthly Production plan - month 4	Global Monthly Production plan - month 5	Global Monthly Production plan - month 6	Global Monthly Production plan – Additional information	Average Global Monthly Production output of previous year	Peak Global Monthly Production output of previous year
M3.1	M3.2.1	M3.2.2	M3.2.3	M3.2.4	M3.2.5	M3.2.6	M3.3	M3.4	M3.5

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

Tag	Explanation
ID	M3.1
Name	Unit of measurement
Description	Unit of measurement for the information submitted in tags M3.2.1 – M3.2.6 and M3.4 and M3.5 needs to be provided and can be either kilogram or unit. The unit of measurement for the quantity of active substances produced will be inserted as "kg" where the operation type corresponds to "Manufacturer of active substance", and as "unit" where the operation type corresponds to "Processing operations for the medicinal product" (which is the operation type name for the production of manufactured item as bulk without packaging and labelling) if the file is downloaded from the ESMP.
Example	*kg*
Conformance	Conditional
Data type	String

Validation rule	• If the Representative product is reported:
	  ○ Must not be filled in (to be left empty)
	• If the Representative product is not reported:
	  ○ Must be filled in (mandatory);
	  ○ Must be a valid option between "kg" or "Unit" (not case sensitive);
	  ○ Must be reported as "kg" if the Operation type is "Manufacturer of active substance";
	  ○ Must be reported as "Unit" if the Operation type is "Processing operations for the medicinal product".

Destination reference	MAH Manufacturing information template / column P

Tag	Explanation
ID	M3.2.1
Name	Global Monthly Production plan - month 1
Description	Global monthly production plan for the API or manufactured item as bulk without packaging and labelling for the respective manufacturer (manufacturer information applicable to CAPs only) in the unit of measurement as in M3.1 for the first month of the forecasting period.
Example	*130*
Conformance	Conditional
Data type	Integer

Tag	Explanation

Validation rule	• If the Representative product is reported:
	  ○ Must not be filled in (to be left empty)
	• If the Representative product is not reported:
	  ○ Must be filled in (mandatory);
	  ○ Must be a whole number between 0 and 99999999.

Destination reference	MAH Manufacturing information template / column Q

Tag	Explanation
ID	M3.2.2
Name	Global Monthly Production plan - month 2
Description	Global monthly production plan for the API or manufactured item as bulk without packaging and labelling for the respective manufacturer (manufacturer information applicable to CAPs only) in the unit of measurement as in M3.1 for the second month of the forecasting period.
Example	*120*
Conformance	Conditional
Data type	Integer

Validation rule	• If the Representative product is reported:
	  ○ Must not be filled in (to be left empty)
	• If the Representative product is not reported:
	  ○ Must be filled in (mandatory);
	  ○ Must be a whole number between 0 and 99999999.

Destination reference	MAH Manufacturing sites and production plan template / column R

Tag	Explanation
ID	M3.2.3
Name	Global Monthly Production plan - month 3
Description	Global monthly production plan for the API or manufactured item as bulk without packaging and labelling for the respective manufacturer (manufacturer information applicable to CAPs only) in the unit of measurement as in M3.1 for the third month of the forecasting period.
Example	*120*
Conformance	Conditional
Data type	Integer

Tag	Explanation

Validation rule	• If the Representative product is reported:
	  ○ Must not be filled in (to be left empty)
	• If the Representative product is not reported:
	  ○ Must be filled in (mandatory);
	  ○ Must be a whole number between 0 and 99999999.

Destination reference	MAH Manufacturing information template / column S

Tag	Explanation
ID	M3.2.4
Name	Global Monthly Production plan - month 4
Description	Global monthly production plan for the API or manufactured item as bulk without packaging and labelling for the respective manufacturer (manufacturer information applicable to CAPs only) in the unit of measurement as in M3.1 for the fourth month of the forecasting period.
Example	*110*
Conformance	Conditional
Data type	Integer

Validation rule	• If the Representative product is reported:
	  ○ Must not be filled in (to be left empty)
	• If the Representative product is not reported:
	  ○ Must be filled in (mandatory);
	  ○ Must be a whole number between 0 and 99999999.

Destination reference	MAH Manufacturing information template / column T

Tag	Explanation
ID	M3.2.5
Name	Global Monthly Production plan - month 5
Description	Global monthly production plan for the API or manufactured item as bulk without packaging and labelling for the respective manufacturer (manufacturer information applicable to CAPs only) in the unit of measurement as in M3.1 for the fifth month of the forecasting period.
Example	*120*
Conformance	Conditional
Data type	Integer

Tag	Explanation

Validation rule	• If the Representative product is reported:
	  ○ Must not be filled in (to be left empty)
	• If the Representative product is not reported:
	  ○ Must be filled in (mandatory);
	  ○ Must be a whole number between 0 and 99999999.

Destination reference	MAH Manufacturing information template / column U

Tag	Explanation
ID	M3.2.6
Name	Global Monthly Production plan - month 6
Description	Global monthly production plan for the API or manufactured item as bulk without packaging and labelling for the respective manufacturer (manufacturer information applicable to CAPs only) in the unit of measurement as in M3.1 for the sixth month of the forecasting period.
Example	*120*
Conformance	Conditional
Data type	Integer

Validation rule	• If the Representative product is reported:
	  ○ Must not be filled in (to be left empty)
	• If the Representative product is not reported:
	  ○ Must be filled in (mandatory);
	  ○ Must be a whole number between 0 and 99999999.

Destination reference	MAH Manufacturing information template / column V

Tag	Explanation
ID	M3.3
Name	Global Monthly Production plan – additional information
Description	Any further information on the global monthly production plans.
Example	*Minor fluctuations in production foreseen in the first four months.*
Conformance	Optional
Data type	String, free text
Validation rule	Must not exceed the maximum length of 2000 characters

Tag	Explanation
Destination reference	MAH Manufacturing information template / column V

Tag	Explanation
ID	M3.4
Name	Average global monthly production output of previous year
Description	Average global monthly production output of the year prior to the start of reporting requirements for the API or manufactured item as bulk without packaging and labelling for the respective manufacturer (manufacturer information applicable to CAPs only) calculated as the production output average for the whole previous year (Jan - Dec), divided by 12 months, entered in the unit of measurement.
Example	*120*
Conformance	Conditional
Data type	Integer
Validation rule	• If: - the Representative product is not reported, and, - the Operation type is reported as "manufacturer of active substance" or "processing operations for the medicinal product", and, - the Manufacturing sites status is reported as "active", and, - the Is the site a contract manufacturer? is reported as "no": ○ Must be filled in (mandatory); ○ Must be a whole number between 0 and 99999999. • Else, must not be filled in (to be left empty)
Destination reference	MAH Manufacturing information template / column W

Tag	Explanation
ID	M3.5
Name	Peak global monthly production output of previous year
Description	The peak global monthly production output of the previous year describes the month with the highest production output of the year prior to the start of reporting requirements for the API or manufactured item as bulk without packaging and labelling for the respective manufacturer (manufacturer information applicable to CAPs only), entered in the unit of measurement.
Example	*150*
Conformance	Conditional

Tag	Explanation
Data type	Integer
Validation rule	• If: - the Operation type is reported as "manufacturer of active substance" or "processing operations for the medicinal product", and, - the Manufacturing sites status is reported as "active", and, - the Is the site a contract manufacturer? is reported as "no": ○ Must be filled in (mandatory); ○ Must be a whole number between 0 and 99999999. • Else, must not be filled in (to be left empty)
Destination reference	MAH Manufacturing information template / column X

3.6. Alternative therapies

3.6.1. Product information

To collect information on alternative therapies for medicinal products in scope of reporting requirements in the ESMP, the platform will generate a webform, which will be tailored to the user's affiliation and include the specific products in scope of reporting requirements for a particular crisis or MSSG-led preparedness exercise. The "product information" section displays details about critical medicinal products, and groups all CAPs by their invented name, active substances and pharmaceutical form, whereas NAPs will be grouped only by their active substances and pharmaceutical form.

The webform will be pre-populated with information previously submitted to the EMA via PMS.

Data elements for product information		
Invented name	Active substance(s)	Pharmaceutical form
P1.2.3	P1.3.2	P1.6.2

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

Tag	Explanation
ID	P1.2.3
Name	Invented name
Description	Invented name of centrally authorised medicinal products. This data element is pre-populated in the webform in the ESMP.
Example	*Esempin*
Conformance	Not applicable
Data type	String

Tag	Explanation
Validation rule	Not applicable
Destination reference	ESMP webform

Tag	Explanation
ID	P1.3.2
Name	Active substance(s)
Description	Active substance(s) contained in the medicinal product. This data element is pre-populated in the webform in the ESMP.
Example	*paracetamol*
Conformance	Not applicable
Data type	String
Validation rule	Not applicable
Destination reference	ESMP Webform

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 webform in the ESMP.
Example	*Film-coated tablet*
Conformance	Not applicable
Data type	String
Validation rule	Not applicable
Destination reference	ESMP webform

3.6.2. Alternative therapies

The "alternative therapies" section displays information about availability of alternative therapies, whether as standalone active substances or compositions of active substances. The webform will display all compositions of non-critical valid authorised products in the EU/EEA and allow you to choose one or multiple standalone active substances or compositions of active substances. An option to indicate that there are no available alternatives is also provided.

Data elements for alternative therapies	
Alternative therapies	No alternatives
L1.1	L1.2

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

Tag	Explanation
ID	L1.1
Name	Alternative therapies
Description	Any active substances or compositions of active substances that can be used as alternative therapies. If applicable, multiple values may be entered.
Example	*ibuprofen*
Conformance	Conditional
Data type	String

Validation rule	• If the No alternatives box is not ticked:
	  ○ Must be filled in (mandatory);
	  ○ Must be a valid active substance/composition of a valid product authorised in the EU/EEA;
	  ○ Multiple entries can be selected.
	• Either the Alternative therapies (this field) or the No alternatives (L1.2) must be filled in, but not both.

Destination reference	ESMP webform

Tag	Explanation
ID	L1.2
Name	No alternatives
Description	Indicate if there are no alternative therapies for the respective product by ticking the box.
Example	*Not applicable*

Tag	Explanation
Conformance	Conditional
Data type	Tick box
Validation rule	• If the Alternative therapies is not reported, must be ticked (mandatory); • Either the No alternatives (this field) or the Alternative therapies (L1.1) must be filled in, but not both.
Destination reference	ESMP webform

Annex 1 – RMS lists and term

Marketing status

Only to be used for the insertion of data for Marketing Status for NAPs
RMS list 100000072052 | https://spor.ema.europa.eu/rmswi/#/lists/100000072052/terms

Identifier	Term name
100000072074	Not marketed
100000072075	No data provided
100000072083	Marketed
200000026055	Never marketed
230000000000	Temporarily unavailable

Supply chain distribution shortage

RMS list 200000028549 | https://spor.ema.europa.eu/rmswi/#/lists/200000028549/terms

Identifier	Term name
200000028583	Active substance intermediate
200000028584	Active substance
200000028585	Supply of raw materials, excipients, packaging components
200000028586	Finished product manufacturing
200000028587	Primary packaging
200000028588	Secondary packaging
200000028589	Batch control testing
200000028590	Batch release
200000028591	Importation
200000028592	Distribution of released products
200000028593	Not related to supply chain issues
200000028594	Other

Shortage root cause

RMS list 200000028648 | https://spor.ema.europa.eu/rmswi/#/lists/200000028648/terms

Identifier	Term name
200000028689	Manufacturing issues - Manufacturing issues preventing production/release
200000028690	Manufacturing issues - Restrictions on people
200000028691	Manufacturing issues - GMP non - compliance
200000028692	Manufacturing issues - Capacity issues
200000028694	Quality issues - Suspected defective product preventing release of batches to the market
200000028695	Quality issues - Suspected defective product requiring batch recall
200000028697	Regulatory issues - Marketing authorisation restricted/suspended
200000028698	Regulatory issues - Regulatory approval delay
200000028700	Unexpected increased demand - Consumer driven stockpiling
200000028701	Unexpected increased demand - Member State driven stockpiling
200000028702	Unexpected increased demand - Changes in prescribing behaviour
200000028703	Unexpected increased demand - Change in use (off label or through changes in MA)
200000028704	Unexpected increased demand - Increased demand due to unavailability from other MAHs
200000028706	Distribution issues - Air transport
200000028707	Distribution issues - Sea transport
200000028708	Distribution issues - Land transport
200000028709	Distribution issues - Export restrictions
200000028710	Distribution issues - Import restrictions
200000028712	Commercial reasons - Pricing and reimbursements
200000028713	Commercial reasons - Insolvency
200000028714	Commercial reasons - Prioritisation of other markets
200000028715	Commercial reasons - Business strategy (other)
200000043380	Other

Shortage mitigation and prevention plan

RMS list 200000028617 | https://spor.ema.europa.eu/rmswi/#/lists/200000028617/terms

Identifier	Term name
200000028633	Alternative active substance manufacturer
200000028634	Alternative finished product manufacturer
200000028635	Alternative batch control site
200000028636	Alternative batch release site
200000028637	Supply of product in foreign language labelling
200000028638	Supply of alternative unauthorised product
200000028639	Release of product with minor quality defects
200000028640	Increase production capacity of current site(s)
200000028641	Supply of other presentation(s) of the same product
200000028642	Use of exceptional change management process (ECMP)
200000028643	Resolve manufacturing or quality issue(s)
200000028644	Change mode of transportation
200000028645	Expedited shipment and shipment under quarantine
200000028646	Prioritisation of supplies to critical customers
200000029652	Alternative sources of raw/starting materials
200000028647	Other

Shortage impact risk assessment

RMS list 200000033599 | https://spor.ema.europa.eu/rmswi/#/lists/200000033599/terms

Identifier	Term name
200000033600	High
200000033601	Medium
200000033602	Low

Manufacturing activity

RMS list 100000160406 | https://spor.ema.europa.eu/rmswi/#/lists/100000160406/terms

Identifier	Term name
100000160407	Manufacturer responsible for batch certification
100000160408	Quality control testing of medicinal product
100000160409	Microbiological testing: sterility
100000160410	Microbiological testing: non - sterility
100000160411	Chemical/Physical testing
100000160412	Biological testing
100000160413	Processing operations for the medicinal product
100000163618	Processing of non - sterile medicinal product
100000163709	Processing of sterile medicinal product - aseptically prepared
100000163737	Processing of sterile medicinal product - terminally sterilised
100000160414	Manufacturing of finished products intermediate
100000160415	Manufacturing of solvent / diluent
100000160448	Quality control testing of active substance
100000160449	Microbiological testing: sterility
100000160450	Microbiological testing: non - sterility
100000160451	Chemical/Physical testing
100000160452	Biological testing
100000160453	Manufacturing of active substance intermediate
100000163713	Manufacturing of active substance intermediate by chemical synthesis
100000163714	Manufacturing of active substance intermediate using biological processes
100000163715	Active substance intermediate physical processing
100000160454	Packaging of active substance
100000163716	Primary Packaging of active substance
100000163717	Secondary Packaging of active substance
100000160455	Storage and/or distribution of active substance
100000160456	Sterilisation
100000160457	Filtration
100000160458	Dry heat
100000160459	Moist heat

Identifier	Term name
100000160460	Chemical
100000160461	Gamma irradiation
100000160462	Electron beam
100000160463	Primary packaging
100000160464	Secondary packaging
100000160465	Physical Importation
100000160466	Storage and/or distribution of medicinal product
100000160466	Manufacturing of active substance
100000163843	Manufacturing of active substance by chemical synthesis
100000163844	Extraction of active substance from natural sources
100000163845	Manufacturing of active substance using biological processes
100000163846	Active substance physical processing
100000160476	Preparation of Working Cell Bank
100000160477	Storage of Master Cell Bank and/or Working Cell Bank
100000160478	Bioequivalence Contract Research Organisation (CRO)
100000160479	Manufacturing of ancillary medicinal product
100000160480	Manufacturing of medical device