



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

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

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Revision history

Date	Description
29/01/2025	V1.1 Added Chapter 4. Crisis and MSSG-led preparedness submissions Added Chapter 5. Support
07/03/2025	V1.2 Updated Chapter 2.4 with the new sign in process with email address authentication Update of screenshots across the guide to reflect changes in the ESMP user interface
13/05/2025	V1.3 Updated Chapter 1 with background steps needed to ensure a streamlined reporting process Updated Chapter 3 and Chapter 4 with preliminary requirements Minor updates to Chapter 3.1 on the appearance of the platform home page during normal circumstances versus during a crisis or MSSG-led preparedness action Updated the data element name and conformance of the following data element tables: Routine shortage reporting (Chapter 3), Marketing status NAPs (Chapter 4), Availability information (Chapter 4). Update of Routine shortage reporting data elements table (table 1): <ul style="list-style-type: none">• Changed the data element "Packaging" to "Package description"• Changed "Root cause of the shortage - additional information" conformance from optional to conditional• Changed "Shortage prevention and mitigation plans - ongoing and planned steps" conformance from optional to conditional• Changed "Shortage impact risk assessment - additional information" conformance from optional to conditional• Changed "Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report" conformance from optional to conditional → Users are advised to consult the ESMP Implementation guide for MAHs for details on conditionality and applicable validation rules. Update of Marketing status NAPs data elements table (table 2): <ul style="list-style-type: none">• Changed the data element "Packaging" to "Package description" Update of Availability information data elements table (table 3): <ul style="list-style-type: none">• Changed the data element "Packaging" to "Package description"



Date	Description
28/04/2026	<p>V1.4</p> <p>Routine reporting of shortages of CAPs (Chapter 3):</p> <ul style="list-style-type: none">• Chapter 3.2.2: Reference to readable RMS IDs added• Chapter 3.3: Addition of further guidance on reporting and updating shortage notifications,• Chapter 3.4: Explanation added on automated notification alert to MAH for outdated shortage reports <p>Crisis and MSSG-led preparedness submissions (Chapter 4):</p> <ul style="list-style-type: none">• Preliminary requirements, point 1: Paragraph edited on mandatory PMS data completeness (including structured package and manufacturing information data)• Preliminary requirements, point 2: clarification that CAP marketing status affects generation of Availability information template only, other submissions not affected by products' marketing status.• Chapters 4.3.2 and 4.4.2: Reference to readable RMS IDs added• Chapter 4.5: The inclusion of NAP manufacturing data from PMS, where available, in the data submission templates for Manufacturing information• Chapter 4.6: Added updated screenshots of the search bar for substances and compositions in the webform for the submission of Alternative therapies

Table of abbreviations

Abbreviation	Full name
CAP	Centrally authorised product
EC	European Commission
EEA	European Economic Area
EMA	European Medicines Agency
ESMP	European Shortages Monitoring Platform
EU	European Union
FY	Full Year
IAM	Identity & Access Management (EMA Account Management Portal)
ID	Identifier
i-SPOC	industry Single Point of Contact
MAH	Marketing authorisation holder
ME	Major Event
MS	Member State
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
NAP	Nationally authorised product
NCA	National competent authority
OMS	Organisation Management Services (part of SPOR)
PMS ID	Product Management Service Identifier
PCID	Packaged Medicinal Product Identifier
PHE	Public Health Emergency
PMS	Product Management Services (part of SPOR)
RMS	Referentials Management Services (part of SPOR) ¹
SME	Subject Matter Expert
SPOC	Single Point of Contact
SPOR	Management Services for Substances, Products, Organisations and Referential Terms

¹ RMS provides referentials lists and terms. RMS supports the continuous exchange of data between information systems across the European medicines regulatory network and the pharmaceutical industry. ESMP uses RMS lists and IDs to ensure correct data submission, please refer to the [ESMP Implementation Guide for Marketing Authorisation Holders](#), Annex 1 – RMS list and terms, to consult possible values and correspondent terms. For further information about RMS please consult additional resources as [Referentials Management Service \(RMS\) | European Medicines Agency \(EMA\)](#) and [RMS Web UI](#).



Abbreviation	Full name
YTD	Year To Date

1. Scope of this guidance

The European Shortages Monitoring Platform (ESMP) user guide for marketing authorisation holders (MAHs) describes the reporting processes that MAHs must follow to ensure the successful completion of electronic submissions related to the supply and availability of medicinal products for human use to the European Medicines Agency (EMA) through the ESMP.

This guide delivers detailed guidance and instructions on the procedural and technical aspects for the reporting processes through electronic submissions. The objective of this guide is to support MAHs with their obligations to report sets of information on shortages, supply, and demand for medicinal products, including information on marketing status and marketing cessations to EMA as per Regulation (EU) 2022/123, with a focus on the general provisions and Article 10 of the regulation.

This ESMP user guide for MAHs is a single source of information where MAH users can find guidance on how to use the ESMP and links to further information and resources. This user guide is supported by the [ESMP Implementation Guide for Marketing Authorisation Holders](#)² which provides detailed information on the technical specifications, clarifying data sets and data elements in scope of reporting requirements to the EMA.

This guide covers only the processes and requirements specifically related to reporting via the ESMP and does not address preparatory actions to support reporting frameworks and to ensure a streamlined communication and reporting process, such as registering an [industry Single Point of Contact \(i-SPOC\)](#)³ or managing product master data in the [Product Management Service \(PMS\)](#)⁴. Nevertheless, please note:

1. It is mandatory to designate and register an [industry Single Point of Contact \(i-SPOC\)](#) to facilitate timely and effective communication with the EMA regarding the supply and availability of medicinal products and to update the contact when necessary. All pharmaceutical companies with centrally or nationally authorised medicinal products in the EU are required to register an i-SPOC. This means that an i-SPOC must be registered for every individual MAH affiliate holding products in the EU. The i-SPOC must be registered through the EMA's [IRIS platform](#) and maintained in accordance with EMA's [IRIS guide for applicants: Chapter 9. Registration of an MAH i-SPOC on supply and availability](#).
2. Enter and maintain accurate and complete product master data, including pack sizes and manufacturing site information within the EMA's [Product Management Service \(PMS\)](#) before reporting via the ESMP. Accurate product and manufacturing data must be fully populated in PMS to ensure that products are available for selection in ESMP. Products lacking accurate or up-to-date information in PMS will not be available for reporting in the ESMP.

² https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

³ <https://www.ema.europa.eu/en/news/call-companies-register-their-industry-single-point-contact-i-spoc-supply-and-availability>

⁴ <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services>

1.1. What is the ESMP?

The ESMP is an IT platform used by EMA to collect information from national competent authorities (NCAs) and marketing authorisation holders (MAHs) on availability, supply, and demand of centrally authorised products (CAPs) and nationally authorised products (NAPs) in specific circumstances. The ESMP aims to help prevent, detect, and manage shortages, ensuring improved availability of medicines across the European Union (EU) and European Economic Area (EEA).

MAHs are required to report information on supply and availability of medicines via the ESMP in three instances:

- **Crisis situations**, during public health emergencies (PHEs) or major events (MEs), for medicinal products in scope of a list of critical medicines it monitors for that particular crisis;
- **MSSG-led preparedness**, when requested by EMA's [Executive Steering Group on Shortages and Safety of Medicinal Products](#) (MSSG), for a sub-set of both centrally and nationally authorised medicines included in a list created for that particular action;
- **Normal circumstances**, enabling marketing authorisation holders to routinely report shortages of centrally authorised products.

In particular, MAHs will be requested to report different information according to the situation:

- **In crisis and MSSG-led preparedness situations**, MAHs will be requested to share information such as shortage details, their prevention and mitigation plans, potential alternative therapies, marketing status, market share, sales volume, forecasts of sales and supply, stock information, manufacturing details, production plan and capacity, and others;
- **In normal circumstances**, MAHs are requested to share information on shortages of CAPs such as shortage details, prevention and mitigation plans, shortage impact assessment, potential alternative therapies, and others.

Reporting processes for the abovementioned instances are described further in this guide.

For additional information on the ESMP context and background, please refer to the [ESMP webpage](#)⁵ on EMA's website, including the [Frequently asked questions on the ESMP](#).

For additional information on EMA's role in preparing for and managing crisis situations, see: [Crisis management and preparedness](#)⁶ page on EMA's website.

⁵ <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform>

⁶ <https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-and-management>

2. Accessing the ESMP

To use the ESMP you need to have:

- (1) an **active EMA user account**, and,
- (2) the **ESMP Industry User role** assigned to your active EMA user account.

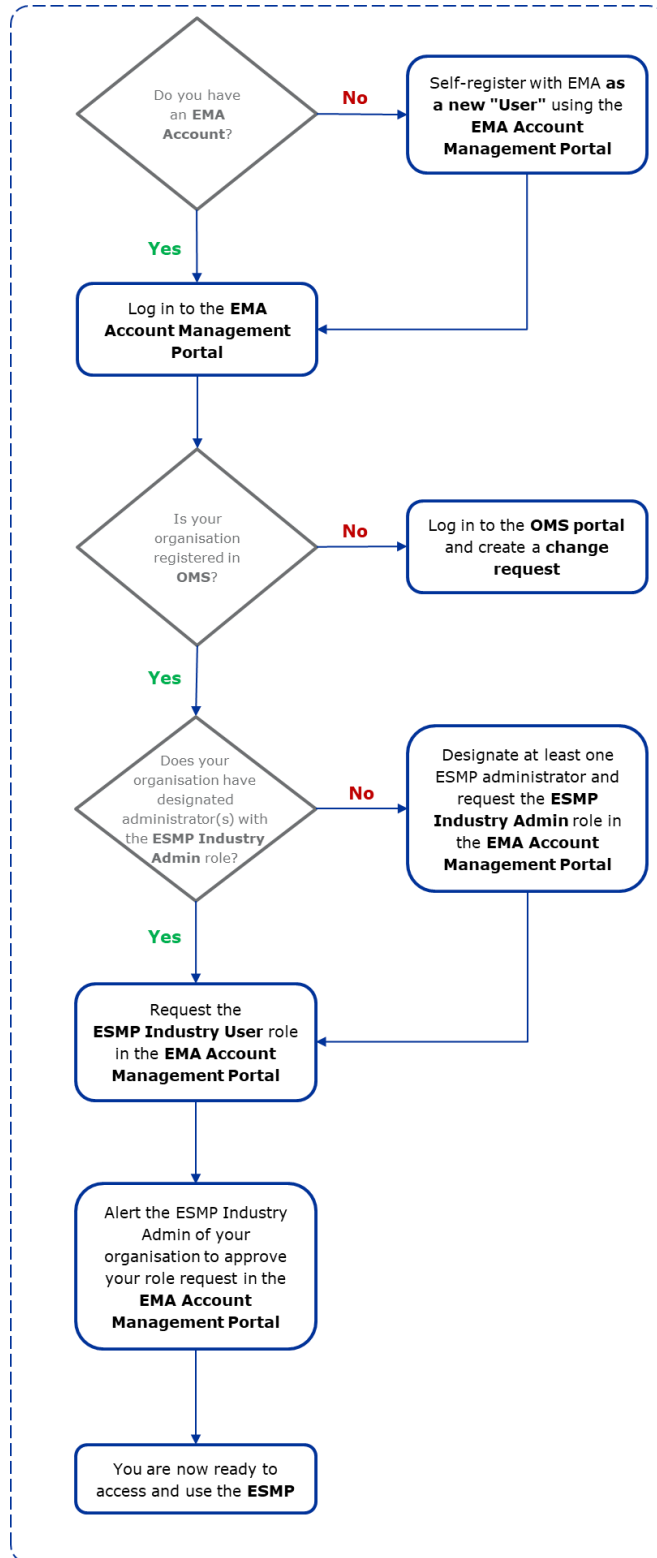
Please note that the **organisation** on whose behalf you will be acting must be **registered in the EMA's [Organisation Management Service \(OMS\)](#)**⁷ in order to request the necessary user access role(s) and, subsequently, submit data via ESMP. See section 2.2. for more information.

Please follow the flow chart and the instructions in the following sub-chapters to fulfil all the access requirements and gain access to the ESMP.

⁷ <https://spor.ema.europa.eu/omswi/#/>



Figure 1: Flow chart of ESMP access requirements and process of requesting access



2.1. How to create an EMA account

The EMA Account Management Portal (IAM) is EMA’s secure online platform where you can request and manage the access for all EMA applications.

- a) If you already have an active EMA user account, please log in to the [EMA Account Management portal](#)⁸. Refer to this platform to seek guidance on how to:
 - [Verify whether you already have an EMA account](#)
 - [Re-activate your EMA account](#)
 - [Recover your credentials](#)
 - [Retrieve your username](#)
 - [Reset your password](#)

- b) If you do not yet have an active EMA user account, you need to self-register with EMA as a new “user” (see information on the [EMA Account Management portal](#)⁹)

2.2. Is your organisation registered in OMS?

The MAH on whose behalf you will be acting needs to be registered in the [EMA’s Organisation Management Service \(OMS\)](#)⁷. OMS is the single repository of organisational data maintained by EMA.

If the MAH is not registered with EMA, log in to the OMS portal with your EMA account credentials, create a change request, and complete the necessary steps to complete organisation registration.

Please note: Registration of a new organisation can take **5 to 10 working days**.

Relevant OMS documentation can be found in the document repository under the [documents tab of the OMS portal](#)⁷, further information is available also on the [EMA Website](#)¹⁰.

2.3. How to request the necessary ESMP user access roles

Once you have an EMA account and your organisation is correctly registered in the EMA’s OMS, you can request access roles for specific EMA applications on behalf of your organisation. Please consult the detailed step by step instructions at this link: [EMA Account Management | Request user access roles](#)¹¹.

The ESMP administrator role

Your organisation must nominate at least one person who will be responsible for approving and revoking ESMP access role requests from users within that same organisation.

Those designated administrator(s) must request the “**ESMP Industry Admin**” role in the [EMA Account Management portal](#).

User type	Access role name
Industry user(s) ESMP administrator	ESMP Industry Admin <i>External Organisation Administrator (optional)</i>

⁸ <https://register.ema.europa.eu/identityig/home.jsf>

⁹ <https://register.ema.europa.eu/identityig/home.html>

¹⁰ <https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-and-referential-spor-master-data/organisation-management-service-oms>

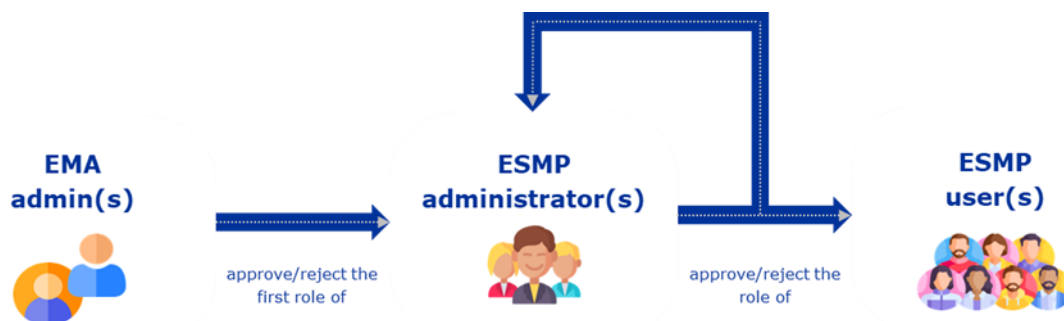
¹¹ <https://register.ema.europa.eu/identityig/help/requestaccess.html#newrequestaccess>

- a) If no one in your organisation has this role, follow the instructions of [how to request User Administrator role](#)¹². The approval of the first administrator is validated by the EMA and can take up to **2 working days**.
- b) If at least one person in the organisation you are affiliated with already has the “ESMP Industry Admin” role, this person will be able to manage any subsequent access role request(s) for both ESMP access roles (the “ESMP Industry Admin” and the “ESMP Industry User”) on behalf of your organisation.

Please note that whoever has the “ESMP Industry Admin” role can the approve or reject access role requests.

For more information about the User Administrator role, consult the [User Administrator Guide](#)¹³.

Figure 2: ESMP access management approval workflow



Note: as an alternative to the “ESMP Industry Admin” role, users who will perform the administrator role may want to request instead the **External Organisation Administrator** role. Once validated by the EMA, this role allows approving or rejecting access roles requests not only for ESMP but also for other EMA-run systems within your organisation/country. More information about this role can be found on [this webpage](#).

The ESMP user role

The “ESMP Industry Admin” role aims to exclusively handle users’ access management for an MAH. It does not, by itself, provide access to the ESMP. Any user who intends to access and perform different operations in the ESMP, needs to request the “**ESMP Industry User**” role in the [EMA Account Management portal](#)¹⁴. ESMP Industry Admins also need to request the “ESMP Industry User” role in addition to the Admin role if they wish to access the ESMP.

For a detailed step to step guidance on how to request this role, please consult the [EMA Account Management | Request user access roles](#)¹⁵.

User type	Access role name
Industry user(s)	ESMP Industry User

¹² <https://register.ema.europa.eu/identityiq/help/requestaccess.html#requestuseradmin>


¹³ <https://register.ema.europa.eu/identityiq/help/useradmin.html>

¹⁴ <https://register.ema.europa.eu/identityiq/home.jsf>

¹⁵ <https://register.ema.europa.eu/identityiq/help/requestaccess.html#newrequestaccess>

2.4. How to log in to the ESMP

To log in to the ESMP, please follow the steps described below. Note that you need to have been granted the “ESMP Industry User” access role as described in chapter 2.3. before you can log in to the ESMP.

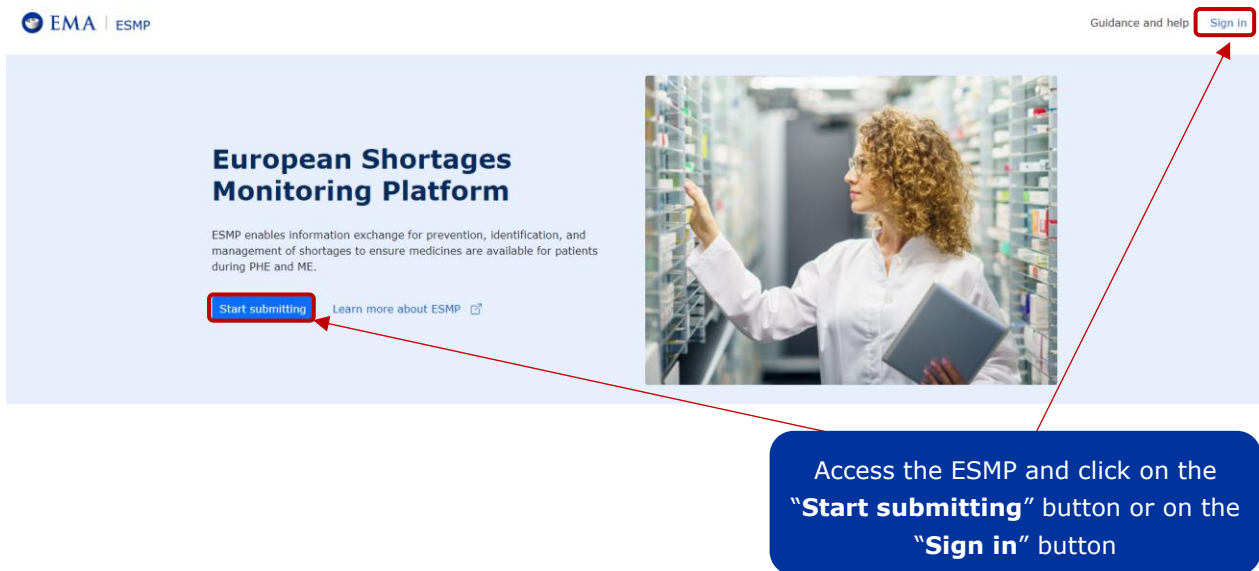
 Please refer to [Sign In · EMA Account Management](#) for more details about EMA authentication methods.

Step 1

Access the ESMP by opening this link: <https://esmp.ema.europa.eu>.

Click on the “**Start submitting**” button or on the “**Sign in**” button as shown in figure 3 to log in.

Figure 3: ESMP welcome page - start the sign in process.



Step 2

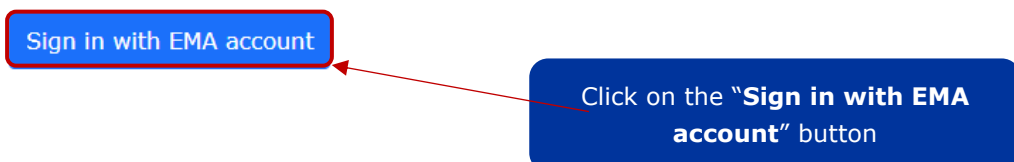
Click on the “**Sign in with EMA account**” button to proceed with the sign in process.

Figure 4: ESMP sign in process - select Sign in with EMA account

Sign in

To sign into ESMP, you need an active EMA user account with the necessary user access roles.

You can create a new user account, apply for user access roles, reset your password or recover your username using the [EMA account management portal](#).

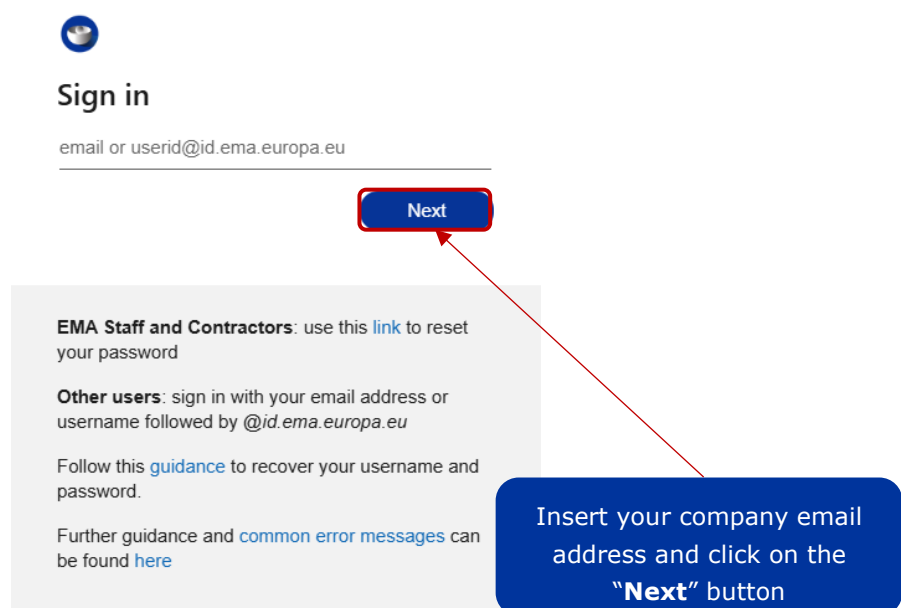


Step 3

EMA has introduced email authentication to improve both security and usability of EMA applications. This eliminates the need for users to remember their EMA username and password. Users may opt-in to email authentication through EMA Account Management by following these [detailed instructions](#).

With email address authentication, you must use your organisation email address to access to ESMP. To sign in, you must use your organisation email (e.g.: name.surname@medicinesorg.com) and click on the “**Next**” button (as shown in figure 5).

Figure 5: ESMP sign in process - enter your company email address



Step 4

Depending on your email address the system evaluates the available authentication options:

1. Email user principal name (upn) and credentials - Domains federated with Azure AD.

If your email domain is federated with Azure AD, you will be redirected to your domain's authentication page (as shown in figure 6). The process may vary depending on your organisations' settings. For example:

- if your email address is name.surname@medicinesorg.com, the domain address is @medicinesorg.com. Enter the password associated with your account and click on the “Sign in” button;
- if your organisation has Single Sign-on (SSO) configured, the authentication step may be skipped automatically.

2. Email and code - Receiving a code sent to your email.

If your email domain is not federated with Azure AD and your email is not linked to a Microsoft account, you will be prompted the “Enter code” window. The system will notify you that a verification code has been sent to your email (as shown in figure 7). Enter the one-time password (OTP) to complete the sign-in process.

Figure 6: Example of a company's login page – Enter your password

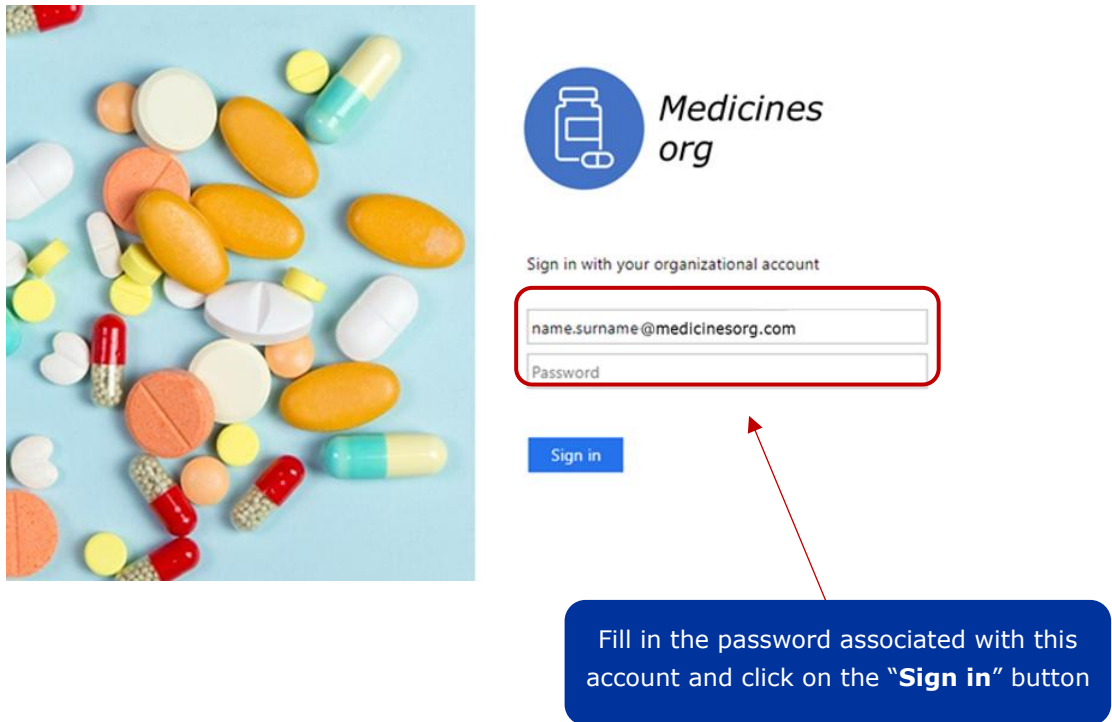


Figure 7: Enter code window - Enter the passcode received via email

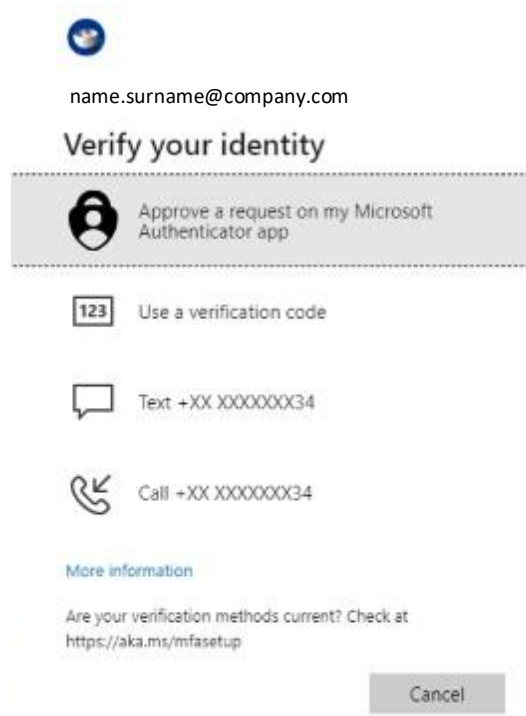


Step 5

Verify your identity through a multi-factor authentication.

Logging into the ESMP requires a **multi-factor authentication** (MFA) i.e. you are granted access to the ESMP only after successfully completing more than one authentication mechanism. In practice, this involves verifying your identity using an additional authentication method beyond your email and password or one-time password (OTP) (steps 1 to 4). MFA enhances security by adding an extra layer of protection, reducing the risk of unauthorised access to your account and safeguarding your data.



Figure 8: Verify your identity



Select one of the following authentication methods to verify your identity. The additional authentication step can be completed using the Microsoft Authenticator app, which is considered the most secure option, or through a text message or phone call. Follow the instructions below to set up your preferred method of authentication.

- **Microsoft Authenticator app**

The authenticator app is the most secure and convenient authentication method. Use the Microsoft Authenticator app on your registered mobile device to verify your identity in one of the following ways:

-  **Push notification:** Approve the notification received on your mobile device by entering the number displayed on the login screen.
-  **Verification code:** Enter the code generated by your mobile authenticator app.

-  **Text message verification**

Enter the code sent to your registered mobile phone and click the “Verify” button.

-  **Call message verification**

You will receive a phone call to your registered mobile phone. Follow the instructions provided during the call to approve the sign in attempt.

Setup of Multi-Factor Authentication (MFA)

Access [My Account](#) to set up or manage your MFA authentication methods. Detailed guidance on the setup process is available through [this link](#).

- **Microsoft Authenticator app**

Follow the steps available in [this link](#) to set up the Microsoft Authenticator app.

NOTE: the mobile device used for the Microsoft Authenticator app must support QR code scanning. If needed, you may need to install a QR Code reader before proceeding with the setup.

- **Other Authentication Methods – Mobile Text message or Phone Call**

Follow the steps provided in [this link](#) to register the phone number where you wish to receive text messages or phone calls for authentication.

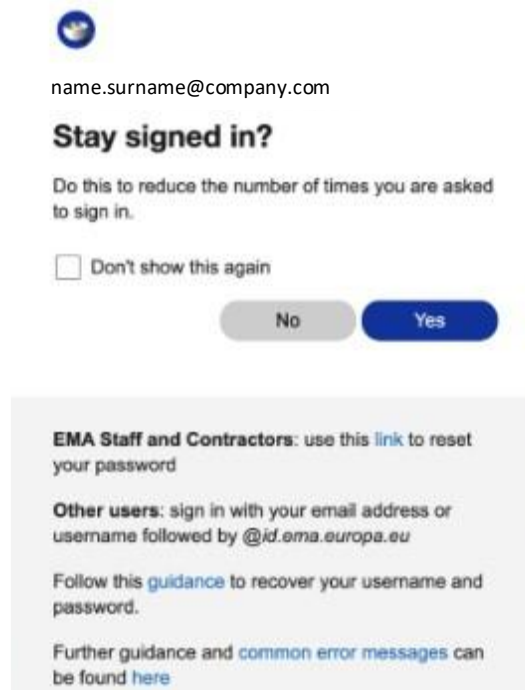
NOTE: text message or phone call options can be selected during any sign-in attempt, provided a phone number has been set up.

- **Other Authentication Methods – Office Phone Call**

Follow the steps provided in [this link](#) to set up your office phone for receiving authentication calls.

Step 6

Figure 9: Stay signed in?



name.surname@company.com

Stay signed in?

Do this to reduce the number of times you are asked to sign in.

Don't show this again

No Yes

EMA Staff and Contractors: use this [link](#) to reset your password

Other users: sign in with your email address or username followed by [@id.ema.europa.eu](#)

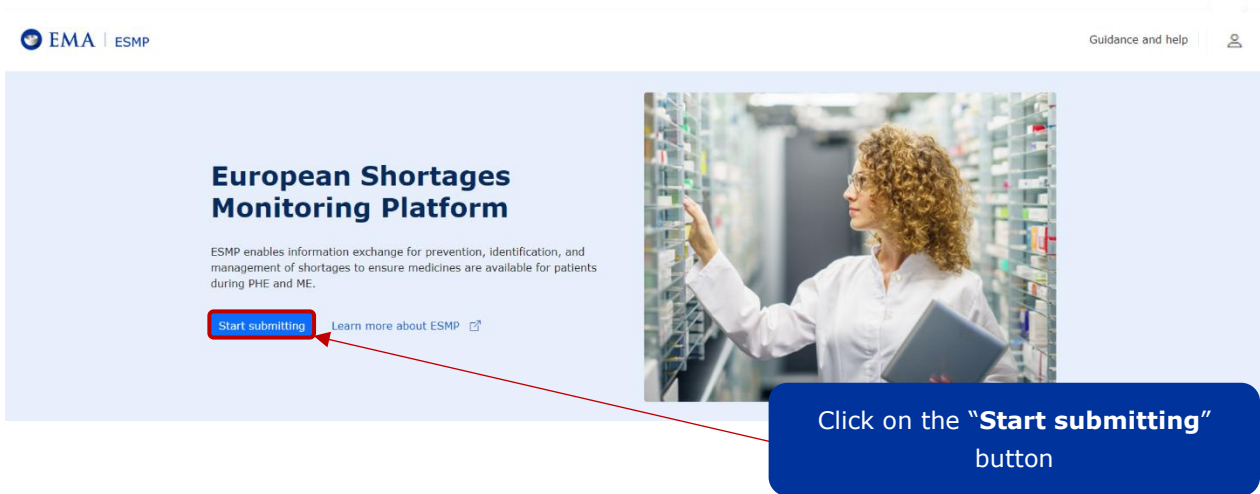
Follow this [guidance](#) to recover your username and password.

Further guidance and [common error messages](#) can be found [here](#)

Click the **Yes** button, if you are logged in from a trusted device and you want to limit the number of times you are asked to sign in.

If you are redirected to the welcome page, click on the **"Start submitting"** button to access the ESMP Routine shortage reporting page in normal circumstances.

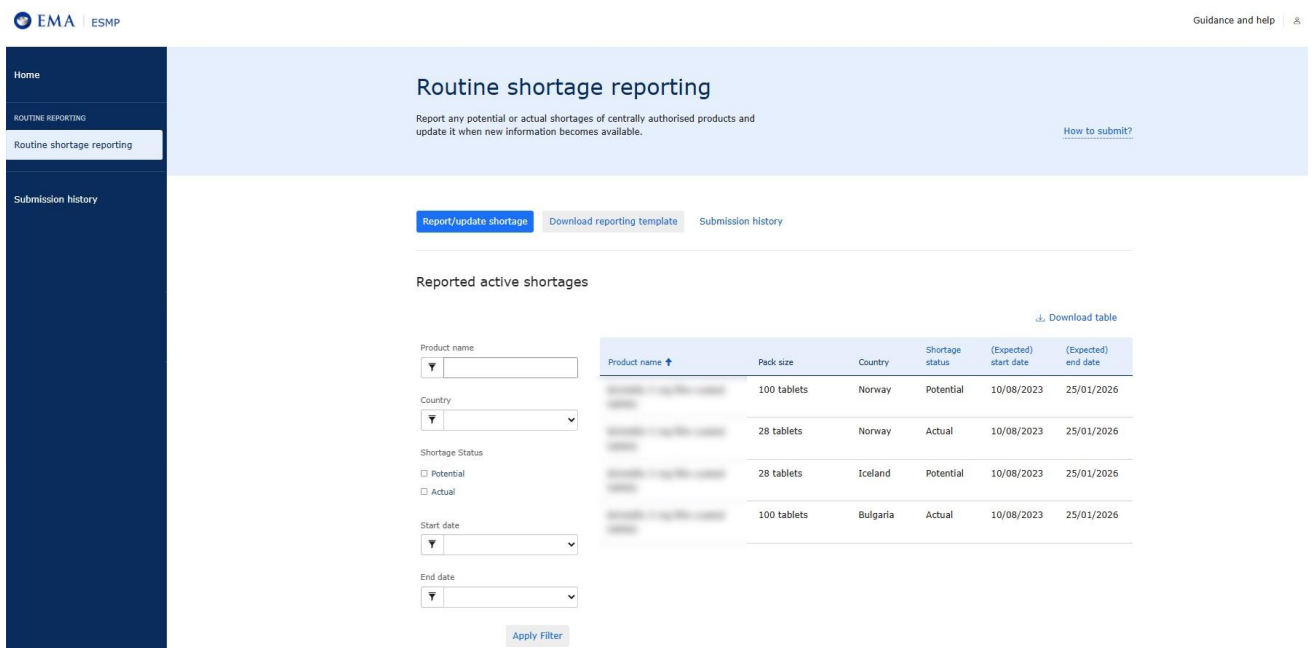
Figure 10: ESMP welcome page - start submitting



Once you have successfully signed in, you will be redirected to the ESMP Routine shortage reporting page, as shown in figure 11.

In case a crisis is declared or an MSSG-led preparedness action is activated, you will be directed to the ESMP Home page. Please refer to section 4.1. on the latter.

Figure 11: ESMP Routine shortage reporting page



3. Routine reporting of shortages of CAPs

Normal circumstances refer to a period outside of a public health emergency (PHE), major event (ME), or an MSSG-led preparedness action. In normal circumstances, EMA will monitor relevant medicines to prevent and manage shortages which might lead to a PHE or ME. To this end, MAHs are required to report shortages of centrally authorised products (CAPs) when they are made aware of a potential or actual shortage.

In the "Routine shortage reporting" section of the ESMP, you will be required 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 risk assessment;
- Alternative therapies
- Additional information

The following paragraphs describe the processes for reporting data in each of these categories via the ESMP.

Preliminary requirements

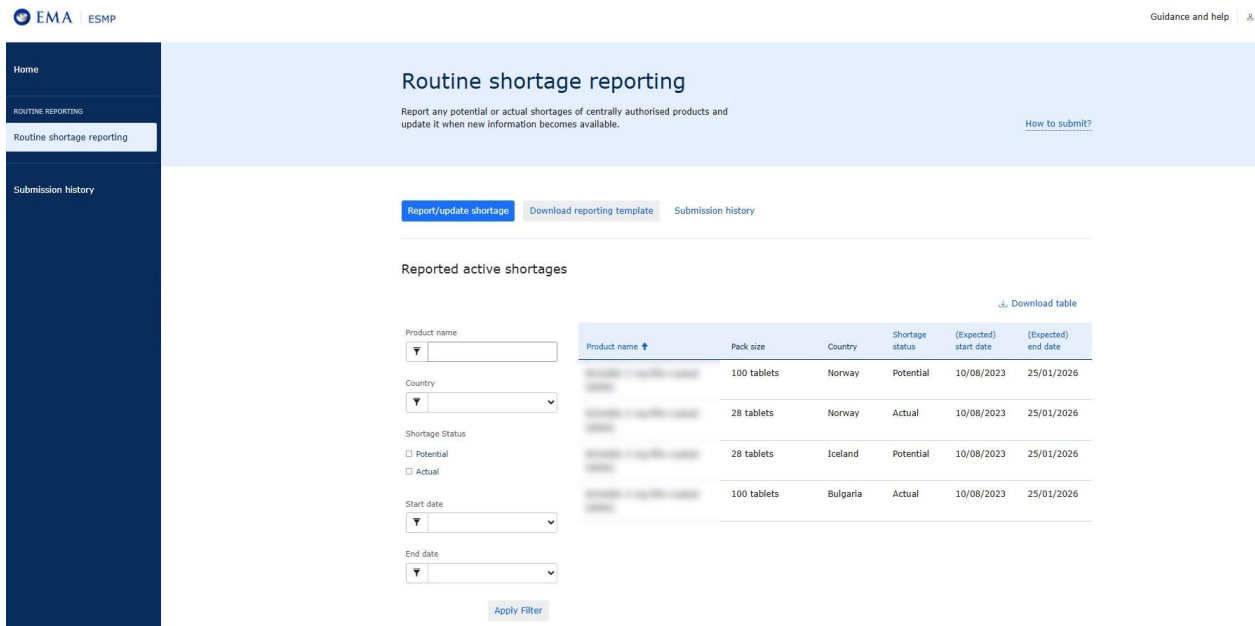
Prior to submitting shortage notifications via the ESMP, MAHs are required to ensure the following prerequisites are in place:

1. Record and maintain marketing status information of CAPs in the [IRIS platform](#). Data will be retrieved only for presentations which have been indicated as "Marketed" or "Temporarily unavailable" in specific EU/EEA countries. Product presentations for which marketing status information has not been submitted in IRIS, and products for which marketing status has been indicated as "Not marketed" or "Never marketed", will not be retrieved; hence, entries for such presentation and country combinations will not be pre-populated in the data submission templates in the ESMP.
2. Create an active EMA account and request the appropriate user role ("ESMP Industry User") to access and operate within the ESMP, as outlined in Chapter 2 of this guide.

3.1. How to navigate the platform during normal circumstances

During normal circumstances, the [ESMP Home page](#) (and the left-side navigation menu) will display only the 'Routine shortage reporting' and 'Submission history' sections. Sections related to crisis or MSSG-led preparedness submissions will only appear when a crisis is declared, or MSSG-led preparedness action is active. For more information on crisis and MSSG-led preparedness submissions, refer to Chapter 4 of this guide.

Figure 12: Routine shortage reporting – Main page



3.1.1. Report or update a shortage

The “Report/update shortage” button enables you to submit new information regarding a shortage by uploading the routine shortage submission template saved on your computer. The information present in the uploaded file will overwrite any information you may have previously inserted for a particular product and country. When updating a shortage, it is also possible to change the information in specific rows and leave the data in the rows pertaining to other products/countries without changing the values that were previously submitted. All the information present in the Excel file at the time of data upload must reflect the latest known information on a particular shortage.

3.1.2. Download a reporting template

The “Download reporting template” button navigates to the product selection that shows all the centrally authorised products of your organisation, displayed at the level of medicinal product with its corresponding PMS ID. It allows you to select the products you wish to report information for. Once you have selected one or multiple products, you will be able to download the data submission template for Routine shortage reporting which will list all those products at the level of the packaged medicinal product with its corresponding data from PMS, displayed once per each EU/EEA country if applicable, its marketing status data from IRIS (where the marketing status is “Marketed” or “Temporarily unavailable”) and any shortage information you have previously submitted, if any.

3.1.3. Submission history

The “Submission history” section displays all the data submissions you have performed and whether they were successful or not. By clicking on each of the submission IDs, it is possible to navigate to preview the submission details of each of those submissions and the validation errors present at the time, if any.

3.1.4. Reported active shortages

The “Reported active shortages” section displays all the previously reported actual or potential shortages of products that are under your organisations’ product portfolio. It provides an overview of all the shortages that still need to be monitored and followed up on by the MAH until the shortage is resolved.

This table will show the essential information on the shortage such as which product it concerns, the country where it is occurring, the shortage status, and the shortage (expected) start and end dates. It will display the latest information on those shortages, regardless of whether it was you or your colleagues who have reporting rights to the same products who submitted this information.

You are able to filter the data by the product name (use an asterisk (*) to search using a part of the name), the status of the shortage (active or potential only), the country of shortage, and shortage dates.

Download table

The “Download table” button, on the right side of the webpage, enables you to download an Excel file containing the information of all the previously reported active actual or potential shortages of products that are under your organisations’ product portfolio, listed also in the “Reported active shortage” table below.

3.2. How to report shortages of CAPs through the ESMP

In order to report the necessary information, users will be able to access the ESMP, through which it will be possible to download, compile, and upload a dedicated template.

Please find below the step-by-step process to carry out the submission of data on shortages of CAPs through the ESMP.

Step-by-step process

3.2.1. Part 1: Download a reporting template

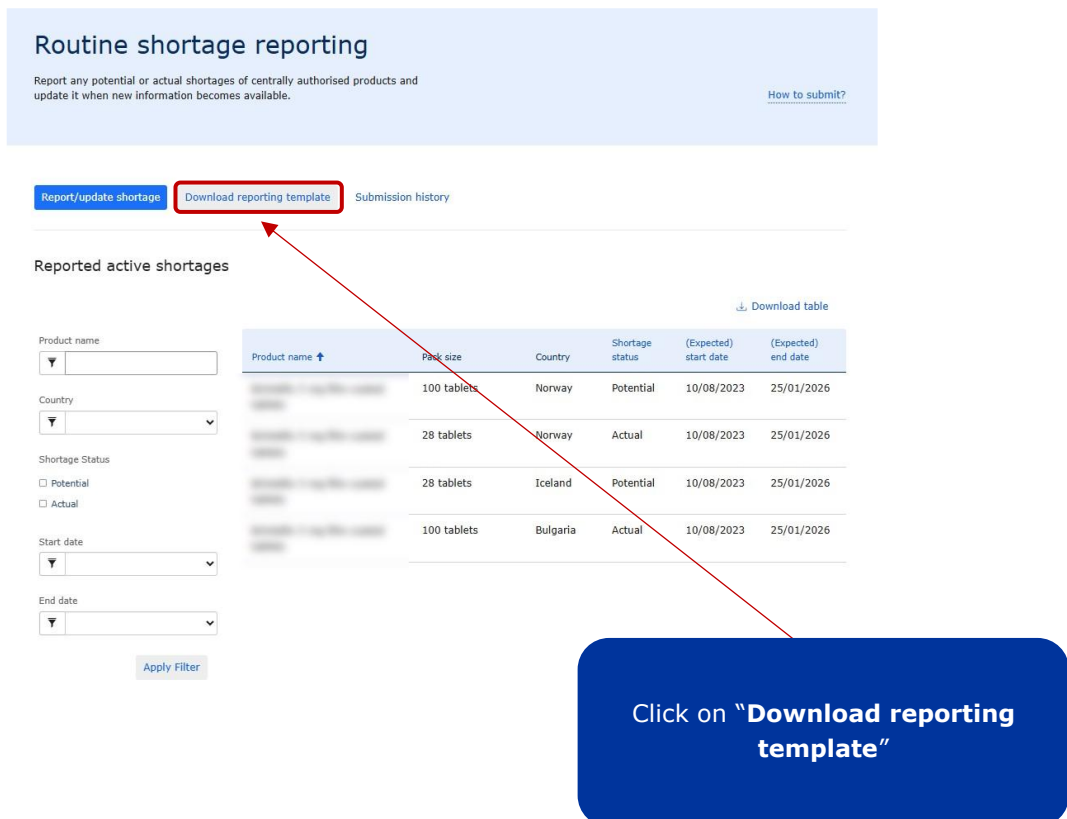
Step 1

In the “**Routine shortage reporting**” page you will find medicinal products associated with your organisation(s), for which actual or potential shortages were previously reported. You are able to filter the entries displayed in the table by “Product name”, “Shortage status”, “Country”, “Start date” and “End date”.

In this page you can choose between three different options “Report/update shortage”, “Download reporting template”, and “Submission history”.

To obtain a pre-populated template with the product details against which you can enter the relevant shortage information, you are requested to click on “**Download reporting template**”.

Figure 13: Routine shortage reporting – Download reporting template



Routine shortage reporting

Report any potential or actual shortages of centrally authorised products and update it when new information becomes available. [How to submit?](#)

Report/update shortage **Download reporting template** Submission history

Reported active shortages [Download table](#)

Product name:

Country:

Shortage Status: Potential Actual

Start date:

End date:

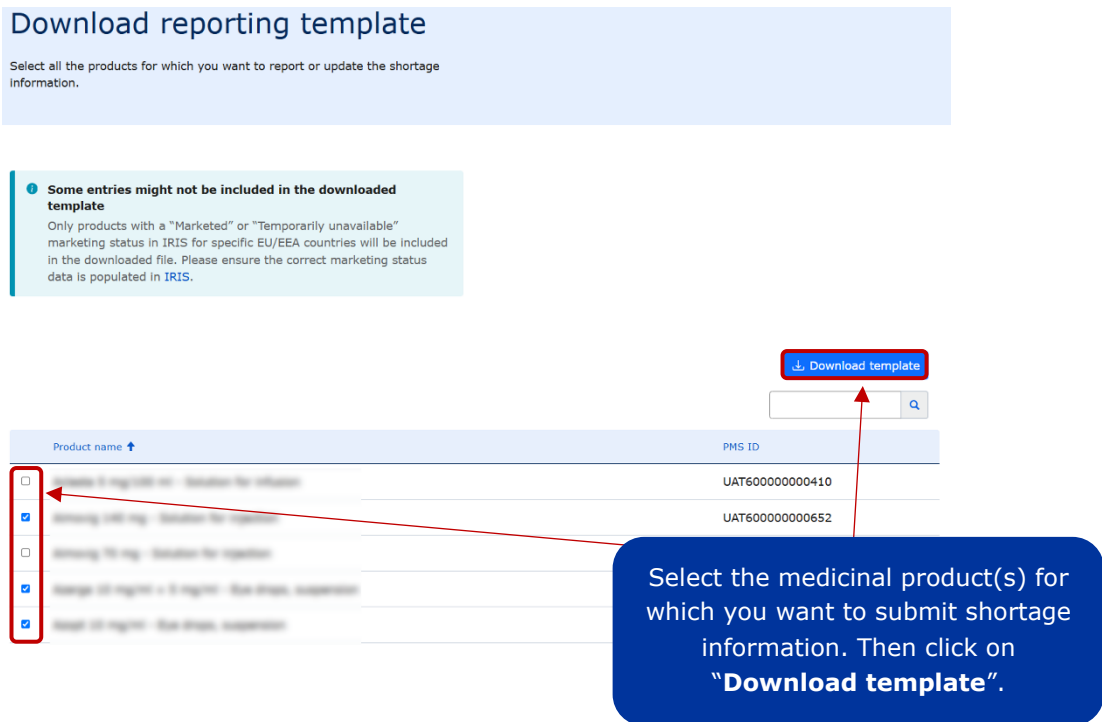
Product name ↑	Pack size	Country	Shortage status	(Expected) start date	(Expected) end date
Product name	100 tablets	Norway	Potential	10/08/2023	25/01/2026
Product name	28 tablets	Norway	Actual	10/08/2023	25/01/2026
Product name	28 tablets	Iceland	Potential	10/08/2023	25/01/2026
Product name	100 tablets	Bulgaria	Actual	10/08/2023	25/01/2026

Click on “**Download reporting template**”

Step 2

You will be redirected to the **“Download reporting template”** page. Here you will find all centrally authorised products associated with your organisation(s). Select the medicinal product(s) for which you want to submit shortage information by ticking the respective box on the left. Multiple products can be selected. Then click on **“Download template”** to proceed. Note the warning message reminding that some entries might not be included in the downloaded template, because only products with **“Marketed”** or **“Temporarily unavailable”** marketing status in IRIS will be listed here. Remember to ensure the correct marketing status data is populated in [IRIS](#)¹⁶.

Figure 14: Routine shortage reporting – Download reporting template – Products selection



Download reporting template

Select all the products for which you want to report or update the shortage information.

Some entries might not be included in the downloaded template
Only products with a **“Marketed”** or **“Temporarily unavailable”** marketing status in IRIS for specific EU/EEA countries will be included in the downloaded file. Please ensure the correct marketing status data is populated in [IRIS](#).

Product name	PMS ID
<input type="checkbox"/> ...	UAT600000000410
<input checked="" type="checkbox"/> ...	UAT600000000652
<input type="checkbox"/> ...	
<input checked="" type="checkbox"/> ...	
<input checked="" type="checkbox"/> ...	

Download template

Select the medicinal product(s) for which you want to submit shortage information. Then click on **“Download template”**.

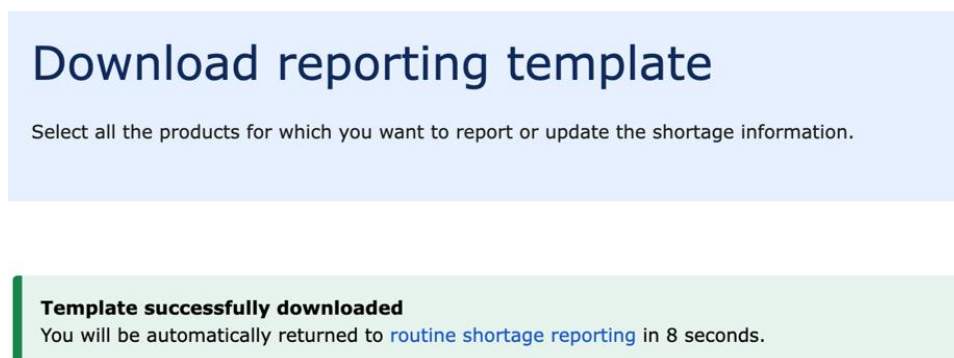
Step 3

The system will generate a template listing details of the selected medicinal product(s).

When the platform notifies: **“Template successfully downloaded”**, as shown in figure 15, the download process has been completed.

Please note: the system might require a few minutes to load the necessary information.

Figure 15: ESMP Downloading the reporting template



Download reporting template

Select all the products for which you want to report or update the shortage information.

Template successfully downloaded
You will be automatically returned to [routine shortage reporting](#) in 8 seconds.

¹⁶ <https://iris.ema.europa.eu/SignIn?ReturnUrl=%2fmyDraftSubmissions%2f>

Step 4

Open the folder on your computer where the downloaded files are stored. You will find an Excel file with the name “**esmp-shortage-<timestamp>.xlsx**”. The template will contain the data presented at the level of a packaged medicinal product and each EU/EEA country and will have one column for each data element described in table 1 below.

This template will include the most recent data previously submitted to EMA through IRIS (for marketing status of CAPs) and the ESMP, if applicable.

When downloading a template to update a previous submission, the template will display previously submitted data. If you submitted in the relevant fields with numerical RMS IDs, this data will be downloaded and displayed as readable RMS IDs.

Figure 16: Template in the Downloads folder

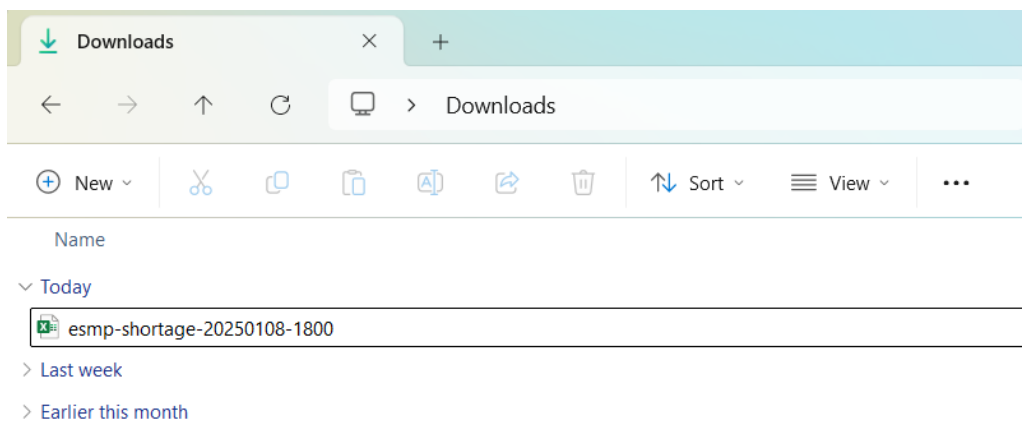


Figure 17: Example of pre-populated template for routine shortage reporting for CAPs

Country	Marketing Status	Shortage Start	Shortage End	Point in Time	Root Cause	Quality	Isi Quality	Isi Manufacture	Country	Regulator	Regulator	Unexpected	Unexpected	Country	Distributor
AT	Temporarily Unavailable	22/12/2022	19/01/2023	20/01/2023	2000000028	2000000028	200000028694								
BG	Marketed	Actual	22/12/2022	19/01/2023	20/01/2023	2000000028	2000000028684		IS,NO						
IS	Marketed	Actual	22/12/2022	19/01/2023	20/01/2023	2000000028	2000000028686								
LI	Temporarily Unavailable	Actual	22/12/2022	19/01/2023	20/01/2023	2000000028	2000000028686					200000028700		AT,BG	
NO	Marketed	Actual	22/12/2022	19/01/2023	20/01/2023	2000000028	2000000028687								200000028
BG	Marketed	No shortage													

⚠ Important! Through the [IRIS portal](#)¹⁷ you will be able to create new submissions to change the marketing status of your products. Please ensure that marketing status information of all your products is inserted correctly and is up to date, consulting the [View Marketing Status Report · IRIS](#) webpage¹⁸, because marketing status data affects the possibility of reporting the required information in the ESMP. You will be able to submit all relevant information required for routine shortage reporting only for products that have the marketing status “Marketed” or “Temporarily Unavailable” in a particular country. It is important to note that you will not be able to submit information required in the ESMP for products in countries where in IRIS the products are stated to be “Not marketed” or “Never marketed” and entries for those particular product and country combinations will not be pre-populated in the data submission templates downloaded from the ESMP. If the information on the

¹⁷ <https://iris.ema.europa.eu/myDraftSubmissions/>

¹⁸ <https://iris.ema.europa.eu/SignIn?ReturnUrl=%2Fviewmarketingstatusreport%2F>

marketing status of CAPs is not populated or not up to date in IRIS, please perform the necessary changes in IRIS, after which the information will be reflected in the ESMP within approximately 5-15 minutes.

3.2.2. Part 2: How to populate the template

File naming conventions


Remember that only data in the first worksheet will be processed, therefore do not create other worksheets in the Excel file. The order of columns contained in the template should not be modified and no additional column should be added. Make sure that the file extension remains **".xlsx"**. The file name can be modified and customised as preferred by the user, the system will recognise and process the Excel document with any name.

How to complete the data fields in the template

The required sections of the template must be completed before uploading the file. Make sure to respect the validation rules of every data element. Each data element and the details on how the relevant information needs to be inserted is described in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)¹⁹. Please consult this guide for further details to ensure the data will be correctly and successfully uploaded in the ESMP.


Table 1, which you can find below, provides an overview of all data elements reported in the columns of the template for the submission to the ESMP. All mandatory and conditional (which become mandatory based on the information inserted in other fields) elements must be provided to successfully upload the file.

The **"Product information" fields will be pre-populated** by the system in the template, transferring product data already stored in the EMA's Product Management Service (PMS), as well as marketing status data for CAPs from IRIS, into ESMP. If you want to find out more about the product information contained within PMS, please consult the [PMS Implementation of International Organization for Standardization \(ISO\) standards for the identification of medicinal products \(IDMP\) in Europe](#)²⁰.

 You should not make changes to the product information fields, because the product information changed in the ESMP templates will not be transferred into PMS. The pre-populated fields are listed in table 1 for clarity and completeness.

Important:

- Make sure to **insert the information at the level of packaged medicinal product and the country of shortage**.
- Where applicable, make sure to separate multiple values in one field with a semicolon, such as when entering multiple root causes of a shortage (entered either as numerical RMS IDs - e.g. "200000028689;200000028700" or readable IDs – e.g. "ManufProdRel;UnexIncDemCoStock") or multiple countries affected (CN;CO).

 When pasting numerical **RMS identifiers**, which are 12-digit IDs, Excel codifies data to insert information in the system. In the Excel cell, the value might be reported as: "2E+11" due to Excel default settings. In this case you can change the cell format into "Text", as shown in figure 18 below,

¹⁹ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

²⁰ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-2_en.pdf

to show the RMS identifiers correctly. Nevertheless, if the inserted numerical RMS ID can be processed in "2E+11" format, if reported correctly.

⚠️ When inserting **date information**, always remember to respect the DD/MM/YYYY format. Due to Excel default settings, it might happen that the cell format could change into Long date or Short date, generating a format error in the submission phase. To avoid this error, it is possible to insert an " ' " (apostrophe) just before the date (i.e. '12/05/2025), this will overcome any format constraint generated in Excel.

It would be good practice to select all the cells of the Excel file and change the format into "Text", to avoid any error as the two just described.

It is possible to report shortages of multiple products in a single upload file.

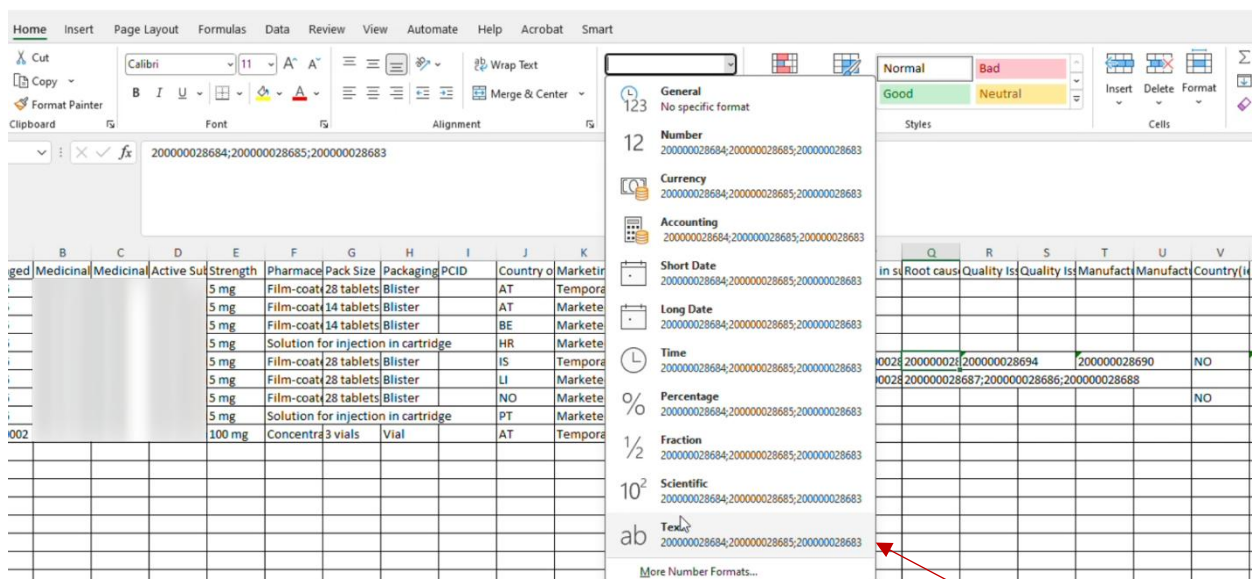
⚠️ The pre-populated template downloaded from the ESMP will list the product data per each EU/EEA country separately. If you would like to report a shortage for only some of those countries, you are encouraged not to delete the rows pertaining to the other countries where there is no shortage, but to leave those rows in the file and populate their shortage status with "No shortage". Not other fields need to be populated for countries where there is no shortage. Information on the absence of a shortage in a particular country is also important for the EMA to assess the extent of the shortage.

To report that a shortage is resolved, the user must perform a follow-up submission for the product and country in question to insert the most recent information and must ensure all the data elements pertaining to the shortage in question are populated in the file. For a resolved shortage please enter the shortage status as "Resolved" and not as "No shortage".

Shortages are never considered to be resolved automatically by the ESMP and require user action to ensure the information is up to date at all times.

Once a shortage is reported to be resolved via the ESMP, the downloaded file will no longer display the previously reported shortage in the reporting template file next time a user proceeds to generate it.

Figure 18: Change cell format in the downloaded template



Select "Text" format to correctly view numerical RMS identifiers

Table 1: Routine shortage reporting - data elements

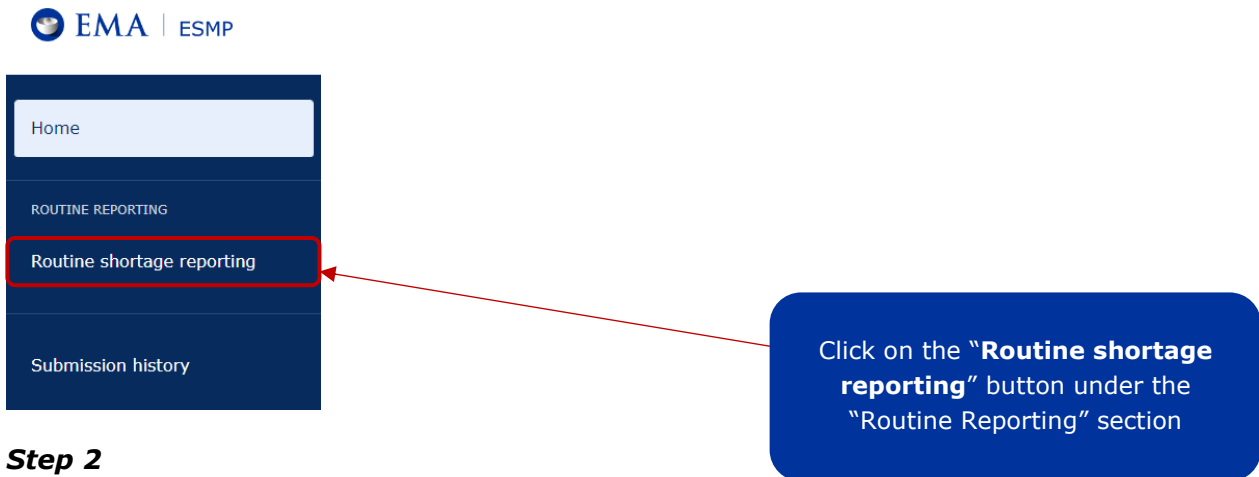
Data category	Data element name	Conformance
Product information	Package PMS ID	Pre-populated
	Full product name	Pre-populated
	Short product name	Pre-populated
	Active substance	Pre-populated
	Strength	Pre-populated
	Pharmaceutical form	Pre-populated
	Pack size	Pre-populated
	Package description	Pre-populated
	PCID	Pre-populated
	Country of authorisation	Pre-populated
Marketing status	Pre-populated	
Shortage information	Shortage status	Mandatory
	Shortage start date or expected start date	Conditional
	Shortage end date or expected end date	Conditional
	Point in supply chain at which disruption occurs	Conditional
	Root cause of the shortage	Conditional
	Countries in which manufacturing issues occur	Conditional
	Countries in which unexpected increased demand occurs	Conditional
	Countries in which distribution issues occur	Conditional
Root cause of the shortage - additional information	Conditional	
Shortage prevention and mitigation plans	Shortage prevention plans and mitigation plans	Conditional
	Shortage prevention plans and mitigation plans - ongoing and planned steps	Conditional
Impact assessment	Affected population estimate	Optional
	Market share	Optional
	Shortage impact risk assessment	Conditional
	Shortage impact risk assessment - additional information	Conditional
Alternatives therapies	Alternatives therapies available?	Conditional
	Alternative substances	Conditional
Additional information	Rapid Alert reference number	Optional
	Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report	Conditional
	Reference to related pending regulatory action	Optional
	Required NCA actions, if any	Optional

3.2.3. Part 3: Upload of the data into ESMP

Step 1

On the left-side navigation menu, click on the “**Routine shortage reporting**” button, under the “Routine reporting” section.

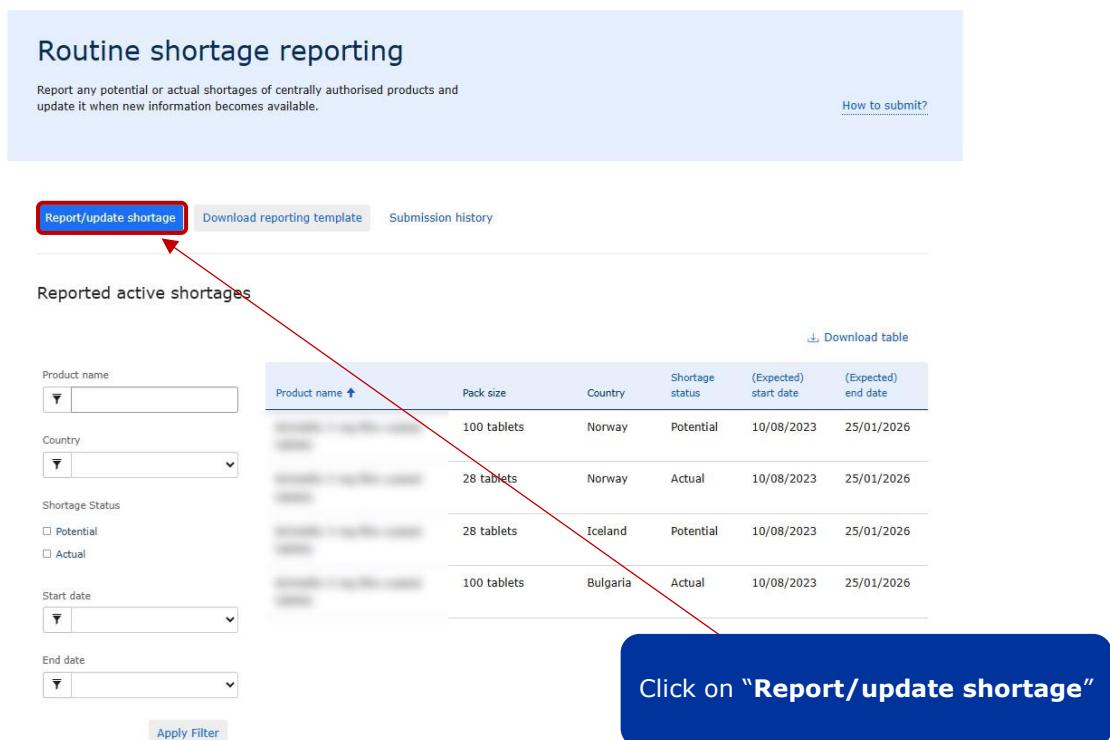
Figure 19: Left-side navigation menu– Routine shortage reporting



Step 2

You will be transferred to the “**Routine shortage reporting**” page, here you can choose between three different buttons: “Report/update shortage”, “Download reporting template”, and “Submission history”. In this phase, you are requested to click on “**Report/update shortage**”.

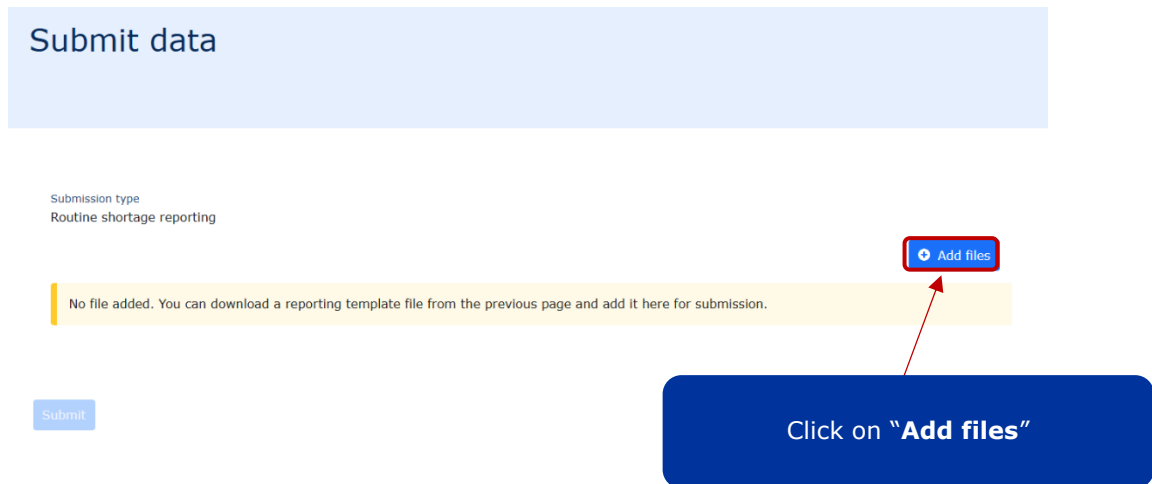
Figure 20: Routine shortage reporting – Report/update shortage



Step 3

A page will open called **"Submit data"**. Click on **"Add files"**. A dialog box will open, allowing you to upload a file to the ESMP.

Figure 21: Submit data – Add file

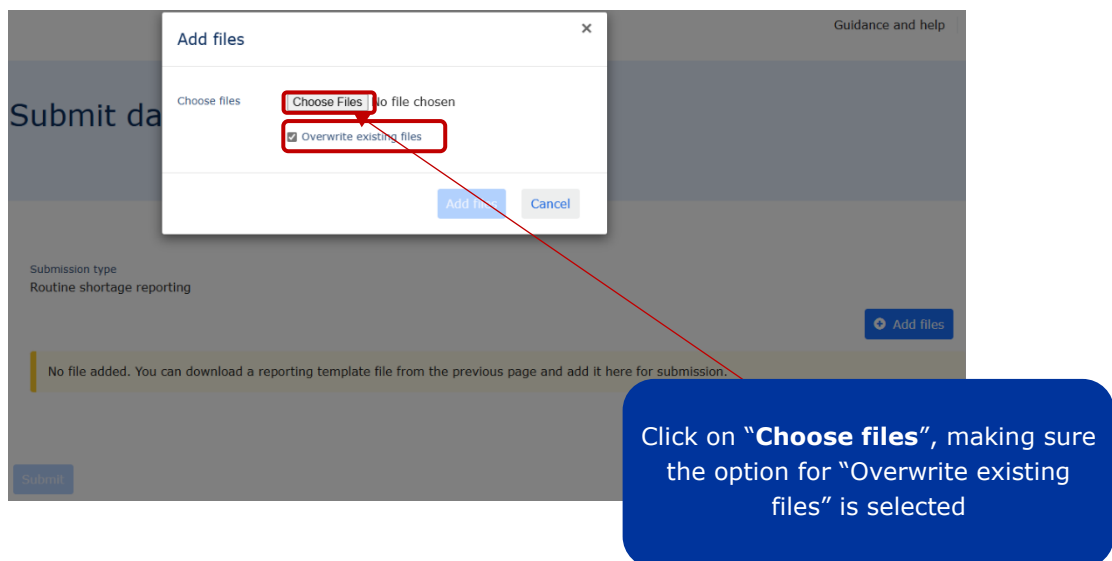


Step 4

Click on **"Choose files"**, making sure the option for **"Overwrite existing files"** is selected. This will open a dialogue window on your computer. From there, locate the file you want to submit in the folder on your computer where you saved it.

⚠️ The system only accepts the selection of one file at a time for submission. In case you select multiple files for submission, after clicking on **"Add files"**, the error message **"Only one file can be uploaded for a submission."** will be displayed. Therefore, please select only one file.

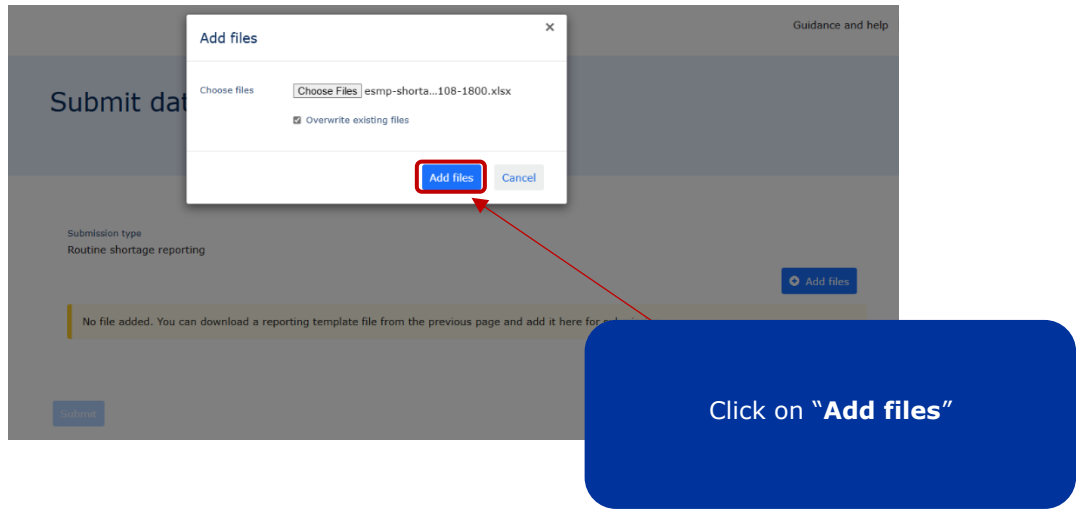
Figure 22: Submit data – Dialogue box – Choose file - Overwrite existing files



Step 5

Once you have selected a file, the name of the file will be shown next to the **"Choose Files"** button. Click on **"Add files"** to add this file to the upload page.

Figure 23: Submit data –Dialogue box – Add file

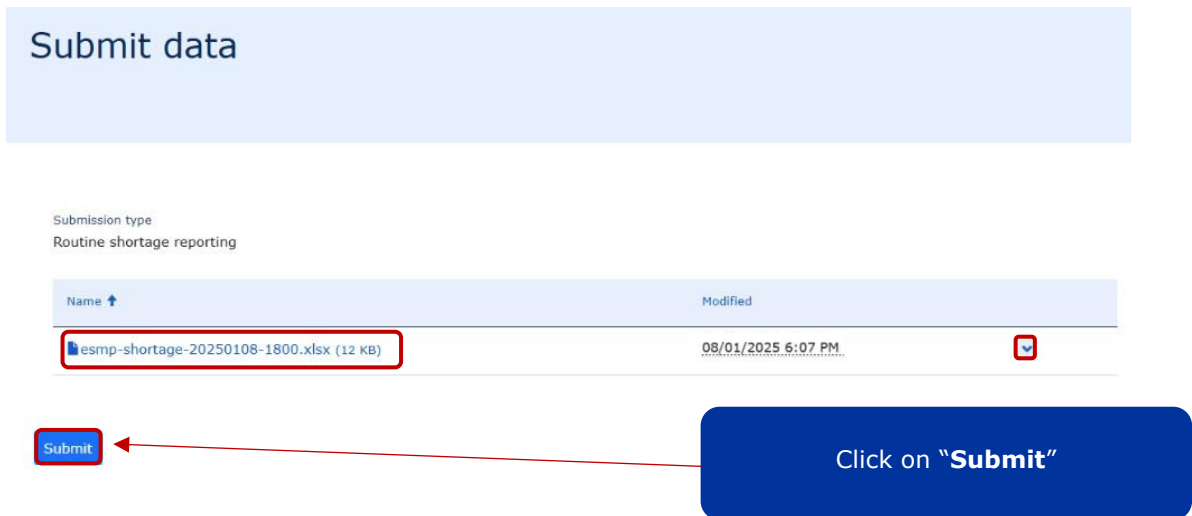


Step 6

The file you added will be listed in the table, as show in figure 24 below. If it is the correct file, click on **“Submit”**. This will start the validation process of the file.

If it is not the correct file, click on the arrow on the right side of the screen and delete the selected file, then restart the upload process from step 1.


Figure 24: Submit data – Submit button



Step 7

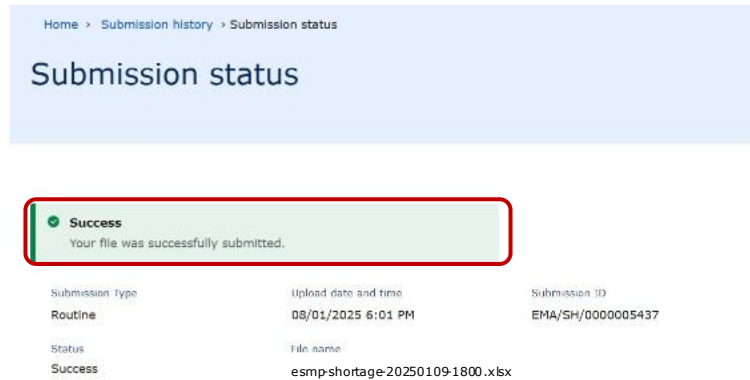
Validation of the submitted file may take some time. Feel free to close the page or move to another page while the file is being processed, since the submission will proceed in the background. To retrieve the details of the current submission or any past submission, consult the “Submission history” page.

A page called **“Submission status”** will open, showing a summary of the upload details: submission type, upload date and time, submission ID, the file name, the status and the error messages, if any.

 The outcome of a submission on the “Submission status” page may require some time to be displayed, depending on the number of fields in the submitted file. You may leave the “Submission status” page at any time. The processing of the submitted file will continue in the background. You may return to the “Submission status” page via the “Submission history” page.

If your upload is successful, the “**Upload status**” will state “**Success**” (figure 25). Your upload is therefore successfully completed.

Figure 25: Routine shortage reporting – Submission status: Success



If your upload fails, the “**Upload status**” will show “**Failed**”. If this happens, please review the “**Validation results**” section at the bottom of the page. The validation results’ section lists errors encountered in the file, along with their location in the file (row number and column letter, or a dot where the error applies to the whole row or column; for example, “.2” means that the error refers to the whole row, “..” means that the error refers to the whole file), and an error message detailing what caused the error. Make sure you scroll through the entire validation results’ section to view all errors.

You may also click on “Download validation results” to download an Excel file listing the errors.

Figure 26: Routine shortage reporting – Submission status: Failed

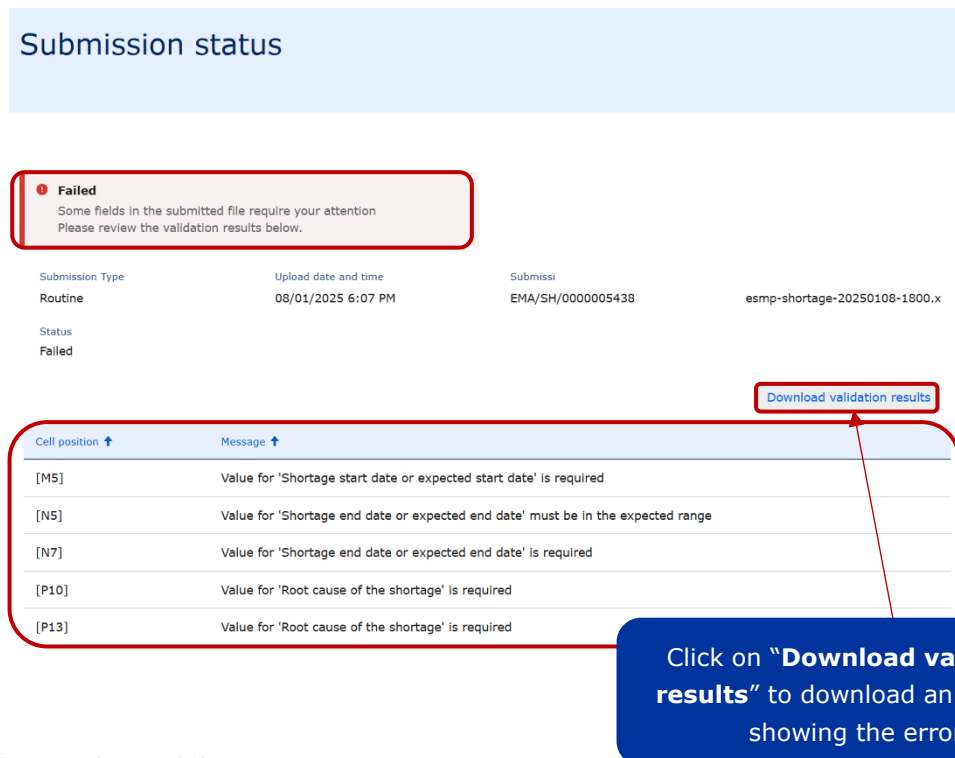


Figure 27: Validation results - Excel file view

	1	2
1	Cell position	Message
2	[M5]	Value for 'Shortage start date or expected start date' is required
3	[N5]	Value for 'Shortage end date or expected end date' must be in the expected range
4	[N7]	Value for 'Shortage end date or expected end date' is required
5	[P10]	Value for 'Root cause of the shortage' is required
6	[P13]	Value for 'Root cause of the shortage' is required

Open the **“esmp-validation-results-routine-shortage” Excel file** to view the details of the reported errors. For further information on the listed errors and validation rules that may prevent you from successfully completing your submission, consult the requirements for each data set and data element as described in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)²¹. Re-open the submission file that you wish to upload from your computer and address each of the described errors in the **“esmp-validation-results-routine-shortage”** file. Save your changes and repeat the upload process with the amended file.


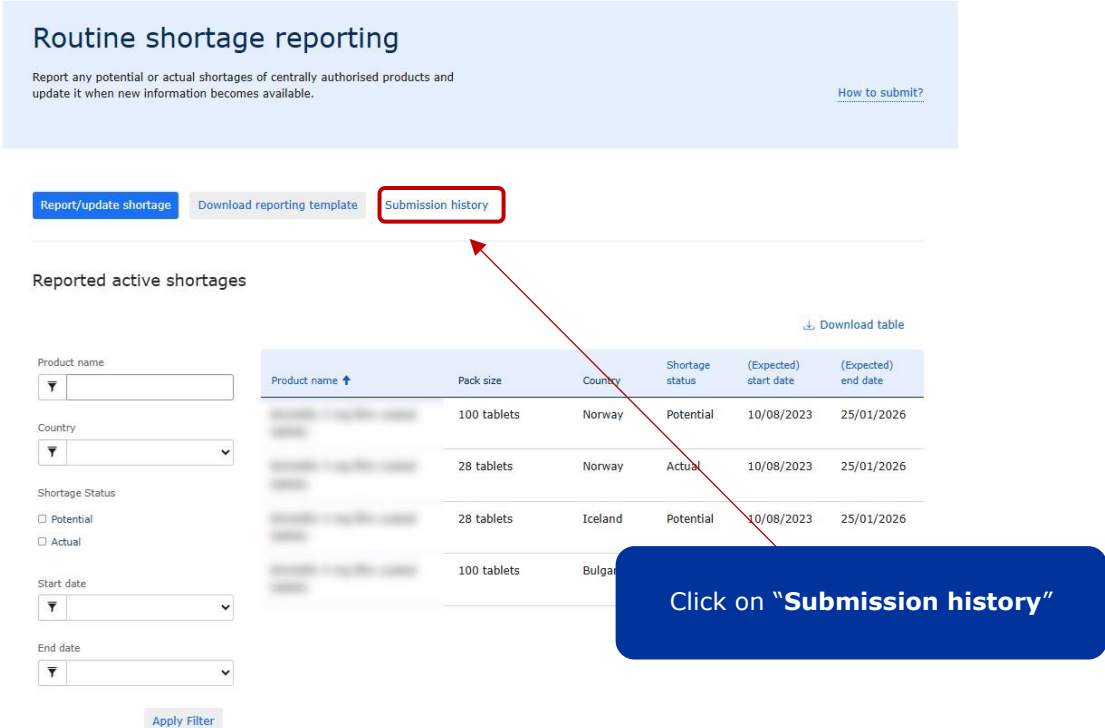
 All upload summary details from all previous submissions, whether successful or failed, are recorded and can be viewed within the ESMP in the “Submission history” section. To access it, click on the **“Submission history”** button on the left-side navigation menu, or access it from the **“Routine shortage reporting”** page.

Figure 28: Routine shortage reporting – Submission history



Routine shortage reporting

Report any potential or actual shortages of centrally authorised products and update it when new information becomes available. [How to submit?](#)

Report/update shortage Download reporting template **Submission history**

Reported active shortages Download table

Product name:

Country:

Shortage Status: Potential Actual

Start date:

End date:

Product name ↑	Pack size	Country	Shortage status	(Expected) start date	(Expected) end date
...	100 tablets	Norway	Potential	10/08/2023	25/01/2026
...	28 tablets	Norway	Actual	10/08/2023	25/01/2026
...	28 tablets	Iceland	Potential	10/08/2023	25/01/2026
...	100 tablets	Bulga...			

Click on **“Submission history”**

On the **“Submission history”** page you can review all your past submissions, including details such as submission ID, type, submission status (e.g., success or failed), and the date of submission.

²¹ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

It is possible to filter the recordings by “Type” and “Submission status” using the filters on the left side of the screen.

Figure 29: Routine shortage reporting – Submission history page

Submission history

Type

Submission status

Apply

Submission ID	Submission Type	Submission status	Start Date/Time of the upload
EMA/SH/0000003229	Availability	Success	19/04/2024 9:50 AM
EMA/SH/0000003062	Routine	Failed	10/04/2024 3:14 PM
EMA/SH/0000003063	Routine	Failed	10/04/2024 3:23 PM
EMA/SH/0000003064	Routine	Success	10/04/2024 3:36 PM
EMA/SH/0000002761	Routine	Failed	14/03/2024 3:17 PM
EMA/SH/0000002774	Availability	Failed	15/03/2024 6:32 PM
EMA/SH/0000002776	Routine	Failed	15/03/2024 6:41 PM
EMA/SH/0000003567	Marketing status NAPs	Failed	11/06/2024 10:58 AM
EMA/SH/0000002871	Routine	Success	
EMA/SH/0000002873	Routine	Failed	
EMA/SH/0000002874	Routine	Success	

Click on the “**Submission ID**” to consult the upload details of a particular submission

For more information about a particular submission, click on its “**Submission ID**”. The “**Submission status**” page for the selected submission will open, as shown in figure 30. Here you will find information about submission type, end of the upload, submission ID, file name, and the upload status, and the error messages, if any.

Figure 30: Routine shortage reporting – Submission history – Submission status

Home > Submission history > Submission status

Submission status

✔ **Success**
Your file was successfully submitted.

Submission Type	Upload date and time	Submission ID
Routine	08/01/2025 6:01 PM	EMA/SH/0000005437
Status	File name	
Success	esmp-shortage-20250109-1800.xlsx	

3.3. Further guidelines and recommendations

The information on shortages submitted in the ESMP must be kept up to date. Any correction or update to the data is performed by uploading a file with new information.

To update the information on previously submitted entries, you can choose to download a template for the product in question from the ESMP, which will always give you the latest version of the submitted data, and then amend and upload that file. Alternatively, you can amend and upload a file used previously to report a shortage which was saved locally on your computer, however please ensure internal coordination if multiple users are submitting data for the same product portfolio, to prevent overwriting data in the ESMP with outdated or incorrect information. When submitting an update to a previously reported shortage, please ensure the submission file only contains the relevant entries you wish to update; the file does not need to contain the entries for which no updates are available.

Where possible, submit comprehensive updates for the shortage entries. High-quality, well-timed updates support faster assessment and reduce follow-up queries.

When a shortage is resolved, all the relevant data elements need to be populated in the template as for reporting an active or potential shortage (such as the correct shortage start and end dates, root cause of shortage, etc.) to allow for the tracking of which specific shortage of that product was resolved. In this case also the shortage status needs to be entered as "Resolved" and not as "No shortage".

General guidelines on updating shortage statuses:

- A 'Potential' shortage should be updated to 'Actual' when the shortage becomes actual.
- A 'Potential' shortage should be updated from 'Potential' to 'Resolved' when the shortage was prevented and did not occur.
- An 'Actual' shortage should be updated to 'Resolved' when the shortage is closed. Update also correct shortage start and end dates and any additional relevant information.
- Do not update a potential or actual shortage to 'No shortage'. This should be done only exceptionally, in case shortage information was submitted in error, e.g., different product or different country.

3.4. After a shortage is reported

The EMA will be reviewing all reported shortages and reaching out to the MAH if more information or follow-up actions are required.

ESMP sends automated reminders on open shortages to remind MAHs to review and update reported shortage information for outdated shortage information. Reminders are sent for potential shortages when the reported expected shortage start date has passed, and for actual shortages when the expected shortage end date has passed. The reminders are sent from EMA-IRIS@ema.europa.eu once weekly to the ESMP user who submitted the shortage notification and the i-SPOC. The subject line includes the required action and product name, MAH name, and an IRIS reference number for the communication. In case you have a follow-up query on this reminder, do not change the subject line and keep the sender email address in copy.

The ESMP user is prompted to review and update the shortage information, particularly the shortage status, expected or actual shortage dates, and any other relevant information that may have changed or have since become available to the MAH.

4. Crisis and MSSG-led preparedness submissions

In times of crises (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 action, MAHs are required to report information on centrally and nationally authorised products deemed as critical or in scope of the action. 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, MAHs are required to report information on products included in a list of medicines to be monitored for MSSG-led crisis preparedness. In both cases, MAHs will be informed of the scope and start date of the reporting through their i-SPOC before the reporting requirements take effect, if medicines considered critical for this particular situation fall within the MAHs product portfolio. In this case, MAHs will have to submit the following information for medicinal products in scope of reporting requirements:

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

The following chapters describe the processes for reporting data in each of these categories via the ESMP.

Preliminary requirements

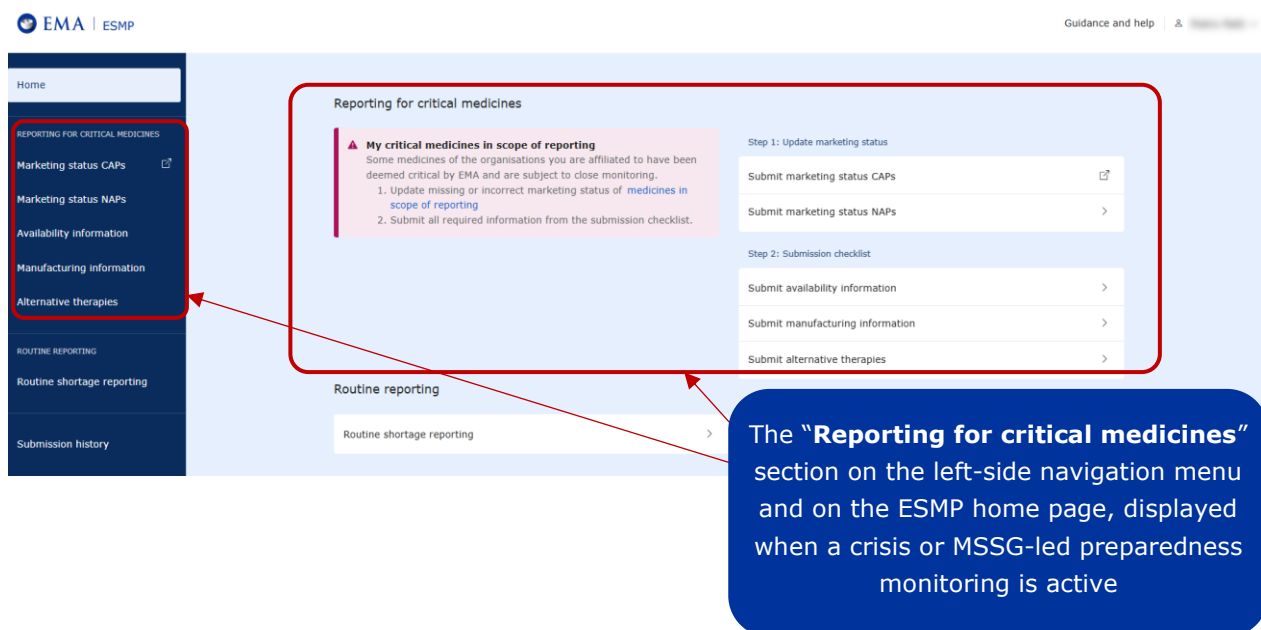
Prior to submitting notifications via the ESMP, MAHs are required to ensure the following prerequisites are in place:

1. Ensure that accurate and complete product master data, including structured package information and manufacturing site information for NAPs, is entered within the EMA's Product Management Service (PMS) for products in scope of reporting for the specific crisis or MSSG-led preparedness action in question. If this information is not available or up to date, it must be added or corrected in PMS before initiating ESMP submissions within two weeks after the notification of the reporting requirements.
2. Record and maintain marketing status information of CAPs in the IRIS platform. When generating the Availability information template, data 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 reported in IRIS, and products for which marketing status has been indicated as "Not marketed" or "Never marketed", will not be retrieved; hence, entries for such product and country combinations will not be pre-populated in the Availability information data submission templates in the ESMP. Ensure the Marketing status information in IRIS is accurate and up to date.
The Manufacturing information template and Alternative therapies webform are generated independently of the marketing status information.
3. Create an active EMA account and request the appropriate user role ("ESMP Industry User") to access and operate within the ESMP, as outlined in Chapter 2 of this guide.

4.1. How to navigate the platform during a crisis or MSSG-led preparedness

Whenever a crisis is declared or MSSG-led preparedness monitoring is active, the [ESMP Home page](#) (and the left-side navigation menu) will display the “Reporting for critical medicines” section which contains additional information pertaining to such an event. It includes a notification to inform users that medicines of the organisations you are affiliated to have been deemed critical for a public health emergency or major event; additionally, it contains quick links to the pages where users are required to fulfil reporting obligations (i.e.: Marketing status CAPs, Marketing status NAPs, Availability information, Manufacturing information and Alternative therapies).

Figure 31: ESMP Home page and left-side navigation menu when a crisis or MSSG-led preparedness monitoring is active



4.1.1. How to view your critical medicines and their marketing status

The ESMP allows you to view all the medicines under your product portfolio that have been marked as critical for a particular crisis or MSSG-led preparedness action. The marketing status information for all your products in scope of a relevant list of critical medicines will be shown as well. For CAPs, it will reflect the marketing status data previously inserted via IRIS. For the relevant NAPs, it will show marketing status data previously submitted through the ESMP, if applicable.

Please note that the “**My critical medicines**” page will only be accessible when there is a particular crisis or MSSG-led preparedness action. To access this information, click on “**medicines in scope of reporting**” on the notification on left side of the [Home page](#)²², as shown in figure 32.

Figure 32: Reporting for critical medicines start page - crisis submission checklist

²² <https://esmp.ema.europa.eu/home/>

Reporting for critical medicines


▲ My critical medicines in scope of reporting
Some medicines of the organisations you are affiliated to have been deemed critical by EMA and are subject to close monitoring.

1. Update missing or incorrect marketing status of **medicines in scope of reporting**
2. Submit all required information from the submission checklist.

Routine reporting

Routine shortage reporting >

Step 1: Update marketing status

Submit marketing status CAPs 

Submit marketing status NAPs >

Step 2: Submission checklist

Submit availability information >

Submit manufacturing information CAPs >

Submit alternative therapies >


Click on "medicines in scope of reporting"

The "My critical medicines" page contains a list of your critical medicinal products in scope of reporting requirements for a given PHE/ME, showing the related marketing status information.

Figure 33: Crisis and MSSG-led preparedness submission - review list of critical medicines

My critical medicines

Please review and update missing or incorrect marketing status for all products in your reporting scope. Only products marked as 'Marketed' or 'Temporarily Unavailable' are eligible for reporting shortages.

Update marketing status NAPs
Update marketing status CAPs 

Product name [Download table](#)

Pack size

CAP/NAP

Apply

Product name	Pack size	Country	CAP/NAP	Marketing status
CAP A 50 µg - Solution for injection	1 pre-filled pen	Croatia	CAP	Marketed
CAP A 50 µg - Solution for injection	1 pre-filled pen	Netherlands	NAP	Temporarily unavailable
CAP A 50 µg - Solution for injection	12 pre-filled pens	Liechtenstein	CAP	▲ No Data Provided
CAP A 50 µg - Solution for injection	12 pre-filled pens	Slovakia	NAP	▲ No Data Provided
CAP A 50 µg - Solution for injection	3 pre-filled pens	Estonia	NAP	▲ No Data Provided

⚠ Important! Please ensure that the marketing status information of all your products is inserted correctly and is up to date, because the marketing status data affects the possibility of reporting other required information. You will be able to submit all relevant data in the "Availability information" submission flow required for crisis and MSSG-led reporting **only for products that are "Marketed" or "Temporarily Unavailable" in a particular country**. It is important to note that you won't be able to submit information required in the ESMP for products in countries where the products are stated to be "Not Marketed" or "Never Marketed". Entries for those particular product and country combinations will not be pre-populated in the "Availability information" data submission templates in the ESMP.

4.2. How to submit the Marketing status for critical medicines (CAPs)

For CAPs, the marketing status details are pre-populated with data retrieved from the IRIS platform. Therefore, to modify the information about marketing status of your centrally authorised products

(CAPs), you must access IRIS and submit changes directly through the IRIS platform. These will be then automatically transferred and reflected in the ESMP.

To do that, on the left-side navigation menu, click on the “**Submit marketing status CAPs**” button.


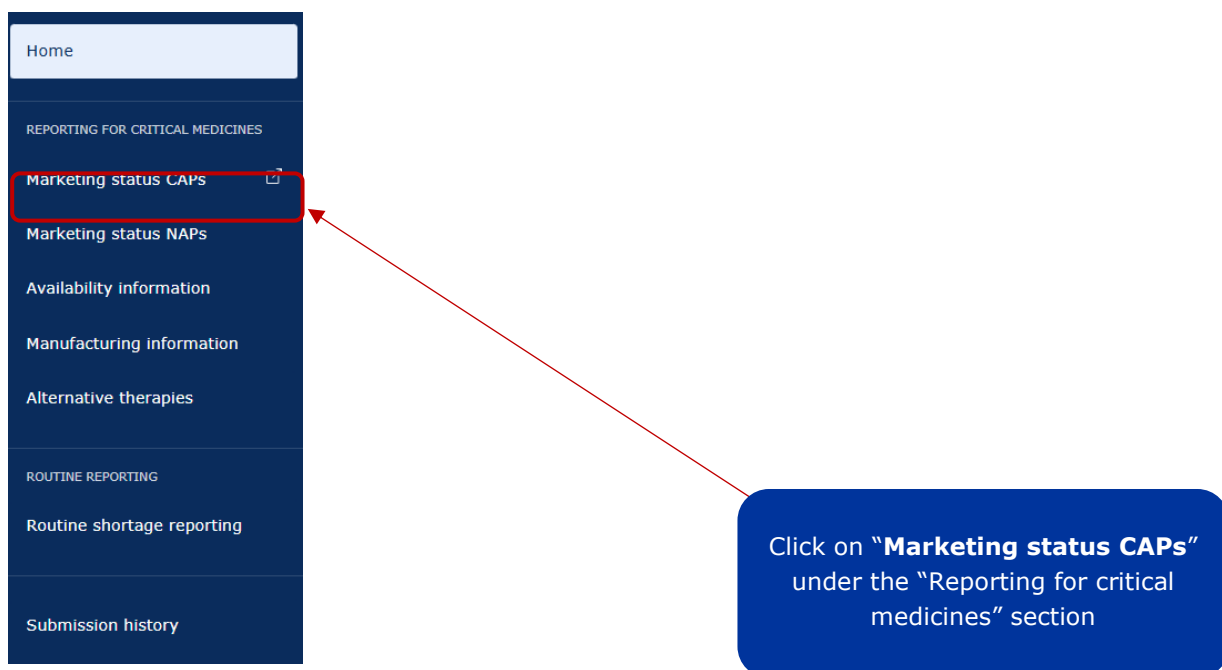
The  symbol means that you will be re-directed to the relevant page of the IRIS platform (outside the ESMP). Consult chapter 6 of the [IRIS guide for applicants](#)²³ for more information on the Marketing Status submission procedure in IRIS, and the relevant sections of the [EMA's website: Notifying a change of marketing status](#)²⁴. For more information how to acquire IRIS user roles, consult chapter 5 of the [IRIS guide to Registration and RPIs](#)²⁵.

Figure 34: Left-side navigation menu – Marketing status CAPs button



4.3. How to submit the Marketing status for critical medicines (NAPs)

Data on the marketing status of nationally authorised products (NAPs; including products authorised through 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 are 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.

Step-by-step process

4.3.1. Part 1: Download template

Step 1

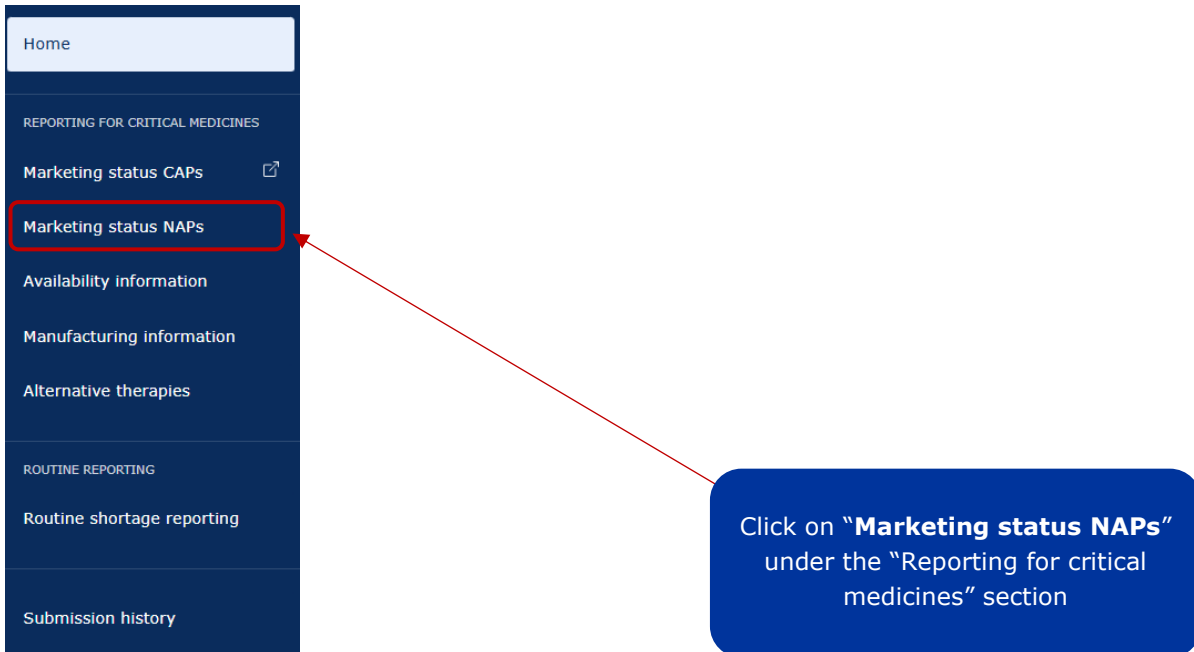
In the home page, under the “Reporting for critical medicines” section of the left-side navigation menu, click on “**Marketing status NAPs**”.

²³ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants_en.pdf

²⁴ <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/notifying-change-marketing-status>

²⁵ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-and-rpis_en.pdf

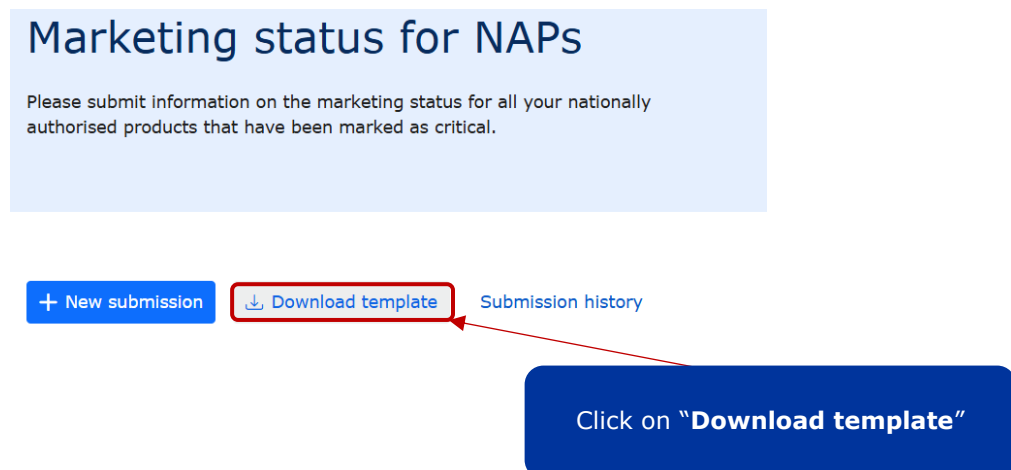
Figure 35: Left-side navigation menu – Marketing status NAPs button



Step 2

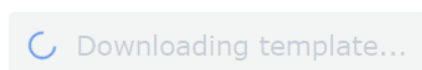
On the "Marketing status NAPs" page you can choose between three different options: "New submission", "Download template", and "Submission history". To access the template needed for submission, click on "Download template".

Figure 36: Marketing status NAPs - Download template



While the download is being processed, the button will show a spinner and the 'Downloading template...' information. Once the download is finished, the button goes to its initial state.

Figure 37: Marketing status NAPs – Downloading template

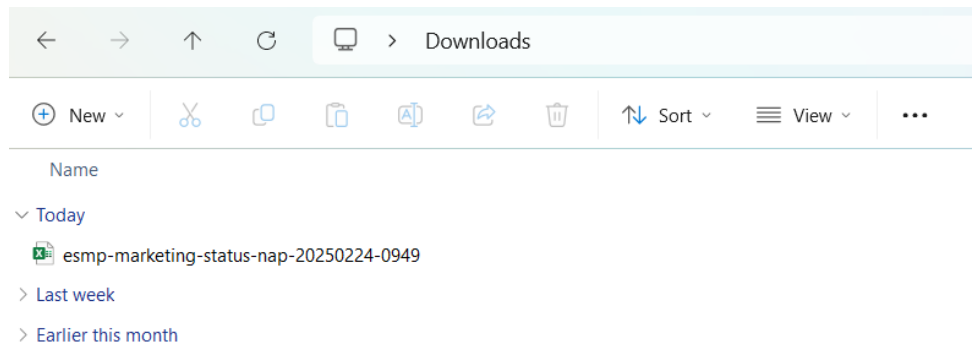


Step 3

Open the folder on your computer where the downloaded files are stored. You will find an Excel file with the name “**esmp-marketing-status-nap-<timestamp>.xlsx**”. The template will include one column for each data element, as described in table 2.

If applicable, this template will include NAP marketing status data previously submitted to EMA through ESMP.

Figure 38: Find the downloaded template in the Downloads folder of your computer



4.3.2. Part 2: How to work on the downloaded template

File conventions

Remember that only data in the first worksheet will be processed, therefore do not create other worksheets in the Excel file. The order of columns contained in the template must not be modified and no additional columns must be added. Make sure that the file extension remains “.xlsx”. The file name can be modified as preferred by the user, the system will recognise and process the Excel document even with a different name.

How to complete the data fields in the template

The required sections of the template must be completed before uploading the file. Make sure to respect the validation rules of every data element. Each data element and the details on how the relevant information needs to be inserted is described in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)²⁶. Please consult this guide for further details to ensure the data will be correctly uploaded in the ESMP.


Table 2, which you can find below, provides an overview of all data elements reported in the columns of the template for the submission to the ESMP. All mandatory elements must be provided to successfully upload the file. For the “Marketing status” field you are required to fill in RMS identifiers (RMS IDs²⁷). You can copy and paste RMS IDs (either numerical 12-digit values or the readable IDs) from the Marketing status list, contained in the “Annex 1 – RMS lists and terms”, that can be found in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)²⁸.

²⁶ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

²⁷ RMS provides referentials lists and terms. RMS supports the continuous exchange of data between information systems across the European medicines regulatory network and the pharmaceutical industry. ESMP uses RMS lists and IDs to ensure correct data submission, please refer to the [ESMP Implementation Guide for Marketing Authorisation Holders](#), Annex 1 – RMS list and terms, to consult possible values and correspondent terms. For further information about RMS please consult additional resources as [Referentials Management Service \(RMS\) | European Medicines Agency \(EMA\)](#) and [RMS Web UI](#).


²⁸ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf


The “**Product information**” fields will be pre-populated by the system in the template, transferring product data already stored in the EMA’s Product Management Service (PMS). For more information about the product information contained within PMS, please consult the [PMS Implementation of International Organization for Standardization \(ISO\) standards for the identification of medicinal products \(IDMP\) in Europe](#)²⁹.

 You should not make changes to the product information fields, because the product information changed via the ESMP will not be transferred into PMS. The pre-populated fields are listed in Table 2 for clarity and completeness.

Important:

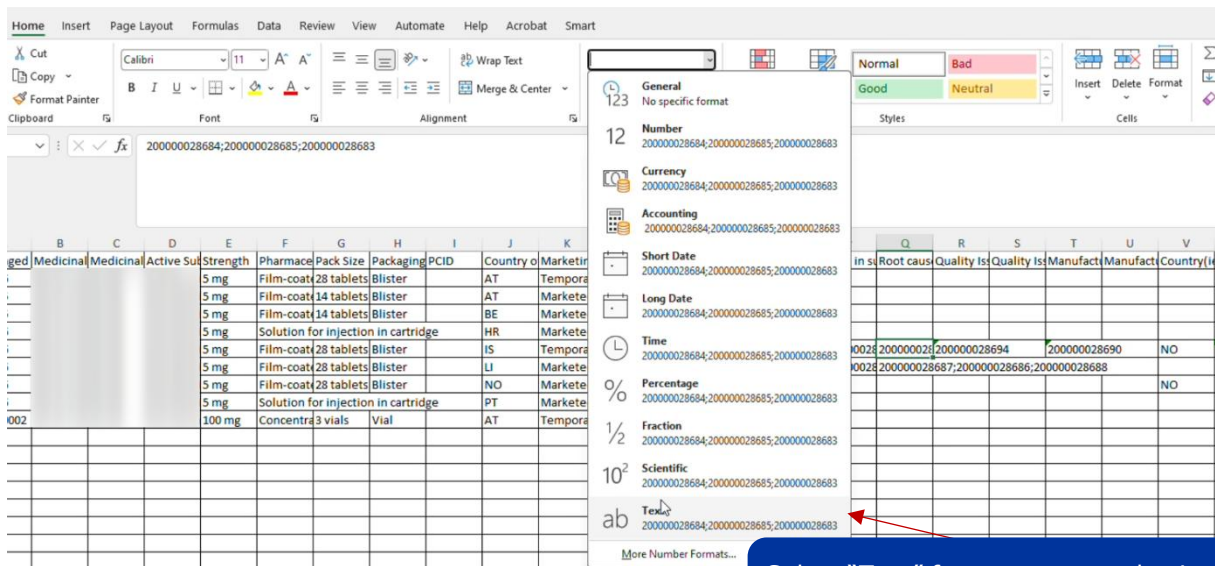
- Make sure **to insert the information at the level of packaged medicinal product**.

 When pasting numerical RMS identifiers (which are 12-digit IDs that codify data used to insert information in the system) into a cell, the value might be displayed as: “2E+11”. This is due to the Excel default settings. If the right numerical RMS identifier has been added into the cell, the displayed “2E+11” should not constitute an issue. Nevertheless, you may change the cell format into “Text”, as shown in figure 39 below, to show the full numerical RMS identifiers.

 When inserting **date information**, always remember to respect the DD/MM/YYYY format. Due to Excel default settings, it might happen that the cell format could change into Long date or Short date, generating a format error in the submission phase. To avoid this error, it is possible to insert an “ ’ ” (apostrophe) just before the date (i.e. ‘12/05/2025), this will overcome any format constraint generated in Excel.

As a good practice, select all the cells of the Excel file and change the format into “Text”, to avoid any errors as the two just described.

Figure 39: How to change the cell format in the reporting template



Select "Text" format to correctly view numerical RMS identifiers

Table 2. Crisis: Marketing status NAPs data elements

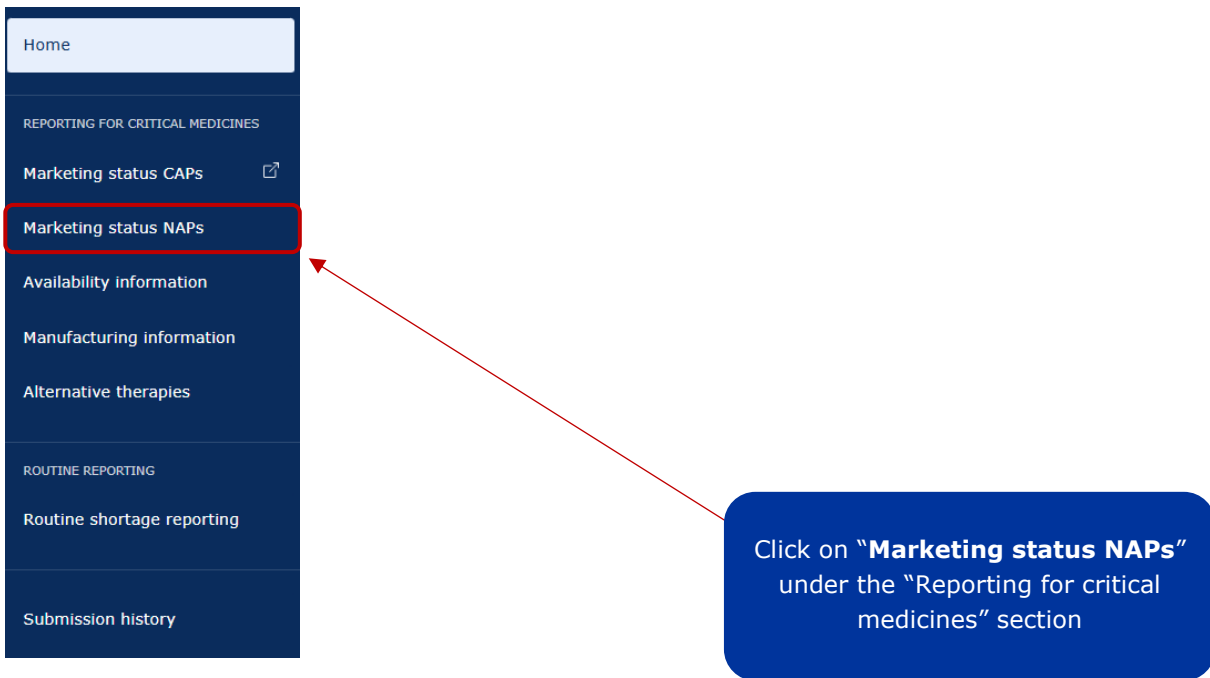
Data category	Data element name	Conformance
Product information	Package PMS ID	Pre-populated
	Full product name	Pre-populated
	Short product name	Pre-populated
	Active substance	Pre-populated
	Strength	Pre-populated
	Pharmaceutical form	Pre-populated
	Pack size	Pre-populated
	Package description	Pre-populated
	PCID	Pre-populated
Marketing status details	Country of authorisation	Pre-populated
	Marketing status	Mandatory
	Date of planned permanent withdrawal	Conditional
	Planned withdrawal comment	Conditional

4.3.3. Part 3: Upload of the data into ESMP

Step 1

Under the "Reporting for critical medicines" section of the left-side navigation, click on "**Marketing status NAPs**".

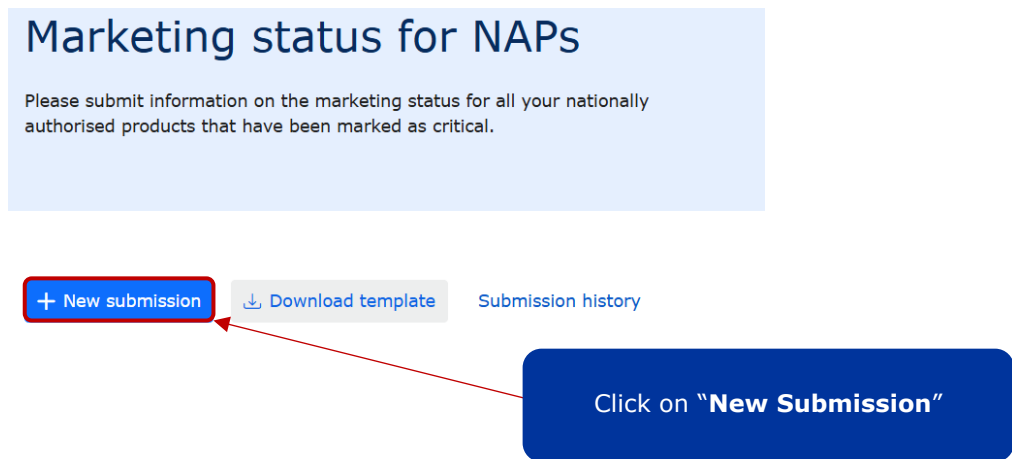
Figure 40: Left-side navigation menu – Marketing status NAPs button



Step 2

On the "Marketing status NAPs" page you can find three different buttons: "New submission", "Download template", and "Submission history". In this step you are requested to click on "New Submission". A page called "Submit data" will open.

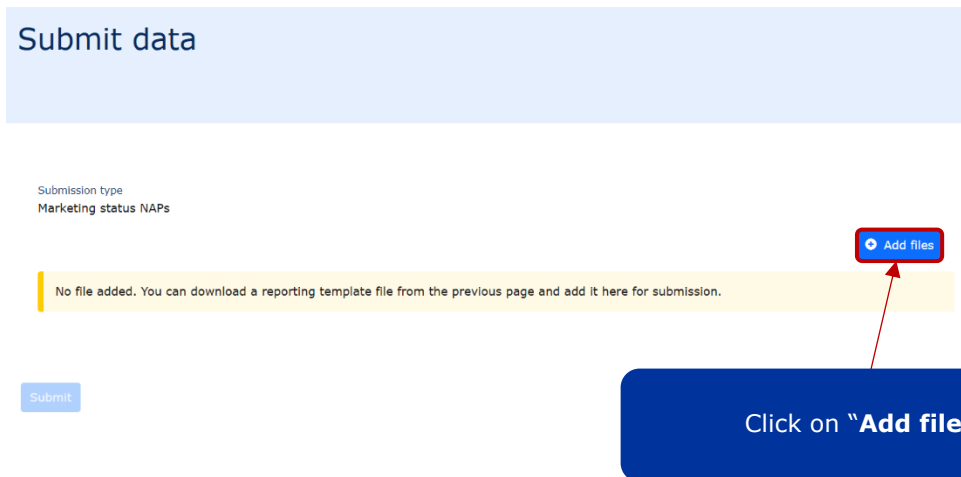
Figure 41: Marketing status for NAPs – Submit data



Step 3

Click on "Add files" on the right side of the page called "Submit data". This will open a dialogue box allowing you to upload a file into the ESMP.

Figure 42: Submit data – Add file



Step 4

Click on **“Choose files”**, making sure the option for **“Overwrite existing files”** is selected. This will open a dialogue window on your computer. From there, locate the file you want to submit in the folder on your computer where you saved it.


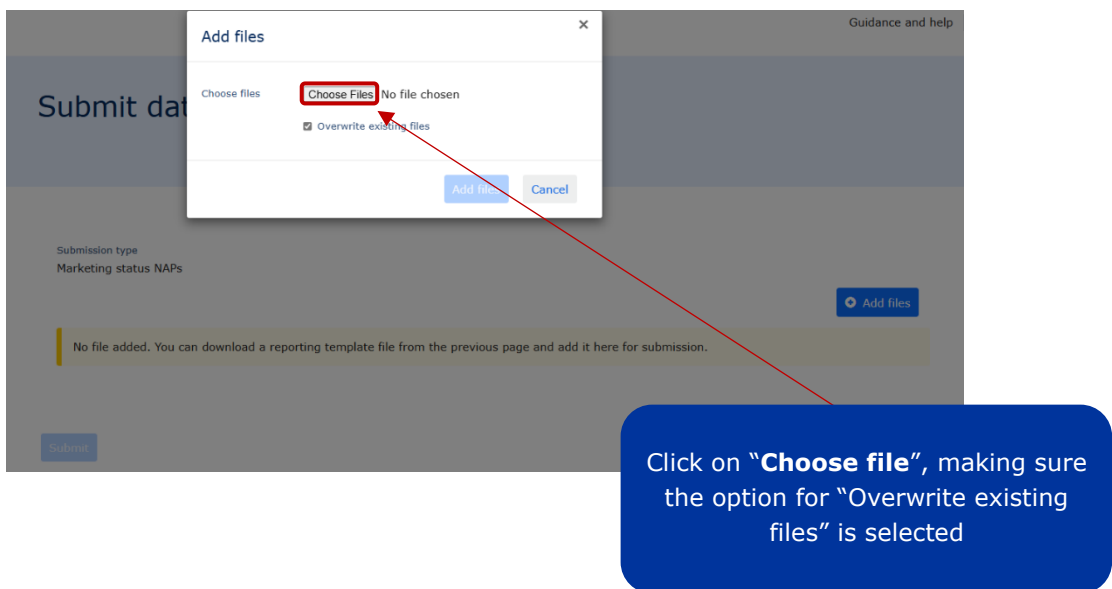
 The system only accepts the selection of one file at a time for submission. In case you select multiple files for submission, after clicking on **“Add files”**, the error message **“Only one file can be uploaded for a submission.”** will be displayed. Therefore, please select only one file.

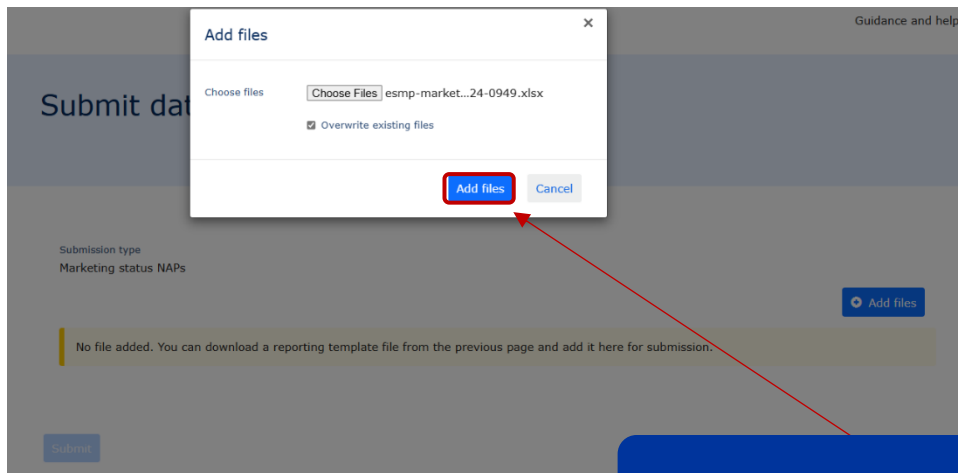
Figure 43: Submit data – Dialogue box, Choose file, Overwrite existing files



Step 5

Once you have selected a file, the name of the file will be shown next to the **“Choose Files”** button. Click on **“Add files”** to add this file to the upload page.

Figure 44: Submit data – Dialogue box – Add file



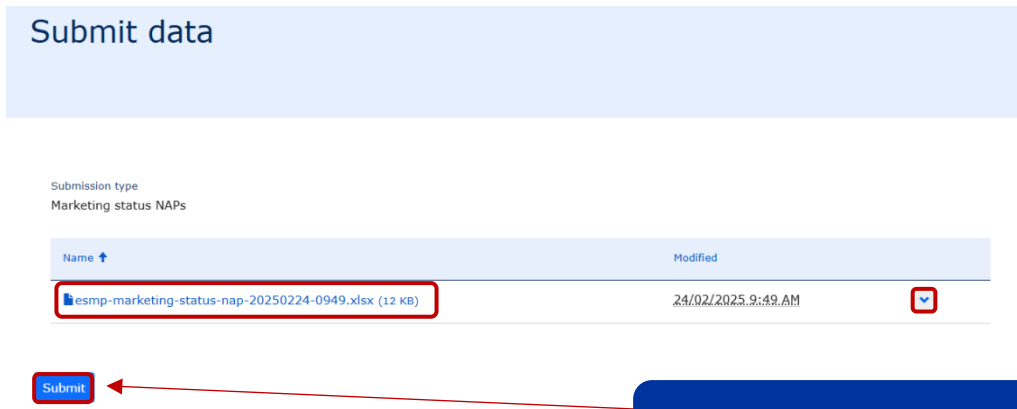
Click on "Add files"

Step 6

The file you added will be listed in the table, as shown in figure 45 below. If it is the correct file, click on "Submit". This will start the validation process of the file.

If it is not the correct file, click on the arrow on the right side of the screen and delete the selected file, then restart the upload process from step 1.

Figure 45: Submit data – Submit



Click on "Submit"

Step 7

Validation of the submitted file may take some time. Feel free to close the page or move to another page while the file is being processed, since the submission will proceed in the background. To retrieve the details of the current submission or any past submission, consult the "Submission history" page.

A page called "Submission status" will open, showing a summary of the upload details: submission type, upload date and time, submission ID, the file name, the status and the error messages, if any.


 The outcome of a submission on the "Submission status" page may require some time to be displayed, depending on the number of fields in the submitted file. You may leave the "Submission status" page at any time. The processing of the submitted file will continue on the background. You may return to the "Submission status" page via the "Submission history" page. If your upload is successful, the "Upload status" will display "Success" (figure 46). Your upload is therefore successfully completed, and your submission is final.

Figure 46: Marketing status for NAPs – Submission status – Submission summary - Success

Home > Submission history > Submission status

Submission status

✔ **Success**
Your file was successfully submitted.

Submission type	Upload date and time	Submission ID
Marketing status NAPs	24/02/2025 1:41 PM	EMA/SH/0000005954
Status	File name	
Success	esmp-marketing-status-nap-20250224-0949.xl	

If your upload fails, the **“Upload status”** will show **“Failed”**. If this happens, please review the list of validation results at the bottom of the page. The validation results’ section lists errors encountered in the file, along with their location in the file (row number and column letter, or a dot where the error applies to the whole row or column; for example, “.2” means that the error refers to the whole row, “..” means that the error refers to the whole file), and an error message detailing what caused the error. Make sure you scroll through the entire validation results’ section to view all errors.

You may also click on **“Download validation results”** to download an Excel file listing all the errors.

Figure 47: Marketing status for NAPs – Submission status – Submission summary - Fail

Home > Submission history > Submission status

Submission status

❌ **Failed**
Some fields in the submitted file require your attention
Please review the validation results below.

Submission type	Upload date and time	Submission ID
Marketing status NAPs	13/02/2025 9:04 PM	EMA/SH/0000005849
Status	File name	
Failed	esmp-marketing-status-nap-20250213-2101.xl	

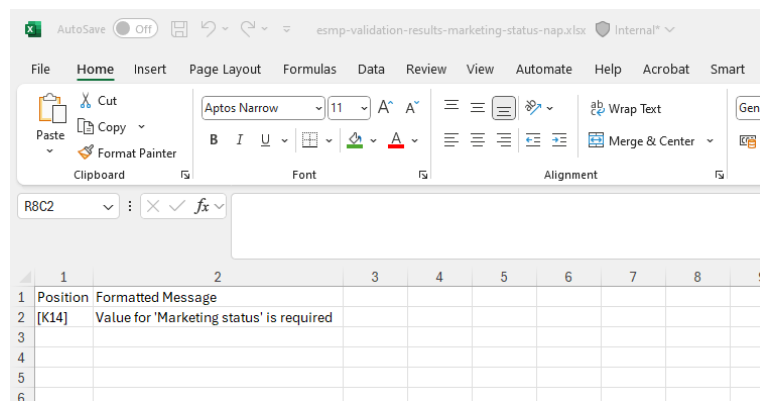
Validation results

[Download validation results](#)

Cell position ↑	Message ↑
[K14]	Value for 'Marketing status' is required

Click on **“Download validation results”** to download an Excel file showing all the errors

Figure 48: Validation results – Excel file view



Open the “**esmp-validation-results-marketing-status-nap**” Excel file to view the details of the reported errors. For further information on the listed errors and validation rules that may prevent you from successfully completing your submission, consult the requirements for each data set and data element as described in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)³⁰. Re-open the submission file that you wish to upload from your computer and address each of the described errors in the “**esmp-validation-results-marketing-status-nap**” file. Save your changes and repeat the upload process with the amended file.


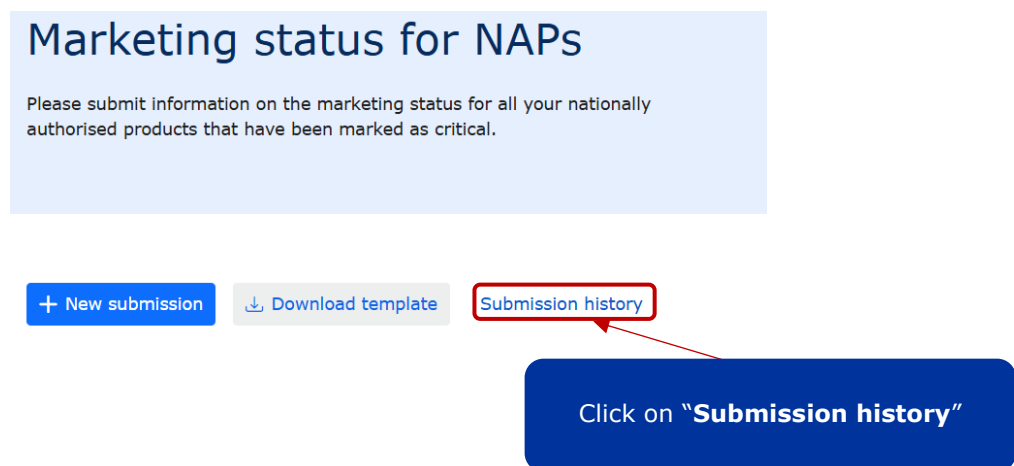
 All upload summary details from all previous submissions, whether successful or failed, are recorded and can be viewed within the ESMP on the “Submission history” section. To access it, click on the “**Submission history**” button on the left-side navigation menu, or access it from the “**Marketing status for NAPs**” page.

Figure 49: Marketing status for NAPs – Submission history



On the “**Submission history**” page you can review all your past submissions, including details such as submission ID, type, submission status (e.g., success or failed), the date of submission and details about who performed the submission.

It is possible to filter the recordings by “**Type**” and “**Submission status**” using the filters on the left side of the screen.

Figure 50: Marketing status for NAPs – Submission history page

³⁰ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

Submission history

Submission type
▼

Submission status
▼

Apply

Submission ID	Type	Submission status	Submitted on ↓
EMA/SH/0000005925	Marketing status NAPs	Success	18/02/2025 11:08 AM
EMA/SH/0000005901	Availability information	Success	17/02/2025 1:16 PM
EMA/SH/0000005849	Marketing status NAPs	Failed	13/02/2025 9:04 PM
EMA/SH/0000005848	Marketing status NAPs	Failed	
EMA/SH/0000005847	Marketing status NAPs	Failed	
EMA/SH/0000005783	Marketing status NAPs	Failed	

Click on the **“Submission ID”** to consult the upload details of a particular submission

For more information about a particular submission, click on its **“Submission ID”**. The **“Submission status”** page for the selected submission will open, as shown in figure 51. Here, you will find information about the submission type, the end date/time of the upload, the submission ID, the file name, the upload status and the validation results (if applicable).

Figure 51: Marketing status for NAPs – Submission history – Submission status

Home > Submission history > Submission status

Submission status

Failed

Some fields in the submitted file require your attention
Please review the validation results below.

Submission type	Upload date and time	Submission ID
Marketing status NAPs	13/02/2025 9:02 PM	EMA/SH/0000005848
Status	File name	
Failed	esmp-marketing-status-nap-20250213-2101.xl	

4.4. How to submit Availability information

During a crisis or upon request of the MSSG, MAHs are required to report Availability information (including shortage data, sales volume and forecasts) for medicinal products in scope of reporting requirements – either included in the list of critical medicines for a specific public health emergency or major event or included in a list of medicines to be monitored for MSSG-led preparedness, respectively.

To report Availability information, you are requested to access the “**Availability information**” section on the left-side navigation menu and proceed with the submission of data.

The submission of data is performed by downloading a template from the “Availability information” section – pre-populated with the products in scope of the crisis or the MSSG-led preparedness action and with previously submitted data (if any), inserting the required data for each medicinal product in scope of reporting, and uploading the file directly in the ESMP, following a successful validation.

Please find below the step-by-step process to carry out the submission of Availability information through the ESMP.

The frequency of data submission is determined by the MSSG for each particular crisis or MSSG-led preparedness action and will be communicated before the reporting requirements take effect.

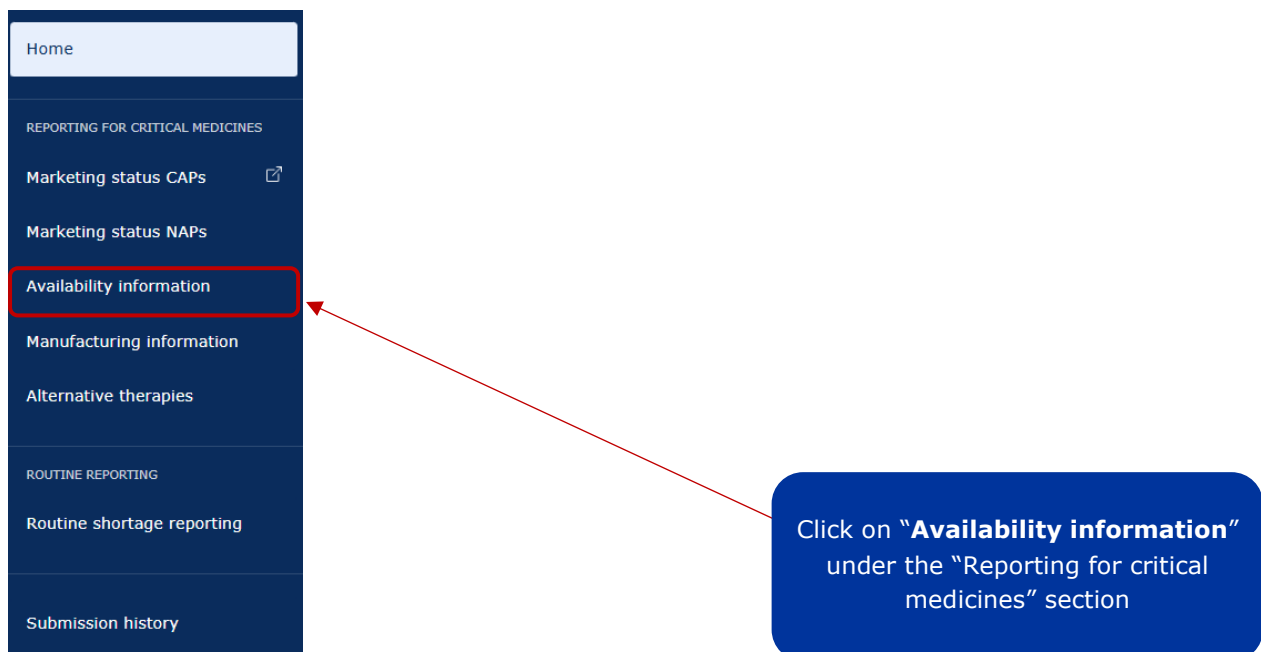
Step-by-step process

4.4.1. Part 1: Download template

Step 1

In the home page, on the left-side navigation menu, click on “**Availability information**” under the “Reporting for critical medicines” section.

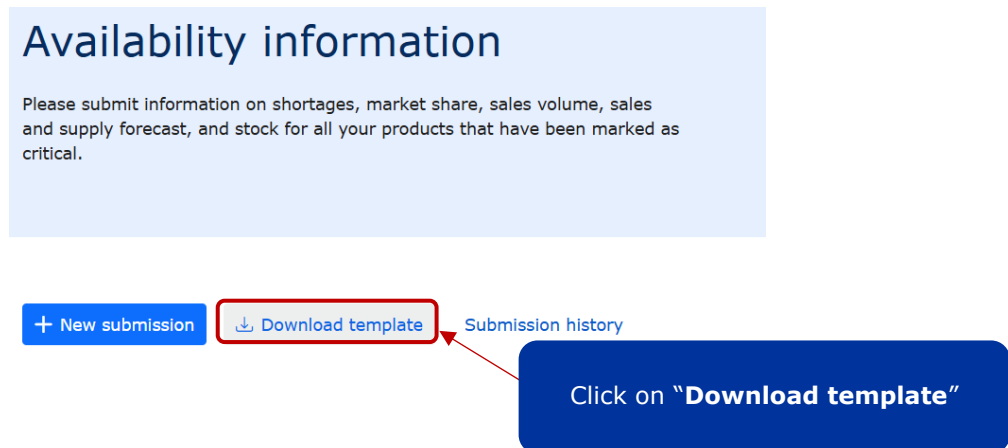
Figure 52: Left-side navigation menu – Availability information button



Step 2

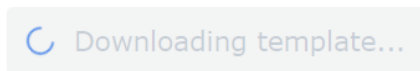
On the “**Availability information**” page you can choose between three different options: “New submission”, “Download template”, and “Submission history”. To access the template needed for data submission, click on “**Download template**”.

Figure 53: Availability information – Download template



While the download is being processed, the button will show a spinner and the “**Downloading template...**” information, as shown in figure 54. Once the download is finished, the button goes to its initial state.

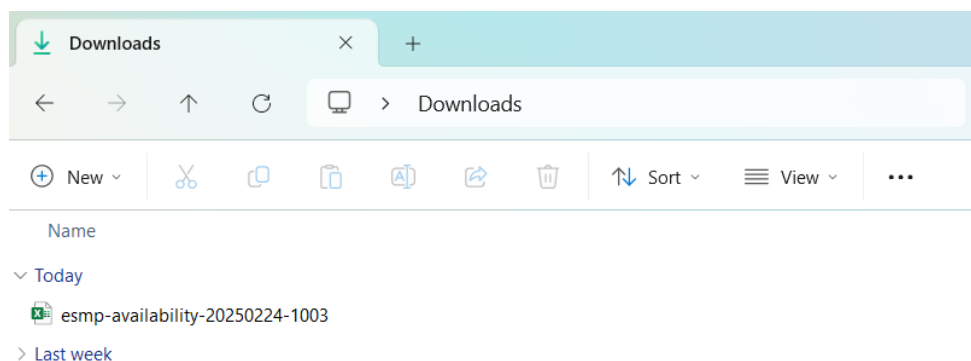
Figure 54: Availability information – Downloading template



Step 3

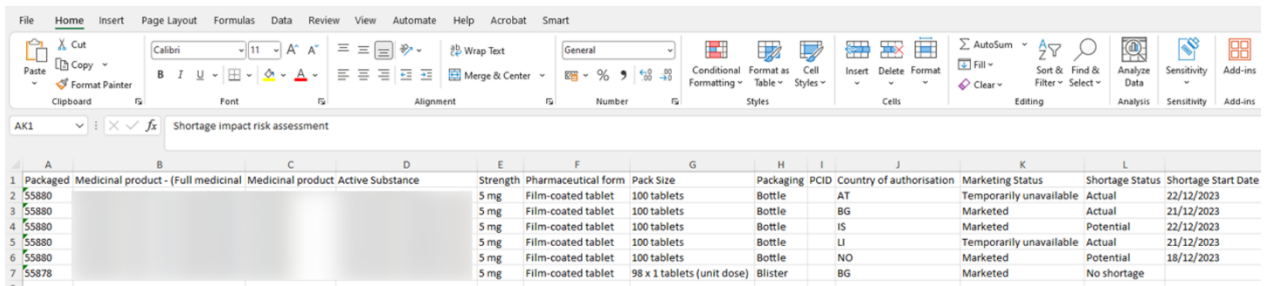
Open the folder on your computer where the downloaded files are stored. You will find an Excel file with the name “**esmp-availability-<timestamp>.xlsx**” (figure 55). The template will include one column for each data element, as described in table 3.

Figure 55: Find the downloaded template in the Downloads folder of your computer



If applicable, this template will include relevant data previously submitted to EMA through IRIS (for marketing status of CAPs) and/or ESMP (figure 56).

Figure 56: Example of a populated downloaded template



A	B	C	D	E	F	G	H	I	J	K	L	M	
1	Packaged	Medicinal product - (Full medicinal	Medicinal product	Active Substance	Strength	Pharmaceutical form	Pack Size	Packaging	PCID	Country of authorisation	Marketing Status	Shortage Status	Shortage Start Date
2	5880				5 mg	Film-coated tablet	100 tablets	Bottle		AT	Temporarily unavailable	Actual	22/12/2023
3	5880				5 mg	Film-coated tablet	100 tablets	Bottle		BG	Marketed	Actual	21/12/2023
4	5880				5 mg	Film-coated tablet	100 tablets	Bottle		IS	Marketed	Potential	22/12/2023
5	5880				5 mg	Film-coated tablet	100 tablets	Bottle		LI	Temporarily unavailable	Actual	21/12/2023
6	5880				5 mg	Film-coated tablet	100 tablets	Bottle		NO	Marketed	Potential	18/12/2023
7	5878				5 mg	Film-coated tablet	98 x 1 tablets (unit dose)	Blister		BG	Marketed	No shortage	

⚠ Important! Through the [IRIS portal](https://iris.ema.europa.eu/myDraftSubmissions/)³¹ you will be able to create new submissions to change the marketing status of your CAP products. Please ensure that marketing status information of all your CAP products is inserted correctly and is up to date, consulting the [View Marketing Status Report · IRIS](https://iris.ema.europa.eu/ViewMarketingStatusReport) webpage³², because marketing status data affects the possibility of reporting the required information in the ESMP. If the information on the marketing status of CAPs is not populated or not up to date in IRIS, please perform the necessary changes in IRIS, after which the information will be reflected in the ESMP within approximately 5-15 minutes. You will be able to submit all relevant information required for Availability information reporting only for products that have the marketing status “Marketed” or “Temporarily Unavailable” in a particular country. The information on the marketing status for NAPs, for product in scope of crisis or MSSG-led preparedness reporting, is done in the ESMP via the dedicated “Marketing status for NAPs” data submission flow. It is important to note that you will not be able to submit information required in the ESMP for products in countries where in IRIS (for CAPs) and in ESMP (for NAPs) the products are stated to be “Not marketed” or “Never marketed” and entries for those particular product and country combinations will not be pre-populated in the data submission templates for Availability information downloaded from the ESMP.

³¹ <https://iris.ema.europa.eu/myDraftSubmissions/>

³² <https://iris.ema.europa.eu/SignIn?ReturnUrl=%2Fviewmarketingstatusreport%2F>

4.4.2. Part 2: How to work on the downloaded template

File conventions


Note that only data in the first worksheet will be processed, therefore do not create other worksheets in the Excel file. The order of columns contained in the template must not be modified and no additional column must be added. Make sure that the file extension remains “.xlsx”. The file name can be modified as preferred by the user, the system will recognise and process the Excel document even with a different name.

How to complete the data fields in the template

The required sections of the template must be completed before uploading the file. Make sure to respect the validation rules of every data element. Each data element and the details on how the relevant information needs to be inserted is described in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)³³. Please consult this guide for further details to ensure the data will be correctly uploaded in the ESMP.


Table 3, which you can find below, provides an overview of all data elements reported in the columns of the template for the submission to the ESMP. All mandatory elements must be provided to successfully upload the file. For some fields, you are required to fill in RMS identifiers (RMS IDs). You can copy and paste RMS IDs from the relevant lists, contained in the “Annex 1 – RMS lists and terms”, that can be found in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)³³.


The “**Product information**” (columns A to K) **fields will be pre-populated** by the system in the template, transferring product data already stored in the EMA’s Product Management Service (PMS), as well as marketing status data for CAPs from IRIS, into ESMP. If you want to find out more about the product information contained within PMS, please consult the [PMS Implementation of International Organization for Standardization \(ISO\) standards for the identification of medicinal products \(IDMP\) in Europe](#)³⁴.

 You should not make changes to the product information fields, because the product information changed via the ESMP will not be transferred into PMS. The pre-populated fields are listed in table 3 for clarity and completeness.

Important:

- Make sure to **insert the information at the level of packaged medicinal product**.
- Where applicable, make sure to separate multiple values in one field with a semicolon, such as when entering multiple root causes of a shortage (entered either as numerical RMS IDs - e.g. “200000028689;200000028700” or readable IDs – e.g. “ManufProdRel;UnexIncDemCoStock”) or multiple countries affected (CN;CO).

 When pasting numerical RMS identifiers (which are 12-digit IDs that codify data used to insert information in the system), into a cell, the value might be displayed as: “2E+11”. This is due to the Excel default settings. If the right numerical RMS identifier has been added into the cell, the displayed “2E+11” should not constitute an issue. Nevertheless, you may want to change the cell format into “Text”, as shown in figure 57 below, to show the numerical RMS identifiers.

 When inserting **date information**, always remember to respect the DD/MM/YYYY format. Due to Excel default settings, it might happen that the cell format could change into Long date or Short date, generating a format error in the submission phase. To avoid this error, it is possible to insert an “ ’ ”

³³ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

³⁴ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-2_en.pdf

(apostrophe) just before the date (i.e. `12/05/2025), this will overcome any format constraint generated in Excel.

It would be a good practice to select all the cells of the Excel file and change the format into "Text", to avoid any errors as the two just described.

Figure 57: How to change the cell format in the reporting template

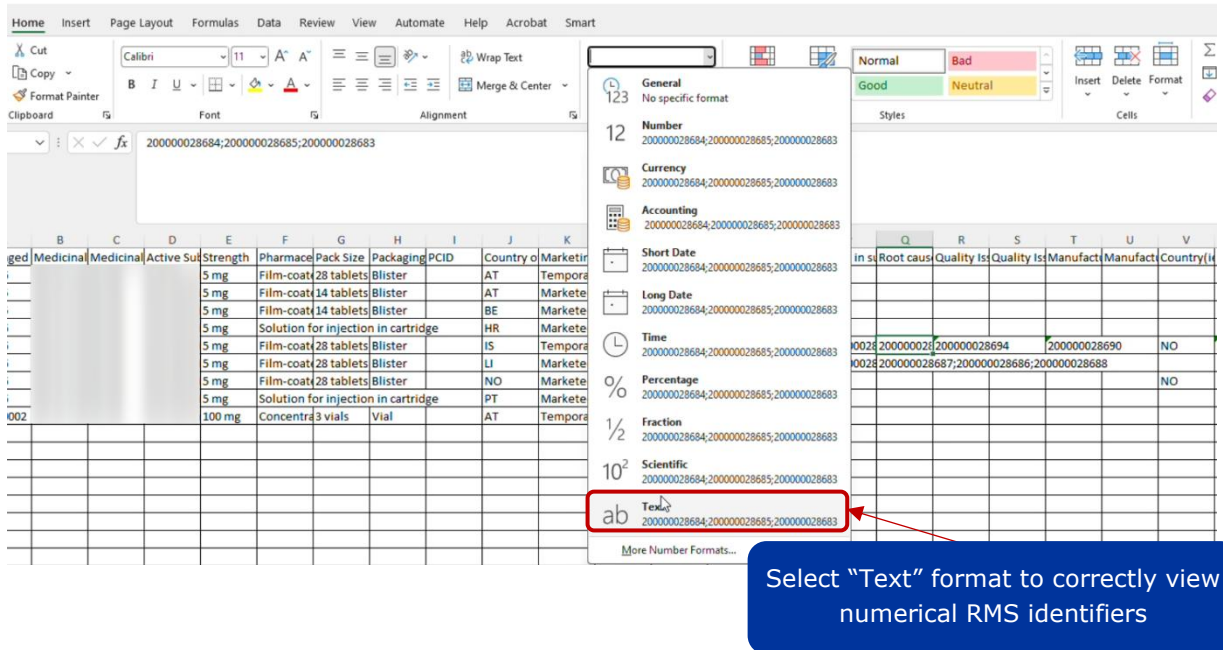


Table 3: Crisis – Availability information data elements

Data category	Data element name	Conformance
Product information	Package PMS ID	Pre-populated
	Full product name	Pre-populated
	Short product name	Pre-populated
	Active substance	Pre-populated
	Strength	Pre-populated
	Pharmaceutical form	Pre-populated
	Pack size	Pre-populated
	Package description	Pre-populated
	PCID	Pre-populated
	Country of authorisation	Pre-populated
Shortage information	Marketing status	Pre-populated
	Shortage status	Mandatory
	Shortage start date or expected start date	Conditional
	Shortage end date or expected end date	Conditional
	Point in supply chain at which disruption occurs	Conditional
Root cause of the shortage	Conditional	



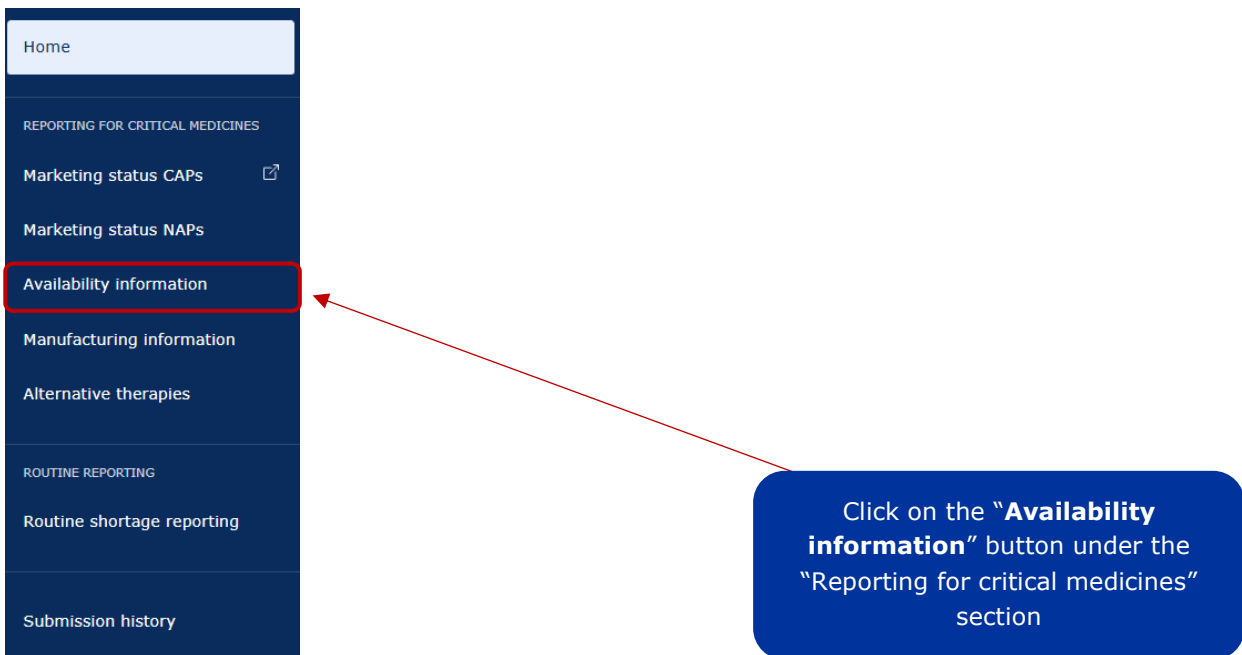
Data category	Data element name	Conformance
	Countries in which manufacturing issues occur	Conditional
	Countries in which increased demand occurs	Conditional
	Countries in which distribution issues occur	Conditional
	Root cause of the shortage - additional information	Optional
Shortage prevention and mitigation plans	Shortage prevention and mitigation plans	Conditional
	Mitigation & prevention plan – ongoing and planned steps	Optional
Market share	Market share	Optional
	Additional information on market share	Optional
Sales volume and forecast	Sales volume pre-PHE/ME	Mandatory
	Sales volume current	Mandatory
	Sales volume forecast - month 1	Mandatory
	Sales volume forecast - month 2	Mandatory
	Sales volume forecast - month 3	Mandatory
	Sales volume forecast - month 4	Mandatory
	Sales volume forecast - month 5	Mandatory
	Sales volume forecast - month 6	Mandatory
	Sales volume - additional information	Optional
Supply forecast and stock information	Supply forecast - month 1	Mandatory
	Supply forecast - month 2	Mandatory
	Supply forecast - month 3	Mandatory
	Supply forecast - month 4	Mandatory
	Supply forecast - month 5	Mandatory
	Supply forecast - month 6	Mandatory
	Supply forecast – additional information	Optional
	Available stocks	Mandatory
	Desired safety stock	Mandatory
Stocks – additional information	Optional	

4.4.3. Part 3: Upload of the data into ESMP

Step 1

On the left-side navigation menu click on the “**Availability information**” button under the “Reporting for critical medicines” section.

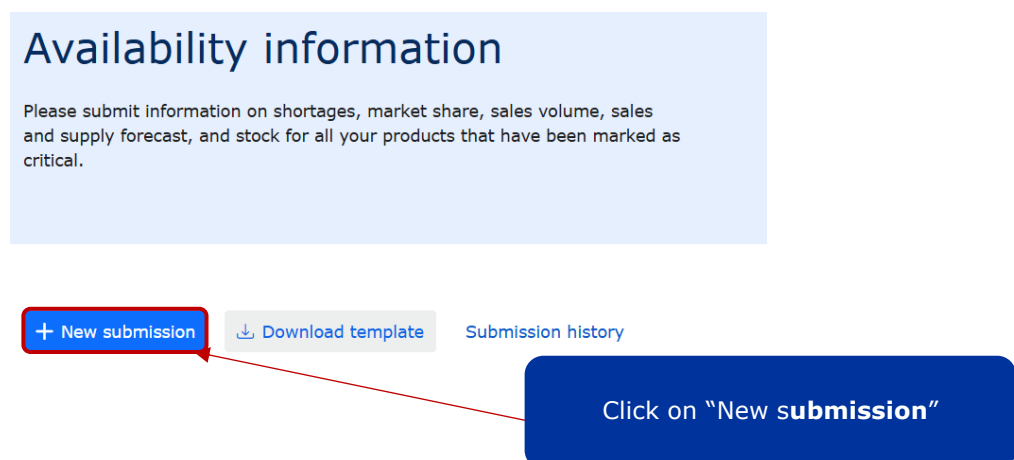
Figure 58: Left-side navigation menu – Availability information



Step 2

On the “**Availability information**” page you can find three different buttons “New Submission”, “Download template”, and “Submission history”. In this step, you are requested to click on “**New submission**”. A page called “**Submit data**” will open.

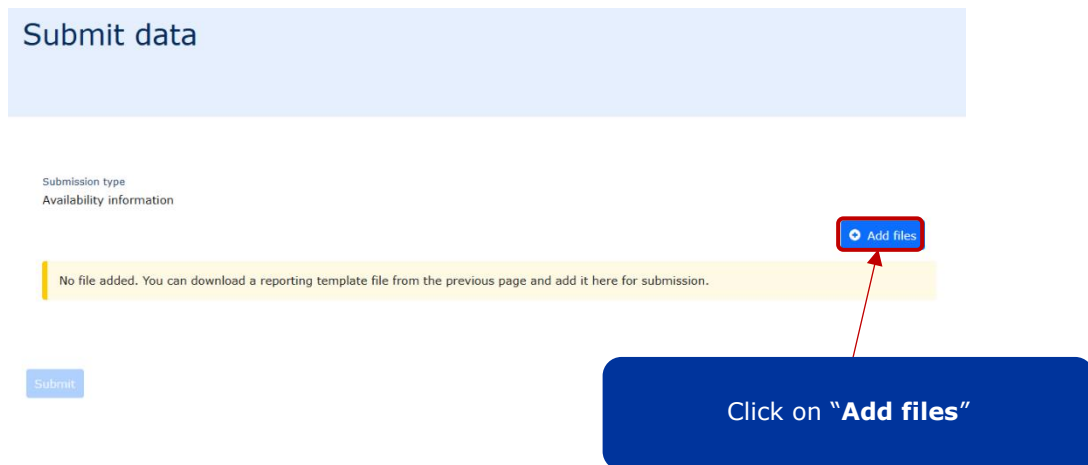
Figure 59: Availability information – New Submission



Step 3

Click on “**Add files**” in the page called “**Submit data**”. This will open a dialogue box allowing you to upload a file into the ESMP.

Figure 60: Submit data – Add file



Step 4

Click on "**Choose files**", making sure the option for "Overwrite existing files" is selected. This will open a dialogue window on your computer. From there, locate the file you want to submit in the folder on your computer where you saved it.


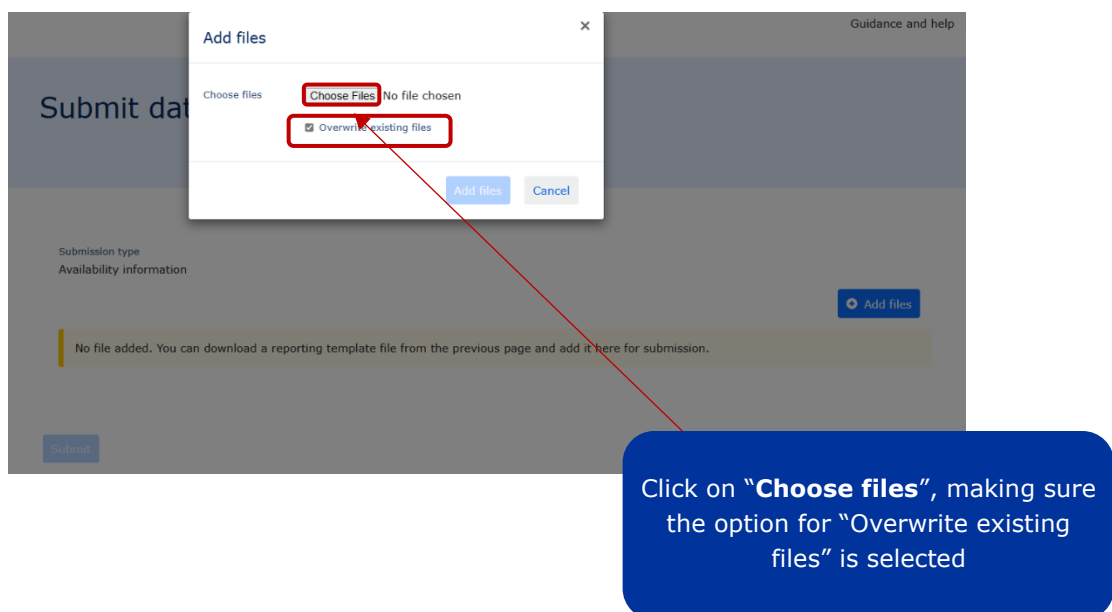
 The system only accepts the selection of one file at a time for submission. In case you select multiple files for submission, after clicking on "Add files", the error message "Only one file can be uploaded for a submission." will be displayed. Therefore, please select only one file at a time.

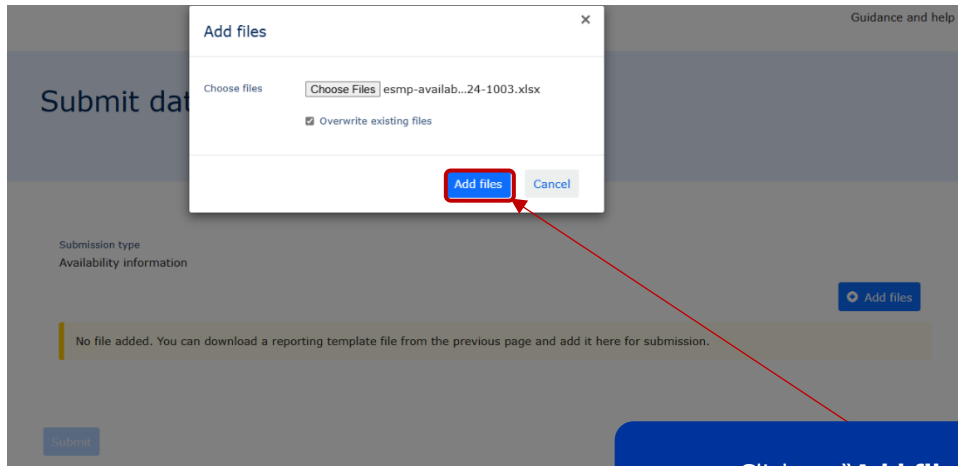
Figure 61: Submit data – Dialogue box – Choose file - Overwrite existing files



Step 5

Once you have selected a file, the name of the file will be shown next to the "Choose Files" button. Click on "**Add files**" to add this file to the upload page.

Figure 62: Submit data – Dialogue box – Add file



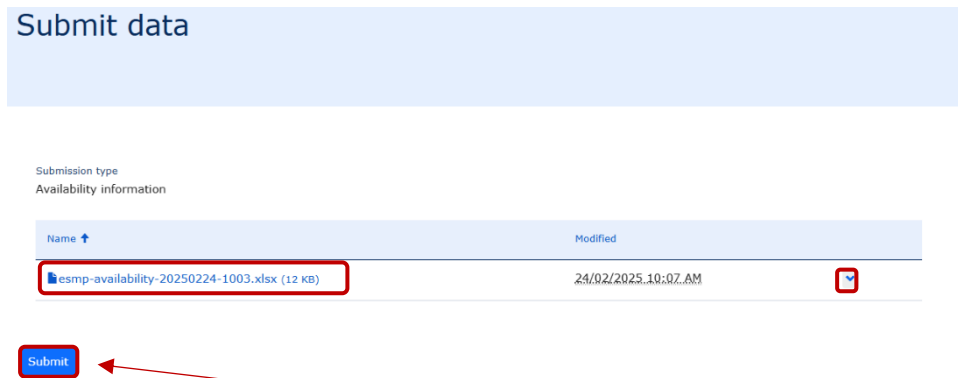
Click on "Add files"

Step 6

The file you added will be listed in the table, as show in figure 63 below. If it is the correct file, click on "Submit". This will start the validation process of the file.

If it is not the correct file, click on the arrow on the right side of the screen and delete the selected file, then restart the upload process from step 1.

Figure 63: Submit data– Submit




Click on "Submit"

Step 7

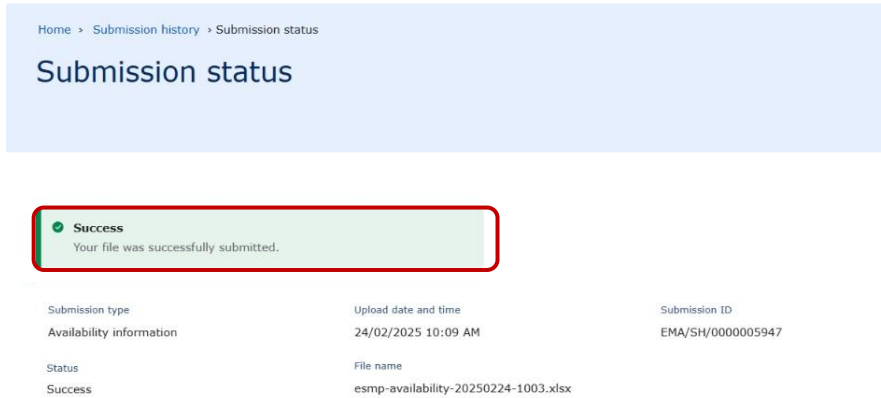
Validation of the submitted file may take some time. Feel free to close the page or move to another page while the file is being processed, since the submission will proceed in the background. To retrieve the details of the current submission or any past submission, consult the "Submission history" page.

A page called "Submission status" will open, showing a summary of the upload details: submission type, upload date and time, submission ID, the file name, the status and the error messages, if any.

 The outcome of a submission on the "Submission status" page may require some time to be displayed, depending on the number of fields in the submitted file. You may leave the "Submission status" page at any time. The processing of the submitted file will continue on the background. You may return to the "Submission status" page via the "Submission history" page.

If your upload is successful, the “**Upload status**” will display “**Success**” (figure 64). Your upload is therefore successfully completed, and your submission is final.

Figure 64: Availability information – Submission status – Submission summary - Success



Home > Submission history > Submission status

Submission status

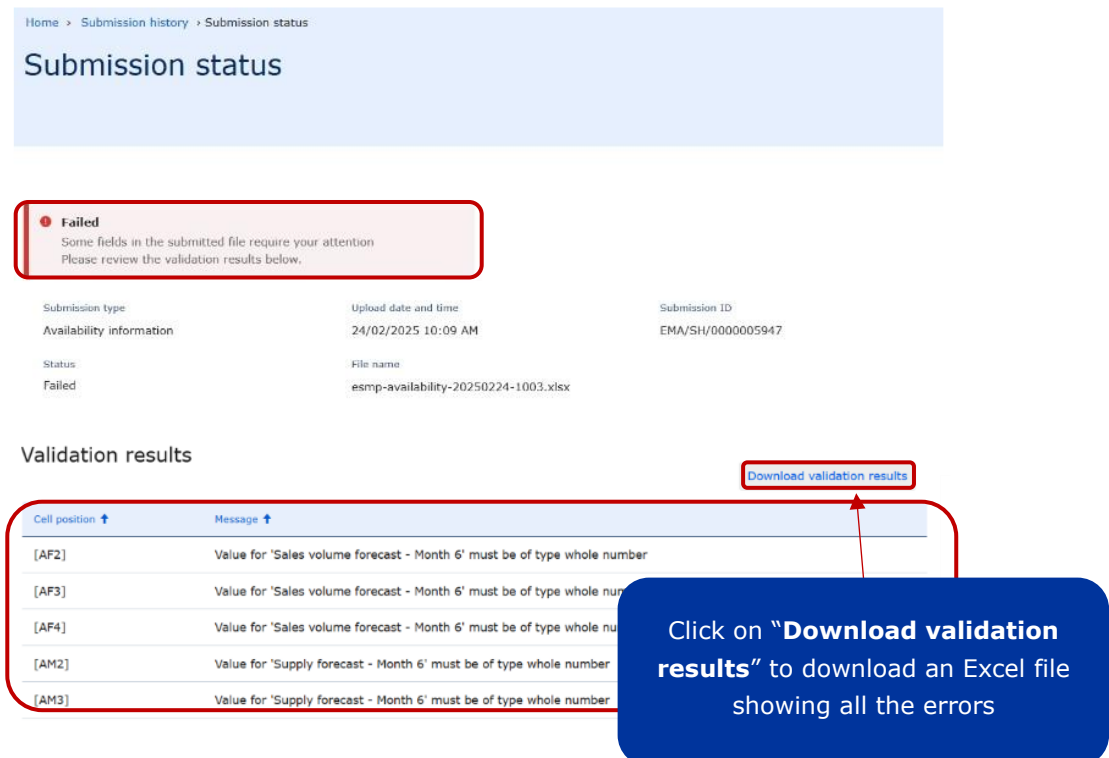
Success
Your file was successfully submitted.

Submission type	Upload date and time	Submission ID
Availability information	24/02/2025 10:09 AM	EMA/SH/0000005947
Status	File name	
Success	esmp-availability-20250224-1003.xlsx	

If your upload fails, the “**Upload status**” will show “**Failed**”. If this happens, please review the list of validation results on the bottom of the page. The validation results’ section lists errors encountered in the file, along with their location in the file (row number and column letter, or a dot where the error applies to the whole row or column; for example, “.2” means that the error refers to the whole row, “..” means that the error refers to the whole file), and an error message detailing what caused the error. Make sure you scroll through the entire validation results’ section to view all errors.

You may also click on “**Download validation results**” to download an Excel file listing all the errors.

Figure 65: Availability information – Submission status – Submission summary - Fail



Home > Submission history > Submission status

Submission status

Failed
Some fields in the submitted file require your attention
Please review the validation results below.

Submission type	Upload date and time	Submission ID
Availability information	24/02/2025 10:09 AM	EMA/SH/0000005947
Status	File name	
Failed	esmp-availability-20250224-1003.xlsx	

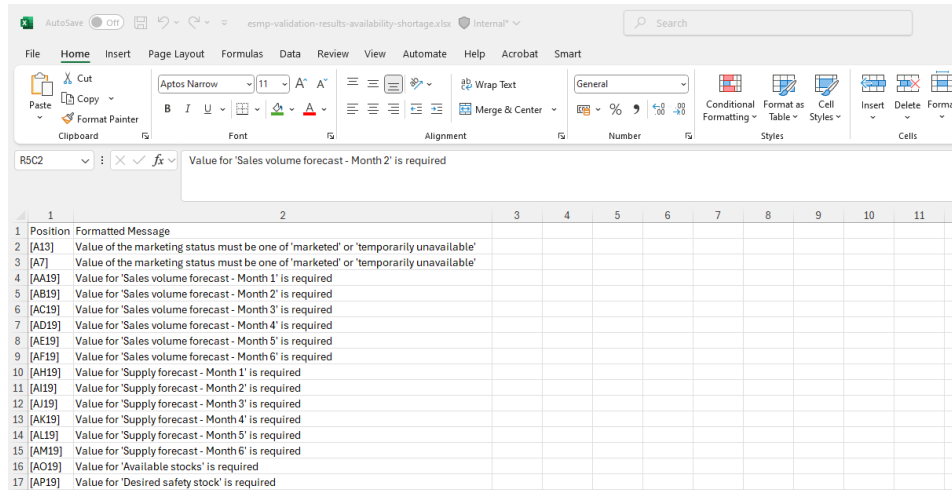
Validation results

[Download validation results](#)

Cell position ↑	Message ↑
[AF2]	Value for 'Sales volume forecast - Month 6' must be of type whole number
[AF3]	Value for 'Sales volume forecast - Month 6' must be of type whole number
[AF4]	Value for 'Sales volume forecast - Month 6' must be of type whole number
[AM2]	Value for 'Supply forecast - Month 6' must be of type whole number
[AM3]	Value for 'Supply forecast - Month 6' must be of type whole number

Click on “**Download validation results**” to download an Excel file showing all the errors

Figure 66: Validation results – Excel file view



Position	Formatted Message
[A13]	Value of the marketing status must be one of 'marketed' or 'temporarily unavailable'
[A7]	Value of the marketing status must be one of 'marketed' or 'temporarily unavailable'
[AA19]	Value for 'Sales volume forecast - Month 1' is required
[AB19]	Value for 'Sales volume forecast - Month 2' is required
[AC19]	Value for 'Sales volume forecast - Month 3' is required
[AD19]	Value for 'Sales volume forecast - Month 4' is required
[AE19]	Value for 'Sales volume forecast - Month 5' is required
[AF19]	Value for 'Sales volume forecast - Month 6' is required
[AH19]	Value for 'Supply forecast - Month 1' is required
[AJ19]	Value for 'Supply forecast - Month 2' is required
[AL19]	Value for 'Supply forecast - Month 3' is required
[AK19]	Value for 'Supply forecast - Month 4' is required
[AL19]	Value for 'Supply forecast - Month 5' is required
[AM19]	Value for 'Supply forecast - Month 6' is required
[AO19]	Value for 'Available stocks' is required
[AP19]	Value for 'Desired safety stock' is required

Open the **“esmp-validation-results-availability-shortage” Excel file** to view the details of the reported errors. For further information on the listed errors and validation rules that may prevent you from successfully completing your submission, consult the requirements for each data set and data element as described in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)³⁵. Re-open the submission file that you wish to upload from your computer and address each of the described errors in the **“esmp-validation-results-availability-shortage”** file. Save your changes and repeat the upload process with the amended file.


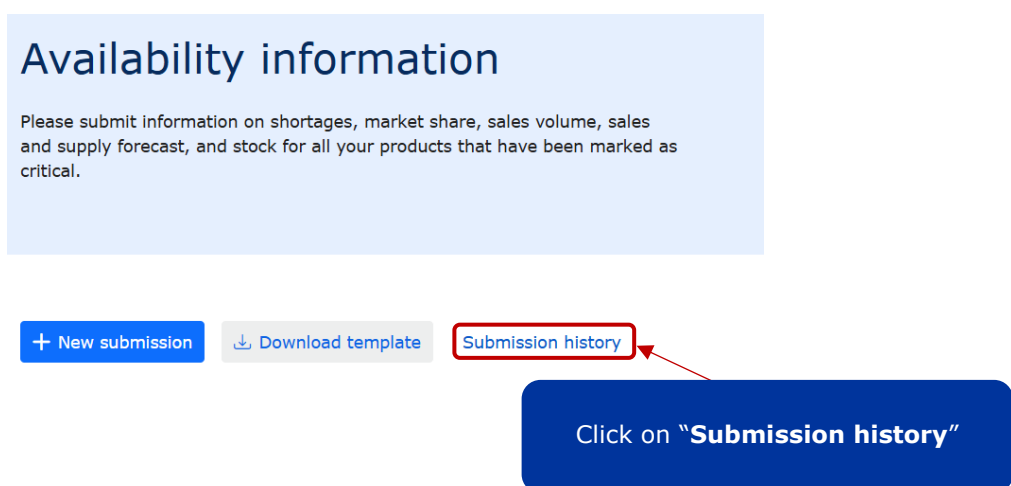
 All upload summary details from all previous submissions, whether successful or failed, are recorded and can be viewed within the ESMP on the “Submission history” section. To access it, click on the **“Submission history”** button on the left-side navigation menu, or access it from the **“Availability information”** page.

Figure 67: Availability information – Submission history

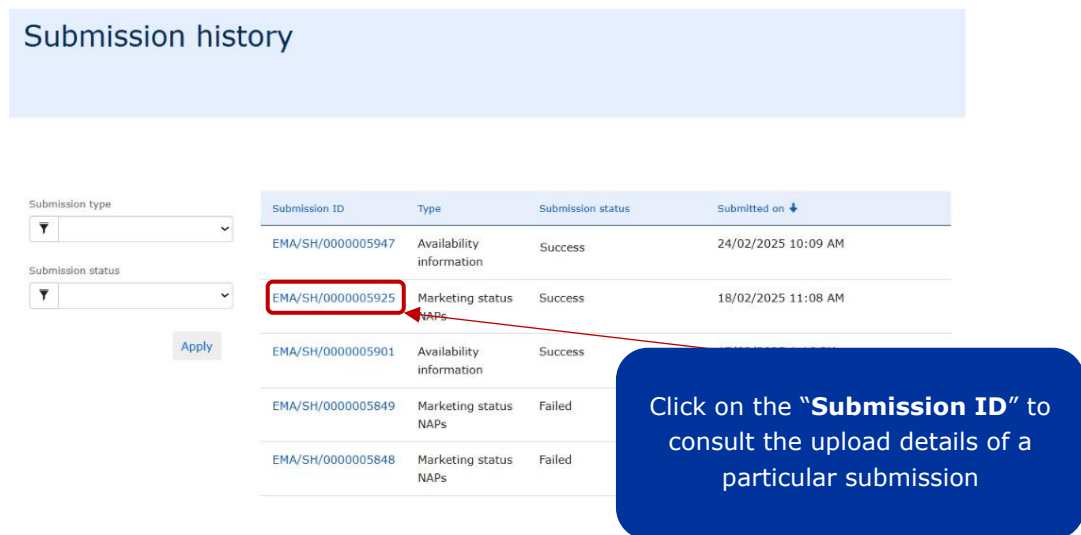


³⁵ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

The “**Submission history**” page provides you an overview of all your past submissions. On the summary table, each past submission is defined by a submission ID, a submission type, a submission status (i.e. success or failed), and an upload date/time.

It is possible to filter the recordings by “Type” and “Submission status” using the filters on the left side of the screen.

Figure 68: Availability information – Submission history page



Submission history

Submission type: [Dropdown]

Submission status: [Dropdown]

Apply

Submission ID	Type	Submission status	Submitted on ↓
EMA/SH/0000005947	Availability information	Success	24/02/2025 10:09 AM
EMA/SH/0000005925	Marketing status NAs	Success	18/02/2025 11:08 AM
EMA/SH/0000005901	Availability information	Success	
EMA/SH/0000005849	Marketing status NAs	Failed	
EMA/SH/0000005848	Marketing status NAs	Failed	

Click on the “**Submission ID**” to consult the upload details of a particular submission

For more information about a particular submission, click on its “**Submission ID**”. The “**Submission status**” page for the selected submission will open, as shown in figure 69. Here you will find information about the submission type, the upload date/time, the submission ID, the file name, the upload status and the validation results (if applicable).

Figure 69: Availability information – Submission history – Submission status



Home > Submission history > Submission status

Submission status

Success
Your file was successfully submitted.

Submission type	Upload date and time	Submission ID
Availability information	24/02/2025 10:09 AM	EMA/SH/0000005947
Status	File name	
Success	esmp-availability-20250224-1003.xlsx	

4.5. How to submit Manufacturing information

To collect Manufacturing information on medicinal products in scope of reporting requirements for a particular crisis or MSSG-led preparedness action, the ESMP will generate a template which you can download, compile, and upload back to the ESMP. This template will be tailored to the user's affiliation and pre-filled with specific products in scope of reporting requirements and pre-populated with manufacturing information from PMS. The template will also be pre-populated with Manufacturing information previously submitted to the EMA through ESMP, if applicable.

Please **do not change the pre-populated fields which have been retrieved from other EMA systems** pertaining to product information or manufacturing locations linked to different steps of manufacturing while completing the submission procedure. Any changes to product information via ESMP will not be processed by the system, hence will not generate any changes in the PMS database.

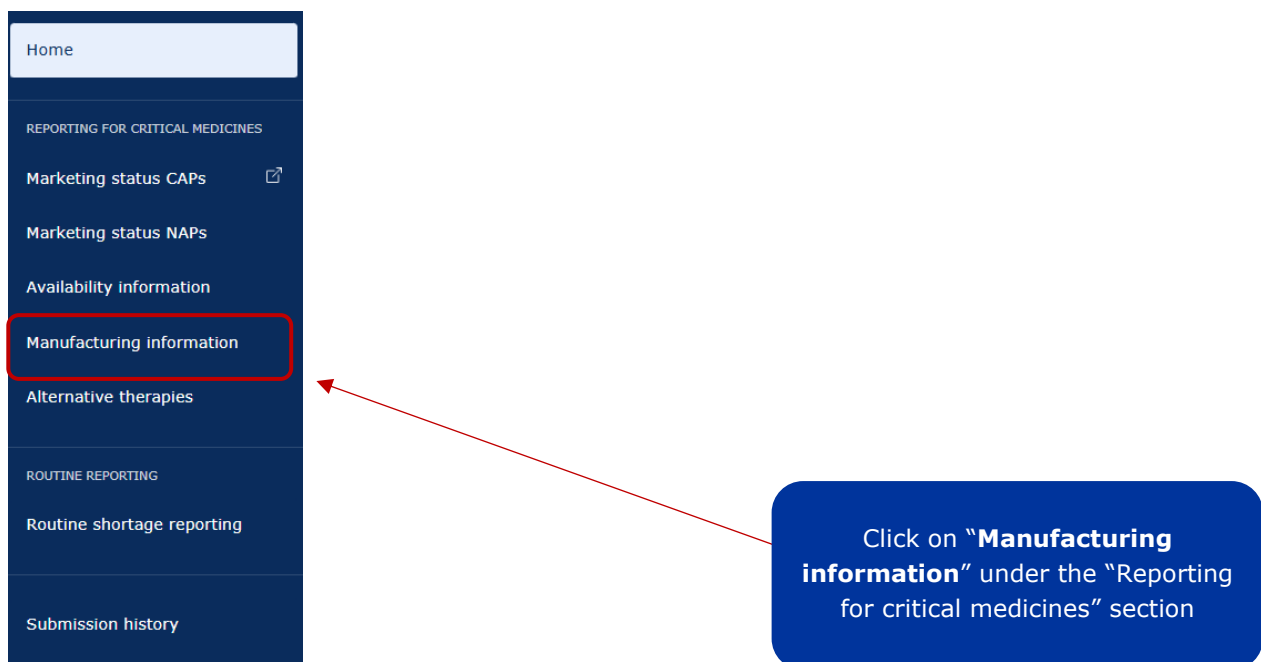
Step-by-step process

4.5.1. Part 1: Download template

Step 1

In the home page, on the left-side navigation menu, click on "**Manufacturing information**" under the "Reporting for critical medicines" section.

Figure 70: Left-side navigation menu – Manufacturing information



Step 2

On the "**Manufacturing information**" page you can choose between three different options: "New submission", "Download template" and "Submission history". To access the template needed for submission, click on "**Download template**".

Figure 71: Manufacturing information – Download template

Manufacturing information

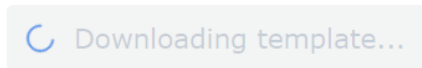
Please submit the information on the manufacturing site details and production plans for all your products that have been marked critical.

[+ New submission](#)
[Download template](#)
[Submission history](#)

Click on "Download template"

While the download is being processed, the button will show a spinner and the 'Downloading template...' information. Once the download is finished, the button goes to its initial state.

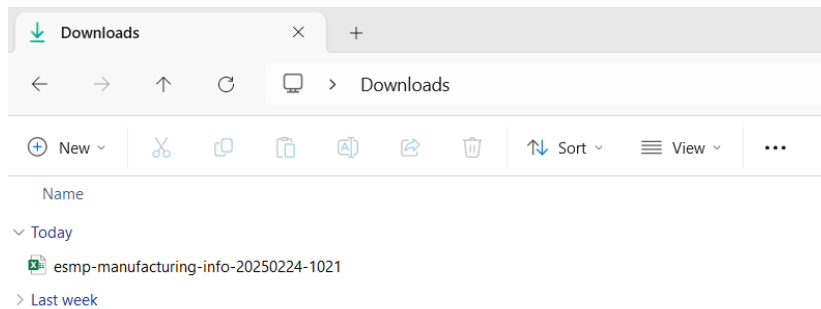
Figure 72: Manufacturing information – Downloading template



Step 3

Open the folder on your computer where the downloaded files are stored. You will find an Excel file with the name "esmp-manufacturing-cap-**<timestamp>.xlsx**". The template will include one column for each data element, as described in table 4.

Figure 73: Find the downloaded template in the Downloads folder of your computer



Where available, this template will include relevant manufacturing site data previously submitted to EMA through PMS. (figure 74).

Figure 74: Example of a populated downloaded template view

	A	B	C	D	E	F	G	H	I
	PMS ID		Active Substance	Manufacturer	Operation Type ID	Operation Type	Organisation ID	Location ID	Address 1: City*
1	500000004130		Vortioxetine						
2	500000004130		Vortioxetine						
3	500000004130		Vortioxetine						
4	500000004130		Vortioxetine						
5	500000004130		Vortioxetine						
6	500000004130		Vortioxetine						
7	500000004130		Vortioxetine						
8	500000004130		Vortioxetine						
9	500000004130		Vortioxetine						
10	500000004130		Vortioxetine						
11	500000004130		Vortioxetine						
12	500000004131		Vortioxetine						
13	500000004131		Vortioxetine						
14	500000004131		Vortioxetine						

4.5.2. Part 2: How to work on the downloaded template

File conventions


Note that only data in the first worksheet will be processed, therefore do not create other worksheets in the Excel file. The order of columns contained in the template must not be modified and no additional column must be added. Make sure that the file extension remains “.xlsx”. The file name can be modified as preferred by the user, the system will recognise and process the Excel document even with a different name.

How to complete the data fields in the template

The required sections of the template must be completed before uploading the file. Make sure to respect the validation rules of every data element. Each data element and the details on how the relevant information needs to be inserted is described in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)³⁶. Please consult this guide for further details to ensure the data will be correctly uploaded in the ESMP.

Table 4, which you can find below, provides an overview of all data elements reported in the columns of the template for the submission to the ESMP. All mandatory elements must be provided to successfully upload the file. For some fields you are required to fill in RMS identifiers (RMS IDs). You can copy and paste RMS IDs from the relevant lists, contained in the “Annex 1 – RMS lists and terms”, that can be found in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)³⁷.

The “**Product information**” fields (columns A to D) and “**Organisation information**” (columns F to L) **will be pre-populated** by the system in the template, transferring product data already stored in the EMA’s Product Management Service (PMS). If you want to find out more about the product information contained within PMS, please consult the [PMS Implementation of International Organization for Standardization \(ISO\) standards for the identification of medicinal products \(IDMP\) in Europe](#)³⁸.

 You should not make changes to the product information fields, because the product information changed via the ESMP will not be transferred into PMS. The pre-populated fields are listed in table 4 for clarity and completeness.

Important:

- Make sure to **insert the information at the level of authorised medicinal product**.
- Where applicable, make sure to separate multiple values in one field with a semicolon, such as when entering multiple root causes of a shortage (entered either as numerical RMS IDs - e.g. “200000028689;200000028700” or readable IDs – e.g. “ManufProdRel;UnexIncDemCoStock”) or multiple countries affected (CN;CO).

Table 4: Crisis – Manufacturing information data elements

Data category	Data element name	Conformance
Product information	PMS ID	Pre-populated
	Full product name	Pre-populated

³⁶ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

³⁷ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

³⁸ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-2_en.pdf

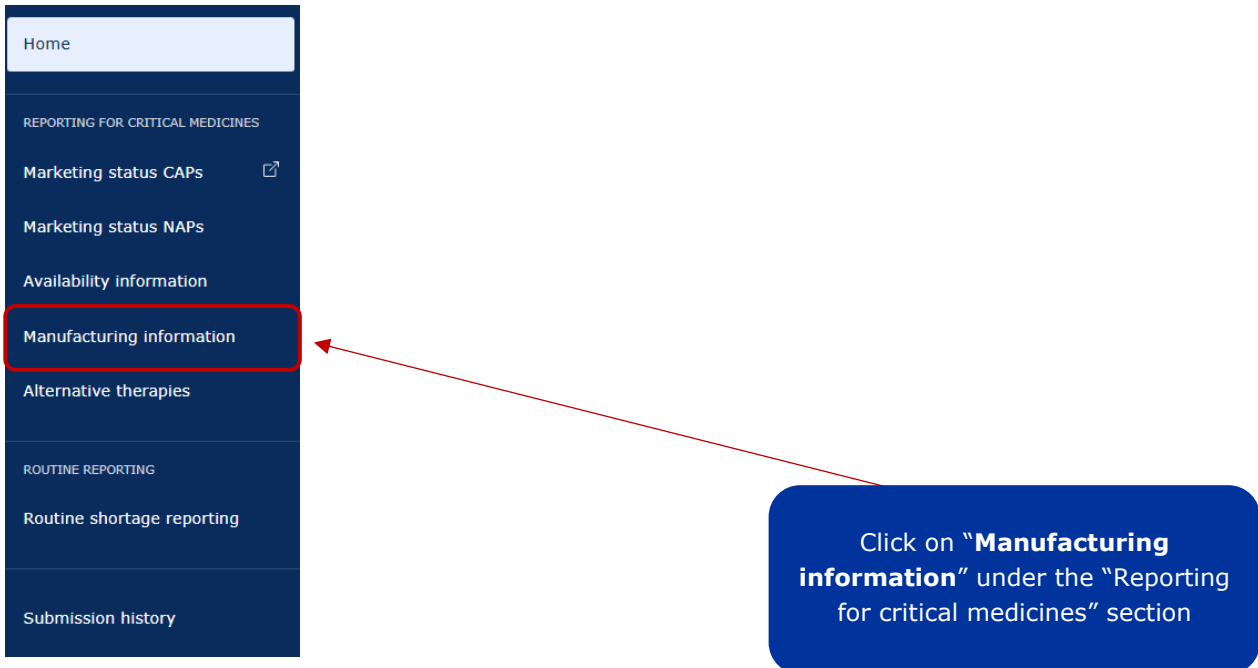
	Active substance SMS ID	Pre-populated
	Active substance	Pre-populated
Representative product	Representative product	Optional
Organisation information	Operation type ID	Mandatory
	Operation type	Optional
	ORG-ID (Manufacturer)	Conditional
	Manufacturer	Optional
	LOC-ID (Manufacturer)	Conditional
	City (Manufacturer)	Optional
Manufacturing details	Country (Manufacturer)	Optional
	Manufacturing site status	Conditional
Alternative sites	Is the site a contract manufacturer?	Conditional
	Alternative site LOC-ID	Conditional
Production capacity	Alternative site Country	Conditional
	Unit of measurement	Conditional
	Global monthly production plan – month 1	Conditional
	Global monthly production plan – month 2	Conditional
	Global monthly production plan – month 3	Conditional
	Global monthly production plan – month 4	Conditional
	Global monthly production plan – month 5	Conditional
	Global monthly production plan – month 6	Conditional
	Global monthly production plan – additional information	Optional
	Average global monthly production output of previous year	Conditional
Peak global monthly production output of previous year	Conditional	

4.5.3. Part 3: Upload of the data into ESMP

Step 1

On the left-side navigation menu, click on the “**Manufacturing information**” button under the “Reporting for critical medicines” section.

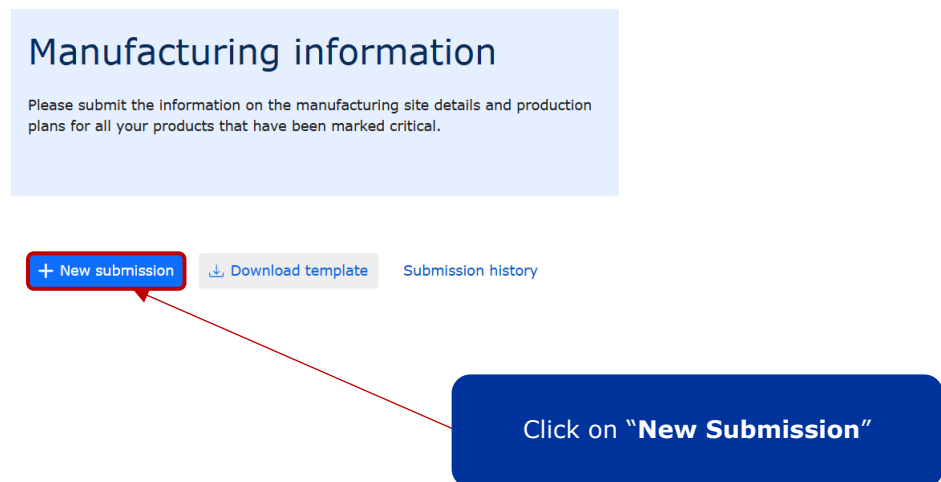
Figure 75: Left-side navigation menu – Manufacturing information



Step 2

On the **"Manufacturing information"** page you can find three different buttons: "New submission", "Download template", and "Submit history". In this step you are requested to click on **"New submission"**. A page called **"Submit data"** will open.

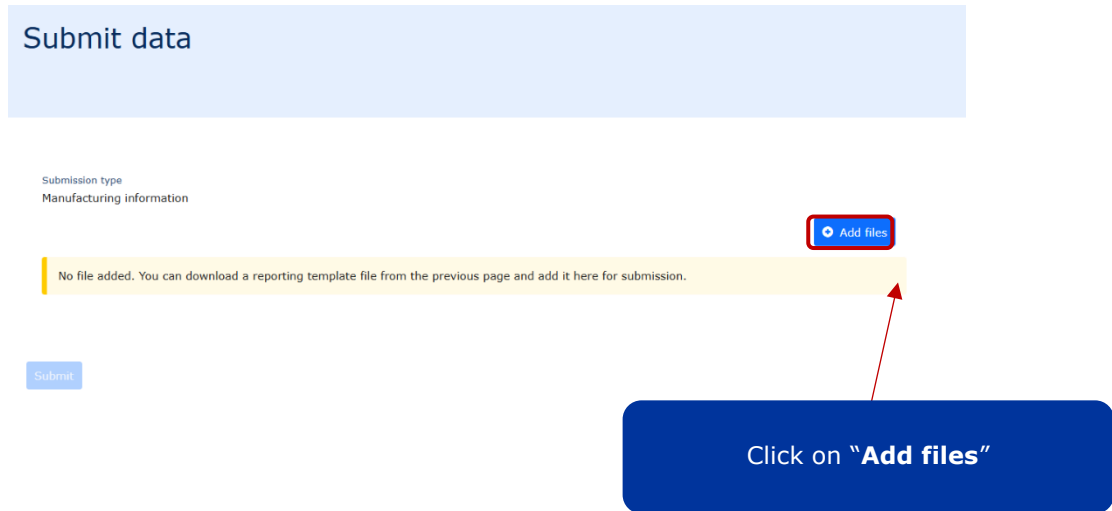
Figure 76: Manufacturing information – Submit data



Step 3

Click on **"Add files"** in the page called **"Submit data"**. This will open a dialogue box allowing you to upload a file into the ESMP.

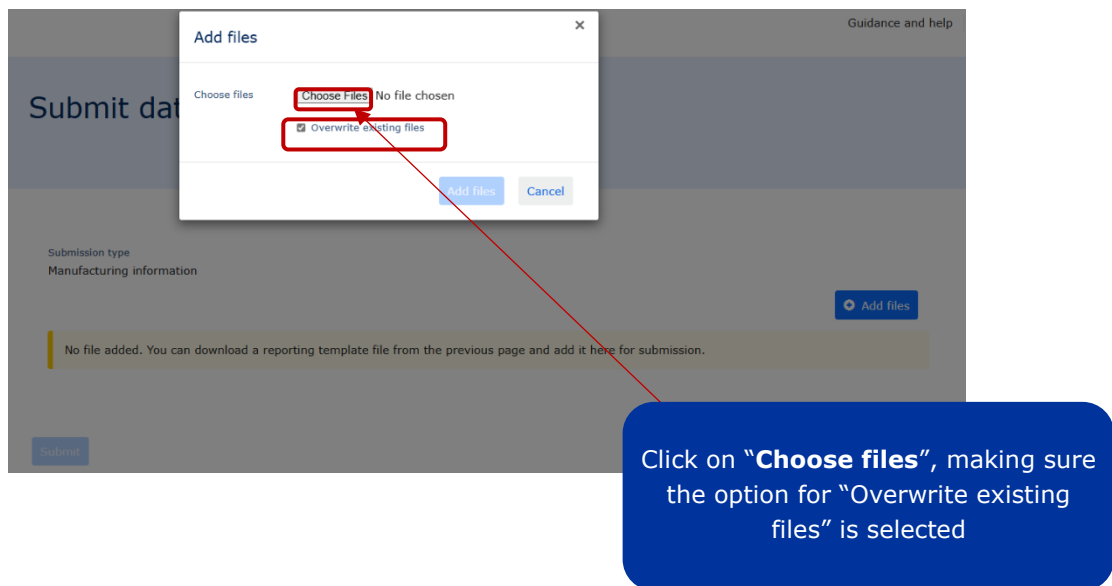
Figure 77: Submit data – Add files



Step 4

Click on **"Choose files"**, making sure the option for **"Overwrite existing files"** is selected. This will open a dialogue window on your computer. From there, locate the file you want to submit in the folder on your computer where you saved it. Please only add one file within a single submission.

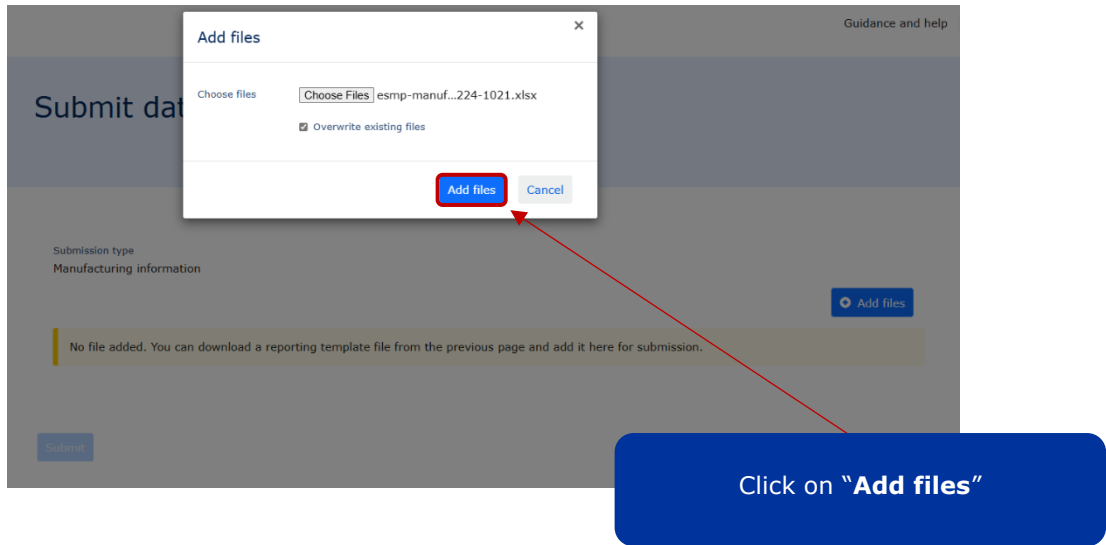
Figure 78: Submit data – Dialogue box – Choose file - Overwrite existing files



Step 5

Once you have selected a file, the name of the file will be shown next to the **"Choose Files"** button. Click on **"Add files"** to add this file to the upload page.

Figure 79: Submit data – Dialogue box – Add files

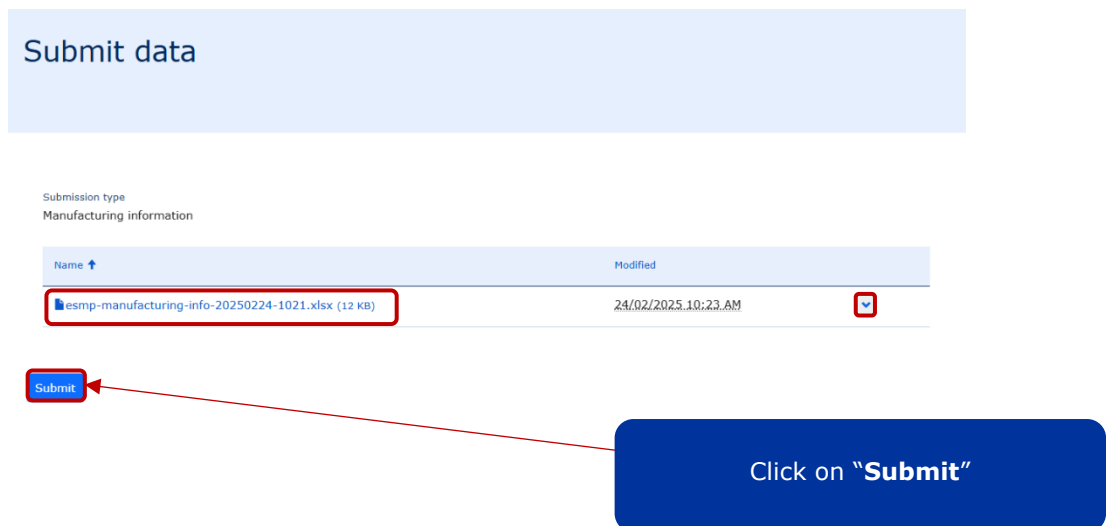


Step 6

The file you added will be listed in the table, as show in figure 80 below. If it is the correct file, click on "Submit". This will start the validation process of the file.

If it is not the correct file, click on the arrow on the right side of the screen and delete the selected file, then restart the upload process from step 1.

Figure 80: Submit data – Submit



Step 7

Validation of the submitted file may take some time. Feel free to close the page or move to another page while the file is being processed, since the submission will proceed in the background. To retrieve the details of the current submission or any past submission, consult the "Submission history" page.

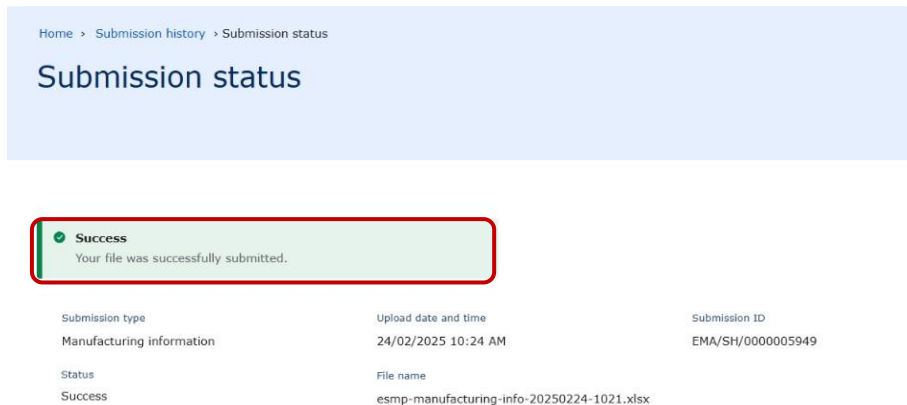
A page called "Submission status" will open, showing a summary of the upload details: submission type, upload date and time, submission ID, the file name, the status and the error messages, if any.

⚠️ The outcome of a submission on the "Submission status" page may require some time to be displayed, depending on the number of fields in the submitted file. You may leave the "Submission

status” page at any time. The processing of the submitted file will continue on the background. You may return to the “Submission status” page via the “Submission history” page.

If your upload is successful, the “**Upload status**” will display “**Success**” (figure 81). Your upload is therefore successfully completed, and your submission is final.

Figure 81: Manufacturing information – Submission status – Submission summary - Success



Home > Submission history > Submission status

Submission status

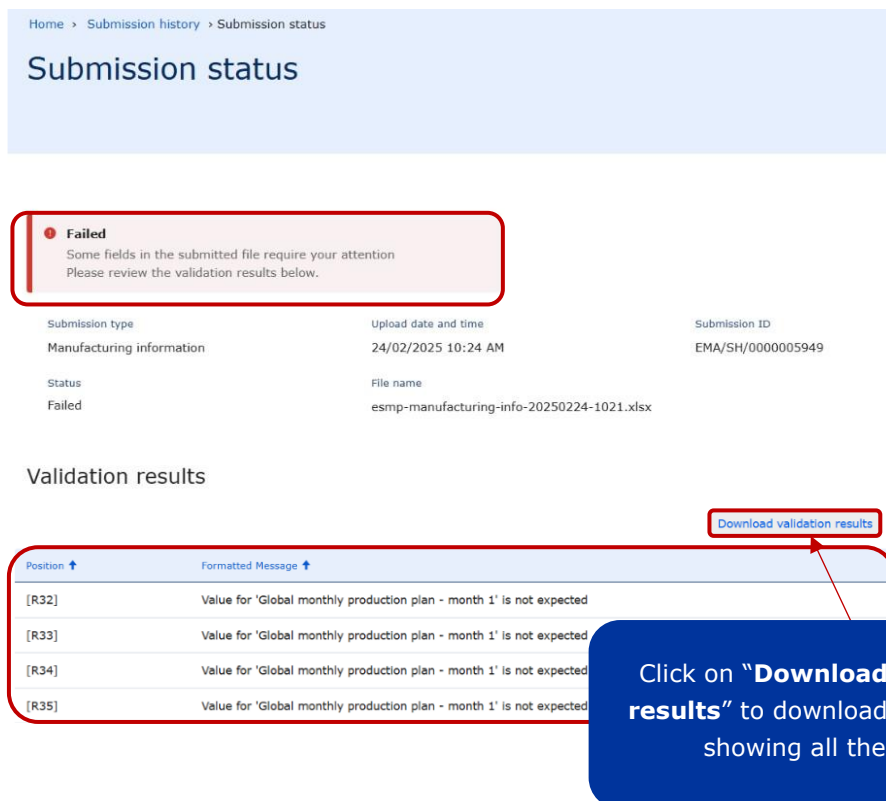
Success
Your file was successfully submitted.

Submission type	Upload date and time	Submission ID
Manufacturing information	24/02/2025 10:24 AM	EMA/SH/0000005949
Status	File name	
Success	esmp-manufacturing-info-20250224-1021.xlsx	

If your upload fails, the “**Upload status**” will show “**Failed**”. If this happens, please review the list of validation results at the bottom of the page. The validation results’ section lists errors encountered in the file, along with their location in the file (row number and column letter, or a dot where the error applies to the whole row or column; for example, “.2” means that the error refers to the whole row, “..” means that the error refers to the whole file), and an error message detailing what caused the error. Make sure you scroll through the entire validation results’ section to view all errors.

You may also click on “**Download validation results**” to download an Excel file listing all the errors.

Figure 82: Manufacturing information – Submission status – Submission summary – Failed status



Home > Submission history > Submission status

Submission status

Failed
Some fields in the submitted file require your attention
Please review the validation results below.

Submission type	Upload date and time	Submission ID
Manufacturing information	24/02/2025 10:24 AM	EMA/SH/0000005949
Status	File name	
Failed	esmp-manufacturing-info-20250224-1021.xlsx	

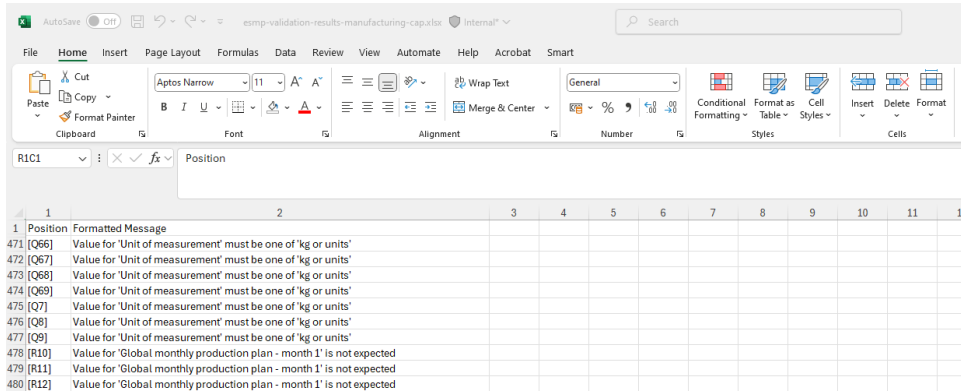
Validation results

Position ↑	Formatted Message ↑
[R32]	Value for 'Global monthly production plan - month 1' is not expected
[R33]	Value for 'Global monthly production plan - month 1' is not expected
[R34]	Value for 'Global monthly production plan - month 1' is not expected
[R35]	Value for 'Global monthly production plan - month 1' is not expected

[Download validation results](#)

Click on “**Download validation results**” to download an Excel file showing all the errors

Figure 83: Validation Error logs – Excel file view



Position	Formatted Message
471 [Q66]	Value for 'Unit of measurement' must be one of 'kg or units'
472 [Q67]	Value for 'Unit of measurement' must be one of 'kg or units'
473 [Q68]	Value for 'Unit of measurement' must be one of 'kg or units'
474 [Q69]	Value for 'Unit of measurement' must be one of 'kg or units'
475 [Q7]	Value for 'Unit of measurement' must be one of 'kg or units'
476 [Q8]	Value for 'Unit of measurement' must be one of 'kg or units'
477 [Q9]	Value for 'Unit of measurement' must be one of 'kg or units'
478 [R10]	Value for 'Global monthly production plan - month 1' is not expected
479 [R11]	Value for 'Global monthly production plan - month 1' is not expected
480 [R12]	Value for 'Global monthly production plan - month 1' is not expected

Open the **“esmp-validation-results-manufacturing” Excel file** to view the details of the reported errors. For further information on the listed errors and validation rules that may prevent you from successfully completing your submission, consult the requirements for each data set and data element as described in the [ESMP Implementation Guide for Marketing Authorisation Holders](#)³⁹. Re-open the submission file that you wish to upload from your computer and address each of the described errors in the **“esmp-validation-results-manufacturing”** file. Save your changes and repeat the upload process with the amended file.


 All upload summary details from all previous submissions, whether successful or failed, are recorded and can be viewed within the ESMP on the “Submission history” section. To access it, click on the **“Submission history”** button on the left-side navigation menu, or access it from the **“Manufacturing information”** page.

Figure 84: Manufacturing information – Submission history

Manufacturing information

Please submit the information on the manufacturing site details and production plans for all your products that have been marked critical.

[+ New submission](#)

[Download template](#)

[Submission history](#)

Click on **“Submission history”**

The **“Submission history”** page provides you with an overview of all your past submissions. On the summary table, each past submission is defined by a submission ID, a submission type, a submission status (i.e. success or failed), and an upload date/time.

It is possible to filter the recordings by “Type” and “Submission status” using the filters on the left side of the screen.

³⁹ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-marketing-authorisation-holders_en.pdf

Figure 85: Manufacturing information – Submission history page

Submission history

Submission type
▼

Submission status
▼

Apply

Submission ID	Type	Submission status	Submitted on ↓
EMA/SH/0000005949	Manufacturing information	Success	24/02/2025 10:24 AM
EMA/SH/0000005947	Availability information	Success	24/02/2025 10:09 AM
EMA/SH/0000005925	Marketing status NAPs	Success	18/02/2025 11:08 AM
EMA/SH/0000005901	Availability information	Success	17/02/2025 1:16 PM
EMA/SH/0000005849	Marketing status NAPs	Failed	13/02/2025 9:04 PM
EMA/SH/0000005848	Marketing status NAPs	Failed	13/02/2025 9:02 PM
EMA/SH/0000005847	Marketing status NAPs	Failed	13/02/2025 8:54 PM
EMA/SH/0000005783	Marketing status NAPs	Failed	11/02/2025 2:04 PM

Click on the **"Submission ID"** to consult the upload details of a particular submission

For more information about a particular submission, click on its **"Submission ID"**. The **"Submission status"** page for the selected submission will open, as shown in figure 86. Here you will find information about the submission type, the upload date/time, the submission ID, the file name, the upload status and the validation results (if applicable).

Figure 86: Manufacturing information – Submission history – Submission status

Home > Submission history > Submission status

Submission status

✔ Success
Your file was successfully submitted.

<p>Submission type Manufacturing information</p> <p>Status Success</p>	<p>Upload date and time 24/02/2025 10:24 AM</p> <p>File name esmp-manufacturing-info-20250224-1021.xlsx</p>	<p>Submission ID EMA/SH/0000005949</p>
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4.6. How to submit Alternative therapies

MAHs are required to report information on alternative therapies for medicinal products in scope of reporting requirements for a particular crisis or MSSG-led preparedness action, with the purpose of aiding the identification of available other therapeutic solutions.

To collect this information the ESMP will generate a page tailored to the user's affiliation and pre-filled with specific products in scope of reporting requirements, grouped and displayed as active substances and pharmaceutical forms, with the addition of the product short name for CAPs. The page will be pre-populated with information previously submitted to the EMA through ESMP, if applicable.

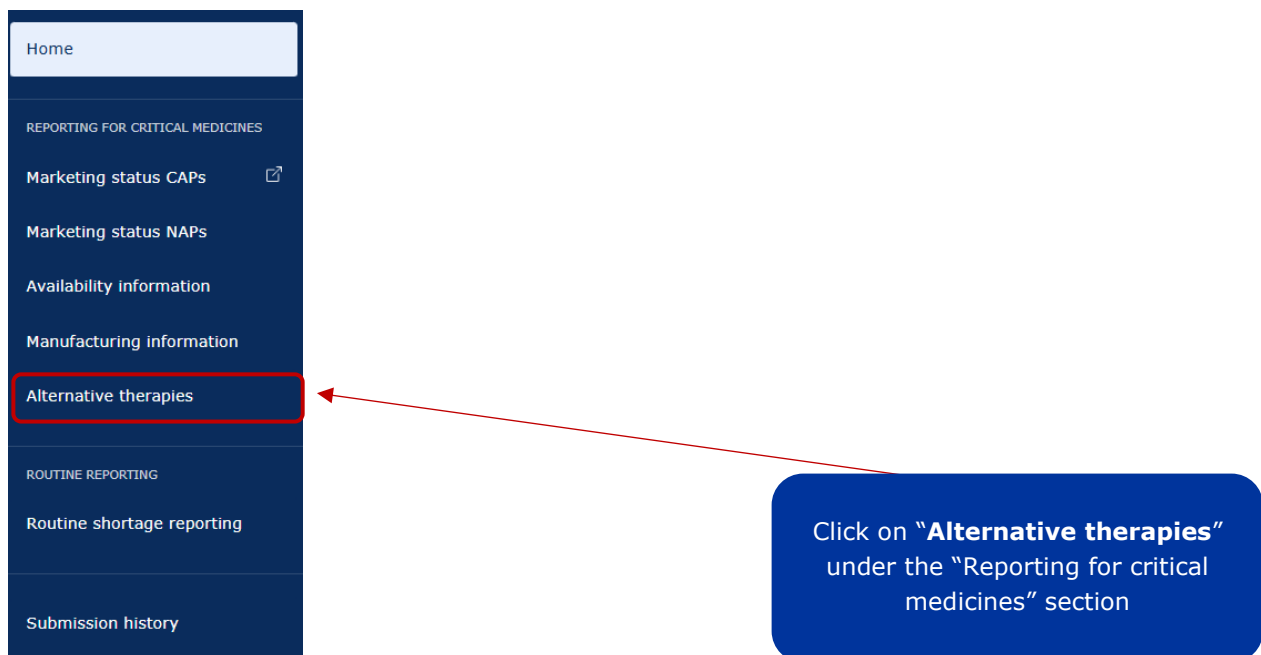
To this end, MAHs are required to report active substances and compositions that can be considered as substitutes to the critical medicinal products.

Step by step procedure

Step 1

On the left-side navigation menu, click on "**Alternative therapies**" under the "Reporting for critical medicines" section.

Figure 87: Left-side navigation menu – Alternatives therapies button



Step 2

In the alternative substances page, each MAH will see their list of **CAPs** listed by their short product name and **active substances of NAPs** which are in the list of critical medicines, organised in a table (figure 88). The columns list respectively: "Invented Name, Active Substance(s), Pharmaceutical form, Alternative substances, No available alternatives".

Click on the "**Modify**" button on the "Alternative substances" column to insert the name of the alternative substance(s) for each entry.

Figure 88: Table for "Alternative therapies"

Alternative therapies

Please submit the information on alternative therapeutic solutions for all your products that have been deemed critical. [How to submit?](#)

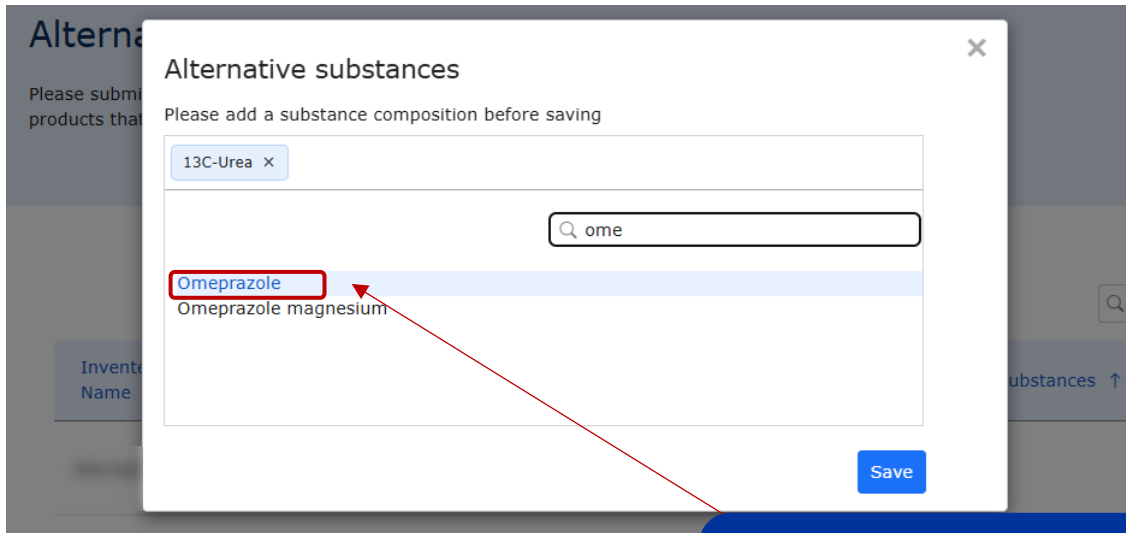
Invented Name ↓↑	Active substance(s) ↑	Pharmaceutical form ↑	Alternative substances ↑	No available alternatives
...	...	Powder for concentrate for solution for infusion	[13C-Urea] Modify	<input type="checkbox"/>
...	...	Concentrate for solution for infusion	Modify	<input checked="" type="checkbox"/>
...	...	Concentrate for solution for infusion	Modify	<input type="checkbox"/>
...	...	Solution for injection	[P...] Modify	<input type="checkbox"/>

Click on the "**Modify**" button beside any listed product to insert the name of alternative substance(s) or compositions

Step 3

A dialog box will open with a free text field. Start writing the name of the relevant substance(s) you want to indicate as viable alternative. A drop-down menu will be automatically generated, listing all available standalone active substances, as well as compositions of multiple active substances. Select from this list the correct alternative you want to indicate.

Figure 89: Dialogue box - Drop-down list of alternative substances

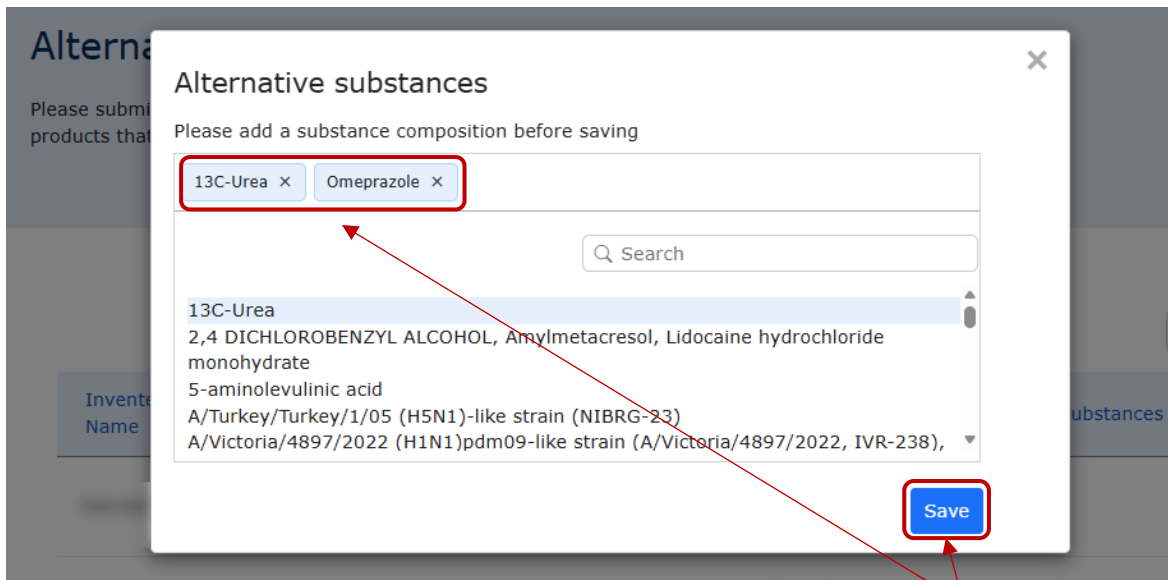


Type the name of the alternative substance(s) you want to indicate **and select** the correct alternative from the drop-down menu


Step 4

After selecting an alternative substance or composition from the drop-down menu, it will appear in blue as shown in the figure below. It is possible to add multiple alternative substances and compositions, repeating the procedure of Step three. Once all the wanted alternative therapies are added, click on **“Save”** to finalise the procedure for that particular product/active substance.

Figure 90: Dialogue box - Selected alternative substance



Once all the alternative therapies are correctly listed in the bar, click on **“Save”**.

 Important: please repeat the explained procedure for each of the medicines listed in your table.

Step 5

Once all information on alternative therapies is correctly inserted, it will be reported in the dedicated column. If a product/active substance does not have any suitable alternative, tick the box in the last column to declare the absence of alternatives.

Figure 91: Completed table for Alternative substances

Invented Name ↓↑	Active substance(s) ↑	Pharmaceutical form ↑	Alternative substances ↑	No available alternatives
		Powder for concentrate for solution for infusion	[13C-Urea], [Omeprazole] Modify	<input type="checkbox"/>
		Concentrate for solution for infusion	Modify	<input checked="" type="checkbox"/>
		Concentrate for solution for infusion	Modify	<input checked="" type="checkbox"/>
		Solution for injection	[Pertuzumab] Modify	<input type="checkbox"/>

Dedicated column to review all the selected alternative substances and compositions

Tick the box in the last column to declare the absence of an alternative for a medicine

Step 6


When all steps have been completed for each medicine, click "**Submit**". A dialog box will open and confirm the successful submission.

Figure 92: Submission of Alternative substances

Invented Name ↓↑	Active substance(s) ↑	Pharmaceutical form ↑	Alternative substances ↑	No available alternatives
		Powder for concentrate for solution for infusion	[13C-Urea], [Omeprazole] Modify	<input type="checkbox"/>
		Concentrate for solution for infusion	Modify	<input checked="" type="checkbox"/>
		Concentrate for solution for infusion	Modify	<input checked="" type="checkbox"/>
		Solution for injection	[Pertuzumab] Modify	<input type="checkbox"/>

[Save](#)

To finalise the process, click **“Submit”**. A dialog box will open and confirm the successful submission.

 Please do not particularly skip step 6 to not lose the added alternative therapies. You must click on the **“Submit”** button in order to save the added information.

5. Support



5.1. Service Desk

For any support with ESMP, please reach out directly via the [ESMP section of the EMA Service Desk portal](#) (Service Now). This includes issues related to accessing the ESMP, seeing unexpected data, uploading data or the system performance.

If you have a user account for a system hosted by EMA, you should use the same username and password for this service. Otherwise, please [sign up for a new account or reset your login credentials](#).

The Service Desk portal is optimised for use with Chrome, Edge, Firefox or Safari web browsers. If you encounter problems, please use one of these browsers instead.


When landing on the ESMP section of the Service Desk, you will have the option to:

-  [Report an issue with ESMP](#), to create a ticket for the issue you are experiencing, or,
-  [Request information about ESMP](#), to create a ticket for the question you have.

Depending on the issue or question, you can select one of the different service offerings:

- ESMP MAH routine CAP shortage reporting;
- ESMP MAH Crisis/MSSG-led preparedness submissions;
- ESMP other (topics covering multiple aspects and/or general nature).

Please provide a clear description of the issue and provide screenshots or the generated pdf as attachment as these can help to solve the query a lot faster.

 The system only sends notifications to the Service Desk when the user specified in the *Raise this request on behalf of* field interacts with the ticket. Therefore, always ensure the *Raise this request on behalf of* field is set to the affected user's name so that the Service Desk is properly notified and can respond accordingly.


This ESMP-targeted communication channel does not replace other established EMA communication channels. Please refer to:

- [EMA Service Desk](#) for questions on the use of the portal and for reporting faults;
- [EMA account management portal](#), for access and registration requests;
- [Ask EMA](#) for general questions not related to a specific submission/procedure.

Figure 93: Form to report an issue with ESMP

Report an issue with ESMP

Request assistance to ESMP



Create a ticket for the issue you are experiencing. Before creating a new ticket, please double check the available guidance - the information you are looking for may be explained there.

- [Learn more about ESMP](#)
- [Frequently asked questions on the ESMP](#)
- [ESMP Implementation guide for MAHs](#)
- [ESMP Prototype templates for MAHs](#)
- [ESMP Implementation guide for NCAs](#)
- [ESMP Prototype templates for NCAs](#)

When creating a ticket, please provide as much detail as possible (incl. step-by-step narrative and/or screenshot(s) as attachments, if/when applicable).

*** Indicate required information**

*** Raise this request on behalf of**

i

x
v

*** Subject**

*** Description**

*** Service Offering**

Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you **NOT** to include attachments that contain:

- Special categories of personal data
- Confidential information

Please read the [Terms of use](#).

In order to add an attachment please indicate that you agree to the Terms of Use

Add attachments

Save as Draft
Submit

Required information


[Subject](#)
[Description](#)

[Service Offering](#)

Figure 94: Form to request information about ESMP

Request information about ESMP

Request assistance to ESMP



Create a ticket for the question you have. Before creating a new ticket, please double check the available guidance - the information you are looking for may be explained there.

- [Learn more about ESMP](#)
- [Frequently asked questions on the ESMP](#)
- [ESMP Implementation guide for MAHs](#)
- [ESMP Prototype templates for MAHs](#)
- [ESMP Implementation guide for NCAs](#)
- [ESMP Prototype templates for NCAs](#)

When creating a ticket, please provide as much detail as possible (incl. step-by-step narrative and/or screenshot(s) as attachments, if/when applicable).

*** Indicate required information**

*** Raise this request on behalf of**

i

x
v

*** Subject**

*** Description**

*** Service Offering**

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Add attachments

Save as Draft
Request

Required information

[Subject](#)
[Description](#)

[Service Offering](#)