



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

European Shortages Monitoring Platform (ESMP) User guide for national competent authorities

Version 1.1

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

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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Revision history

Version	Date	Description
V1.0	29/01/2025	ESMP User guide for NCAs – first publication
V1.1	07/03/2025	ESMP User guide for NCAs – updating chapter 2.3 to replace outdated procedure with the new sign in process with email address authentication Update of screenshots across the user guide to reflect ESMP user interface changes

Table of abbreviations

Abbreviation	Explanation
EEA	European Economic Area
EMA	European Medicines Agency
ESMP	European Shortages Monitoring Platform
EU	European Union
ICU	Intensive Care Unit
ID	Identification
INN	International Non-proprietary Name
ME	Major Event
MAH	Marketing Authorisation Holder
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products (Medicines Shortages Steering Group)
MS	EU Member State
NCA	National Competent Authority
OMS	Organisation Management Services
PHE	Public Health Emergency
PMS	Product Management Services
RMS	Referentials Management Services (part of SPOR) ¹
SMART	ESMP's shortages monitoring and risk analysis tool

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. For further information about RMS please consult additional resources as [Referentials Management Service \(RMS\) | European Medicines Agency \(EMA\)](#) and [RMS Web UI](#).



Abbreviation	Explanation
SmPC	Summary of product characteristics
SMS	Substance Management Services
SPOR	Substance, Product, Organisation, and Referentials

1. Scope of this guidance

The European Shortages Monitoring Platform (ESMP) user guide for national competent authorities (NCAs) describes the reporting processes that NCAs must follow to ensure the successful completion of electronic submissions 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 NCAs with obligations to report sets of information on stock and supply, patient estimations, medicine usage, and national demand for medicinal products as per Regulation (EU) 2022/123, with a focus on the general provisions and Article 11 of the regulation.

This ESMP user guide for NCAs is a single source of information where NCA 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 national competent authorities](#)² which provides detailed information on the technical specifications, clarifying data sets and data elements in scope of reporting requirements to the EMA.

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).

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

- **Crisis situations**, during public health emergencies (PHEs) or major events (MEs), for medicinal products in scope of a list of critical medicines they monitor 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

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

- **In crisis situations**, NCAs will be requested to share information such as stock and supply, patient estimation and medicine usage;
- **In MSSG-led preparedness situations**, NCAs will be requested to share information on national demand.

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](#)³ 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](#)⁴ page on EMA's website.

² https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-national-competent-authorities_en.pdf

³ <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform>

⁴ <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:

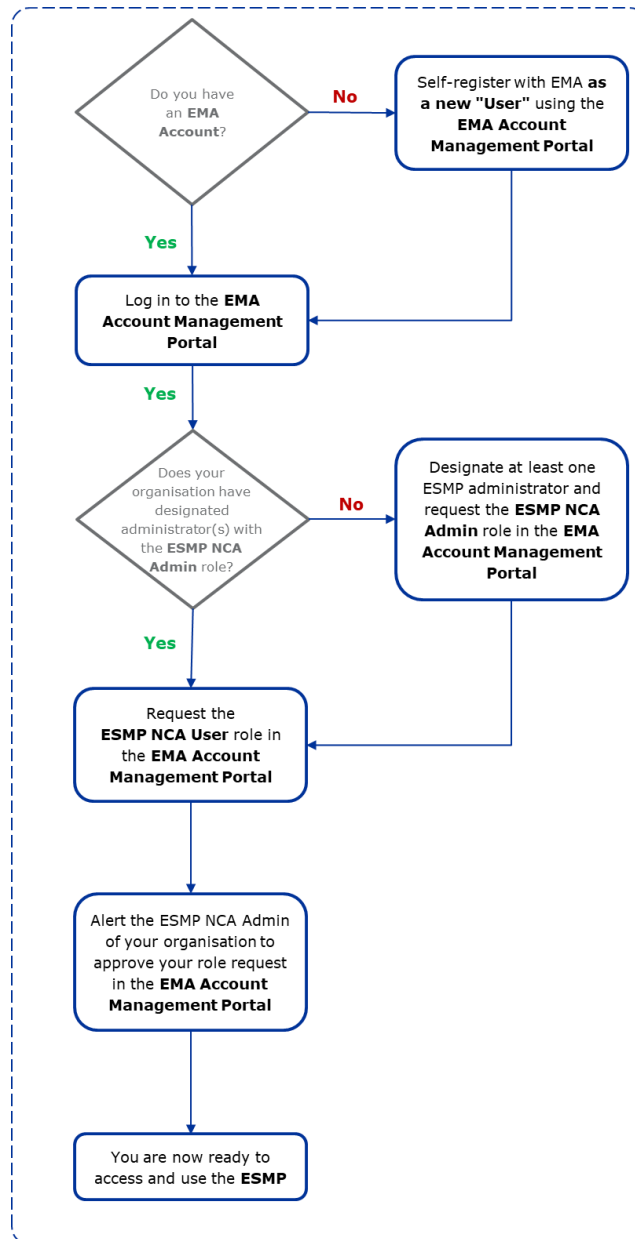
- (1) an **active EMA user account**, and,
- (2) the **ESMP NCA User role** assigned to your active EMA user account.

Please ensure that the information related to the **organisation** on whose behalf you will be acting is accurate and kept up to date in the **EMA's [Organisation Management Service \(OMS\)](#)**⁵.

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.

⁵ <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](#)⁶. 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](#)⁷)

2.2. How to request the necessary ESMP user access roles

Once you have an EMA account, 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](#)⁸.

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 NCA Admin**” role in the [EMA Account Management portal](#).

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

- a) If no one in your organisation has this role, follow the instructions of [how to request User Administrator role](#)⁹. 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 NCA Admin” role, this person will be able to manage any subsequent access role request(s) for both ESMP access roles (the “ESMP NCA Admin” and the “ESMP NCA User”) on behalf of your organisation.

⁶ <https://register.ema.europa.eu/identityig/home.isf>

⁷ <https://register.ema.europa.eu/identityig/home.html>

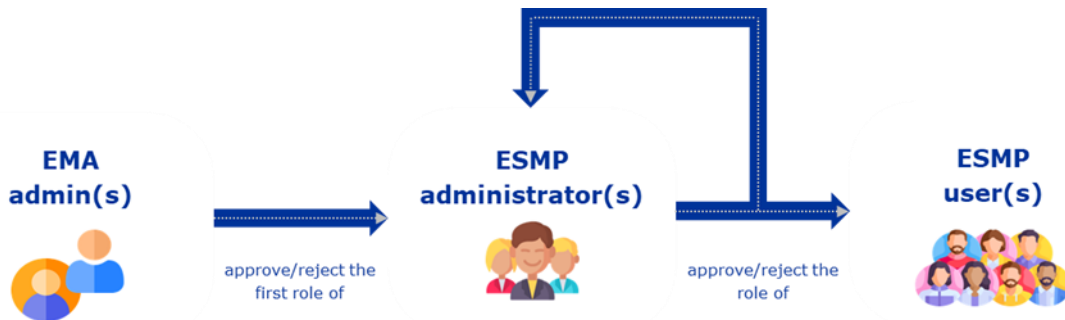
⁸ <https://register.ema.europa.eu/identityig/help/requestaccess.html#newrequestaccess>

⁹ <https://register.ema.europa.eu/identityig/help/requestaccess.html#requestuseradmin>

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

For more information about the User Administrator role, consult the [User Administrator Guide](#)¹⁰.

Figure 2: ESMP access management approval workflow



Note: as an alternative to the “ESMP NCA 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 NCA Admin role aims to exclusively handle users’ access management for an NCA. 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 NCA User**” role in the [EMA Account Management portal](#)¹¹. ESMP NCA Admins also need to request the “ESMP NCA 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](#)¹².

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

¹⁰ <https://register.ema.europa.eu/identityiq/help/useradmin.html>

¹¹ <https://register.ema.europa.eu/identityiq/home.jsf>

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

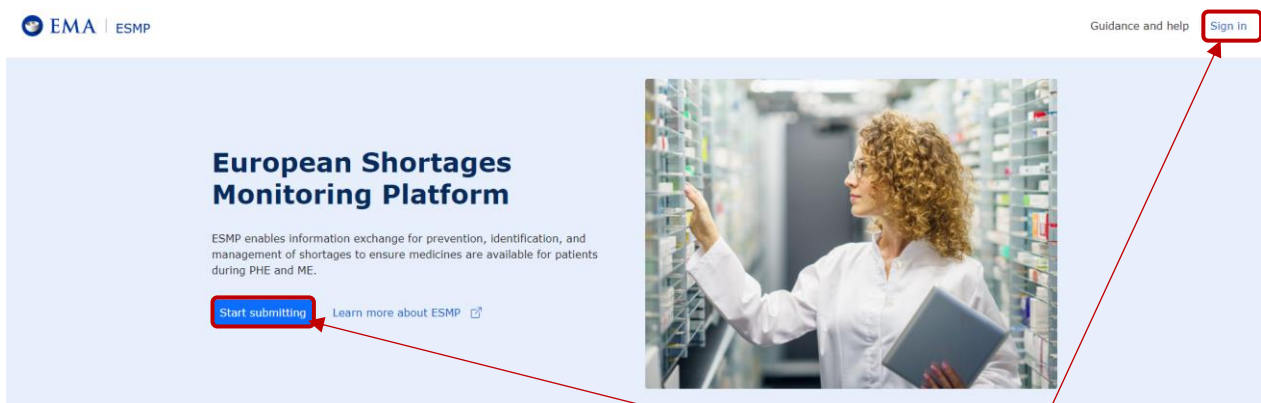
2.3. How do I log in to the ESMP?

To log in to the ESMP, please follow the steps described below. Note that you need to have been granted the “ESMP NCA User” access role as described in chapter 2.2 before you can log in to the ESMP.

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 landing page – Start the sign in process

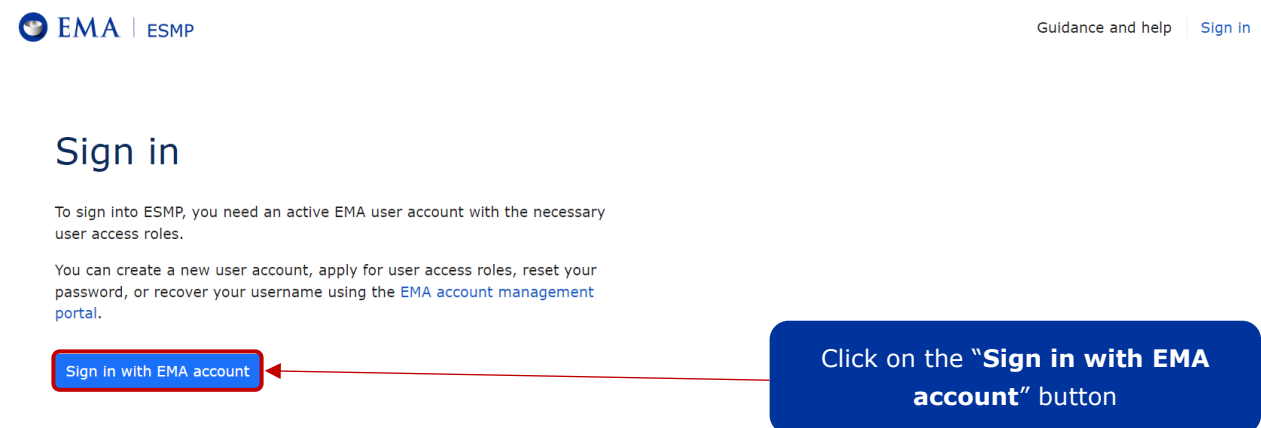


Access the ESMP and click on the “Start submitting” button or on the “Sign in” button

Step 2

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

Figure 4: ESMP sign in process – Sign in with EMA account



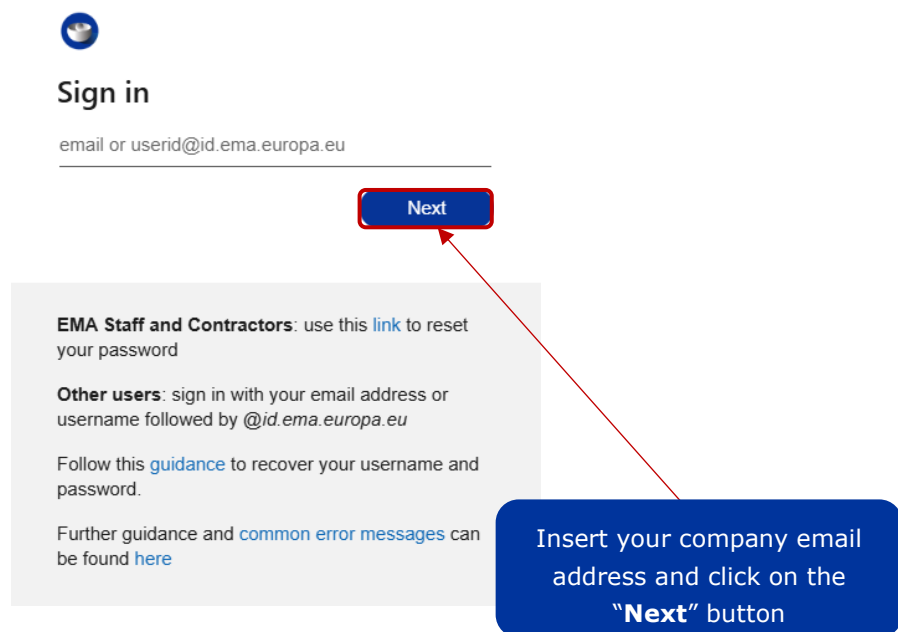
Click on the “Sign in with EMA account” button

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



Sign in

email or userid@id.ema.europa.eu

Next

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](#)

Insert your company email address and click on the “**Next**” button

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

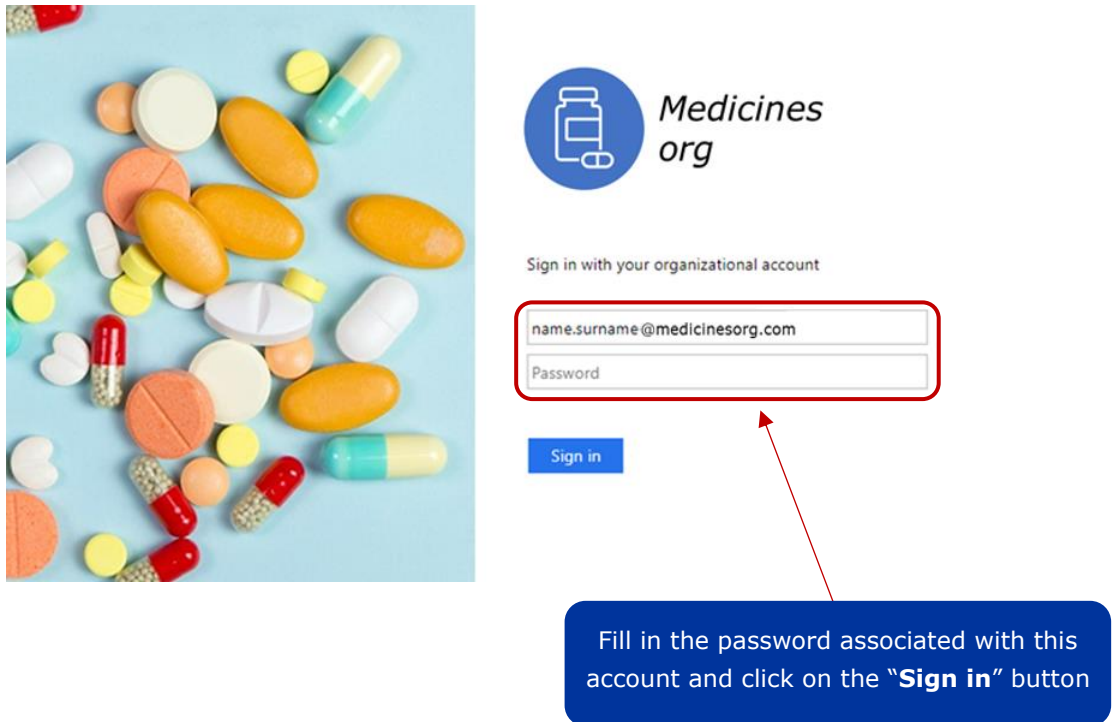


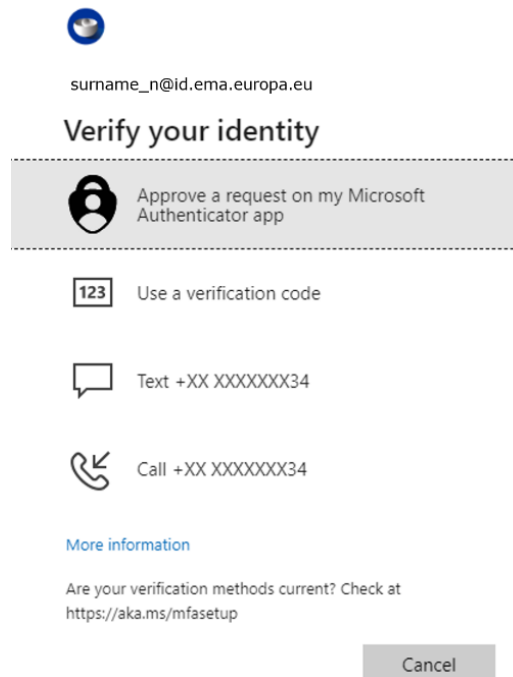
Figure 7: Enter code window - Enter the passcode received via email



Step 5

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 practical terms, this means that, in addition to the standard username and password (steps 1 to 3), you are required to verify your identity with an additional authentication method. MFA adds a layer of security to access your account, and it protects your data from being accessed by an unauthorised third party.



Figure 8: ESMP sign in process – 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.

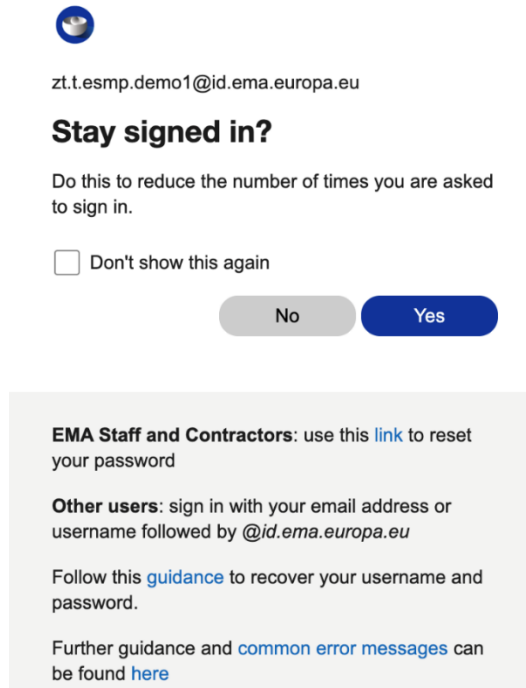
NOTE: text message or phone call options can be selected during any sign-in attempt, provided a phone number has been set up.

- **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: ESMP sign in process – Stay signed in?

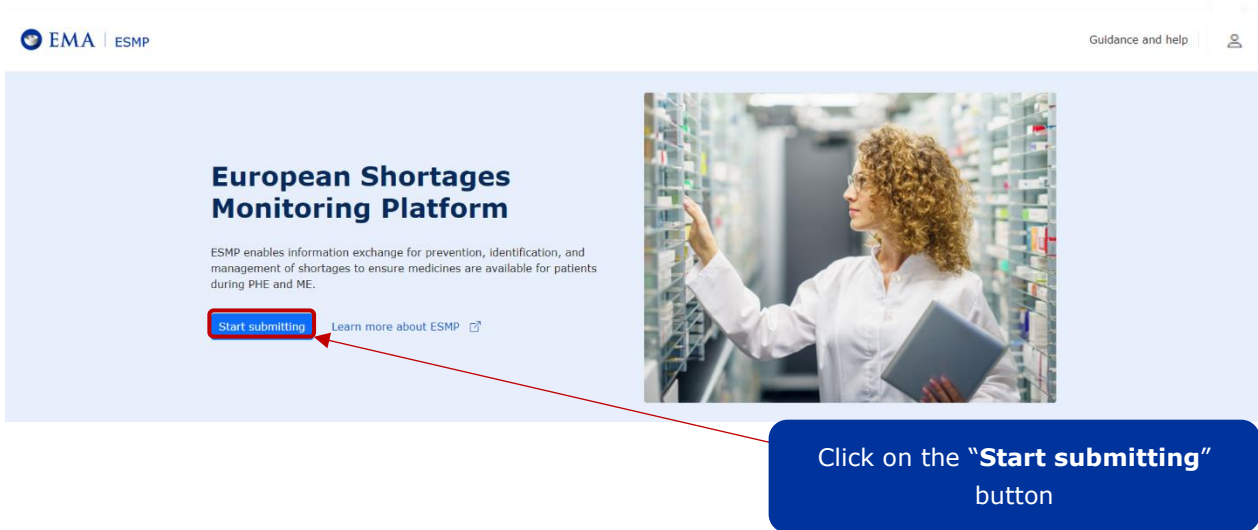


The screenshot shows a sign-in interface for the ESMP. At the top, there is a globe icon and the email address 'zt.t.esmp.demo1@id.ema.europa.eu'. Below this, the question 'Stay signed in?' is displayed in bold. A subtext reads: 'Do this to reduce the number of times you are asked to sign in.' There is a checkbox labeled 'Don't show this again' which is currently unchecked. Below the checkbox are two buttons: 'No' (grey) and 'Yes' (blue). At the bottom, there is a grey box containing helpful information: '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.', and '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.

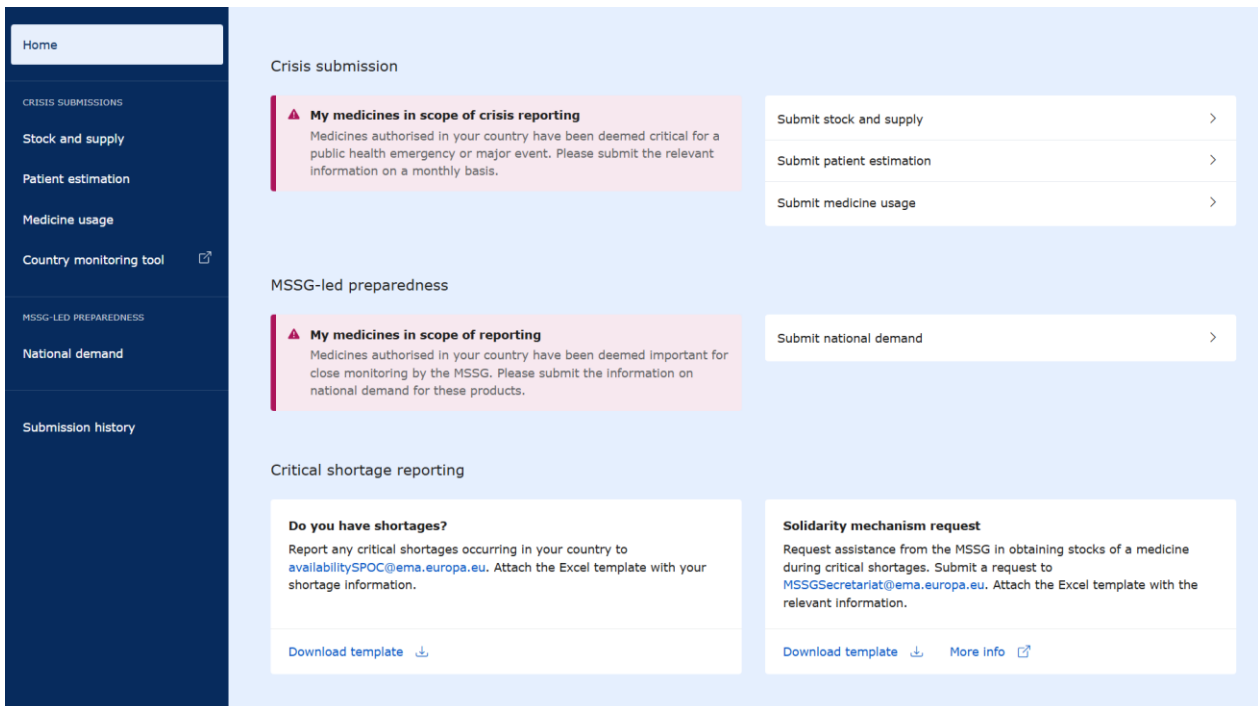
If you are redirected to the welcome page, click on the **“Start submitting”** button to access the ESMP Home page.

Figure 10: ESMP welcome page - start submitting



Once you have successfully signed in, you will be redirected to the ESMP Home page, as shown in figure 11 (in the event of a Crisis and a MSSG-led preparedness action).

Figure 11: ESMP Home page, in the event of a Crisis and a MSSG-led preparedness action



3. Crisis submissions

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

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

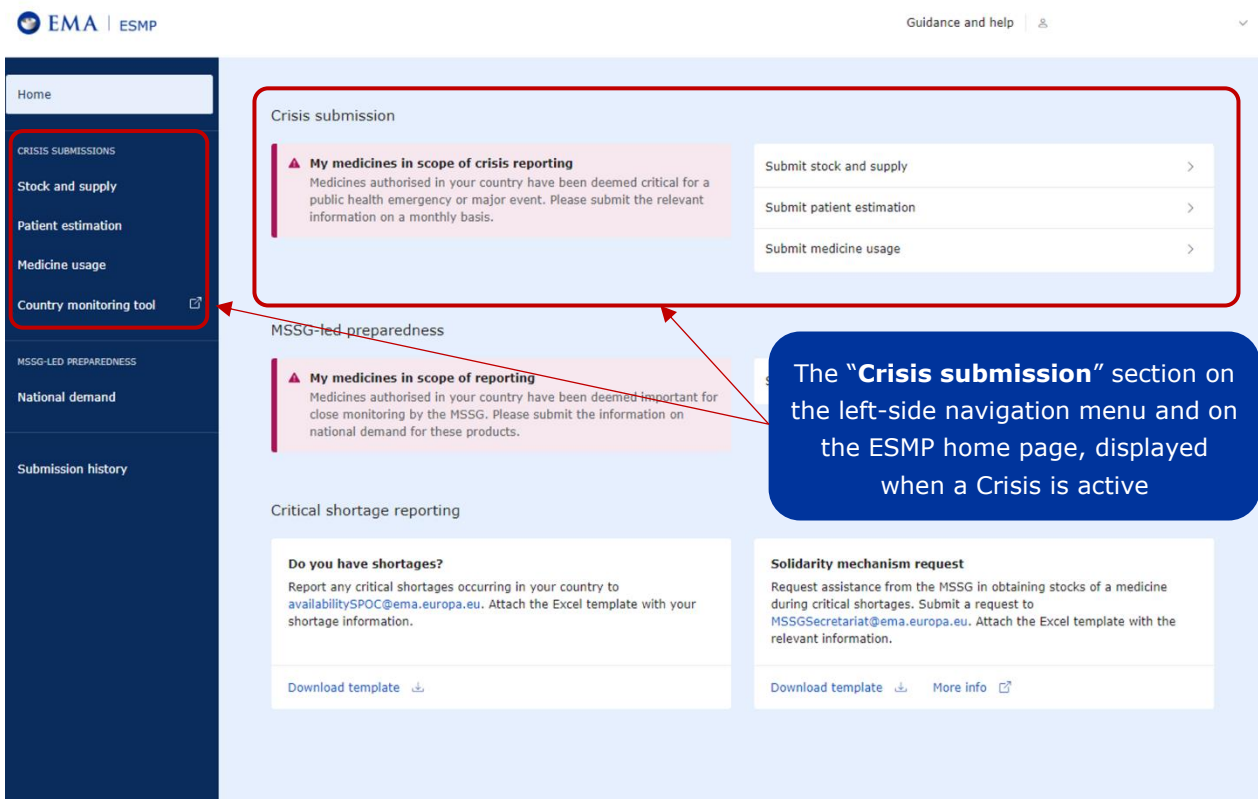
The following chapters describe in depth the different data elements and related details that NCAs will need to submit to fulfil reporting requirements.

3.1. Home page during a Crisis

Whenever a Crisis is declared, the [ESMP Home page](#) (and the left-side navigation menu) will display the 'Crisis submission' section which contains additional information pertaining to such an event. It includes a notification to inform users that medicines authorised in your country 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.: Stock and supply, Patient estimation and Medicine usage). The left-side navigation menu also includes a link to the ESMP's shortages monitoring and risk analysis tool (SMART), an automated analysis and visualisation dashboard that gathers and aggregates member state (MS) relevant supply and demand data. For further information on the SMART, please refer to chapter 5: [SMART – Guidance for NCAs](#).

Independently of any event, the ESMP Home page also includes information on how to report any critical shortages occurring in your country and how to request assistance from the MSSG in obtaining stocks of a medicine during critical shortages. These data submissions are not performed directly in the ESMP.

Figure 12: ESMP Home page and left-side navigation menu when a crisis is active



3.2. How to submit Stock and supply

Data on the available stock in hospitals, pharmacies and wholesalers, strategic reserve, planned minimum stock, historical consumption, and volume of prescriptions for all the products that have been marked as critical in your member state will be requested directly in the ESMP and submitted through this reporting data flow. This data will have to be submitted at a frequency which will be determined by the MSSG and tailored to each event.

The submission of stock and supply data is performed by downloading a template from the "Stock and supply" section which will be pre-filled with the products in scope of the crisis and with previously submitted data (if any), inserting the required data, and uploading the file directly in the ESMP, following a successful validation.

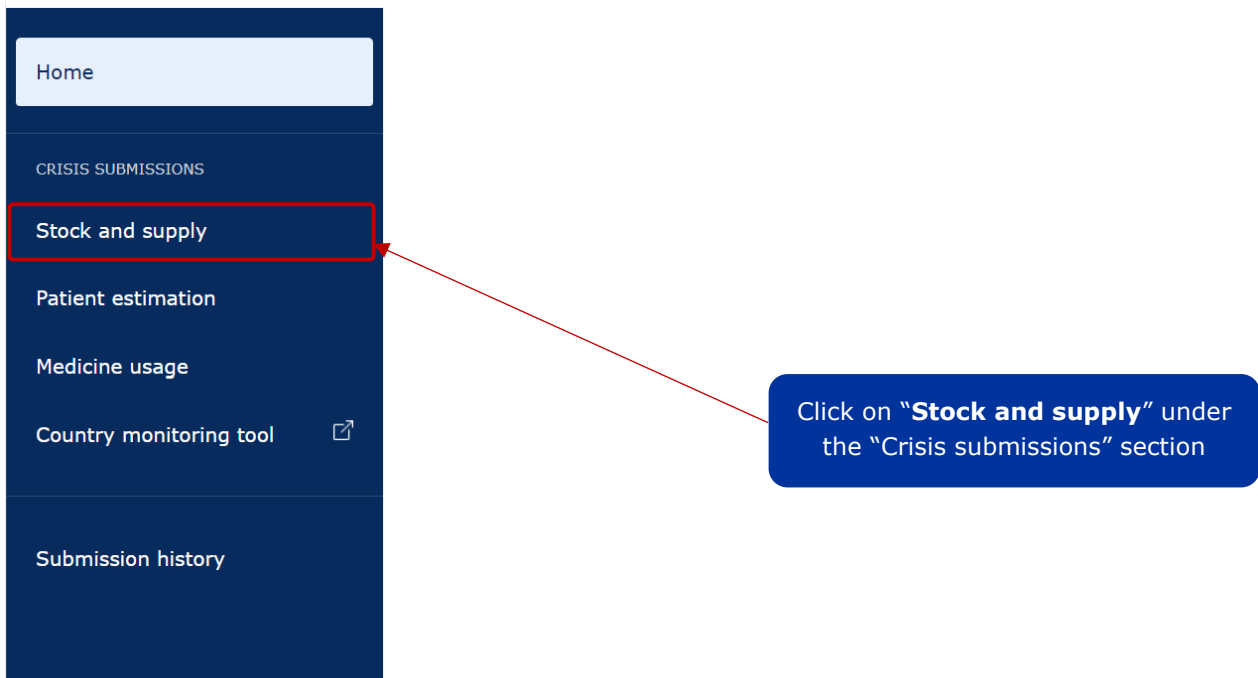
Please find below the step-by-step process to carry out the submission of stock and supply information through the ESMP.

3.2.1 Part 1: Download a reporting template

Step 1

In the home page, on the left-side navigation menu, click on the **"Stock and supply"** button.

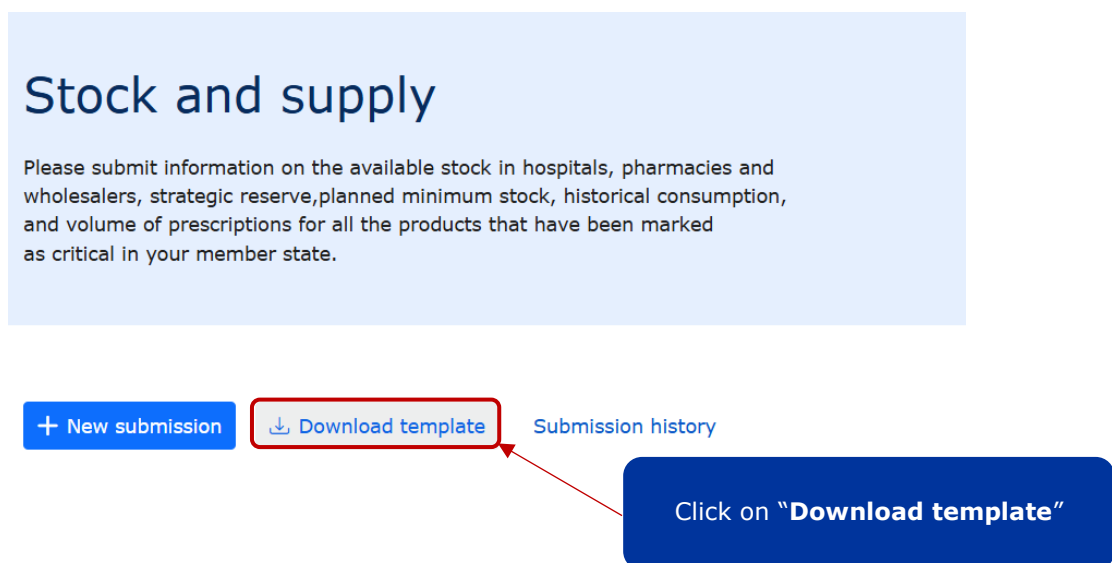
Figure 13: Left-side navigation menu - "Stock and supply" button



Step 2

In the "Stock and supply" page you can choose between three different options: "New submission", "Download template", and "Submission history". To obtain a pre-populated template with the product details against which you can enter the relevant information, you are requested to click on "Download template".

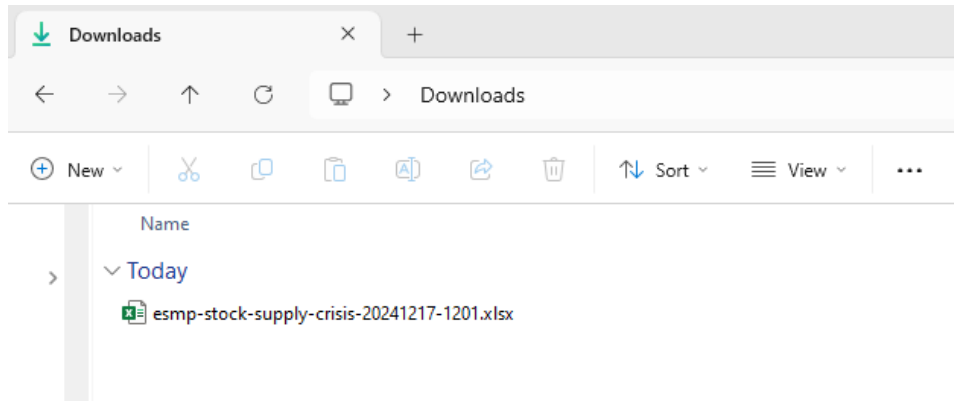
Figure 14: Stock and supply – Download reporting template



Step 3

Open the folder on your computer where the downloaded files are stored. You will find an Excel file with the name “**esmp-stock-supply-crisis-*<timestamp>*.xlsx**”. The template will include one column for each data element described in table 1.

Figure 15: Find the downloaded template in the Downloads folder of your computer



3.2.2 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 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 national competent authorities](#)¹³. Please consult this guide for further details to ensure the data will be correctly 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). 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](#)¹⁴.

¹³ https://www.ema.europa.eu/system/files/documents/other/esmp-implementation-guide-ncas_en_1.pdf

¹⁴ 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

 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 1 for clarity and completeness.

Important:

- **Insert the information at the level of packaged medicinal product.**

It would be good practice to select all the cells of the Excel file and change the format into "Text", to avoid any errors while populating the data.

Figure 16: How to change the cell format in the downloaded template

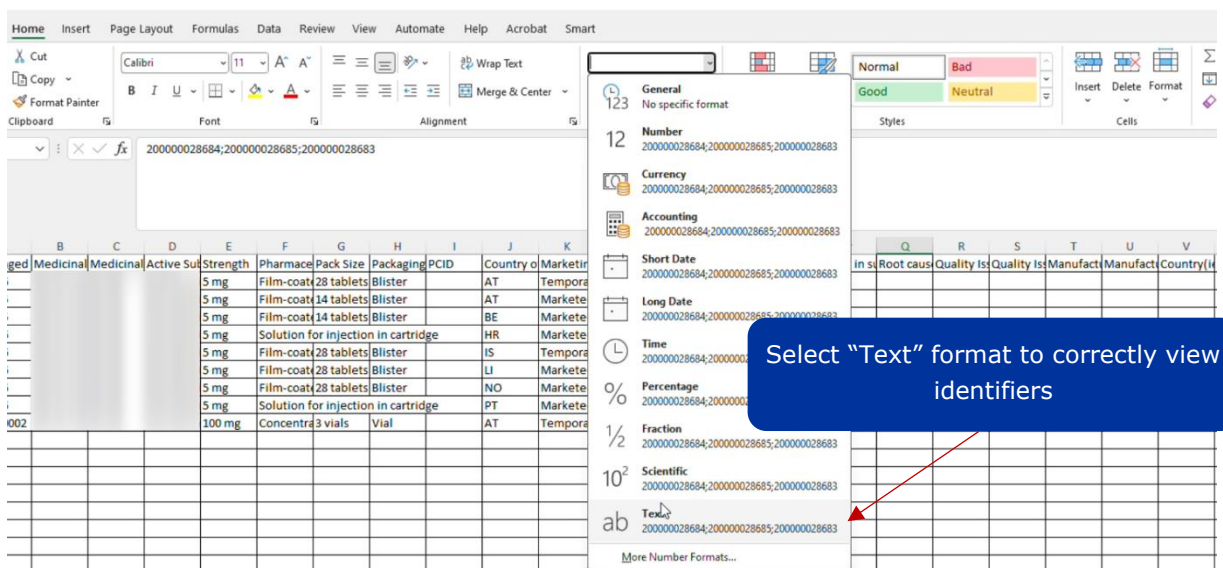


Table 1: Crisis - Stock and supply data elements

Data category	Data element name	Conformance
Product information	Package PMS ID	Pre-populated
	Full product name	Pre-populated
	Short product name	Pre-populated
	MAH	Pre-populated
	Active substance	Pre-populated
	Strength	Pre-populated
	Pharmaceutical form	Pre-populated
	Pack size	Pre-populated
	Packaging	Pre-populated
Member state available stock	Current hospital stock	Mandatory
	Current community pharmacy stock	Mandatory
	Current wholesale distributors stock	Mandatory



Data category	Data element name	Conformance
	Current strategic reserve	Mandatory
Planned minimum stock	Planned minimum stock	Mandatory
Planned strategic reserve	Planned strategic reserve - month 1	Mandatory
	Planned strategic reserve - month 2	Mandatory
	Planned strategic reserve - month 3	Mandatory
	Planned strategic reserve - month 4	Mandatory
	Planned strategic reserve - month 5	Mandatory
	Planned strategic reserve - month 6	Mandatory
Historical consumption	Historical consumption non-PHE/ME need - month 1	Mandatory
	Historical consumption non-PHE/ME need - month 2	Mandatory
	Historical consumption non-PHE/ME need - month 3	Mandatory
	Historical consumption non-PHE/ME need - month 4	Mandatory
	Historical consumption non-PHE/ME need - month 5	Mandatory
	Historical consumption non-PHE/ME need - month 6	Mandatory
Volume of prescriptions	Historical volume of prescriptions - month 1	Optional
	Historical volume of prescriptions - month 2	Optional
	Historical volume of prescriptions - month 3	Optional
	Historical volume of prescriptions - month 4	Optional
	Historical volume of prescriptions - month 5	Optional
	Historical volume of prescriptions - month 6	Optional

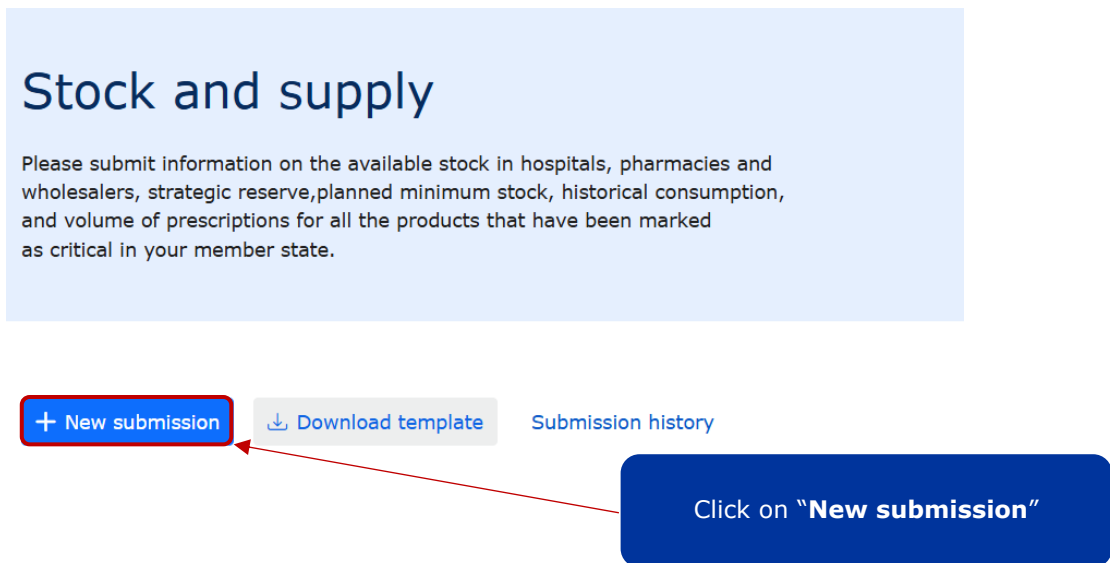
3.2.3 Part 3: Upload of the data into ESMP

Step-by-step process

Step 1

On the “**Stock and supply**” 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.

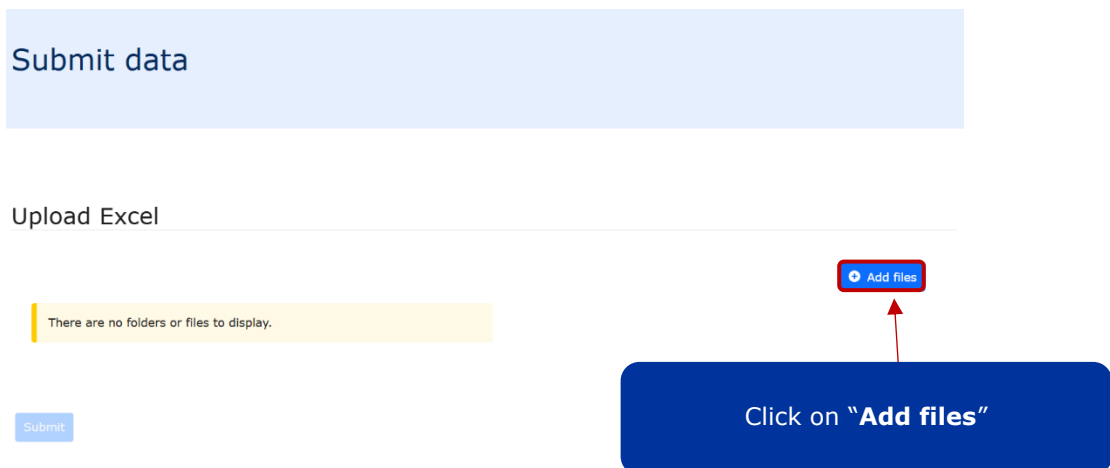
Figure 17: Stock and supply – New submission button



Step 2

Click on “**Add files**” on the right side of the “**Submit data**” page. This will open a dialogue box allowing you to add and upload a file into the ESMP.

Figure 18: Stock and supply – Submit data



Step 3

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.


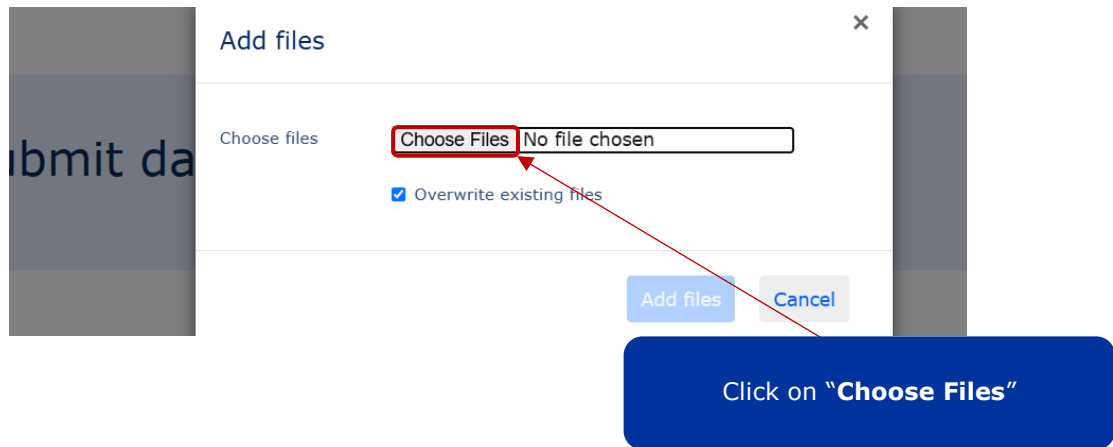
 The system only accepts the selection of one file at a time for submission. In case you select multiple files for submission, after clicking on "Add files", the error message "Only one file can be uploaded for a submission." will be displayed. Therefore, please select only one file at a time.

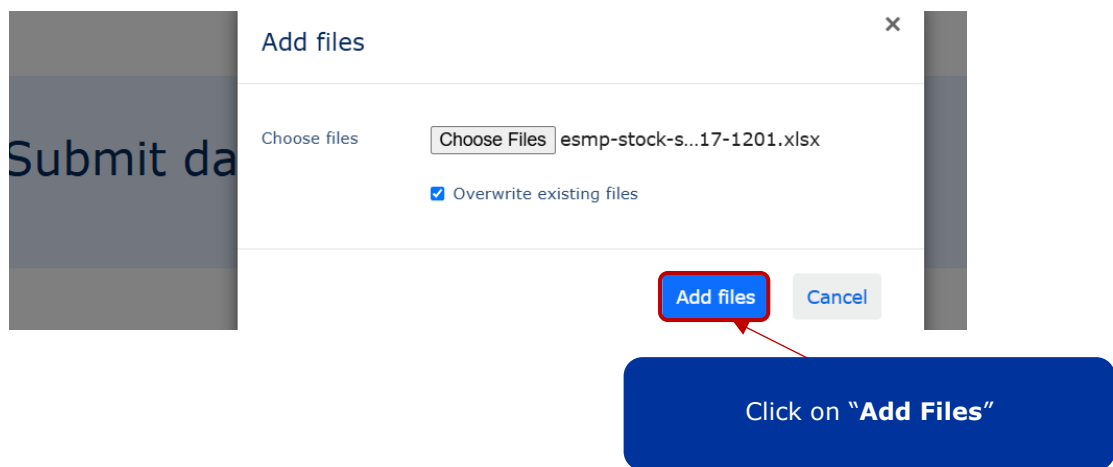
Figure 19: Stock and supply – Choose file to upload



Step 4

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 into the upload page.

Figure 20: Stock and supply – Add file




Step 5

The file you added will be listed on the table for upload, as shown below. If the added file mistakenly does not correspond to the one you intend to submit, use the arrow down to delete it. Upon deletion (from the table), the button "Add file" becomes again active and you can then restart the process from Step 2 to add the wanted file. When you have added the correct file, click on "Submit". This will start the validation process of the file.

Figure 21: Stock and supply – Submit file

Submit data

Upload Excel



Name ↑	Modified
esmp-stock-supply-crisis-20241217-1201.xlsx (17 KB)	less than a minute ago

Submit

Click on "Submit"

Step 6

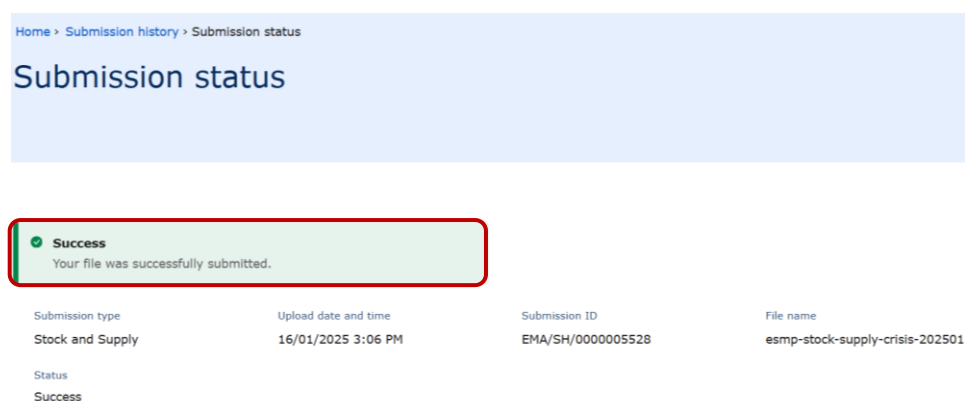
Validation of the submitted file may take some time. Feel free to close the page or move to another page while the file is being processed, since the submission will proceed in the background. To retrieve the details of the current submission or any past submission, consult the "Submission history" page.

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 read "**Success**". Your upload is therefore successfully completed, and your submission is final.

Figure 22: : Stock and supply – Submission status – Success



Home > Submission history > Submission status

Submission status

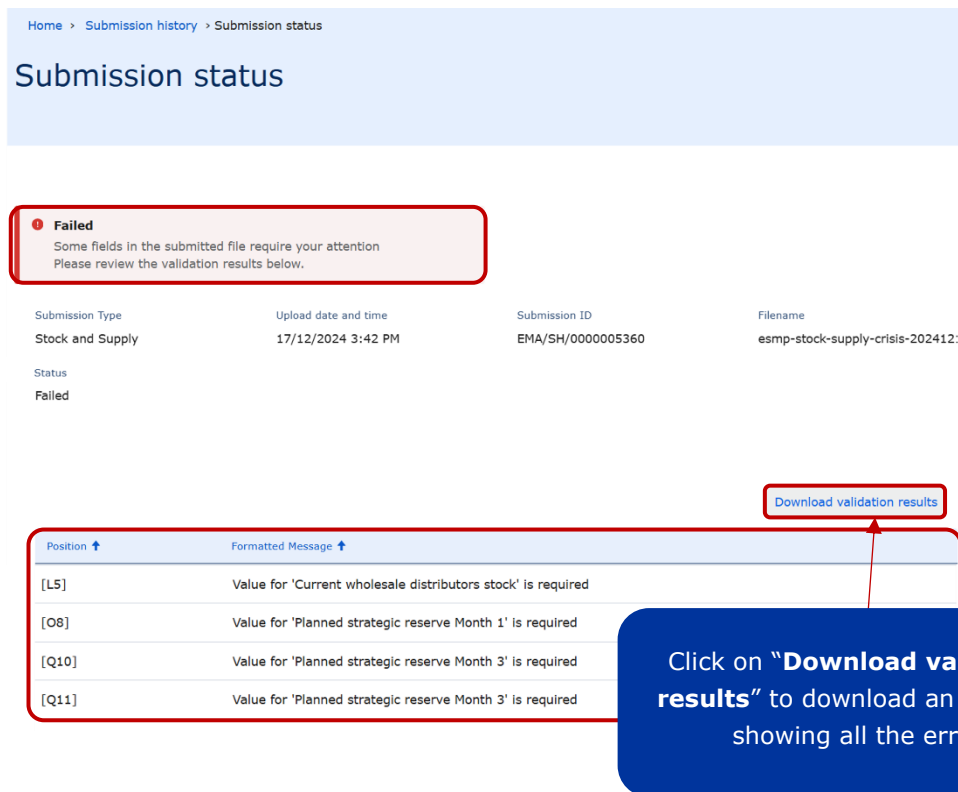
Success
Your file was successfully submitted.

Submission type	Upload date and time	Submission ID	File name
Stock and Supply	16/01/2025 3:06 PM	EMA/SH/0000005528	esmp-stock-supply-crisis-202501:
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 all the errors.

Figure 23: Stock and supply – Submission status – Fail



Home > Submission history > Submission status

Submission status

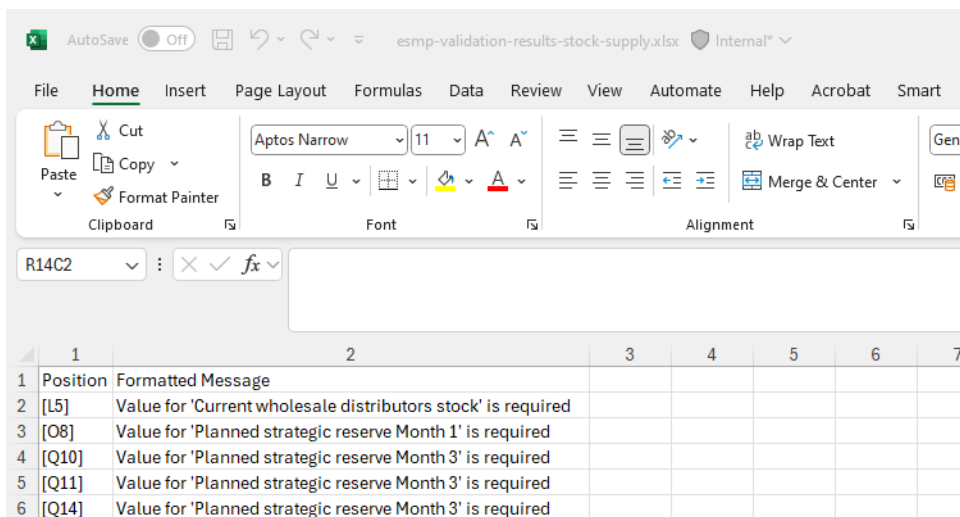
Failed
Some fields in the submitted file require your attention
Please review the validation results below.

Submission Type	Upload date and time	Submission ID	Filename
Stock and Supply	17/12/2024 3:42 PM	EMA/SH/000005360	esmp-stock-supply-crisis-202412:
Status	Failed		

Position	Formatted Message
[L5]	Value for 'Current wholesale distributors stock' is required
[O8]	Value for 'Planned strategic reserve Month 1' is required
[Q10]	Value for 'Planned strategic reserve Month 3' is required
[Q11]	Value for 'Planned strategic reserve Month 3' is required

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

Figure 24: Stock and supply – Validation results – Excel file view



Position	Formatted Message
[L5]	Value for 'Current wholesale distributors stock' is required
[O8]	Value for 'Planned strategic reserve Month 1' is required
[Q10]	Value for 'Planned strategic reserve Month 3' is required
[Q11]	Value for 'Planned strategic reserve Month 3' is required
[Q14]	Value for 'Planned strategic reserve Month 3' is required

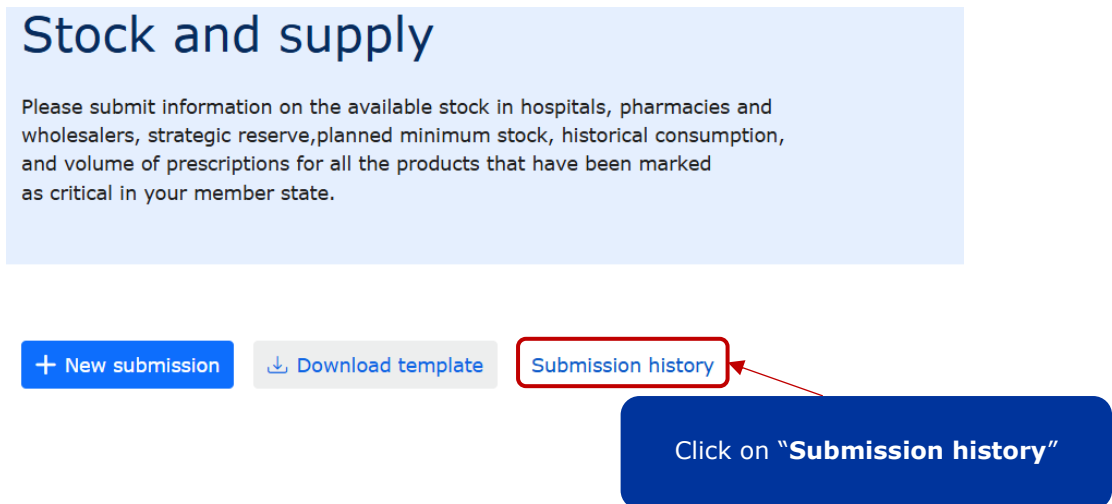
Open the “**esmp-validation-results-stock-supply**” Excel file to view the details of the reported errors. For further information on the listed errors and validation rules that may prevent you from successfully completing your submission, consult the requirements for each data set and data element as described in the [ESMP Implementation guide for national competent authorities](https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-national-competent-authorities_en.pdf)¹⁵. Re-open the submission file that you wish to upload from your computer and address each of the described errors

¹⁵ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-national-competent-authorities_en.pdf

in the **"esmp-validation-results-stock-supply"** file. Save your changes and repeat the upload process with the amended file.

Note: 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 **"Stock and supply"** page.

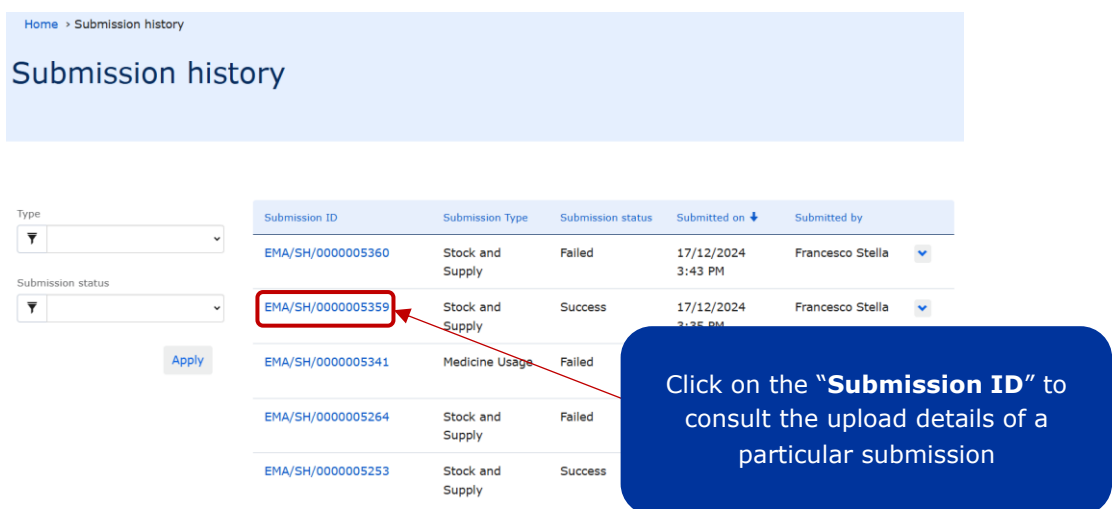
Figure 25: Stock and supply – Submission history



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 26: Stock and supply – Submission history page



For more information about a particular submission, click on its **"Submission ID"**. The **"Submission status"** page for the selected submission will open. 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).

3.3. How to submit Patient estimation

During a crisis, NCAs are required to report Patient estimation information for medicinal products in scope of reporting requirements included in the list of critical medicines for a specific public health emergency or major event.

The submission of patient estimation data is performed by downloading a template from the “**Patient estimation**” section which will be pre-filled with the products in scope of the crisis and with previously submitted data (if any), inserting the required data on the estimated number of patients to be vaccinated, hospitalised or admitted to the intensive care unit (ICU) for all the products that have been marked as critical, 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 patient estimation information through the ESMP.

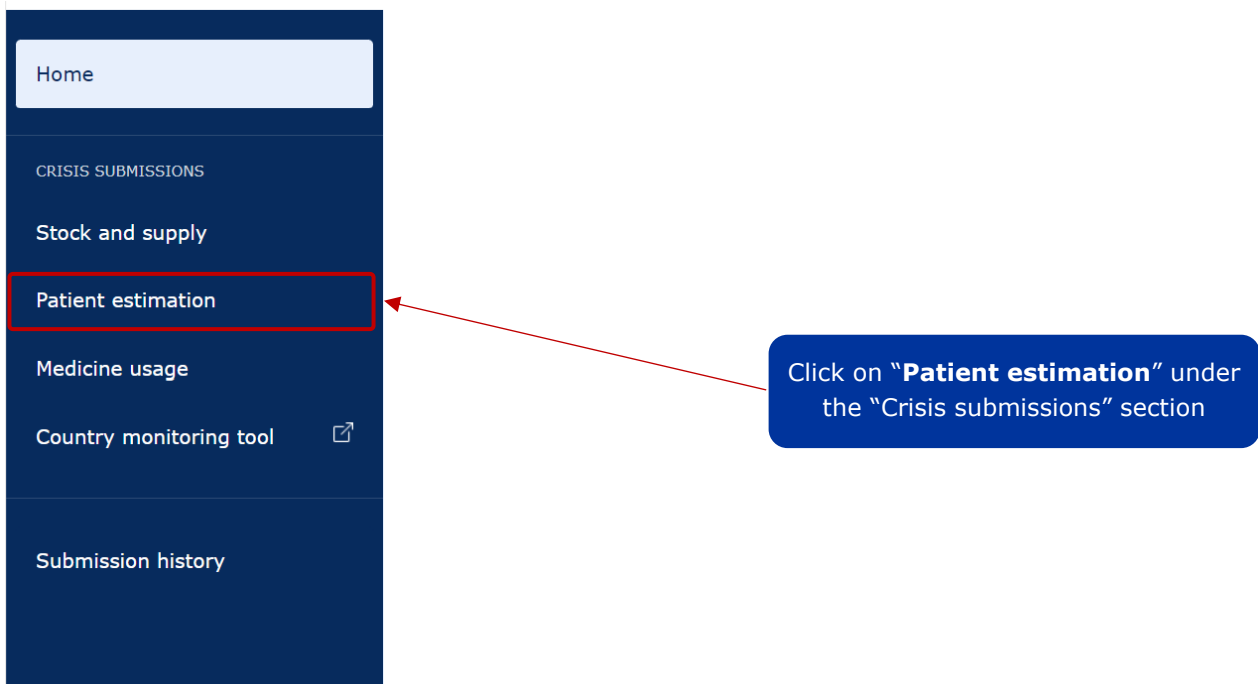
Step-by-step process

3.3.1 Part 1: Download a reporting template

Step 1

In the home page, on the left-side navigation menu, click on the “**Patient estimation**”.

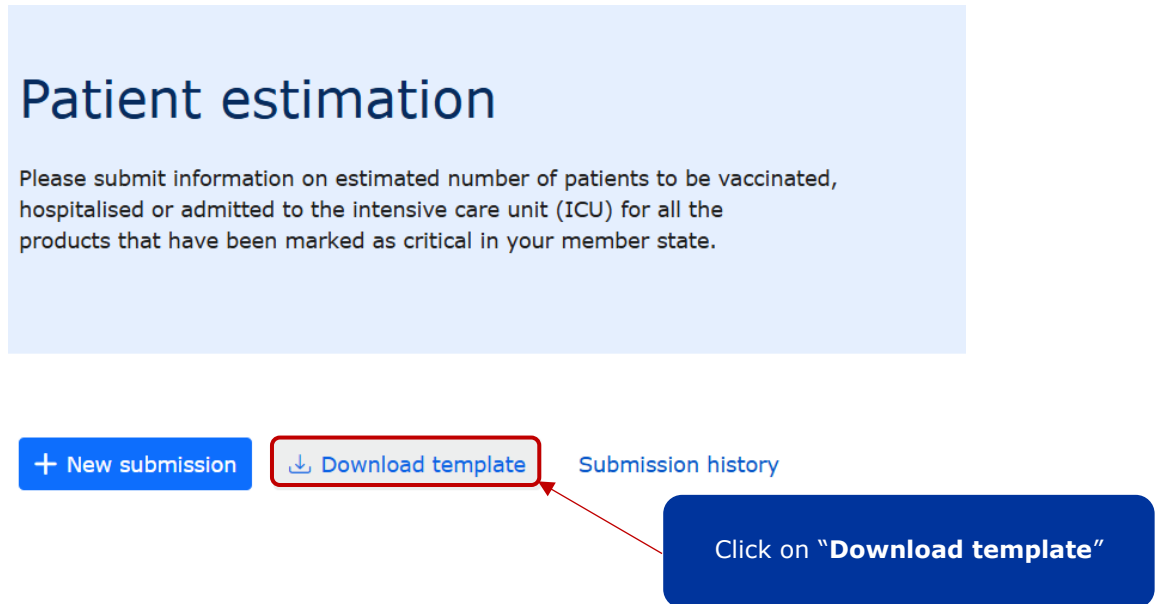
Figure 27: Left-side navigation menu - “Patient estimation” button



Step 2

In the “**Patient estimation**” page you can choose between three different options: “**New submission**”, “**Download template**”, and “**Submission history**”. To obtain a pre-populated template with the product details against which you can enter the relevant information, you are requested to click on “**Download template**”.

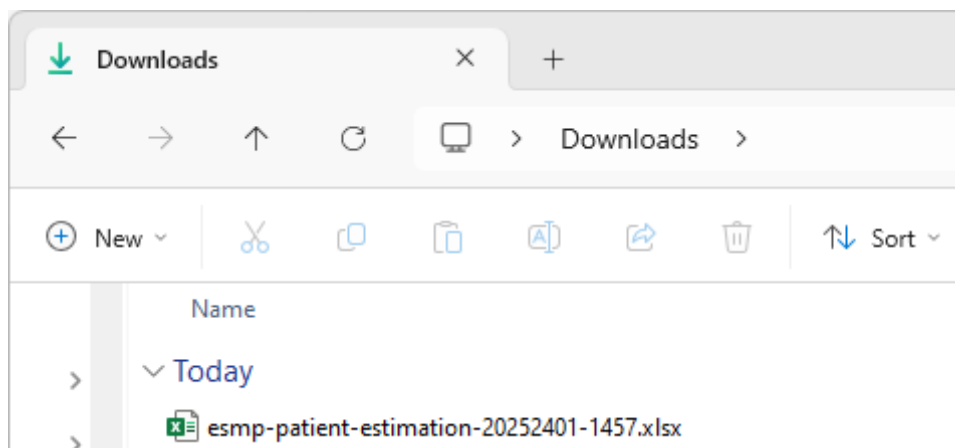
Figure 28: Patient estimation – Download reporting template



Step 3

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

Figure 29: Patient estimation - Downloaded template



3.3.2 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 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 national competent authorities](#)¹⁶. 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 filled in to successfully upload the file. For the “PHE/ME RMS ID” field you are required to fill in an RMS identifier (RMS ID) defined/included in the RMS list “Declared Public Health Emergency or Major Event” with list ID “200000026052”. For more information please consult RMS lists in the [SPOR platform](#)¹⁷ or the [ESMP Implementation guide for national competent authorities](#)¹⁸.

Important:

 When pasting RMS identifiers, which are 12 digits IDs that codify data used 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 need to change the cell format into “Text”, as shown in figure 30 below, to show the RMS identifiers correctly.

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

¹⁶ https://www.ema.europa.eu/system/files/documents/other/esmp-implementation-guide-ncas_en_1.pdf

¹⁷ <https://spor.ema.europa.eu/rmswi/#/lists>

¹⁸ https://www.ema.europa.eu/system/files/documents/other/esmp-implementation-guide-ncas_en_1.pdf

Figure 30: How to change the cell format in the downloaded template

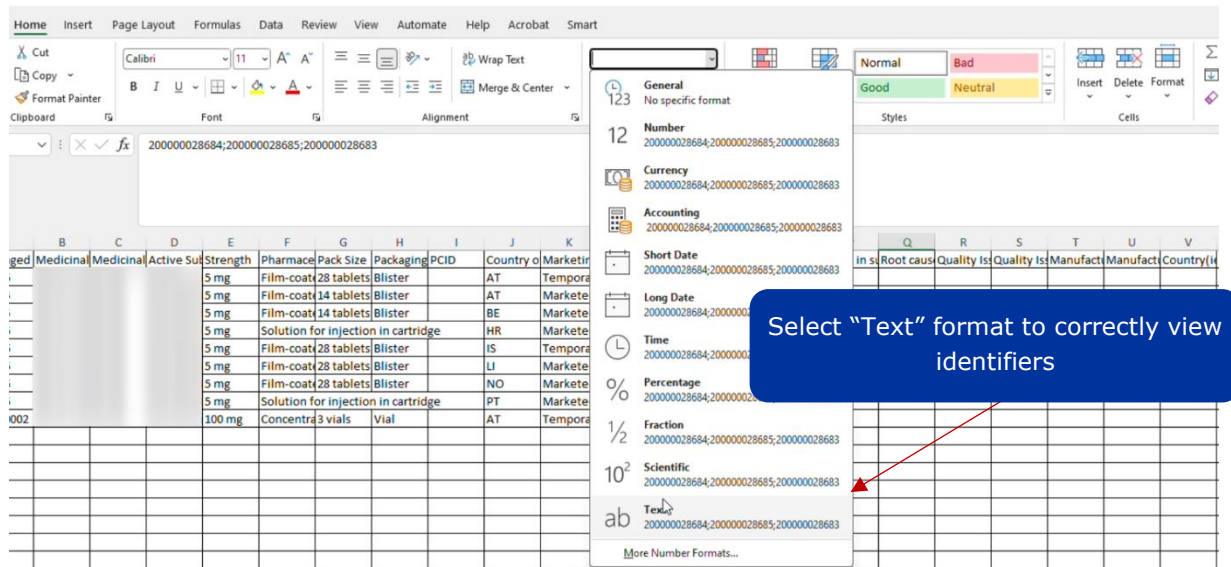


Table 2: Crisis - Patient estimation data elements

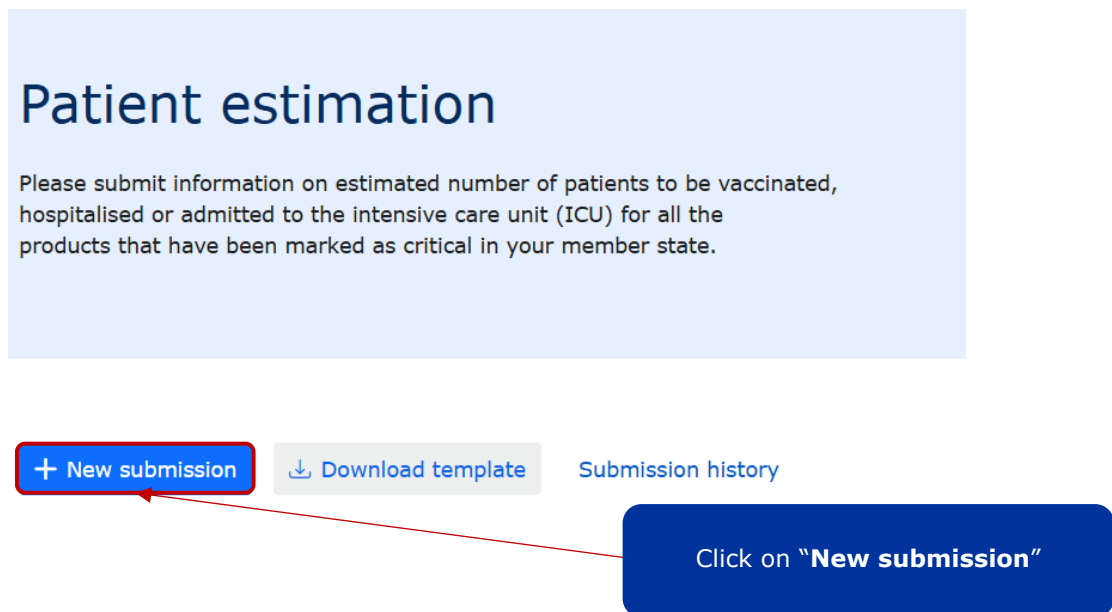
Data category	Data element name	Conformance
Vaccination	Estimated total number of patients - month 1	Mandatory
	Estimated total number of patients - month 2	Mandatory
	Estimated total number of patients - month 3	Mandatory
	Estimated total number of patients - month 4	Mandatory
	Estimated total number of patients - month 5	Mandatory
	Estimated total number of patients - month 6	Mandatory
Hospital	Estimated total number of hospitalized patient-days - month 1	Mandatory
	Estimated total number of hospitalized patient-days - month 2	Mandatory
	Estimated total number of hospitalized patient-days - month 3	Mandatory
	Estimated total number of hospitalized patient-days - month 4	Mandatory
	Estimated total number of hospitalized patient-days - month 5	Mandatory
	Estimated total number of hospitalized patient-days - month 6	Mandatory
ICU	Estimated total number of ICU patient-days - month 1	Mandatory
	Estimated total number of ICU patient-days - month 2	Mandatory
	Estimated total number of ICU patient-days - month 3	Mandatory
	Estimated total number of ICU patient-days - month 4	Mandatory
	Estimated total number of ICU patient-days - month 5	Mandatory
	Estimated total number of ICU patient-days - month 6	Mandatory
	PHE/ME RMS ID	Mandatory

3.3.3 Part 3: Upload of the data into ESMP

Step 1

On the “**Patient estimation**” 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.

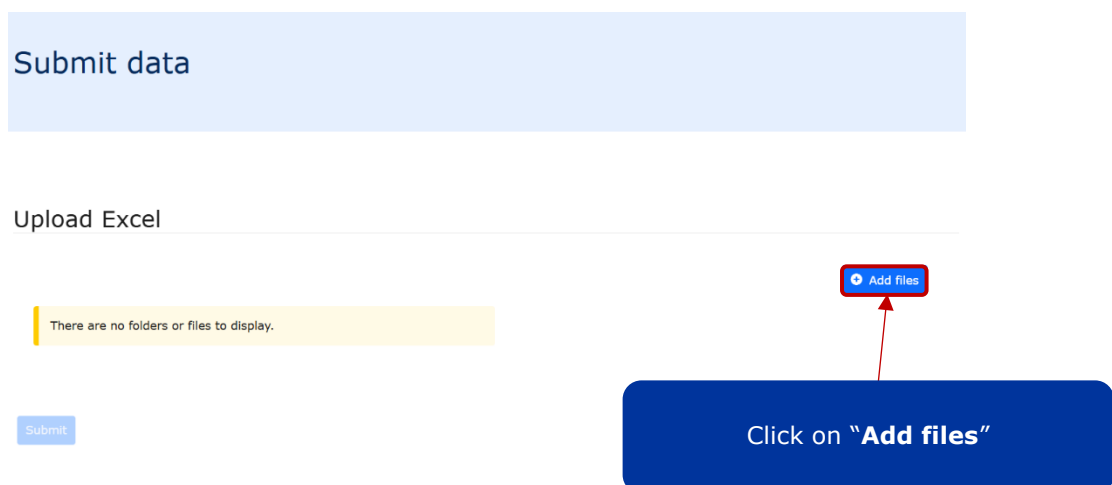
Figure 31: Patient estimation – New submission button



Step 2

Click on “**Add files**” on the right side of the “**Submit data**” page. This will open a dialogue box allowing you to add and upload a file into the ESMP.

Figure 32: Patient estimation – Submit data



Step 3

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.


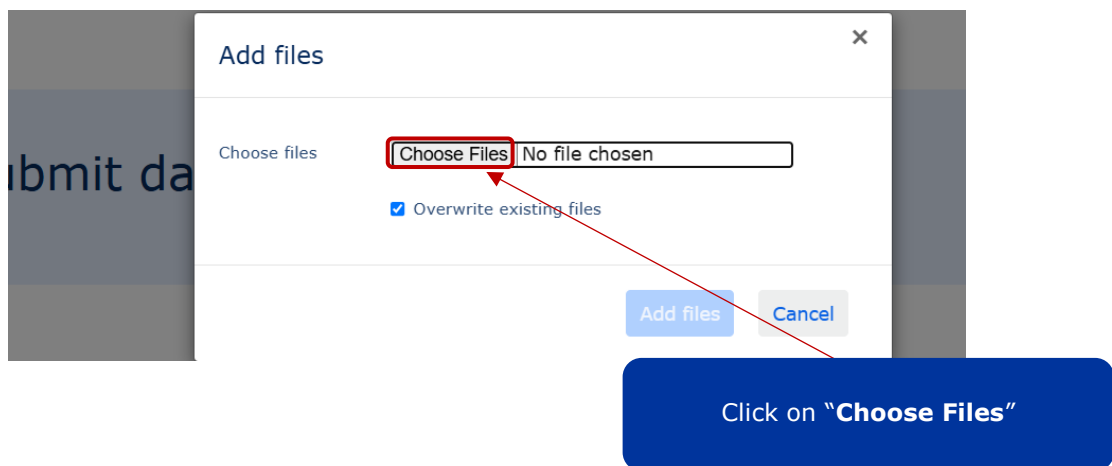
 The system only accepts the selection of one file at a time for submission. In case you select multiple files for submission, after clicking on **“Add files”**, the error message **“Only one file can be uploaded for a submission.”** will be displayed. Therefore, please select only one file at a time.

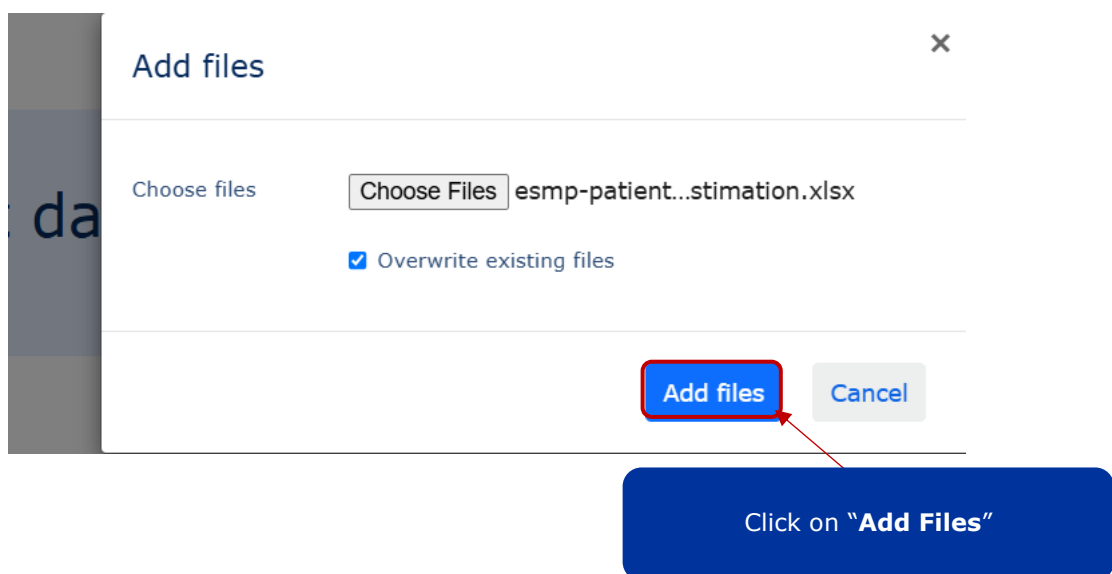
Figure 33: Patient estimation – Choose file to upload



Step 4

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 into the upload page.

Figure 34: Patient estimation - Add file

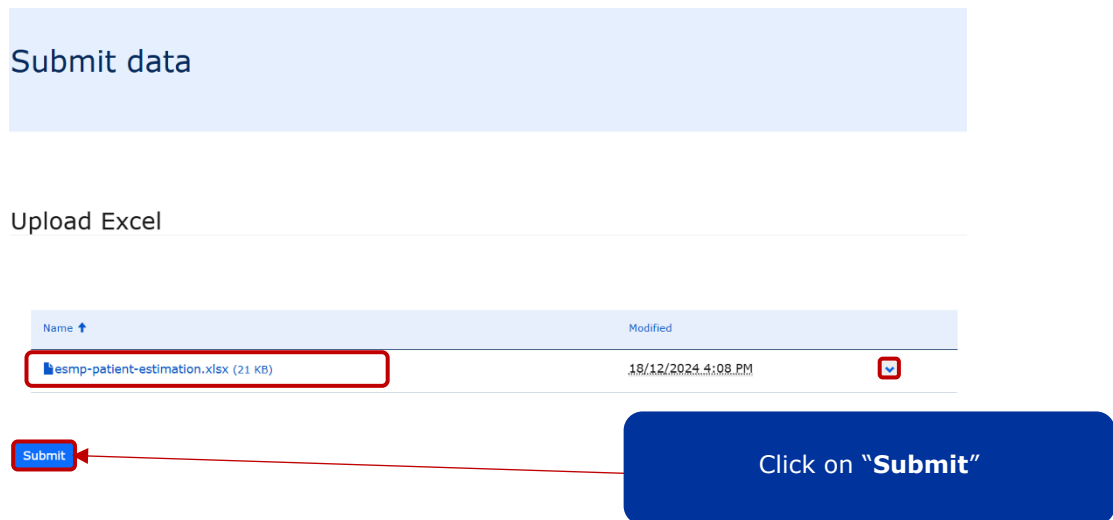


Step 5

The file you added will be listed on the table for upload, as shown below. If the added file mistakenly does not correspond to the one you intend to submit, use the arrow down to delete it. Upon deletion

(from the table), the button "Add file" becomes again active and you can then restart the process from Step 2 to add the wanted file. When you have added the correct file, click on "**Submit**". This will start the validation process of the file.


Figure 35: Patient estimation – Submit file



Step 6

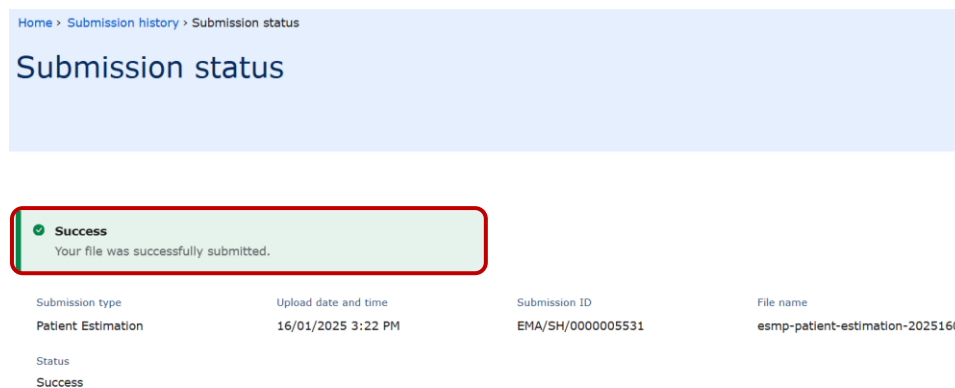
Validation of the submitted file may take some time. Feel free to close the page or move to another page while the file is being processed, since the submission will proceed in the background. To retrieve the details of the current submission or any past submission, consult the "Submission history" page.

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 read "**Success**", while the "**Error log view**" will read "**There are no records to display**". Your upload is therefore successfully completed, and your submission is final.

Figure 36: Patient estimation – Submission status – Success

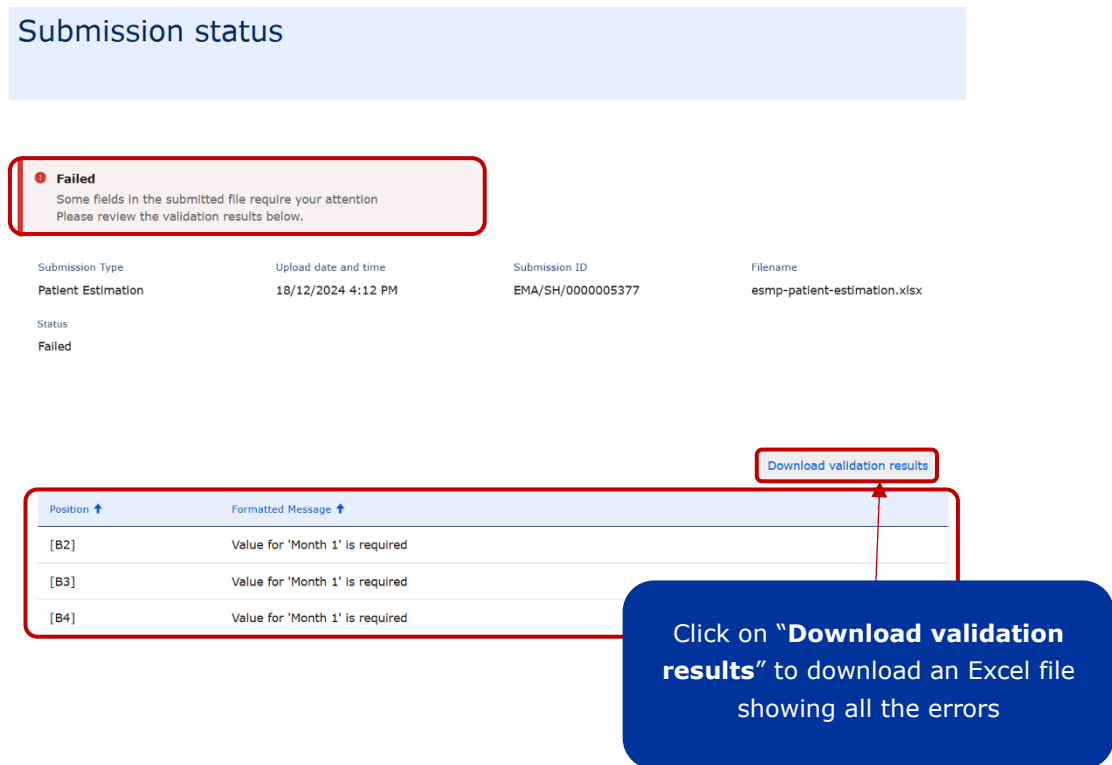


If your upload fails, the "**Upload status**" will show "**Failed**". If this happens, please review the "**Validation results**" section at the bottom of the page. The validation results' section lists errors encountered in the file, along with their location in the file (row number and column letter, 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 all the errors.

Figure 37: Patient estimation – Submission status – Fail



Submission status

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

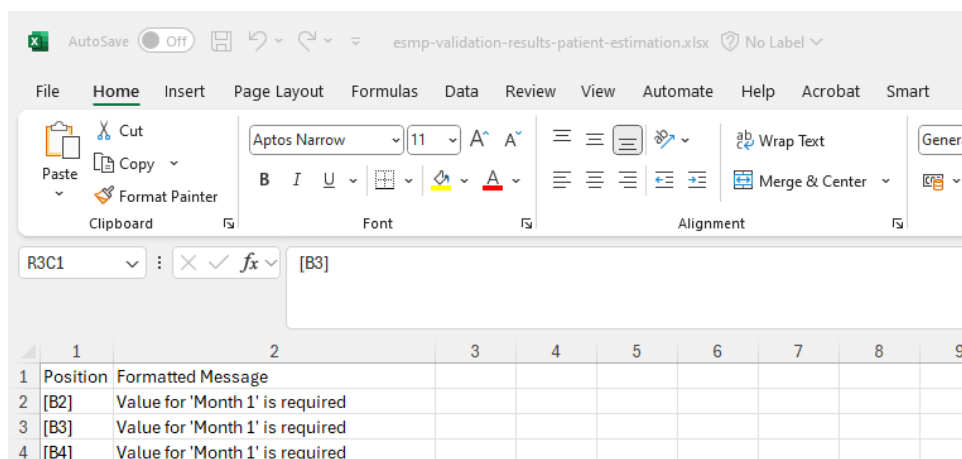
Submission Type	Upload date and time	Submission ID	Filename
Patient Estimation	18/12/2024 4:12 PM	EMA/SH/0000005377	esmp-patient-estimation.xlsx
Status			
Failed			

Position ↑	Formatted Message ↑
[B2]	Value for 'Month 1' is required
[B3]	Value for 'Month 1' is required
[B4]	Value for 'Month 1' is required

[Download validation results](#)

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

Figure 38: Patient estimation – Validation results – Excel file view



AutoSave Off esmp-validation-results-patient-estimation.xlsx No Label

File Home Insert Page Layout Formulas Data Review View Automate Help Acrobat Smart

Clipboard Font Alignment

R3C1 [B3]

	1	2	3	4	5	6	7	8	9
1	Position	Formatted Message							
2	[B2]	Value for 'Month 1' is required							
3	[B3]	Value for 'Month 1' is required							
4	[B4]	Value for 'Month 1' is required							

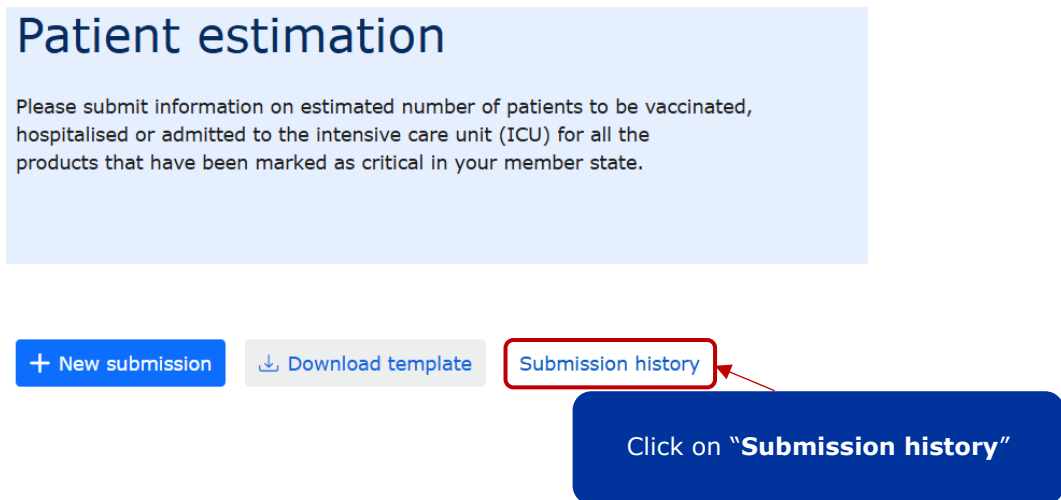
Open the “**esmp-validation-results-patient-estimation**” Excel file and read the details of the reported errors. For further information on the listed errors and validation rules that may prevent you from successfully completing your submission, consult the requirements for each data set and data element as described in the [ESMP Implementation guide for national competent authorities](https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-national-competent-authorities_en.pdf)¹⁹. Re-open the submission file that you wish to upload from your computer and address each of the described

¹⁹ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-national-competent-authorities_en.pdf

errors in the **“esmp-validation-results-patient-estimation”** file. Save your changes and repeat the upload process.

Note: 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 **“Patient estimation”** page.

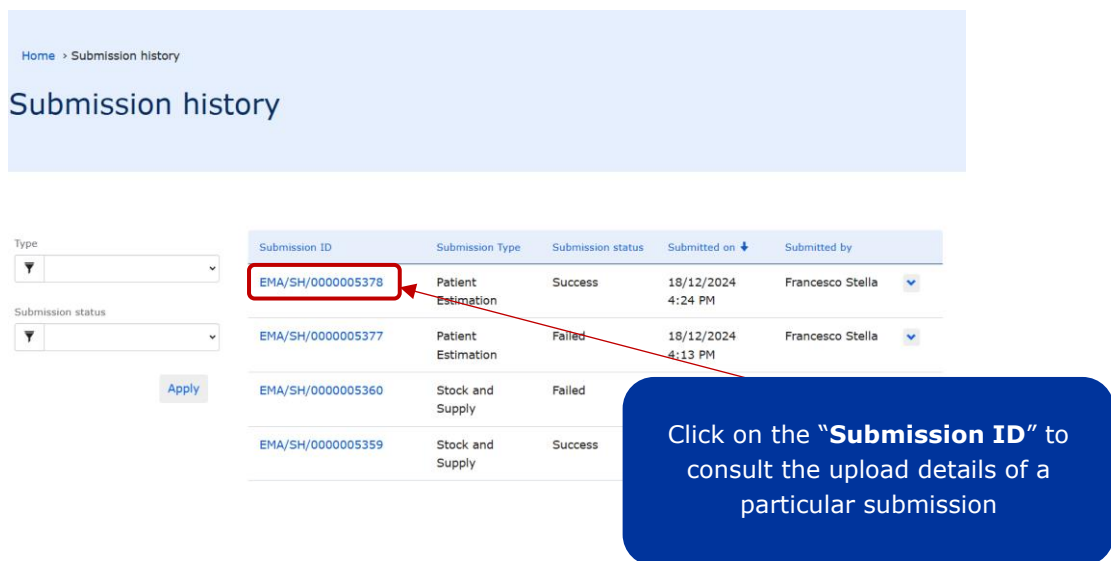
Figure 39: Patient estimation – Submission history



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 40: Patient estimation – Submission history page



For more information about a particular submission, click on its **“Submission ID”**. The **“Submission status”** page for the selected submission will open. 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).

3.4. How to submit Medicine usage

To collect Medicine usage information on medicinal products in scope of reporting requirements for a particular crisis, 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 active substance and pharmaceutical dose form data from the products in scope of reporting requirements. The template will also be pre-populated with information previously submitted to the EMA through ESMP for Medicine usage, if applicable.

Please **do not change the pre-populated fields which have been retrieved from other EMA systems** (e.g. PMS) 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 SPOR database.

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

Step-by-step process

3.4.1 Part 1: Download a reporting template

Step 1

In the home page, on the left-side navigation menu, click on the "**Medicine usage**".

Figure 41: Left-side navigation menu - "Medicine usage" button

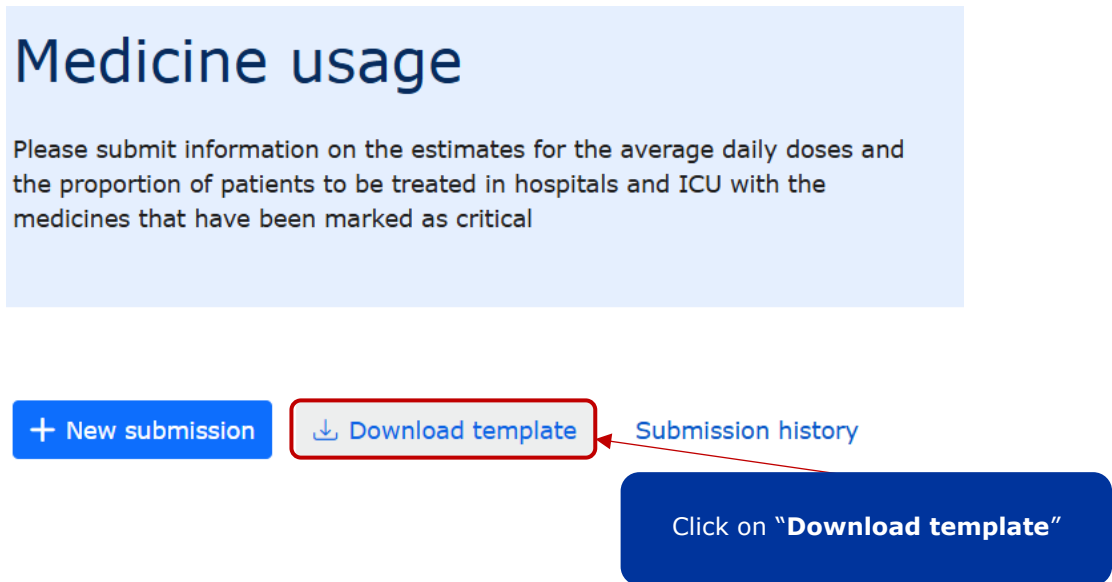


Step 2

On the "**Medicine usage**" page, you can choose between three different options "**New submission**", "**Download template**", and "**Submission history**". To obtain a pre-populated template with the

product details against which you can enter the relevant information, you are requested to click on **“Download template”**.

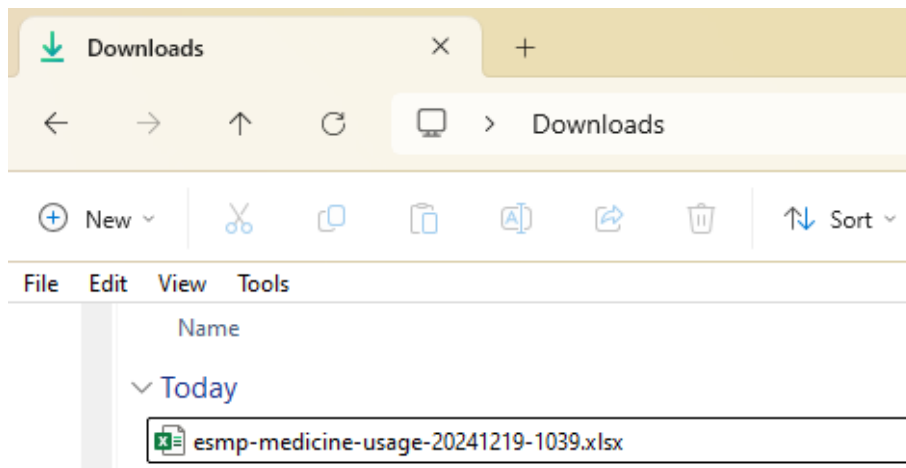
Figure 42: Medicine usage – Download reporting template



Step 3

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

Figure 43: Medicine usage - Downloaded template



3.4.2 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 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 national competent authorities](#)²⁰. Please consult this guide for further details to ensure the data will be correctly uploaded in the ESMP.

In particular, please note that you are only required to provide data either in the Hospital fields or the ICU fields, but not both.

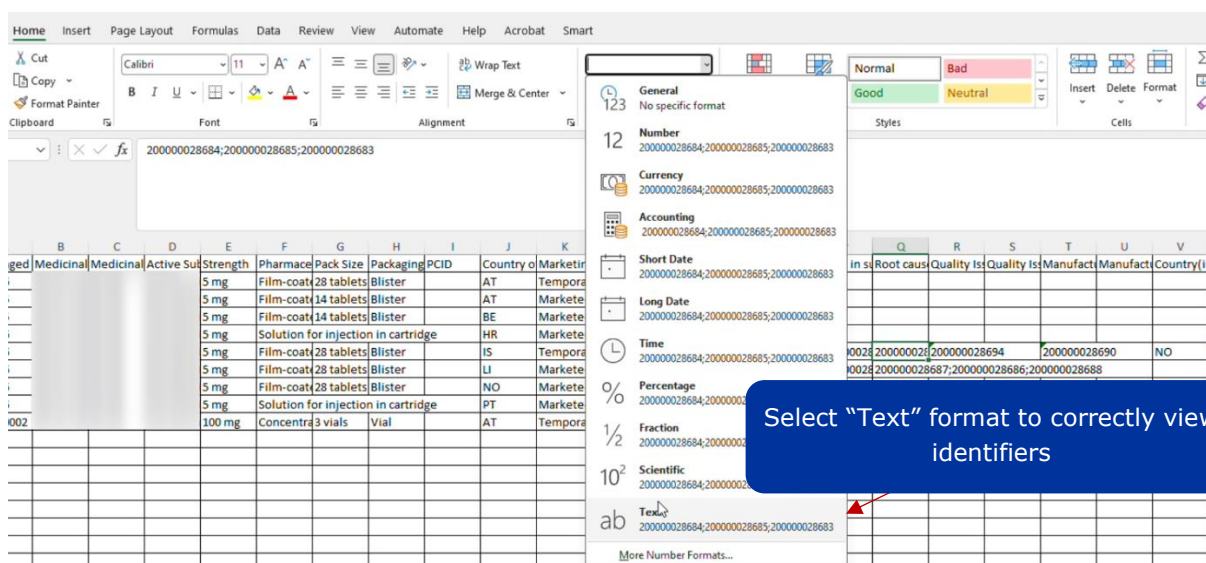
Table 3 provides an overview of all data elements reported in the columns of the template for the submission to the ESMP. All mandatory elements must be filled in to successfully upload the file.

The “Active substance” and the “Pharmaceutical dose form” related **fields will be pre-populated** by the system in the template, retrieving data already from EMA’s Substances and Referential Management Service (SMS and RMS), respectively and tailored to the scope of that particular crisis.

 Please **do not change the pre-populated fields which have been retrieved from other EMA systems** while completing the submission procedure. Any changes to product information submitted into the ESMP will not be processed by the system, hence will not generate any changes in the SPOR database. The pre-populated fields are listed in table 3 for clarity and completeness.

As a good practice, select all the cells of the Excel file and change the format into “Text”, to avoid any errors while populating the data.

Figure 44: How to change the cell format in the downloaded template



²⁰ https://www.ema.europa.eu/system/files/documents/other/esmp-implementation-guide-ncas_en_1.pdf

Table 3: Crisis - Medicine usage data elements

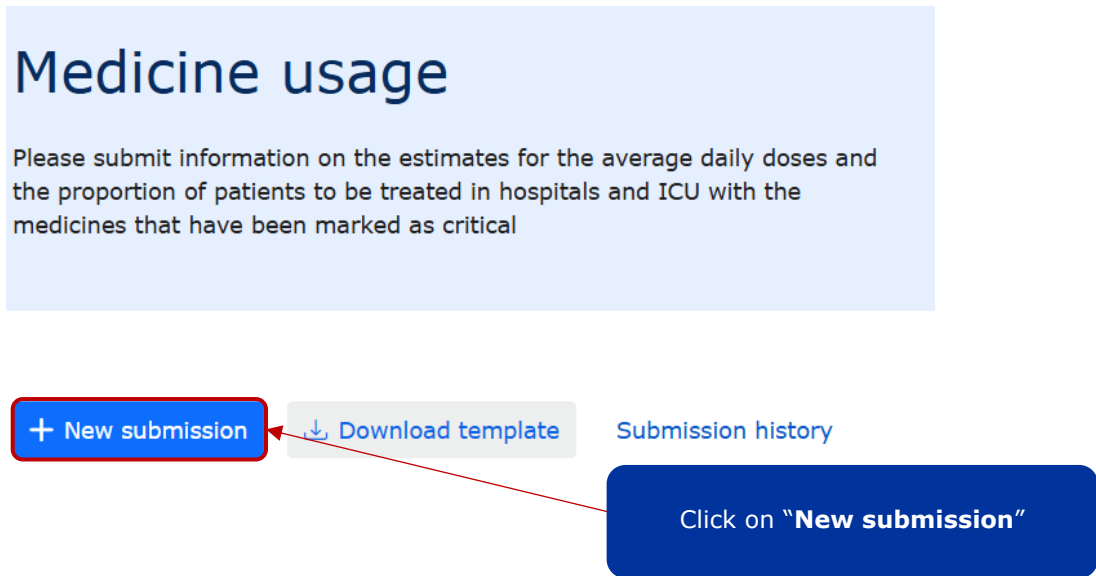
Data category	Data element name	Conformance
Product information	Active substance (SMS ID)	Pre-populated
	Active substance	Pre-populated
	Pharmaceutical dose form (RMS ID)	Pre-populated
	Pharmaceutical dose form	Pre-populated
Patient dosage-Hospital	Average daily dose of medicine per adult patient - hospital (mg/patient-day)	Conditional
	Proportion of estimated patients receiving the medicine - hospital	Conditional
Patient dosage-ICU	Average daily dose of medicine per adult patient - ICU (mg/patient-day)	Conditional
	Proportion of estimated patients receiving the medicine - ICU	Conditional

3.4.3 Part 3: Upload of the data into ESMP

Step 1

On the **"Medicine usage"** 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.

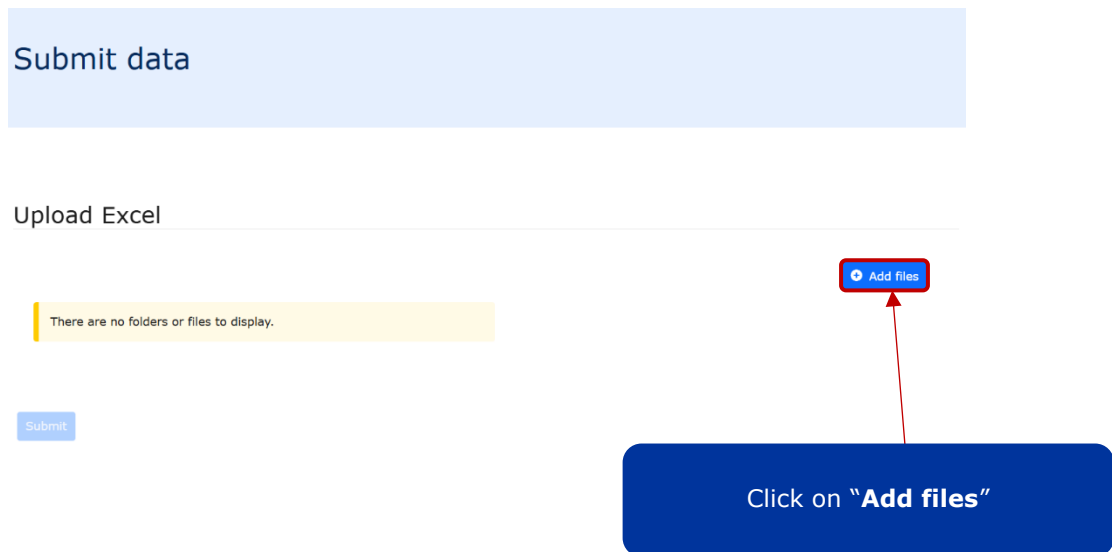
Figure 45: Medicine usage – New submission button



Step 2

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

Figure 46: Medicine usage – Submit data



Step 3

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.


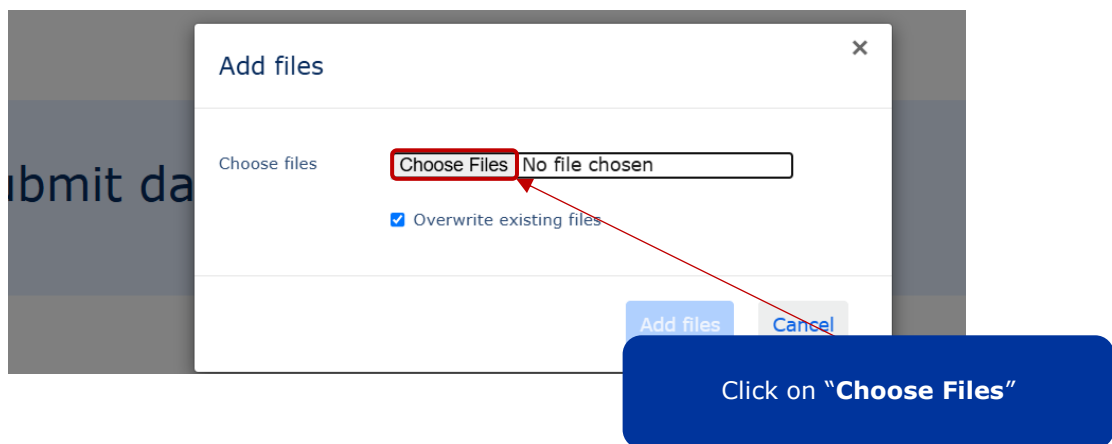
 The system only accepts the selection of one file at a time for submission. In case you select multiple files for submission, after clicking on **“Add files”**, the error message **“Only one file can be uploaded for a submission.”** will be displayed. Therefore, please select only one file at a time.

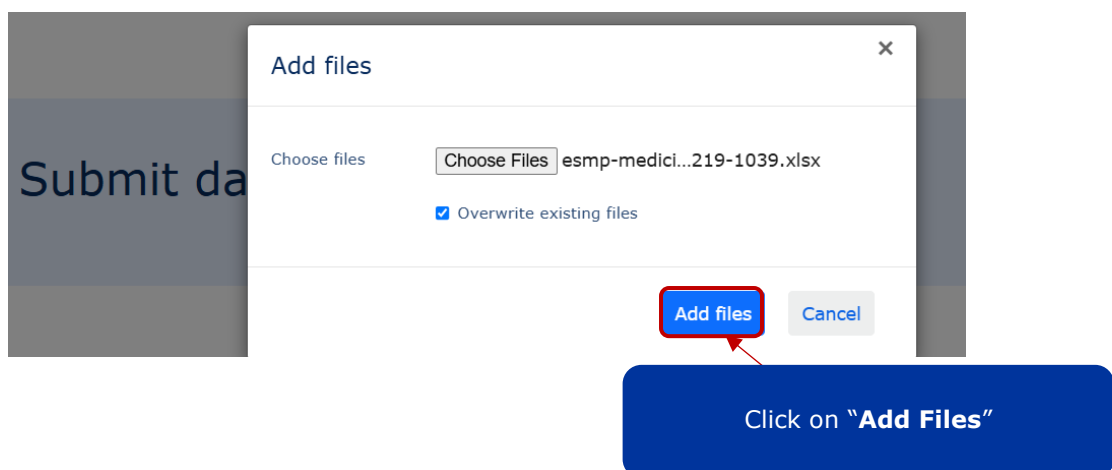
Figure 47: Medicine usage – Choose file to upload



Step 4

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 into the upload page.

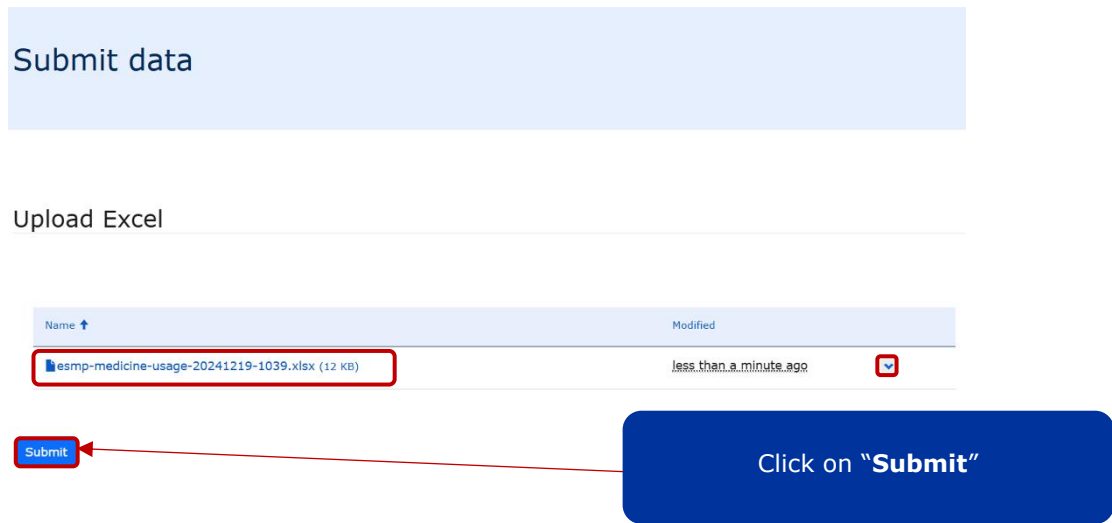
Figure 48: Medicine usage - Add file



Step 5

The file you added will be listed on the table for upload, as shown below. If the added file mistakenly does not correspond to the one you intend to submit, use the arrow down to delete it. Upon deletion (from the table), the button **“Add file”** becomes again active and you can then restart the process from Step 2 to add the wanted file. When you have added the correct file, click on **“Submit”**. This will start the validation process of the file.


Figure 49: Medicine usage – Submit file



Step 6

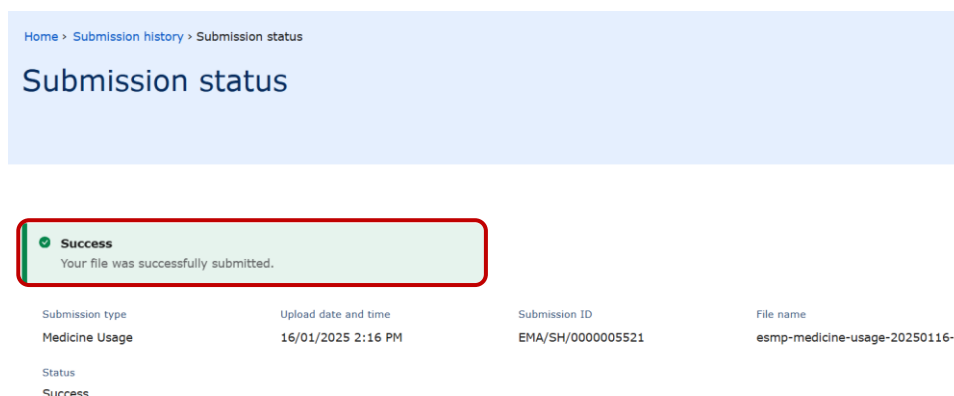
Validation of the submitted file may take some time. Feel free to close the page or move to another page while the file is being processed, since the submission will proceed in the background. To retrieve the details of the current submission or any past submission, consult the "Submission history" page.

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 read "**Success**", while the "**Error log view**" will read "**There are no records to display**". Your upload is therefore successfully completed, and your submission is final.

Figure 50: Medicine usage – upload Success status

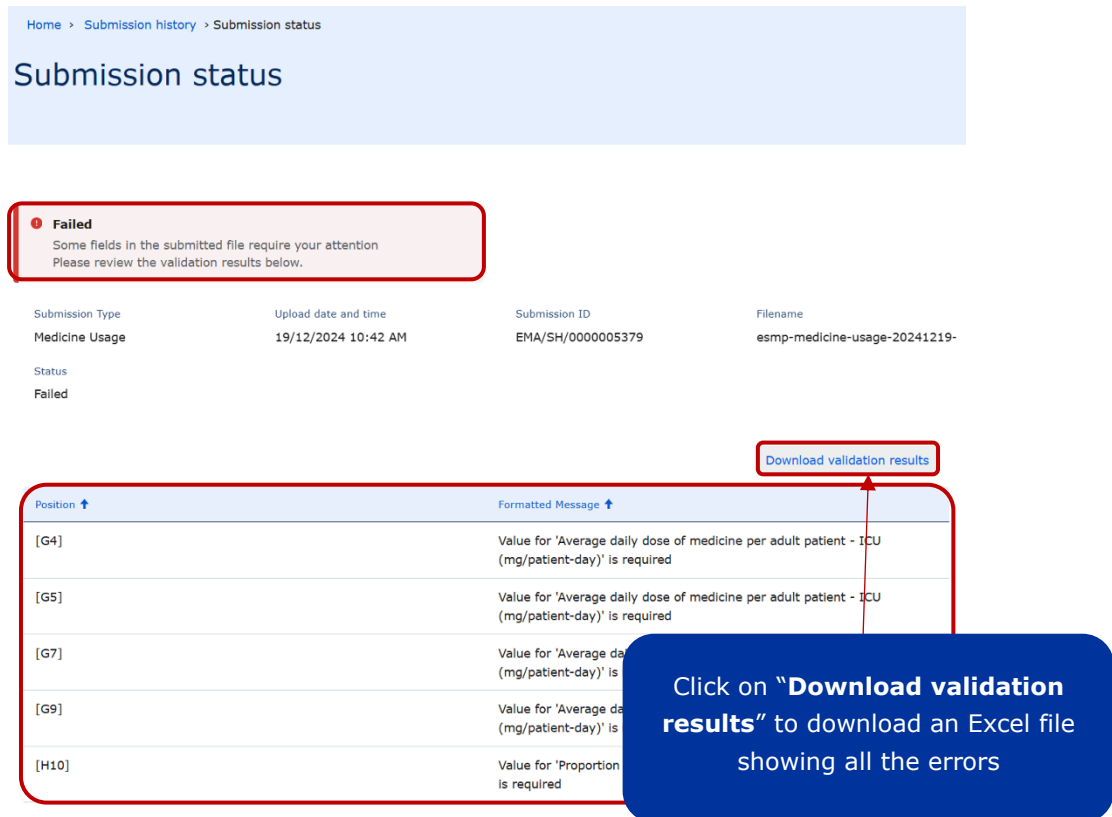


If your upload fails, the "**Upload status**" will show "**Failed**". If this happens, please review the list of **validation results** in the submitted file, which is displayed on the Submission status page, below the metadata on a particular submission. The validation results' section lists errors 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 51: Medicine usage – upload Failed status



Home > Submission history > Submission status

Submission status

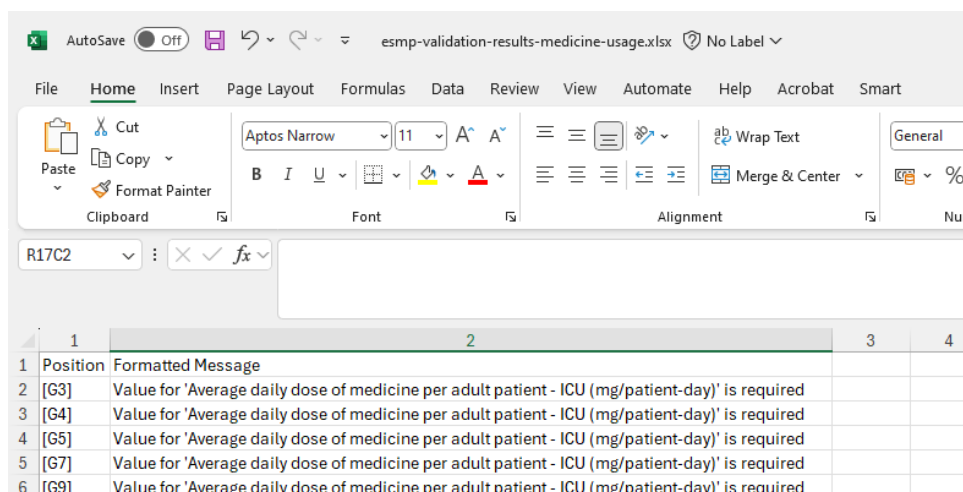
Failed
Some fields in the submitted file require your attention
Please review the validation results below.

Submission Type	Upload date and time	Submission ID	Filename
Medicine Usage	19/12/2024 10:42 AM	EMA/SH/0000005379	esmp-medicine-usage-20241219-
Status	Failed		

Position	Formatted Message
[G4]	Value for 'Average daily dose of medicine per adult patient - ICU (mg/patient-day)' is required
[G5]	Value for 'Average daily dose of medicine per adult patient - ICU (mg/patient-day)' is required
[G7]	Value for 'Average da (mg/patient-day)' is
[G9]	Value for 'Average da (mg/patient-day)' is
[H10]	Value for 'Proportion is required

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

Figure 52: Medicine usage – Validation results – Excel file view



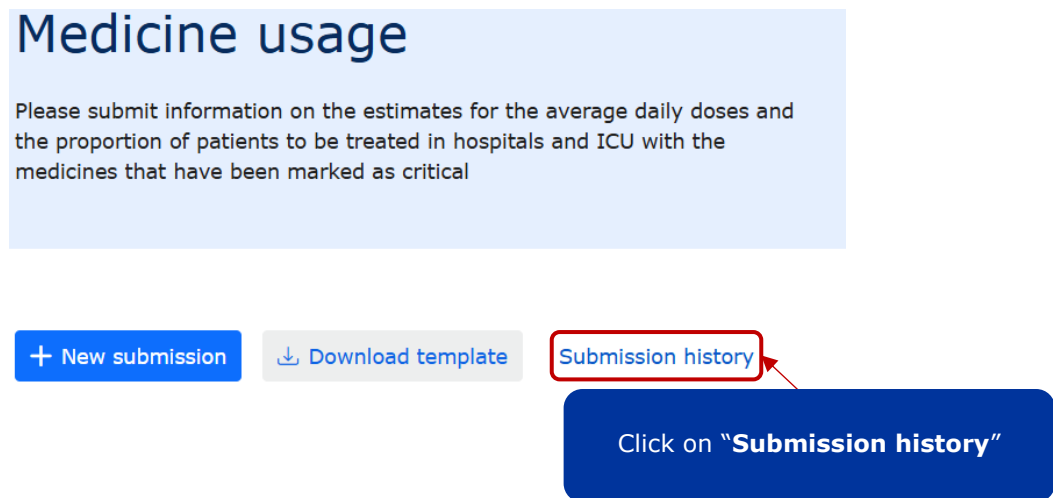
Position	Formatted Message
[G3]	Value for 'Average daily dose of medicine per adult patient - ICU (mg/patient-day)' is required
[G4]	Value for 'Average daily dose of medicine per adult patient - ICU (mg/patient-day)' is required
[G5]	Value for 'Average daily dose of medicine per adult patient - ICU (mg/patient-day)' is required
[G7]	Value for 'Average daily dose of medicine per adult patient - ICU (mg/patient-day)' is required
[G9]	Value for 'Average daily dose of medicine per adult patient - ICU (mg/patient-day)' is required

Open the **“esmp-validation-results-medicine-usage”** Excel file and read 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 national competent authorities](#)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-medicine-usage**” file. Save your changes and repeat the upload process.

Note: 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 “**Medicine usage**” page.

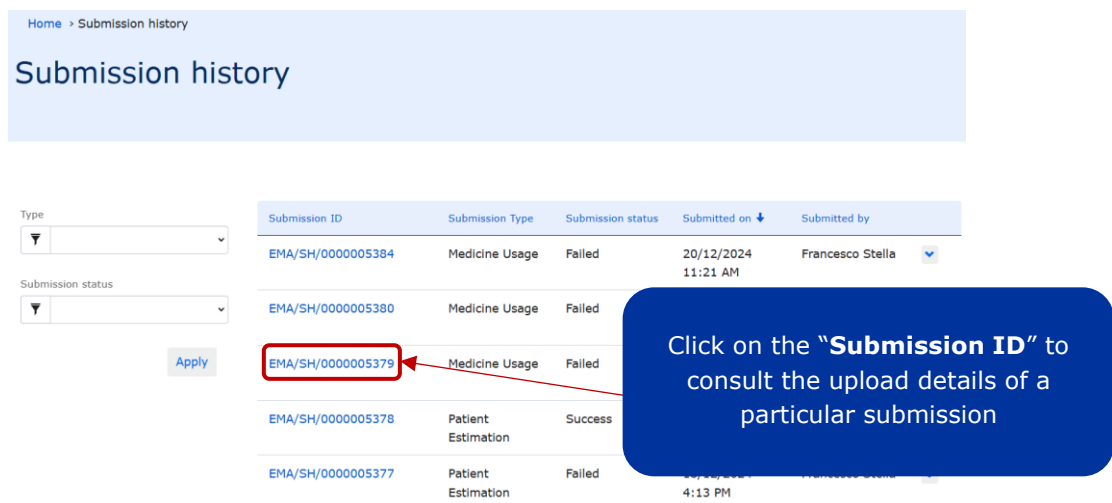
Figure 53: Medicine usage – Submission history



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.

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

Figure 54: Medicine usage – Submission history – Submission status



²¹ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-national-competent-authorities_en.pdf



For more information about a particular submission, click on its "**Submission ID**". The "Submission status" page for the selected submission will open. 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).

4. MSSG-led preparedness submissions

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

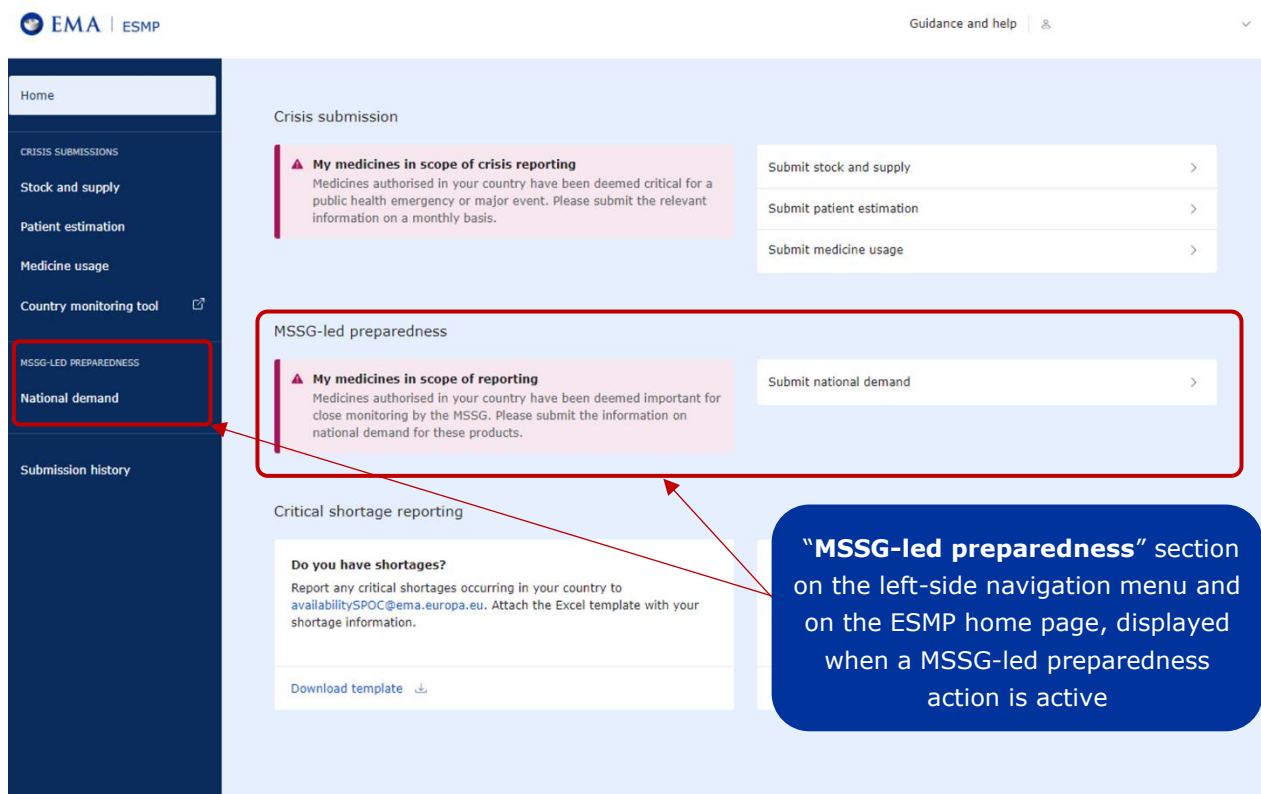
The following chapters describe in depth the different data elements and related details that NCAs will need to submit to fulfil reporting requirements.

4.1. Home page during a MSSG-led preparedness action

Whenever a MSSG-led preparedness action is announced, the [ESMP Home page](#) (and the left-side navigation menu) will display the “MSSG-led preparedness” section, which contains additional information pertaining to that action. It includes a notification to inform users that medicines authorised in your country have been deemed important for close monitoring by the MSSG; additionally, it contains a quick link to the page where users are required to fulfil reporting obligations (i.e.: national demand).

Independently of any event, the ESMP Home page also includes information on how to report any critical shortages occurring in your country and how to request assistance from the MSSG in obtaining stocks of a medicine during critical shortages.

Figure 55: ESMP Home page and left-side navigation menu when a MSSG-led preparedness action is active



The screenshot shows the ESMP Home page interface. The top left corner displays the EMA logo and 'EMA | ESMP'. The top right corner has 'Guidance and help' with a search icon and a dropdown arrow. The left-side navigation menu is dark blue and contains several items: 'Home', 'CRISIS SUBMISSIONS', 'Stock and supply', 'Patient estimation', 'Medicine usage', 'Country monitoring tool', 'MSSG-LED PREPAREDNESS', 'National demand', and 'Submission history'. The 'MSSG-LED PREPAREDNESS' and 'National demand' items are highlighted with a red box. The main content area is light blue and features three sections: 'Crisis submission', 'MSSG-led preparedness', and 'Critical shortage reporting'. The 'Crisis submission' section includes a notification: 'My medicines in scope of crisis reporting' and three buttons: 'Submit stock and supply', 'Submit patient estimation', and 'Submit medicine usage'. The 'MSSG-led preparedness' section includes a notification: 'My medicines in scope of reporting' and a 'Submit national demand' button. The 'Critical shortage reporting' section includes a notification: 'Do you have shortages?' and a 'Download template' button. A blue callout box with white text points to the 'MSSG-led preparedness' section in both the navigation menu and the main content area, stating: '“MSSG-led preparedness” section on the left-side navigation menu and on the ESMP home page, displayed when a MSSG-led preparedness action is active'.

4.2. How to submit National demand

Upon request of the MSSG, NCAs are required to report National demand information for medicinal products in scope of reporting requirements – included in a list of medicines to be monitored for MSSG-led preparedness. The frequency of data submission is determined by the MSSG for each MSSG-led preparedness action.

The submission of national demand data is performed by downloading a template from the “**National demand**” section, which will be pre-filled with the products in scope of the MSSG-led preparedness action and with previous 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 **do not change the pre-populated fields which have been retrieved from other EMA systems** (e.g. PMS) 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 SPOR database.

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

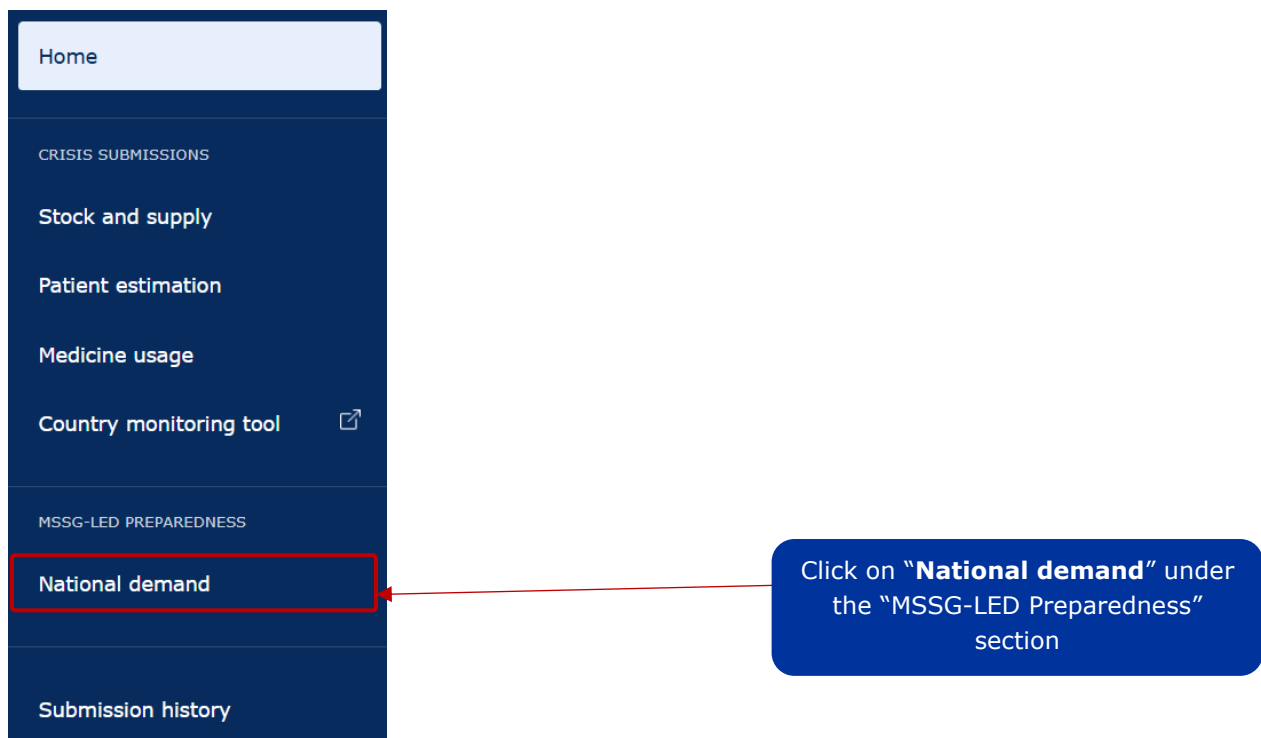
Step-by-step process

4.2.1 Part 1: Download a reporting template

Step 1

In the home page, on the left-side navigation menu, click on the “**National demand**” which resides under the “**MSSG-LED PREPAREDNESS**” section.

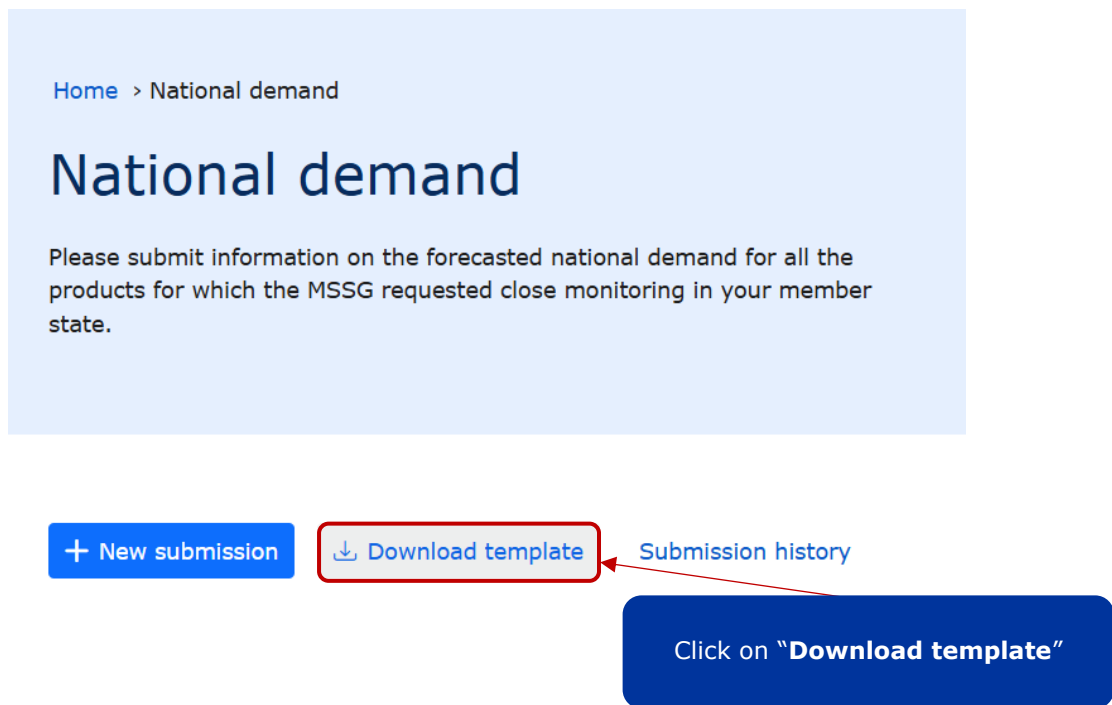
Figure 56: Left-side navigation menu - “National demand” button



Step 2

In the “**National demand**” page you can choose between three different options “**New submission**”, “**Download template**”, and “**Submission history**”. To obtain a pre-populated template with the product details against which you can enter the relevant information, you are requested to click on “**Download template**”.

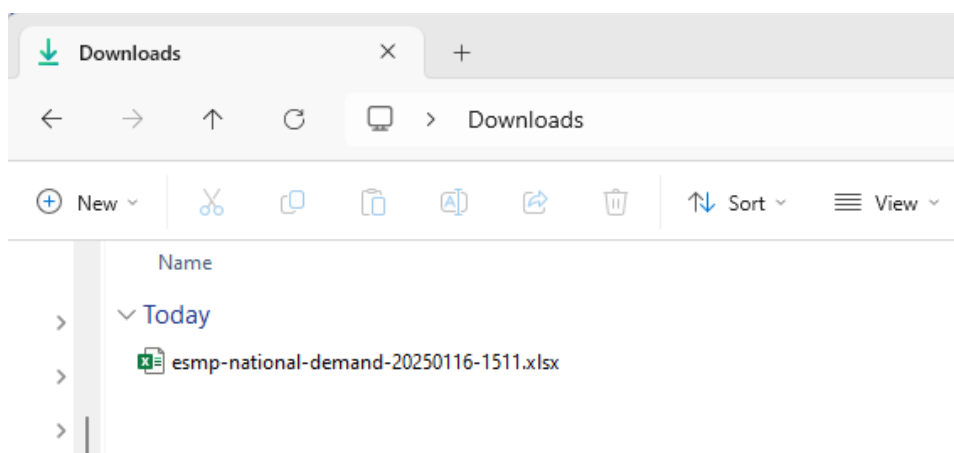
Figure 57: National demand – Download template



Step 3

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

Figure 58: National demand – Find the downloaded template in the Downloads folder of your computer



4.2.2 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 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 national competent authorities](#)²². 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.


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). 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](#)²³.

 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 medicinal product**.

As a good practice, select all the cells of the Excel file and change the format into “Text”, to avoid any errors while populating the data.

 Only for the National Demand feature, users can submit a dataset with empty fields, if they do not have access to particular data at the time of submission, without triggering any errors during the upload process.

²² https://www.ema.europa.eu/system/files/documents/other/esmp-implementation-guide-ncas_en_1.pdf

²³ 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

Figure 59: How to change the cell format in the downloaded template

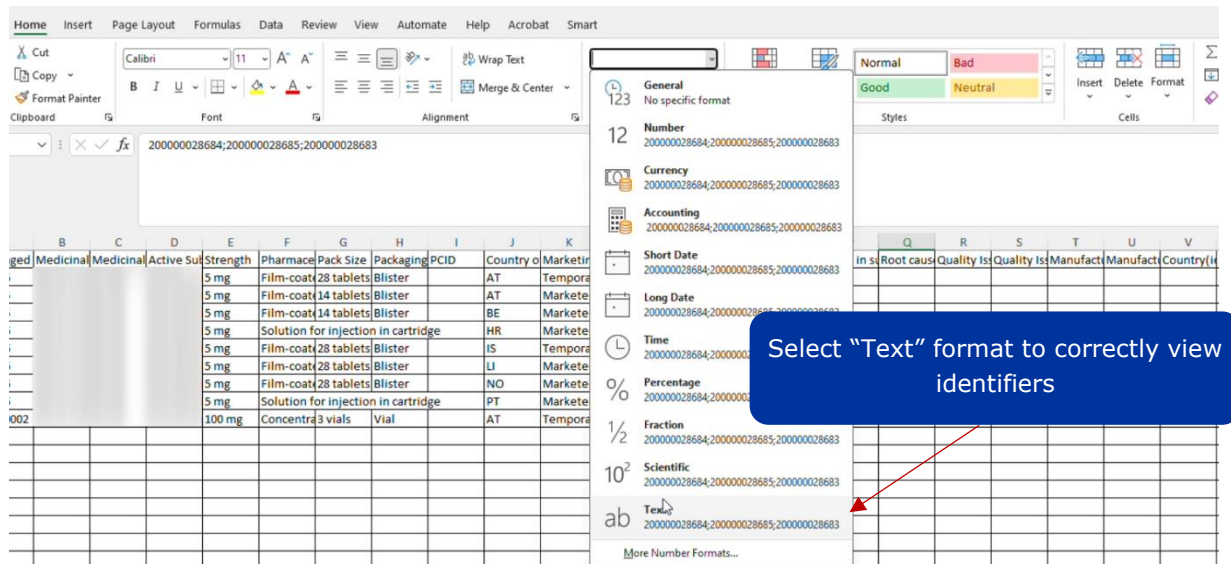


Table 4: MSSG-led preparedness: National demand data elements

Data category	Data element name	Conformance
Product information	PMS ID	Pre-populated
	Full product name	Pre-populated
	Short product name	Pre-populated
	MAH	Pre-populated
	Active substance	Pre-populated
	Active substance strength	Pre-populated
	Pharmaceutical form	Pre-populated
	Unit of presentation	Pre-populated
Demand Forecast	Demand forecast - month 1	Optional
	Demand forecast - month 2	Optional
	Demand forecast - month 3	Optional
	Demand forecast - month 4	Optional
	Demand forecast - month 5	Optional
	Demand forecast - month 6	Optional



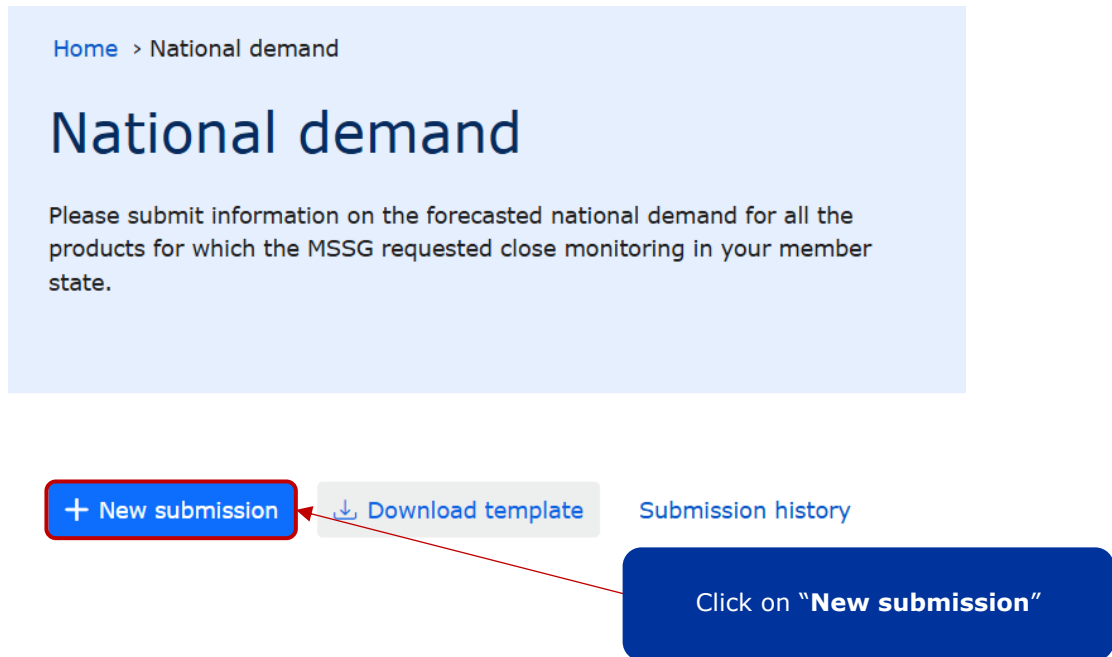
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4.2.3 Part 3: Upload of the data into ESMP

Step 1

On the “**National demand**” 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.

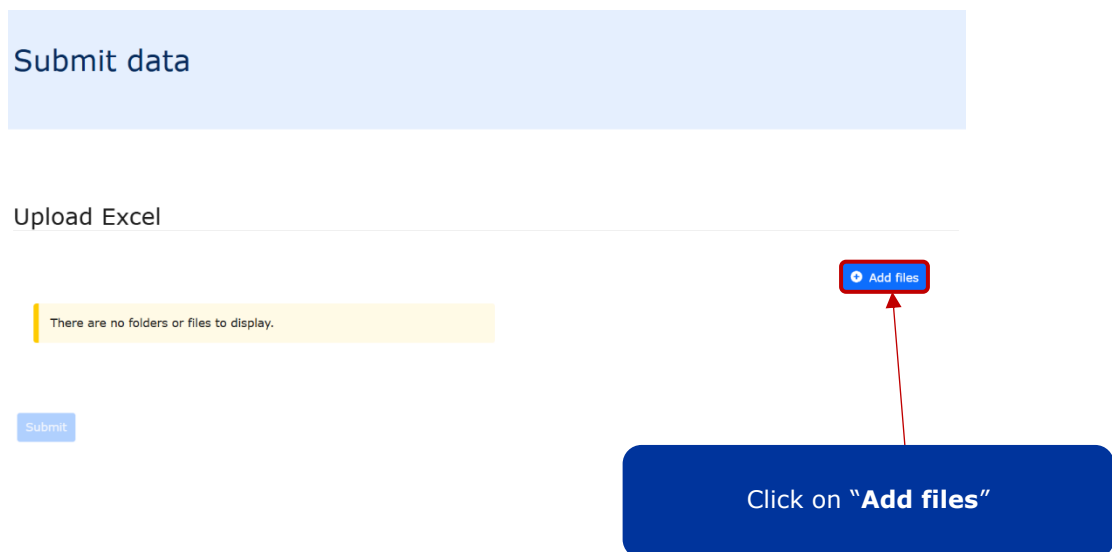
Figure 60: National demand – New submission button



Step 2

Click on “**Add files**” on the right side of the “**Submit data**” page. This will open a dialogue box allowing you to add and upload a file into the ESMP.

Figure 61: National demand – Submit data



Step 3

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.


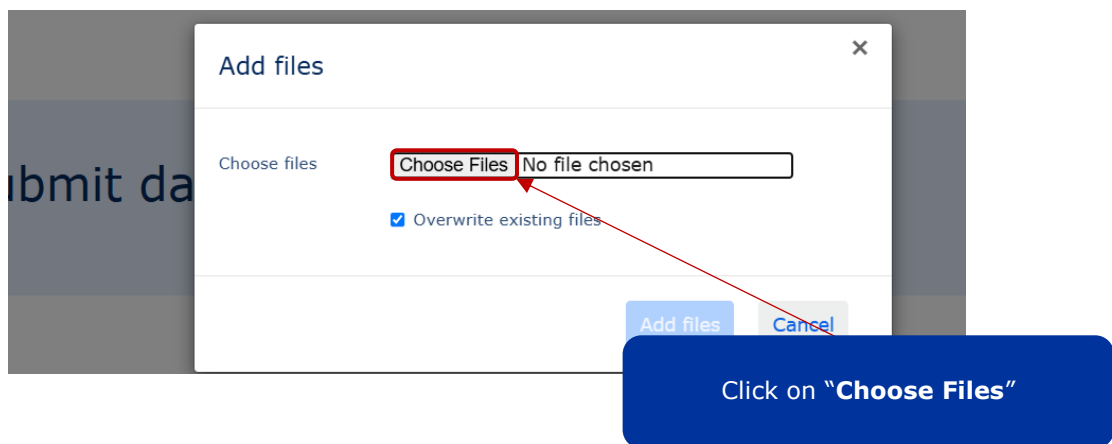
 The system only accepts the selection of one file at a time for submission. In case you select multiple files for submission, after clicking on **“Add files”**, the error message **“Only one file can be uploaded for a submission.”** will be displayed. Therefore, please select only one file at a time.

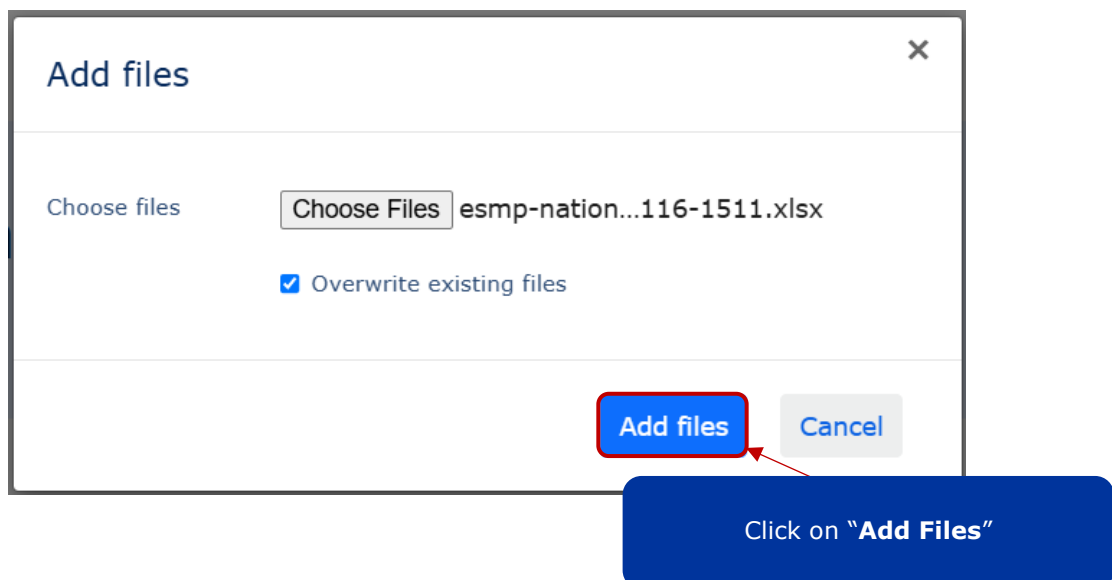
Figure 62: National demand – Choose file to upload



Step 4

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 into the upload page.

Figure 63: National demand - Add file

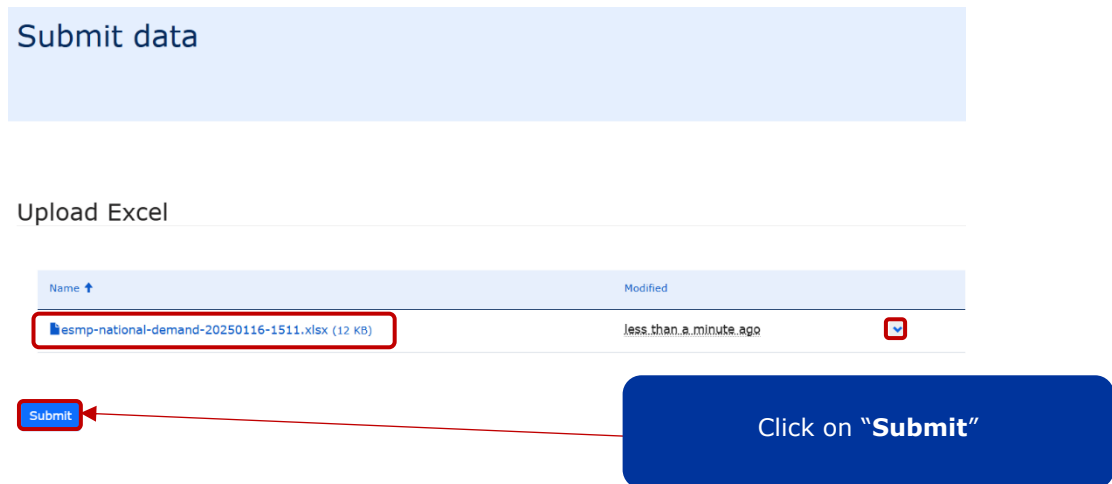


Step 5

The file you added will be listed on the table for upload, as shown below. If the added file mistakenly does not correspond to the one you intend to submit, use the arrow down to delete it. Upon deletion (from the table), the button **“Add file”** becomes again active and you can then restart the process from

Step 2 to add the wanted file. When you have added the correct file, click on "Submit". This will start the validation process of the file.


Figure 64: National demand – Submit file



Step 6

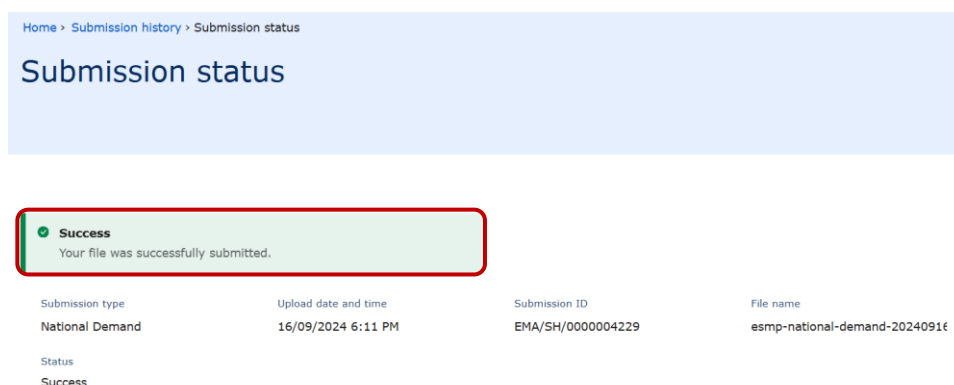
Validation of the submitted file may take some time. Feel free to close the page or move to another page while the file is being processed, since the submission will proceed in the background. To retrieve the details of the current submission or any past submission, consult the "Submission history" page.

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 read "**Success**", while the "**Error log view**" will read "**There are no records to display**". Your upload is therefore successfully completed, and your submission is final.

Figure 65: National demand – upload Success status

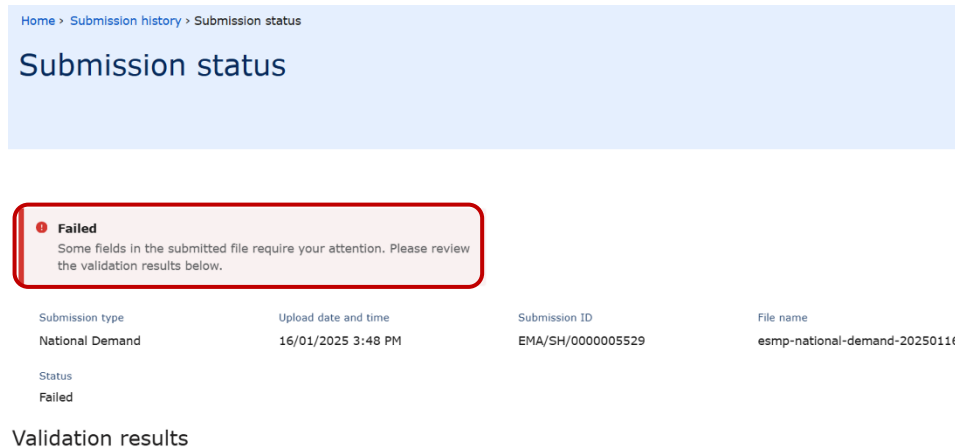


If your upload fails, the "**Upload status**" will show "**Failed**". If this happens, please review the list of **validation results** in the submitted file, which is displayed on the Submission status page, below the metadata on a particular submission. The validation results' section lists errors 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 66: National demand – upload Failed status



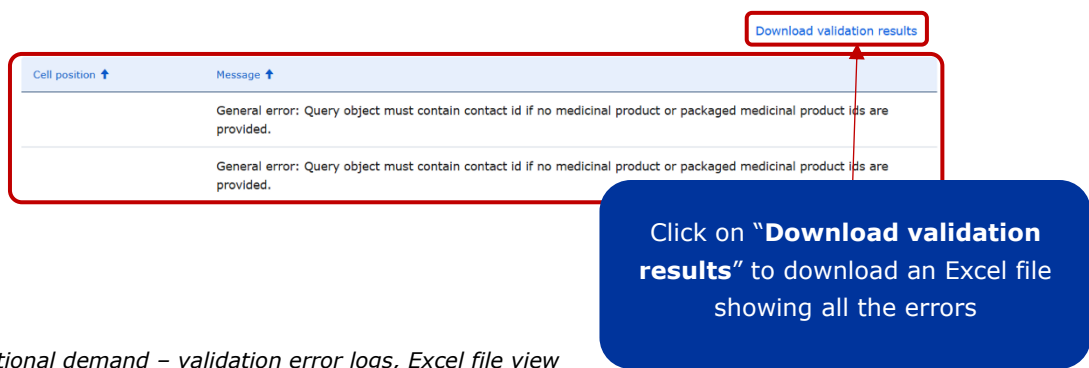
Home > Submission history > Submission status

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	File name
National Demand	16/01/2025 3:48 PM	EMA/SH/0000005529	esmp-national-demand-20250116
Status	Failed		

Validation results

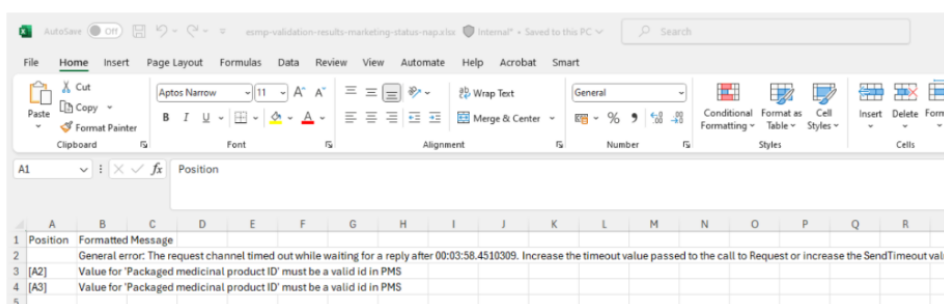


Cell position ↑	Message ↑
	General error: Query object must contain contact id if no medicinal product or packaged medicinal product ids are provided.
	General error: Query object must contain contact id if no medicinal product or packaged medicinal product ids are provided.

Download validation results

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

Figure 67: National demand – validation error logs, Excel file view



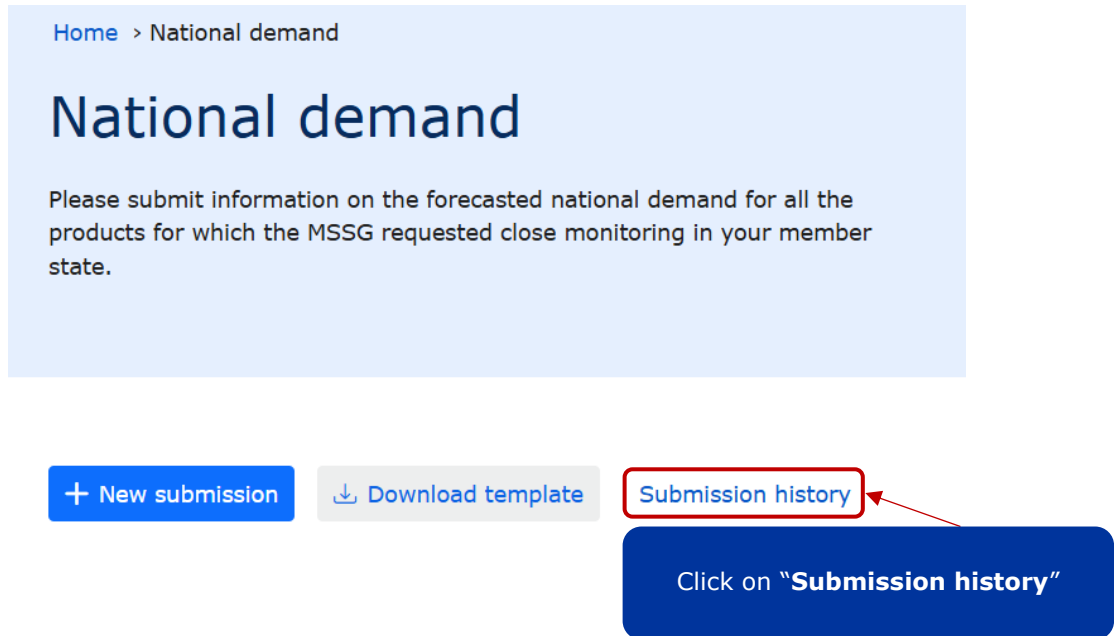
Position	Formatted Message
	General error: The request channel timed out while waiting for a reply after 00:03:58.4510309. Increase the timeout value passed to the call to Request or increase the SendTimeout value
[A2]	Value for 'Packaged medicinal product ID' must be a valid id in PMS
[A3]	Value for 'Packaged medicinal product ID' must be a valid id in PMS

Open the “**validation results**” Excel file and read 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 national competent authorities](https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-national-competent-authorities_en.pdf)²⁴. Re-open the submission file that you wish to upload from your computer and address each of the described errors in the “**validation results**” file. Save your changes and repeat the upload process.

²⁴ https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-implementation-guide-national-competent-authorities_en.pdf

Note: 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 “**National demand**” page.

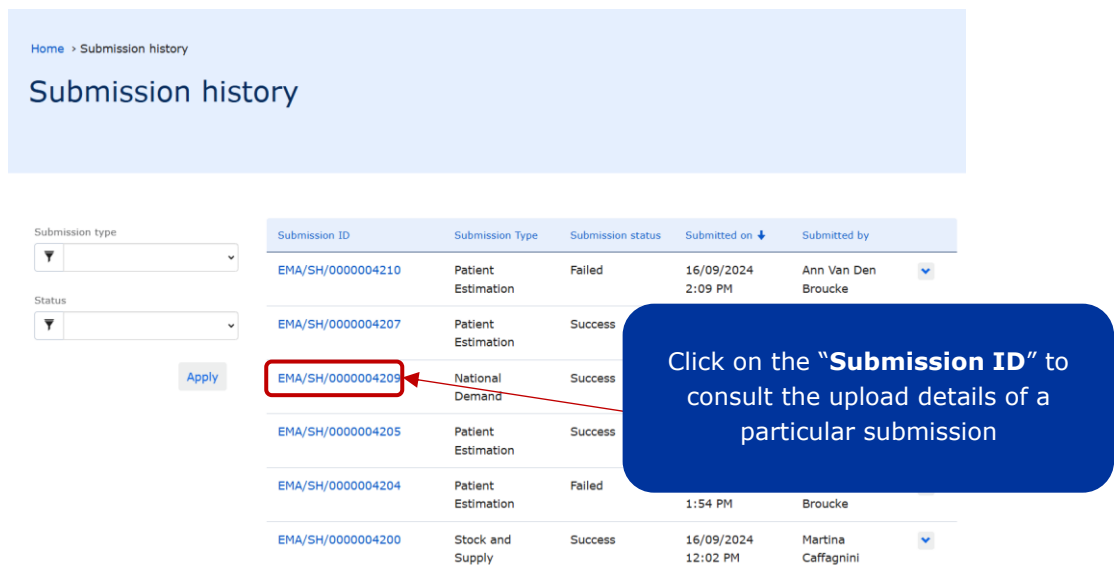
Figure 68: National demand – Submission history



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 69: National demand – Submission history – Submission status



For more information about a particular submission, click on its "**Submission ID**". The "**Submission status**" page for the selected submission will open. Here, you will find information about submission type, end of the upload, submission ID, filename, upload status and the error log.

5. Shortages monitoring and risk analysis tool (SMART)

5.1. Introduction

This guidance is intended to support national competent authorities (NCAs) during the usage of the ESMP's Shortage Monitoring and Risk analysis Tool (SMART).

The ESMP-SMART is an automated risk analysis and monitoring tool intended to be used during crisis situations that aggregates and analyses the supply, stock and needs data, per member state (MS), obtained from NCAs and marketing authorisation holders (MAHs) through the European Shortages Monitoring Platform (ESMP) to allow the monitoring of the supply and demand of medicines with a view to estimate the risk of potential gaps between the supply and demand of medicinal products and identify actual or potential shortages.

Each NCA will have access to a MS dedicated SMART dashboard, showing only elements and indicators relevant for the MS in question. NCAs will not have access to other countries' data nor national SMART dashboards pertaining to other NCAs.

SMART allows for the automatic aggregation, analysis and visualisation of stock, supply and need information and provides a full overview of the situation of a medicinal product on **multiple aggregation levels**.

It uses a **risk-based analysis approach** so the user can provide a PHE/ME patient need scenario to match the stock and supply information against and be able to use the outcomes to determine which medicinal products have the highest risk of experiencing shortages and might need focused attention.

The following sections contain specific information on the establishment of multiple aggregation levels, the automatic matching of supply and demand and the specific way in which EMA handled the matching of supply and demand of vaccines.

5.2. Data aggregation levels

EMA has implemented an aggregation key with multiple levels of granularity, allowing the aggregation and analysis of stock, supply and need information of medicinal products with the same active substance and similar pharmaceutical forms, to increase the flexibility of SMART. This is important as the context of each PHE or ME will be unique with its own context, critical medicinal products, national treatment guidelines and specific requests from crisis steering groups.

As the basis of aggregation key, the PhPID levels were used as proposed by World health Organization (WHO):

- PhPID1 = Active substance(s)
- PhPID2 = Active substance(s) - Strength(s) - Strength unit(s)
- PhPID3 = Active substance(s) - Pharmaceutical Dose Form
- PhPID4 = Active substance(s) - Strength(s) - Strength unit(s) - Pharmaceutical Dose Form

These levels have been implemented into the data analytics platform. For the SMART, some levels were enhanced and some not included according to the needs of the platform. Levels 1 and 2 are deactivated as they are not relevant for monitoring, levels 3 and 4 were updated and renamed to 3.1 and 4.1, and 2 extra levels (5 and 6) were created for the PHE/ME monitoring:

- **Level 3.1:** Active substance + Pharmaceutical form **group***
- **Level 4.1:** Active Substance + Pharmaceutical form **group*** + Strength.
- **Level 5:** Active Substance + Pharmaceutical form **group*** + Strength + Container size/Manufactured product mass**.
- **Level 6** (vaccines only***): ATC code

*Pharmaceutical form group. Manual grouping by EMA of interchangeable pharmaceutical dose forms updated and adjusted to meet the needs of each PHE/ME situation.

**Container size/Manufactured product mass: Either the size of the container (e.g. vial, bottle) or mass of the pre-reconstituted solid form. This PMS data element is not in the [PMS Implementation of International Organization for Standardization \(ISO\) standards for the identification of medicinal products \(IDMP\) in Europe](#)¹⁴ but is present in PMS. This level is implemented to be able to distinguish between medicinal products with liquid administrable dose forms such as concentrates, solutions, emulsions, suspensions, dispersions, liquids or syrups that either need to be reconstituted or stored in a primary packaging such as a bottle, vial, ampoule, etc.

***Level 6: For vaccines that can be used for the same disease, the active substance is not relevant if their indication is the same and they can be used interchangeably. This is, however, a theoretical approach based on the experiences of the COVID-19 and Mpox PHEs.

For the SMART tool, levels 3.1, 4.1 and 6 have been implemented. The user has the opportunity to freely switch between the levels and automatically adjusts the outcomes and visualisations according to the selected level.

Note: Further expansion of the aggregation key will be implemented for subsequent versions of the dashboard and adjustments can be made to accommodate specific PHE/ME situations.

5.3. Analysis of stock, supply and need data

SMART automatically analyses the stock, supply, and need information of each medicinal product to provide the user with relevant outcomes that can be used for the management of emergency situations and assist in effective decision-making at national level.

5.4. Interpretation of the outcomes

When using SMART however, the following points must be kept in mind:

- The tool does **not predict** the future in any capacity. Instead, it employs a **scenario-based approach** to match stock and supply information of medicinal product combinations, using the aggregation key, with the MS need. The outcome provides an estimation of the risk that the total of relevant medicinal products will be insufficient to meet the MS need and can assist in effective decision-making during crises.
- The value of the outcomes is highly dependent on the provided MS need scenario. EMA encourages NCAs to use the most plausible but negative scenario to avoid false negative situations.
- Outcomes are an **estimation of the risk that a gap between the stock, supply and the chosen MS need scenario** of critical medicinal product combinations can occur during the upcoming forecast period, displayed either as:
 - Amount of units still required (unmet demand) to meet the MS need of the chosen scenario or
 - Amount of units in surplus (supply surplus) after having met the MS need of the chosen scenario

Based on stocks, MS need scenario and supply planning at time of submission and under the assumptions that:

- The stocks, and supply forecast were correctly communicated to EMA
 - There are no sudden or unexpected impediments on manufacturing, distribution, etc.
 - That the real need throughout the forecast period does not exceed the estimated MS need
 - The average daily dose per patient is not underestimated and sufficiently reflects the actual average daily need per patient
- If any of the assumptions become invalid, the results of the analysis must be considered void. Adjustments must be made to ensure the assumptions are met again, and the analysis must be redone.

5.4.1 Matching of supply and demand

Objective

Matching of supply and demand is defined as the amount of units that the MS still requires or has in surplus after matching the MS need with the available stock and forecasted supply at the MAH and at MS level for each month, in sequential order, throughout the forecast period.

By evaluating the monthly supply and demand indicators the user can perform a risk analysis of **the capability of the available stock and forecasted supply to cover the needs of the chosen scenario month per month** including all currently included supply, stock and need information of medicinal products.

Risk analysis

As described in 5.3.1 the outcome of matching of supply and demand can either result in an unmet demand or supply surplus:

- **Unmet demand** means as that for this combination of critical medicinal products, the available stock and forecasted supply is **insufficient** to meet the MS need and additional units are required. Actions need to be undertaken to either bring down the MS need or increase the supply.
- **Supply surplus** means that for this combination of critical medicinal products, the available stock and forecasted supply is **sufficient** to meet the MS need.

As such SMART provides automatically generated answers to the following questions:

- is the amount of units available in the supply chain (available stock) and amount of units currently forecasted to become available throughout the forecast period (forecasted supply) sufficient to cover the forecasted number of patients (both PHE and non-PHE) for the entire forecast period, while also establishing the planned minimum stock?
- If so, how many units will still be available after the forecasted number of patients are met and the planned minimum stock is established?
- And if not, how many additional units are still required to meet the forecasted number of patients and establish the planned minimum stock?

Note: The amount of units in surplus or still required is an indication of the risk of the medicinal product combination. SMART provides both the amount of units and a percentage indicator showing the relation of the available stock and forecasted supply and the MS needs. The higher the number, the lower the risk. Similarly, the lower the number the higher the risk.

By evaluating multiple aggregation levels and different critical medicinal product combinations, the user can gain a comprehensive overview of current situation, explore the outcome of multiple scenarios, and observe potential and actual shortages of critical medicines with the goal to identify those situations in which the risk exists of patients not receiving treatment.

Method

Overview of the analysis method:

- **For month 1:** subtract the available stock and forecasted supply of month 1 from the summed MS need of month 1 and the planned minimum stock. This will result in either a supply surplus (negative number) or unmet demand (positive number).



- **For month 2 to 6:** add the outcome of month 1 to the MS need of month 2 and subtract the forecasted supply of month 2 to generate the outcome of month 2. This analysis is then repeated for each month, in sequential order, throughout the forecast period.

As an additional analysis option, SMART allows the user also to **exclude the planned minimum stock** from the monthly analysis to observe the effect of preserving the full stock and supply for the treatment of patients.

Figure 70: SMART – Matching of supply and demand of month 1

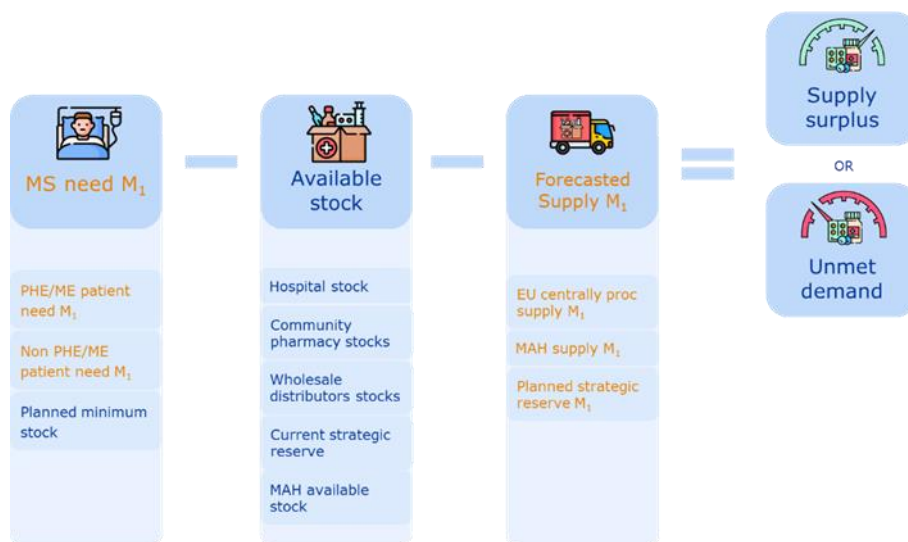
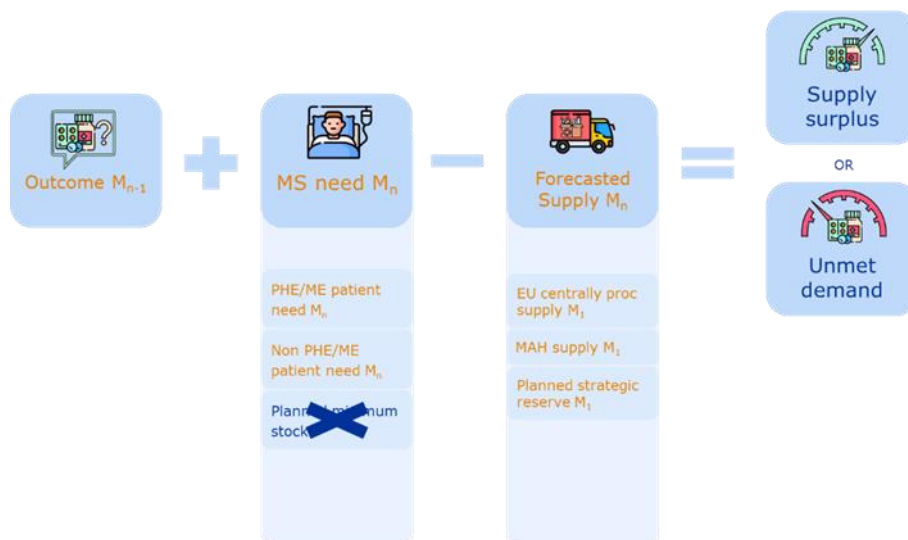


Figure 71: SMART – Matching of supply and demand of month n



5.4.2 Member state demand

Member State demand is defined as the amount of units that the MS still requires or has in surplus after matching the MS need with the available or remaining stock at the MAH and at MS level for each month, in sequential order, throughout the forecast period.

The MS demand provides an estimate of **the capability of the stock to cover the needs of the chosen scenario month per month without the reliance of additional supply**. During a PHE or ME forecasted supply is unsure, and the delivery time and overall quantities can fluctuate wildly over a short period of time. Available stock on the other hand is readily available for treatment of patients. Therefore a second indicator where the forecasted supply is not included in the analysis method.

The analysis method also either results in supply surplus or unmet demand as described in 3.1. The MS demand analysis provides answers to the following questions:

- Is the amount of units available in the supply chain (available stock) sufficient to cover the forecasted number of patients (both PHE and non-PHE) for the entire forecast period, while also establishing the planned minimum stock?
- If so, how many units will still be available after the forecasted number of patients are met and the planned minimum stock is established?
- And if not, how many months can the available stock alone cover the MS needs?

Note: The amount of units in surplus is an indication of the risk of the medicinal product combination. SMART provides both the amount of units and a percentage indicator showing the relation of the available stock and forecasted supply and the MS need. The higher the number the lower the risk the lower the number the higher the risk.

Overview of the analysis method:

- **For month 1:** subtract the available stock from the summed MS need of month 1 and the planned minimum stock. This will result in either a supply surplus (negative number) or unmet demand (positive number).
- **For month 2 to 6:**
 - a. If the outcome of month 1 results in **supply surplus**, the remaining stock is added to the MS need of month 2 to generate the outcome of month 2. This analysis is then repeated for each month, in sequential order, throughout the forecast period.
 - b. If the outcome of month 1 results in **unmet demand**, the analysis ends and the indicator is set as 0 for the subsequent months as there is no more available stock and the NCA must rely on the forecasted supply.

As an additional analysis option, SMART allows the user also to **exclude the planned minimum stock** from the monthly analysis to observe the effect of preserving the full stock and supply for the treatment of patients.

Figure 72: SMART – Member State demand of month 1

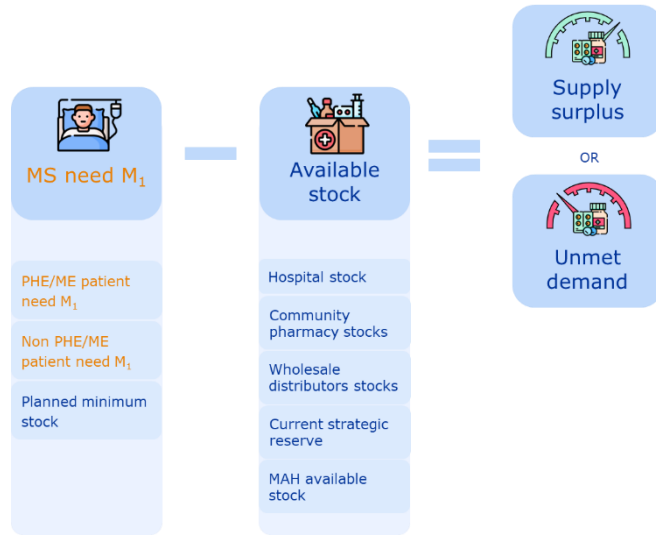
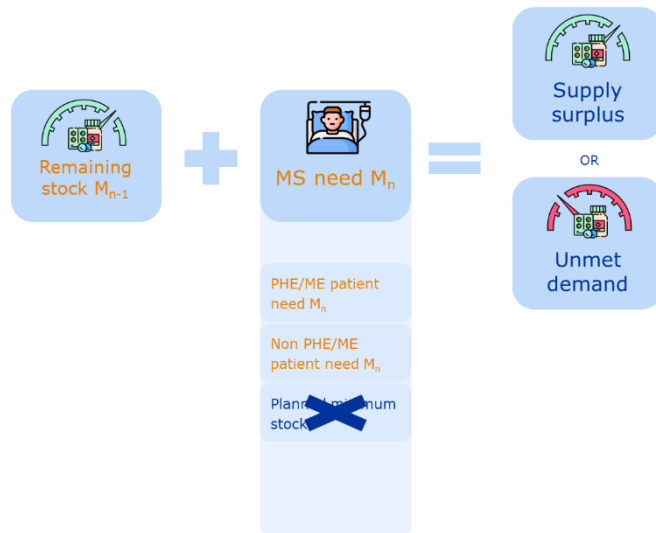
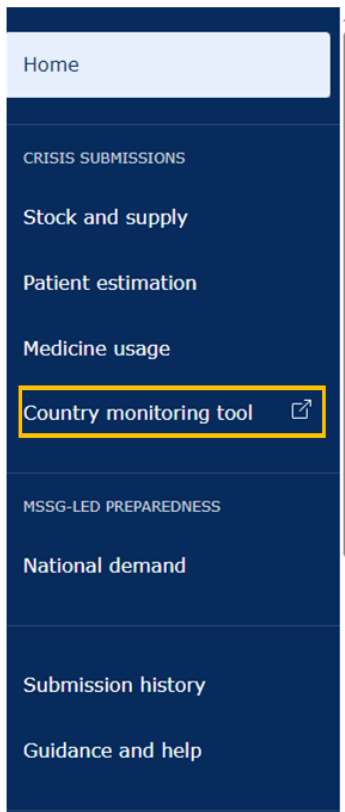


Figure 73: SMART – Member State demand of month n



5.5. Access to SMART

Figure 74: SMART – Access to the country monitoring tool



SMART can be accessed through the ESMP portal. By clicking the “Country monitoring tool” link in the navigation sidebar. See figure 74.

The user role to access the ESMP portal also give you access to SMART. A secondary access role must be assigned to you after verification by EMA to access the commercially sensitive data.

If you receive the message that you do not have access and you are allowed to access SMART, please sent an access request through the [AvailabilitySPOC mailbox](#) . Upon verification of the request, the new user will be given access to the SMART.

5.6. Using the SMART

5.6.1 Resetting the dashboard

Upon accessing SMART, it may either be empty or contain settings from previous sessions. In order for the tool to operate adequately it is essential **to press the reset filter button**.

5.6.2 Overview of the dashboard

The tool is made out of two navigation bars for configuration, and four sections providing an overview of the relevant stock, supply and need data and the outcomes of the matching of supply and demand, with a limited number of pop-ups containing detailed information or background information:

- **Member State Need (Blue)** contains the data elements that make up the total MS need subdivided in monthly estimates of PHE/ME patient need , non-PHE/ME patient need and planned minimum stock as obtained or converted from the NCA. The monthly estimation of patient-days can be viewed by selecting the "Detailed View" link.
- **Available Stock (Orange)** contains the stock across the supply chain as reported by the NCA, as well as the MAH stock. A detailed view of MAH stock (MAHs, amount of packs, medicinal products) can be accessed through clicking on the "Detailed View" icon.
- **Forecast Supply (Green)** contains the MAH supply throughout the forecast period and planned strategic reserve obtained from the NCA. A detailed view of the MAH supply forecast (amount of packs per packaged medicinal product per MAH) can be accessed through the "Detailed View" link.
- **Matching of Supply and Demand Outcomes.** This section shows the outcomes of the different ways the data elements are combined to match supply and demand as indicated above in chapter 3.

5.6.3 Selection of a Medicinal Product Combination

1. **Select the public health emergency** from the navigation banner, even if only one PHE or ME is active.
2. **Select the aggregation level.** As detailed in chapter 5.3 analysis of supply, stock and need information can be aggregated and analyzed on multiple levels. SMART only has levels 3.1, 4.1 and 6 implemented which can be selected in the Aggregation level dropdown menu.
3. **Select the medicinal product combination**
4. **Select the PHE/ME patient need source** to include the correct configuration.

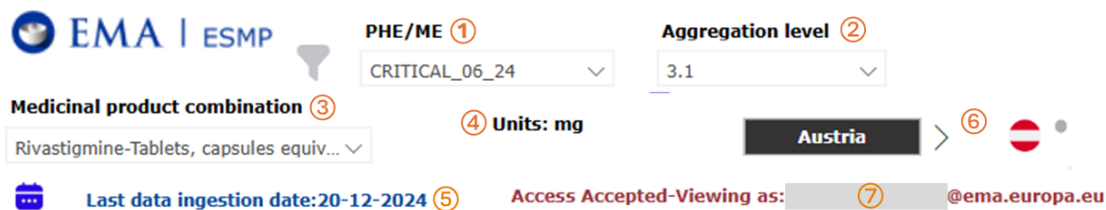
The tool automatically adjusts the outcomes and visualizations according to the selected medicinal product combination.

5. Use the **forecast date slider** to adjust the forecast period range to allow monthly matching of supply and demand as discussed in chapter 3.4. As a standard setting the entire forecast period of 6 months is selected.

- The user can also choose to exclude the '**planned minimum stock**' from the calculations to simulate a scenario without a buffer and where all stock and supply is used to treat the MS need (PHE/ME and non-PHE/ME patient need).

5.6.4 Navigation banner

Figure 75: SMART – Navigation banner



- PHE/ME drop-down menu:** Selection of the PHE/ME you want to monitor. Only one can be selected.
- Aggregation level drop-down menu:** Selection of the Aggregation level. In SMART, currently, the options are 3.1, 4.1 and 6. For an explanation of the levels please see chapter 5.2.
- Medicinal product combination:** Selection of the medicinal product combination the user wants to monitor. The dropdown box can only be used after using the other drop-down boxes.
- Units:** The unit of measurement of the amounts as shown in the dashboard:
 - Aggregation level 3.1: milligrams of active substance of a specific pharmaceutical form group
 - Aggregation level 4.1: milligrams of active substance of a specific pharmaceutical form group and strength
 - Aggregation level 6: the unit is the number of patients as the vaccines are recalculated to the number of patients the stock, supply can treat. PHE/ME patient need indicator uses the numbers directly provided by the NCA.

Note: The possibility to reconfigure SMART from the unit of measurement into a user specified unit of presentation will be considered for subsequent versions of SMART.

- Date of last data ingestion:** The month during which the NCA and data from ESMP was last ingested.
- Member State name and flag:** Each NCA has their own national SMART dashboard that analyses and visualises relevant stock, supply and need data. This is represented by the MS name and flag.
- Access Accepted message:** Message notifying the current user of the tool. This message is displayed if the user has valid access rights.

5.6.5 Navigation sidebar


Figure 76: SMART – Navigation sidebar



The Navigation Sidebar has the following features:

1. **Reset filters:** Allows the user to reset the entire dashboard by removing all the filters.
2. **Forecast Date range:** By adjusting the slider the user can change the forecast period. As a standard setting the forecast period is set to **6 months**. The slider allows the user to select fewer months and see the MS demand and matching of supply and demand for shorter periods up to month 1. The dashboard automatically reconfigures to newly selected forecast period and the outcomes of matching supply and demand are recalculated according to the rules in chapter 5.3.
3. **Functionality diagram:** This link shows the matching of supply and demand pathway diagram for reference. It contains all of the data elements, from which source they are obtained and how they are combined in the dashboard to generate the outcomes. The diagram also contains some additional comments for each of the stock, supply and need data elements.
4. **Line listing:** Accessing this button brings up a pop-up screen with a list of the data elements and the outcomes. You can export this line listing by hovering over the left corner of the screen above the exit button and using the steps below in figure 77 and 78.

Figure 77: SMART – The line listing can be exported by hovering with the mouse indicator above the exit button and selecting the 3 dots.

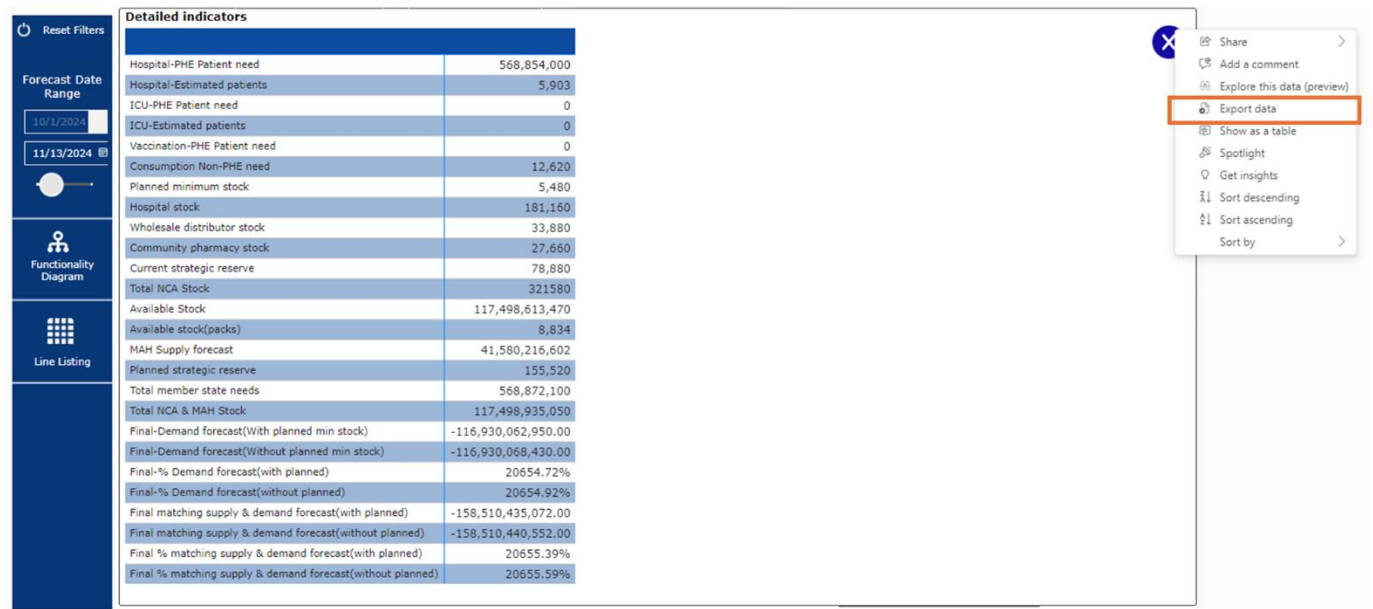


EMA | ESMP | PHE | EAK Level: 3.1 | Aggregation key: All | Units:mg/ml | Austria

Forecast Date Range: 10/1/2024 to 11/13/2024

Detailed indicators	
Hospital-PHE Patient need	568,854,000
Hospital-Estimated patients	5,903
ICU-PHE Patient need	0
ICU-Estimated patients	0
Vaccination-PHE Patient need	0
Consumption Non-PHE need	12,620
Planned minimum stock	5,480
Hospital stock	181,160
Wholesale distributor stock	33,880
Community pharmacy stock	27,660
Current strategic reserve	78,880
Total NCA Stock	321580
Available Stock	117,498,613,470
Available stock(packs)	8,834
MAH Supply forecast	41,580,216,602
Planned strategic reserve	155,520
Total member state needs	568,872,100
Total NCA & MAH Stock	117,498,935,050
Final-Demand forecast(With planned min stock)	-116,930,062,950.00
Final-Demand forecast(Without planned min stock)	-116,930,068,430.00
Final-% Demand forecast(with planned)	20654.72%
Final-% Demand forecast(without planned)	20654.92%
Final matching supply & demand forecast(with planned)	-158,510,435,072.00
Final matching supply & demand forecast(without planned)	-158,510,440,552.00
Final % matching supply & demand forecast(with planned)	20655.39%
Final % matching supply & demand forecast(without planned)	20655.59%

Figure 78: SMART – By clicking on the export data button, the values of the line listing can be exported.



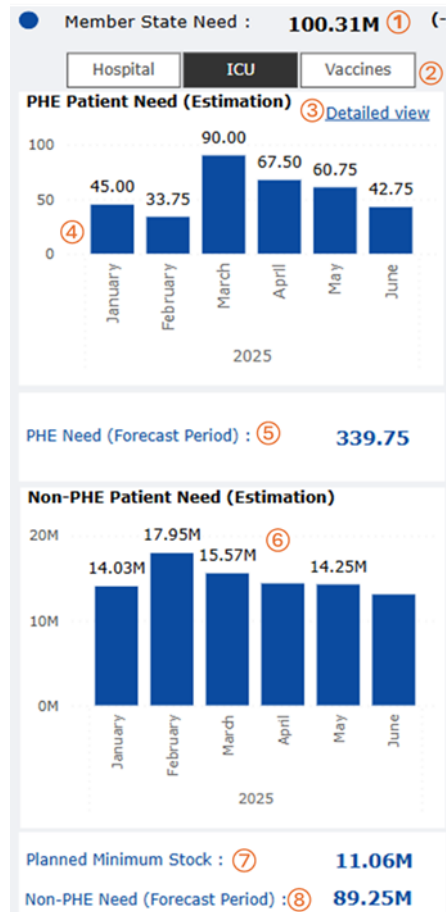
Forecast Date Range: 10/1/2024 to 11/13/2024

Detailed indicators	
Hospital-PHE Patient need	568,854,000
Hospital-Estimated patients	5,903
ICU-PHE Patient need	0
ICU-Estimated patients	0
Vaccination-PHE Patient need	0
Consumption Non-PHE need	12,620
Planned minimum stock	5,480
Hospital stock	181,160
Wholesale distributor stock	33,880
Community pharmacy stock	27,660
Current strategic reserve	78,880
Total NCA Stock	321580
Available Stock	117,498,613,470
Available stock(packs)	8,834
MAH Supply forecast	41,580,216,602
Planned strategic reserve	155,520
Total member state needs	568,872,100
Total NCA & MAH Stock	117,498,935,050
Final-Demand forecast(With planned min stock)	-116,930,062,950.00
Final-Demand forecast(Without planned min stock)	-116,930,068,430.00
Final-% Demand forecast(with planned)	20654.72%
Final-% Demand forecast(without planned)	20654.92%
Final matching supply & demand forecast(with planned)	-158,510,435,072.00
Final matching supply & demand forecast(without planned)	-158,510,440,552.00
Final % matching supply & demand forecast(with planned)	20655.39%
Final % matching supply & demand forecast(without planned)	20655.59%

5.6.6 Member State Need section

The MS need section shows the relevant national need data elements to provide the possibility to evaluate each aspect of the MS need. All numbers in the section have the units of measurement as described in 5.2 point 4. The section has the following indicators:

Figure 79: SMART – Member State Need section



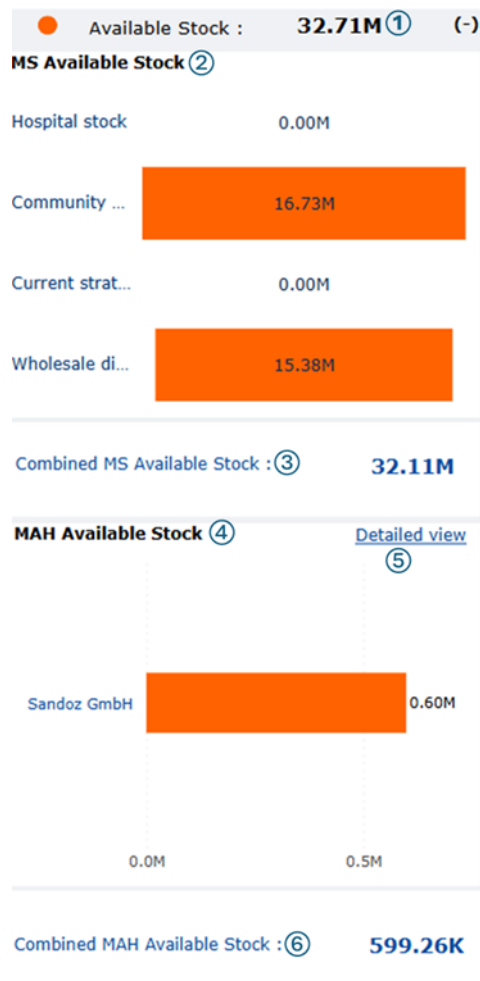
- 1. Combined MAH stock:** Total amount of units in stock at the MAH level. The summation of all the stock of the medicinal products of the individual MAHs.
- 2. Member State need:** Total of all units that a Member State expects to need to treat or vaccinate patients, both PHE specific and non-PHE specific, and buffer for unexpected situations (**summation of PHE/ME patient need, non-PHE/ME patient need and planned minimum stock**). This number is adjusted according to the forecast date range selected.
- 3. Patient estimation selection:** Depending on the use of the medicinal product during the PHE/ME it will either be used in the hospital, ICU specifically or as a vaccine. By selecting 1 of the three buttons, SMART will adjust the dashboard accordingly. The other two possibilities will generate an empty PHE/ME patient need section.
- 4. Detailed view:** Selecting this link opens a pop up displaying the estimated total number of patient-days per month of the forecast period (ICU and Hospital) and number of patients the MS

foresees to vaccinate per month of the forecast period (Vaccines). This is the exact number the NCA has provided in the ESMP patient estimation template.

5. **PHE patient need (estimation) visual:** Column chart displaying the PHE-specific need per month for the months of the forecast period in units of measurement (see 5.2 point 4) allowing the user to evaluate the PHE specific needs across the forecast period. This chart is adjusted according to the forecast date range selected.
6. **PHE patient need (forecast period):** The total sum of units that a Member State expects to need to treat or vaccinate PHE/ME specific patients throughout the forecast period. This number is adjusted automatically according to the forecast date range selected.
7. **Non-PHE patient need (estimation) visual:** Column chart displaying the non-PHE/ME-specific need per month of the forecast period. This allows the user to evaluate the Non-PHE/ME specific needs across the forecast period. This chart is adjusted according to the forecast date range selected.
8. **Planned minimum stock:** The amount of units that should be present in the Member States' supply chain to assure continuity of availability to patients. This number is not per month of the forecast period but a single number that should be present. See chapter 3.1 for more information.
9. **Total non-PHE patient need (forecast period):** the total sum of units that a Member State expects to need in procedures not related to the PHE/ME the months of the forecast period. This number is adjusted according to the forecast date range selected.

5.6.7 Stock section

Figure 80: SMART – Stock section

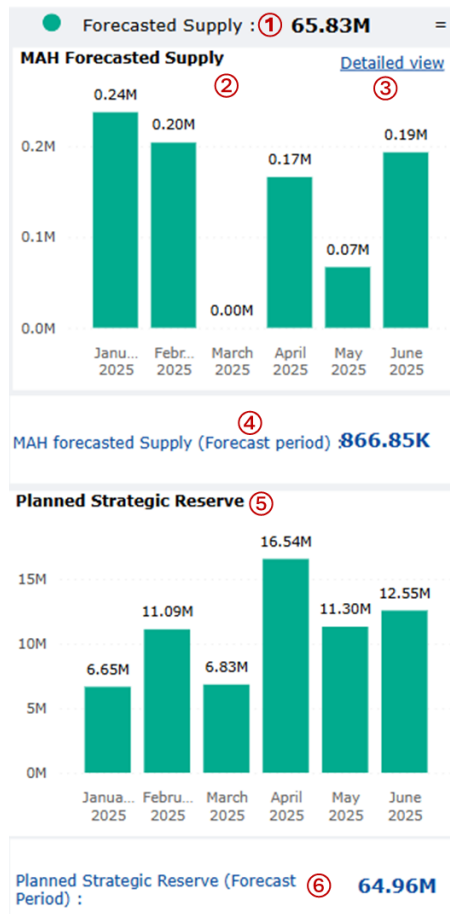


1. **Available stock:** Total of all units that are available across the supply chain at the time of submission to be distributed for the treatment of patients in the shortest possible time frame. The summation of hospital stock, community pharmacy stock, wholesale distributors stock, current strategic reserve and MAH available stock.
2. **MS available stock visual:** Chart displaying hospital stock, community stock, current strategic reserve and wholesale distributor stock. By visualising the individual stocks, the user can observe which part of the supply chain has the biggest stock and act accordingly when confronted with supply gaps. The numbers are displayed in units of measurement.
3. **Combined MS available stock:** Summation of hospital stock, community pharmacy stock, wholesale distributors stock, current strategic reserve.
4. **MAH available stock visual:** Chart displaying the available stock at the level of the MAH (available and in the MAH's ownership) at the time of submission, intended to be distributed to a specific EU/EEA member state as known at time of submission of each individual MAH in units of measurement. The user can observe which MAH has the biggest stock and act accordingly when confronted with supply gaps

5. **Detailed view:** A pop-up screen detailing the MAH stock as amount of packs per packaged medicinal product per MAH in stock at each MAH at the time of submission.
6. **Combined MAH stock:** Total amount of units in stock at the MAH level. The summation of all the stock of the medicinal products of the individual MAHs.

5.6.8 Supply section

Figure 81: SMART - Supply section



1. **Forecasted Supply:** Total of all units that expected to become available on the market per month of the forecast period as planned at the time of submission. The summation of MAH forecasted supply, planned strategic reserve.
2. **MAH forecasted supply visual:** Column chart displaying the combined MAH forecasted supply per month of the forecast period. For the supply per MAH please see the detailed view.
3. **Detailed view:** A pop-up screen detailing the MAH supply as amount of packs per packaged medicinal product per MAH per month of the forecast period as planned at the time of submission.

Note: The user must be prudent when evaluating supply during a PHE/ME and take in mind that due to the highly volatile nature of a PHE/ME, the amounts and timing of forecasted supply might vary highly between submissions.

4. **MAH forecasted supply (forecast period):** summation of each individual MAH forecasted supply expected to become available throughout the forecast period.
5. **Planned strategic reserve visual:** Column chart displaying the combined amount of units planned to be acquired by the MS per month of the forecast period to be included in the strategic reserve.
6. **Planned Strategic Reserve (forecast period):** summation of the planned strategic reserve expected to become available throughout the forecast period.

5.6.9 Matching of supply and demand section

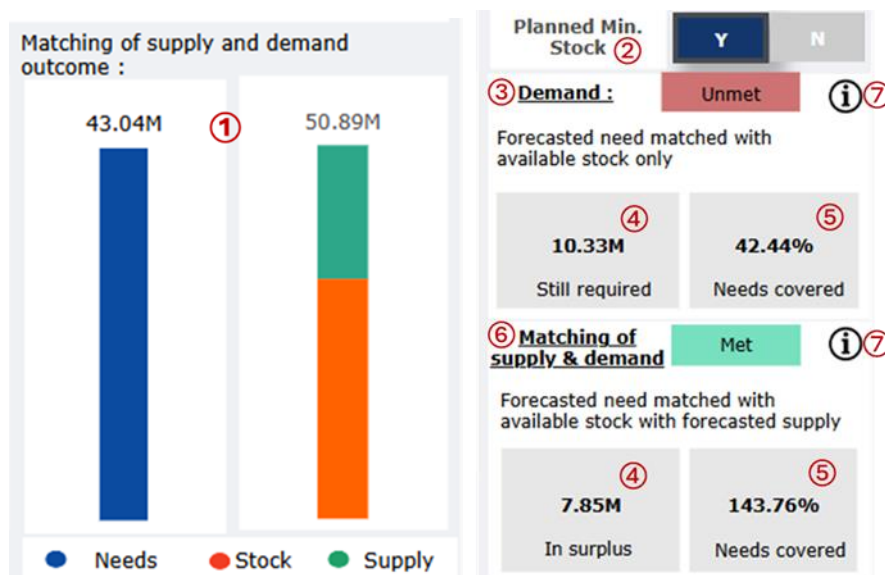
SMART automatically generates the outcomes of the MS Demand and Matching of supply and demand analysis method as described in chapter 5.3.

As a standard setting, the following data elements are included in the MS demand and matching of supply and demand formula, but this can be adjusted:

- The planned minimum stock. However, the user can also generate the outcomes without the planned minimum stock.
- The need and supply of the entire forecast period. Using the forecast data range slider, this can be adjusted to the desired period.

As stated in chapter 3.1, certain considerations need to be considered when interpreting the results of the automatic analysis. **From the moment the considerations are not valid, a new MS patient need scenario needs to be established, uploaded and the results re-evaluated to reflect the new reality.**

Figure 82: SMART – Matching of supply and demand section



1. **Matching of supply and demand visual:** This column chart shows the MS need, available stock and forecasted supply and how they compare to one another.
2. **Planned minimum stock inclusion:** Feature to include (Y) or exclude (N) the planned minimum stock from the demand and supply and demand analysis method as described in 3.2 and 3.3.

3. **MS Demand:** Automatic generation of the MS demand outcome (see chapter 3.3). The tool will also visually show the outcome by displaying either **Unmet** in a red box if there is unmet demand or **Met** in a green box if the need is met and there is a supply surplus.
4. **Outcome in units of measurement:** This indicator shows the outcome of the MS demand analysis or matching of supply and demand analysis. This is the amount of units that are either:
 - **Still required** (Unmet demand) or
 - **In surplus** (Supply surplus)

Note: No negative numbers (for supply surplus) are displayed in the tool, only absolute values, the Red Unmet or Green Met indicate if there is a supply surplus or unmet demand, the number merely shows how large the surplus or requirements are.

5. **Outcome in percentage:** This indicator shows the outcome as percentage of the needs covered, according to the selected forecast period:
 - **<100%** means unmet demand and the percentage shows how much of the need is covered.
 - **>100%** means supply surplus and the percentage shows how large the surplus is in relation with the needs. The percentage above the 100% indicates by how much the need might still increase for supply to still meet demand. The higher the number, the more resilient the current stock and/or upcoming supply is to mitigate unexpected rises in need.
6. **Matching of Supply and Demand:** Automatic generation of the matching of supply and demand calculation (see chapter 3.2) The tool will also visually show the outcome by displaying either Unmet in a red box if there is unmet demand or Met in a green box if the need is met and there is a supply surplus.
7. **Extra information:** This link provides a pop-up screen for both the MS demand and matching of supply and demand calculations and detailing the formulas used in the calculation.



Annex 1: List of terms

General Term	Description
Units	The unit of measurement in which the information of the dashboard is displayed. The specific unit depends on the aggregation level. As a standard setting mg is used as the unit of measurement. For the vaccines number of patients is the unit of measurement.
MS Available Stock	<p>Sum of all units that are available across the supply chain at the time of submission to be distributed for the treatment of patients in a reasonable time frame.</p> <p>These products must already be released by the qualified person responsible and physically available on that level.</p>
Forecasted Supply	<p>Sum of all units that expected to become available on the market per month of the forecast period.</p> <p>This contains all medicinal products prior to release by a qualified person as well as units that not yet manufactured.</p>
Member State Need	Sum of all units that a Member State estimates to need to treat or vaccinate patients, both PHE specific and non-PHE specific, and the buffer for unexpected situations.
MS Demand	The amount of units that the MS still requires or has in surplus after matching the MS need with the available or remaining stock at the MAH and at MS level for each month, in sequential order, throughout the forecast period.
Matching of supply and demand	The amount of units that the MS still requires or has in surplus after matching the MS need with the available stock and forecasted supply at the MAH and at MS level for each month, in sequential order, throughout the forecast period.
Unmet demand	Amount of units still required to meet the MS need of the chosen scenario
Supply Surplus	Amount of units in surplus (supply surplus) after having met the MS need of the chosen scenario
PHE/ME patient need	Amount of units expected to be needed to treat or vaccinate PHE/ME specific patients throughout the forecast period. This data element is estimated using the NCA Patient estimation forecasts and the equivalent data elements taken from the Medicine usage template.
Non-PHE/ME patient need	Amount of units expected to be needed in procedures not related to the PHE/ME throughout the forecast period



General Term	Description
Planned minimum stock	Minimum amount of a medicinal product that should be in the country`s supply chain to assure continuity of supply to patients at any moment in time
Hospital stock Community pharmacy stock Wholesale distributors stock	Amount of units of the relevant medicinal product in stock at the hospital, community pharmacy or wholesale distributors level at time of submission.
Current strategic reserve	Amount of units in stock at the time of submission that have been acquired and are managed by the member state regardless where the stock is stored. This is different from stockpiling requirements applied to wholesale distributors or MAHs which are a part of MS need and need to be captured under planned minimum stock.
MAH available stock	Amount of units in stock at the level of the marketing authorization holder at the time of submission, intended to be distributed to a specific EU/EEA member state.
MAH forecasted supply	Amount of units expected to become available on the market in a specific EU/EEA member state per month of the forecast period.
Planned strategic reserve	Amount of units planned to be acquired throughout the forecast period to be included in the strategic reserve and become available for treatment of patients per month of the forecast period

6. Support



6.1. 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 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 NCA Crisis submissions
- ESMP NCA MSSG-led preparedness submissions
- ESMP NCA solidarity mechanism request
- ESMP NCA critical shortage reporting
- ESMP NCA data analytics dashboard
- 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. 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 83: 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

*** 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 84: 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

*** Subject**

*** Description**

*** Service Offering**

Dear ServiceDesk User,

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

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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

Request

Required information

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

[Service Offering](#)