16 December 2025

European Medicines Agency

Frequently Asked Questions (FAQs) on the European Shortages Monitoring Platform (ESMP)

This FAQ document compiles questions from stakeholders across various channels to address common queries and provide guidance on the European Shortages Monitoring Platform (ESMP). For detailed instructions on how to use the ESMP for routine shortage reporting of centrally authorised products (CAPs) for marketing authorisation holders (MAHs), please refer to the ESMP User guide for MAHs, and consult the training session on routine shortage reporting for MAHs of CAPs. For detailed instructions on crises and MSSG-led preparedness reporting via ESMP for MAHs and NCAs, refer to the ESMP User guide for MAHs, the ESMP User guide for national competent authorities (NCAs), and watch the MAH training session on crisis and MSSG-led preparedness reporting.
Additional information on reporting requirements, including data elements, definitions, and guidelines to ensure submissions pass validation checks, can be found in the ESMP Implementation guide for MAHs and ESMP Implementation guide for NCAs.

For an overview of the ESMP, consult the ESMP webpage and the ESMP Essentials.

For more specific or detailed questions, refer also to the ESMP Essentials Q&A document, available on the ESMP Essentials and Industry Reporting Requirements webinar event page. This resource contains over 130 questions raised by stakeholders, primarily MAHs, during a webinar held on 24 June 2024.

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 An agency of the European Union

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Revision history

Date	Description
13.05.2025	Addition of questions and answers 1.6, 2.14, 2.15, 2.16, 2.17, 2.18 Update of questions and answers 4.3 (including flowchart) and 5.4
16.12.2025	Minor wording updates have been made throughout the document to reflect the current status of activities (e.g., adjustments to verb tenses) Updated and renamed Section 5: Platform development activities Addition of questions 2.2, 2.5, and 3.5 Update of questions and answers 1.6, 5.1, and 5.2 Move of question 5.4 to be 2.22, and update of question and answer *Edit - 29 January 2026:* Figure 1 in question 4.3 was updated for marketing status change to "Not marketed" after shortage reporting

1. General information on ESMP and shortages management in the EU/EEA

1.1. What is the legal basis for the European Shortages Monitoring Platform (ESMP)?

The European Medicines Agency (EMA) set up the ESMP as part of its extended mandate, in line with Regulation (EU) 2022/123 to gather information about medicine availability, supply and demand in order to prevent, detect, and manage human medicine shortages in the European Union (EU) and European Economic Area. For more information, see: Crisis preparedness and management.

1.2. According to EMA, what is a crisis?

Crisis refers to a public health emergency (PHE) or a major event (ME). The EMA has a formal role in preparing for and managing crisis situations affecting the European Union (EU) single market for medicines and medical devices, based on Regulation (EU) 2022/123. For additional information, visit the EMA webpage on crisis preparedness and management.

1.3. What is the definition of a shortage? What is the difference between a potential and actual shortage?

As per Regulation (EU) 2022/123, a 'shortage' is defined as "*a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State […] does not meet the demand for that medicinal product […] at a national level, whatever the cause*".

There is currently no harmonised definition on the EU level for a potential shortage. In general, a potential shortage is a situation that may lead to a shortage. If an MAH foresees the possibility of a shortage of a centrally authorised product (CAP) to happen in a particular market, this should be reported to EMA. There is an ongoing discussion to define what a potential shortage is at the level of the Medicine Shortages SPOC Working Party and more clarity on this will be provided in the future.

1.4. Where can I find definitions for terms and acronyms used across the ESMP?

Most terms and common abbreviations and acronyms used in the context of the ESMP can be found in the ESMP Implementation guide for MAHs, the ESMP Implementation guide for NCAs, and the EMA glossary of regulatory terms.

1.5. Can you explain the different lists of medicines and their use?

The **Union list of critical medicines** is drafted and published by EMA, in collaboration with EU Member States and stakeholders, as part of efforts to prevent shortages and safeguard public health. It comprises of active substances deemed essential for healthcare systems across the EU/EEA, prioritising their continuous supply to prevent shortages that could significantly harm patients and challenge health systems. The first version of the Union list of critical medicines has been published in December 2023, with a second version published in December 2024.

The Union list of critical medicines is not intended to replace existing national lists of critical medicines. EU Member States will continue to use existing lists to support national action, based on national policy decisions. In EU Member States that do not have any lists of critical medicines in place, the Union list could be used to support the development of national lists. National lists are essential to define what medicines are critical on a national level whereas the Union list is a central effort between EMA, the EC and Member States (ministerial level and NCAs) to support actions to ensure supply security on EU/EEA level.

In case of crises or MSSG-led preparedness actions, a **specific list of critical medicines** will be created for each crisis or preparedness situation. These specific lists will define a subset of products (CAPs and non-CAPs (authorised via NP, MRP, DCP)) that will be in scope of mandatory reporting through the ESMP, when this reporting is triggered by the MSSG.

EMA has and will continue to involve or consult several stakeholders, including pharmaceutical industry stakeholders, in the development and updates of the Union list of critical medicines as well as for crisis lists.

Please find here more information on the Overview of medicine lists, the Union list of critical medicines, the Q&A on the Union list of critical medicines, the methodology to identify critical medicines for the Union list of critical medicines and the news article on the first publication of the Union list of critical medicines.

1.6. What is the link between the Union list of critical medicines and reporting requirements in ESMP?

Currently, there is **no direct link** between the Union list of critical medicines and reporting requirements in ESMP. MAHs have no immediate and direct reporting requirements to the ESMP for products in the Union list of critical medicines, except for the standard obligation which applies to notifying EMA of all shortages of any CAPs, regardless of their inclusion in the Union list of critical medicines. MAH reporting in normal circumstances (outside crises and MSSG-led preparedness actions) is confined to shortages of any CAPs, irrelevant of their inclusion in the Union list of critical medicines. National shortage reporting requirements always remain applicable.

MAHs can utilise the Union list of critical medicines as a point of reference to support them to prioritise products for submission of specific product information on pack sizes and manufacturing information to EMA's Product Management Service (PMS). From February 2025, registered MAH and NCA users can use the PMS dynamic product reports available to registered users in the PLM portal (user guidance to access dynamic product reports is available here) to identify the list of products and pack sizes corresponding to the latest version of the Union list of critical medicines. More information: PMS news. NCAs can also use this list to prioritise product mapping in their national systems.

Performing these submissions in PMS as soon as possible will help MAHs and NCAs meet the reporting requirements for the mandatory submission to the ESMP of data on the supply and demand of medicines during crises and MSSG-led preparedness actions. Fully populated and up-to-date information on products on the level of the pack size as well as manufacturing information is a prerequisite for submissions in the ESMP in crisis and MSSG-led preparedness. If missing, MAHs are required to submit this information for the products in scope in PMS within two weeks from the announcement of the specific medicines in scope of the crisis or MSSG-led preparedness.

1.7. What information is shared on the ESMP public platform?

The requirements for the ESMP set in the Regulation (EU) 2022/123) include a public platform which will provide information on actual shortages of medicinal products included in the critical medicines lists in cases in which the Agency has assessed the shortage and has provided recommendations to healthcare professionals and patients. This information, and more, is available in EMA's shortages catalogue.

The general public has access to the landing page of the ESMP, where there are links to EMA's shortages catalogue, and to the national shortages catalogues that list shortages affecting individual Member States.

EMA's ambition is to have a comprehensive EU-wide catalogue of shortages. Currently, the EMA shortages catalogue does not provide a full overview of shortages occurring in the EU/EEA, and the national shortages catalogues list shortages at national level.

1.8. Will there be a transition period for MAHs and NCAs?

For the reporting of CAP shortages in normal circumstances, a transition period between 28 November 2024 to 2 February 2025 took place. Since 2 February 2025, all MAHs need to use the ESMP for the reporting of CAP shortages to EMA. Other reporting obligations done via other systems, e.g. notifying a change of Marketing Status and notification of quality issues, remain applicable. National shortage reporting requirements always remain applicable.

In case of crises or MSSG-led preparedness actions, MAHs need to be ready to report information for medicines during a crisis or a MSSG-led preparedness action as per the specific lists of critical medicines that will be drawn up and will contain a specific sub-set of medicines relevant for the situation. There is no transition period foreseen for crises and MSSG-led preparedness reporting, but MAHs are encouraged to familiarise themselves with the guidance and training materials made available on the ESMP webpage and the training event pages.

For NCAs, in the case of crises or MSSG-led preparedness activities, from February 2025 the ESMP is ready for submissions of data on national demand, stock and supply levels, patient estimations, and medicines usage for a specific sub-set of medicines relevant for the respective situation to support crises or MSSG-led preparedness related activities. However, these ESMP reporting functionalities will only be activated in the system in crises and preparedness actions, and are not visible in the ESMP in normal circumstances.

2. Data submission and reporting requirements

2.1. What is the scope of reporting via the ESMP?

The ESMP enables EMA to monitor the supply, demand and availability of (critical) medicines for human use needed during three different phases: crises (which can be public health emergencies or major events), MSSG-led preparedness, and normal circumstances.

- In **crisis** situations, EMA publishes a list of critical medicines it monitors for each crisis situation. This concerns a crisis specific subset of centrally authorised products (CAPs) and nationally authorised products (non-CAPs). For more information, see: availability of medicines before and during crises.
- **MSSG-led preparedness** aims at monitoring supply and availability of a specific subset of medicines when asked by EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG).
- In **normal circumstances** enabling monitoring of shortages of CAPs which need to routinely be reported to EMA by MAHs.

Find more information here: ESMP informational brief.

2.2. Are personalised medicines, like autologous ex vivo therapies, in scope of shortage reporting via the ESMP?

Regardless of scope or type, centrally authorised products are subject to shortage reporting via the ESMP to EMA (see question 2.1.). Further guidance on shortage reporting processes for this specific group of products will need to be developed in consultation with relevant stakeholders.

2.3. Are shortages of medical devices and veterinary medicines in scope of reporting via the ESMP?

Information on the supply of medical devices and veterinary medicines is out of scope and not covered by the ESMP reporting requirements. For more information you may wish to consult Regulation (EU) 2022/123.

2.4. What and when do MAHs and NCAs need to submit to the ESMP?

The first reporting instance refers to MAH **routine shortage reporting of CAPs**, for which MAHs need to report all potential and actual shortages of CAPs in any EU/EEA country (excluding Northern Ireland) to EMA via the ESMP. MAHs should ensure comprehensive data is updated when new relevant information is available. MAHs' shortage reporting responsibilities to respective NCAs continue to be in place and are regulated under the national requirements.

The second reporting instance refers to **MSSG-led preparedness reporting** by MAHs and NCAs, which may be triggered when there is a need to address events that might lead to a PHE or a ME. These instances will be announced by the MSSG and aimed at a specific group of products to be monitored. This specific list of medicines subject to MSSG-led preparedness reporting may include both CAPs and non-CAPs and will be made up ad hoc and tailored to the specific situation.

The third reporting instance refers to **crisis reporting** by MAHs and NCAs and focuses on immediate actions to handle and mitigate the impact of ongoing or imminent crises, such as a PHE or ME,

triggered by its recognition by the European Commission and concerning the list of critical medicines for that particular PHE or a ME, which may include both CAPs and non-CAPs.

The frequency for MSSG-led preparedness reporting and crisis reporting will be defined by the MSSG. Find more information here: Crisis preparedness and management.

More information on what data elements MAHs and NCAs will need to submit via the ESMP during crisis, MSSG-led preparedness, and MAHs in normal circumstances for CAP shortages, are available in the ESMP Implementation guide for MAHs and in the ESMP Implementation guide for NCAs, which are published on the ESMP webpage, alongside other comprehensive information and trainings.

2.5. Should shortages be reported only if they are of a specific duration, or is reporting also required for shortages lasting as little as one day?

Currently, CAP shortages of any duration should be reported via the ESMP to EMA. The European Commision's proposed pharmaceutical legislation may bring changes to this in the future. The Council has discussed the Commission's proposed pharmaceutical legislation and issued its proposal, which currently states that temporary supply disruptions of medicinal products expected to last more than two weeks in a given Member State must be notified. While this reflects the current position of the Council, it remains subject to change.

2.6. Given the variability in national shortage definitions and reporting requirements, is it acceptable to submit shortage notifications in the ESMP only when a corresponding report is made to the NCA?

If the definition of a shortage provided by Regulation (EU) 2022/123 (see question 1.3) is met, a notification should be submitted to EMA via the ESMP for centrally authorised products for human use. While national reporting requirements vary, this EU-level definition sets the reporting expectations for shortage notifications to EMA. MAHs should notify EMA via the ESMP as soon as they become aware of any potential or actual shortage of a CAP.

2.7. What are the requirements for MAHs regarding shortage prevention and mitigation plans?

Please note there is a difference between:

1. the **Shortage Prevention and Mitigation Plans** (**SPMPs**: Shortage Prevention Plan (SPP) and Shortage Mitigation Plan (SMP)) which currently cannot be submitted via the ESMP to EMA (more information and templates to be found on the EMA webpage), and
2. the **reporting requirement of the data element "shortage prevention and mitigation plans" in the ESMP**. This data element in the ESMP is further described in the ESMP Implementation guide for MAHs, published on the ESMP webpage.

As per 1., **SPMPs**: In case of a crisis (public health emergency or major event) SPPs are mandatory for medicines included in the list of critical medicines for that specific crisis according to article 9.3.k of the Regulation (EU) 2022/123.

MAHs should have in place a SPP for any medicinal product for human use they place on the market of the EU/EEA according to the Good practices for industry for the prevention of human medicinal product shortages. MAHs are advised to use the released templates on a voluntary basis. The implementation of the SPMPs started with a pilot, with a reduced number of products, in which SPMPs were requested

actively. Submission of SPMPs templates via the ESMP is not possible at this point in time, and may become an ESMP functionality with the expansion of the ESMP. For more information, consult: Pilot and guidance to implement shortage prevention and mitigation plans.

As per 2., **ESMP data element**: For the purposes of the reporting via the ESMP, only basic information on the shortage prevention and mitigation plans is required when reporting a shortage or performing data submissions for medicines included in the scope of reporting in the context of a crisis or MSSG-led preparedness, when triggered. However, MAHs are advised to indicate as much detail as possible in the free text field and they may also indicate if they plan to share their filled SPMPs with EMA. More information on this data element is available in the ESMP Implementation guide for MAHs available on the ESMP webpage.

2.8. Which date should MAHs consider as the start date for a shortage?

The potential or actual shortage needs to be reported when the MAH becomes aware that the supply may not or will not meet the demand at national level. The shortage starts at the point in time when the supply will no longer meet the demand. An update to the (expected) start date as well as (expected) end date should be submitted via ESMP as soon as more information becomes available. Kindly also refer to question *2.13. What happens in case data is submitted incomplete?* For more information, please refer to Medicine shortages and availability issues: guidance for companies and Guidance on detection and notification of shortages of medicinal products for MAHs in the Union (EEA).

2.9. How long in advance should MAHs notify a shortage?

MAHs shall notify shortages as early as possible. Following the Guidance on detection and notification of shortages of medicinal products for MAHs in the Union (EEA), a shortage should be notified as early as possible and no later than two months before the actual shortage. MAHs are obliged to report shortages via the ESMP and update and monitor the data until the shortage is resolved. Although there are currently no penalties for late reporting, it is crucial for MAHs to report early, as soon as they have an indication of a potential or actual shortage, and provide sufficient information to EMA, who will work together with them to prevent, mitigate, and manage the impact of the shortage on patients.

For more information, please refer to Medicine shortages and availability issues: guidance for companies and Good practices for industry for the prevention of human medicinal product shortages.

2.10. How will pharmaceutical companies and NCAs be notified about the start of an MSSG-led preparedness action or a crisis?

When an MSSG-led preparedness action is announced or crisis is recognised, EMA will send email notifications to the (industry) single points of contact (SPOCs and i-SPOCs) for relevant stakeholders with products in scope of reporting requirements of the preparedness action or the crisis. NCA SPOCs and MAH i-SPOCs serve as the designated EMA contact point for these notifications. The notification will specify the reporting period's start date and frequency of reporting.

For routine shortage reporting, EMA will not be sending notifications to stakeholders, as reporting in this case is initiated by MAHs based on their awareness of a shortage. In contrast, MSSG-led preparedness or crises will have a defined reporting scope and frequency established by the MSSG. Equally, those stakeholders will be informed regarding the end of such reporting requirements following MSSG's announcement.

2.11. Should an MAH report shortages in countries that they have not launched but the product is imported in that country through parallel distribution?

Reporting to the ESMP is required for marketing authorisation holders. Parallel importers do not need to report to the ESMP unless they hold a marketing authorisation.

2.12. Do shortages or stock outs on the market need to be notified for each pack size of a medicinal product?

Yes. Reporting shortages in the ESMP is at the granularity level of the pack size. For ESMP reporting the PMS packaged product identifier (Package PMS ID as defined in in PMS - ISO IDMP, Chapter 2) is used as the unique product identifier which will ensure that the information inserted in the template is associated with the correct product. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP.

2.13. What happens in case data submitted is incomplete? Will it be possible to change previous shortage submissions?

It is important to notify the EMA as soon as a potential shortage is identified, even if some information is incomplete. Early notifications enable timely engagement to address mitigation and prevention measures. Where information is not available, details may be based on estimates, particularly for potential shortages, and it is acknowledged that this information may not be fully confirmed. Updates should be provided as more information becomes available, ensuring that submitted details remain accurate and up to date. For potential shortages, preliminary details, including an estimated root cause and timelines, are acceptable and can be refined over time, as information becomes available.

MAHs are required to update the submission to ESMP when new information becomes available or previously submitted information is incorrect or outdated. EMA may also contact the submitting user to inquire on further details when needed.

2.14. Will I be able to update the data I previously submitted in the ESMP?

Previously submitted data can be updated by submitting new information in an updated file via the ESMP. The templates generated by the ESMP that can be downloaded for each data submission flow are pre-populated with the latest information submitted by the company or NCA for that particular dataset. If there is any change that the user wishes to insert, the data simply needs to be changed in the data submission file and the newly updated file needs to be uploaded and submitted to the ESMP. EMA will consider the latest submission the latest source of information.

2.15. Is data submitted to ESMP overwritten by new submissions?

When submitting data via ESMP, data from previous submissions on the same packaged products will be overwritten. While you can view the submission history, the available data for review includes only the submission ID, submission type, submission status, date of submission, and the name of the person who submitted the file. The latest information submitted via ESMP can be accessed by downloading the reporting template file for the product(s) in scope. The latest version of the uploaded information will be populated in the downloaded file. It is recommended that each marketing authorisation holder (MAH) establishes internal processes to maintain records of all submitted files and clearly identifies the roles and responsibilities for shortage submissions.

2.16. Will the "Shortage Status" be automatically updated from "Potential" to "Actual" when the start date has been reached or from "Actual" to "Resolved" when the reported end date has been reached? Does this require an additional action from the MAH?

The shortage status does not automatically get updated when the date indicated in the field "Shortage start date or expected start date" nor in the field "Shortage end date or expected end date" is reached as this information may change over time. It is the MAHs responsibility when an actual shortage appears to update the shortage status to "Actual", to ensure the exact start date is indicated (instead of the expected start date, which may have changed) and ensure all other data is up to date in this submission update.

The MAH needs to update the submission in case an actual shortage appears, while keeping in mind the shortage may be prevented by prevention measures. The shortage status can be updated from "Potential" to "Resolved" if the shortage was prevented.
Further, the MAH needs to update the submission when an "Actual" shortage is "Resolved", as the indication of the date in the field "Shortage end date or expected end date" does not automatically trigger the shortage case to be resolved when the indicated date passes. For "Resolved" shortages, MAHs need to indicate the actual shortage end date in the field "Shortage end date or expected end date".

Please also refer to the ESMP Implementation guide for MAHs, chapter *2.3. Shortage information*.

2.17. Can colleagues see each other's submissions in ESMP? Can a co-author be assigned?

To ensure the confidentiality of reporting and considering that an individual performing submissions in the ESMP may be affiliated with multiple marketing authorisation holders, the information contained in ESMP submissions is not shown in the users' submission history. To protect confidential information, the submission history includes only submissions made by the currently logged-in user. However, users can access the most recent information submitted for products that are under their organisation's product portfolio by downloading the submission template for the selected products. This file will contain the latest information, even if submitted by another user.

Additionally, as mentioned in the ESMP User guide for MAHs, chapter 3.1.4, the "Reported active shortages" section displays all the previously reported actual or potential shortages of products that are under your organisation's product portfolio. It provides an overview of all the shortages that still need to be monitored and followed up on by the MAH until the shortage is resolved. For further information on how to download the table please consult the EMSP User guide for MAHs.

2.18. What should I do if the codes in the RMS Shortage root cause list are not representative of the root cause of the shortage I want to report?

The root cause list has been defined by the SPOC Working Party and any potential additions can be considered for adoption at the level of the SPOC Working Party. In case none of the existing values describe the particular situation please choose "Other" and clearly specify in the free text field the details of the situation to allow EMA to perform the assessment of the shortage. However, if you are aware of other common shortage root causes you believe should be added to the list, please propose them via the EMA's Service Desk.

2.19. When notifying a shortage with a root cause related to quality issues, should I also report the quality defect to EMA if the product is not on the market yet?

As stated on the EMA webpage Quality defects and recalls, marketing and/or manufacturing authorisation holders are required to submit a quality defect notification (including suspected quality defects) also in case of restrictions in supply due to a quality defect or a good manufacturing practice issue. This includes batches that are not on the market yet. MAH are requested to submit a quality defect notification to QDEFECT@ema.europa.eu in addition to the shortage notification via ESMP when the root cause is related to quality issues.

2.20. What kind of reports will be generated from the data submitted in the ESMP? Who will have access to these reports?

During crises and MSSG-led preparedness actions EMA will be utilising the ESMP Shortages monitoring and risk analysis tool (SMART), an automated analysis and visualisation tool that analyses and aggregates Member States' supply and demand data and it will be used by the NCAs to access and visualise data for their specific country.

This information on availability, supply and demand gathered from the MAHs and NCAs in crisis and MSSG-led preparedness actions will be analysed by EMA, shared with the SPOC WP, the MSSG and the European Commission and used for decision-making on a European level.

2.21. Why are the crisis and MSSG-led preparedness sections missing from my ESMP view?

The ESMP home page and its side-navigation are custom built to dynamically only show content which is relevant for the user according to the situation:

1. During normal circumstances:
    - the Routine shortage submission process is active and visible for MAH users (to report any shortages of CAPs);
    - the Crisis/ MSSG-led preparedness submission sections are **not** displayed.

2. During crises or when MSSG-led preparedness actions are activated:
    - the Routine shortage submission process is active and visible for MAH users (to report any shortages of CAPs considered non-critical for this particular situation);
    - the Crisis/ MSSG-led preparedness submission sections become visible and accessible (to report availability, supply and demand data for CAPs and non-CAPs critical for this particular situation).
      However, if during crisis and MSSG-led preparedness situations none of the products under the user's organisations product portfolio are considered critical for the situation at hand, the crisis/MSSG-led preparedness sections will be visible, but will not need to be used and a message on the user's home page will state there is no action required for the crisis or MSSG-led preparedness.

Please be assured that in normal circumstances this is the normal functioning of the system and not an error. The ESMP webinar on crisis reporting showed the complete interface to demonstrate all functionalities, including features that are only activated during crisis situations and MSSG-led preparedness actions.

For NCAs:

- To see how the ESMP homepage and left-side navigation menu looks when a crisis is active please see Figure 12 of the EMSP User guide for national competent authorities.
- To see how ESMP homepage and left-side navigation menu looks when a MSSG-led preparedness action is active please see Figure 55 of the ESMP User guide for national competent authorities.

For MAHs:

- To see how the ESMP homepage and left-side navigation menu looks in normal circumstances when only routine shortage reporting is available please see Figure 11 of the ESMP User guide for marketing authorisation holders.
- To see how the ESMP homepage and left-side navigation menu looks when a crisis or MSSG-led preparedness monitoring is active please see Figure 31 of the ESMP User guide for marketing authorisation holders.

2.22. What APIs for machine-to-machine communication with the ESMP are available?

The ESMP Application Programming Interface (API) for specific NCAs and MAHs reporting functionalities has been released. For NCAs, an API is available for submission of national demand by NCAs during MSSG-led preparedness. For MAHs' routine shortage reporting, an API is available for the submission of shortages of centrally authorised products (CAPs) in normal circumstances. Depending on the uptake of these, more APIs may be developed and available in the future.

For further information:

- The ESMP API workshop for **NCAs** took place on 17 February 2025 and aimed to train participants how to register for, test, and use the API. All related materials (API specifications, presentation, recording, Q&A Document, registration instructions to access the test environment) are published on EU-NTC.
- The ESMP API workshop for **MAHs** took place on 24 March 2025 and aimed to train participants how to register for, test, and use the API. All related materials (presentation, recording, Q&A document) are published on the workshop's event page and in the interoperability section of the ESMP webpage (API specifications, registration instructions to access the test environment).

Please also refer to the ESMP webpage's interoperability section and the published documents.

2.23. *What is being done to avoid reporting duplication by MAHs to both EMA and NCAs?*

In parallel with the reporting requirements via the ESMP to EMA, national reporting requirements remain applicable. Information submitted via the ESMP (according to its reporting requirements) is not directly linked and forwarded to NCA's systems. National reporting requirements remain unchanged and must continue as per national guidelines.

Efforts towards achieving EU-level harmonisation on shortage reporting are ongoing. Comprehensive harmonisation depends on achieving full interoperability between the ESMP and national/industry systems, alongside the availability of complete and reliable product data in PMS, including pack sizes

and manufacturer information for all EU/EEA products. This will enable standardisation and mapping across national product systems and PMS.

The reporting of shortages by industry to NCAs remains a national responsibility, and EMA does not influence these processes.

The process of reporting shortages between EMA and NCAs operates differently: NCAs share critical shortages requiring EU-level coordination through the Medicines Shortages Single Points of Contact (SPOC) Working Party. These processes do not alter MAH reporting obligations towards EMA or NCAs.

In the future, achieving interoperability harmonisation of reporting systems is a key goal. EMA is working with the Joint Action CHESSMEN, an entity dedicated to harmonising shortage reporting across the EU, to establish a single reporting standard. However, this requires harmonisation of product information across systems, such as PMS identifiers, and significant progress is needed to connect all systems and avoid duplication of reporting.

3. Access to ESMP

3.1. Are there any specific access requirements for accessing and using the ESMP?

MAHs and NCAs will have to create an EMA account in the EMA Account Management platform (IAM) if they do not already hold one, as these credentials are used to log in to the IRIS platform. Besides, MAHs who do not have IRIS user roles assigned to their EMA accounts will need to request them (e.g. to submit i-SPOC contact details) as described in the relevant documentation. These are separate actions needed for access.

The ESMP user access role can be requested through IAM which has to be approved by the organisations' User Administrator. For MAHs, multiple users may be registered for an MAH and may submit on behalf of an MAH. Users submitting data in the ESMP can be different from the industry single point of contact (i-SPOC). More information is available in the ESMP training for MAHs and the User guide for MAHs published on the ESMP webpage. Additional information for NCA access is available in the ESMP User guide for NCAs and the EU NTC ESMP training course.

3.2. What is the difference between the ESMP Industry Admin and Industry User access roles?

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 ("ESMP Industry Admin"). This person will be able to manage any subsequent access role requests for both ESMP roles (the "ESMP Industry Admin" and the "ESMP Industry User") on behalf of your organisation. Please note that only the "ESMP Industry User" can access the ESMP and perform submissions in ESMP.

More information also available in the published slides and recording of the ESMP training for MAHs (event page) and the User guide for MAHs published on the ESMP webpage.

For more information about the User Administrator role, consult the User Administrator Guide.

3.3. Who has access to the see the ESMP data analytics dashboards and reports and what data will they contain?

The ESMP's Shortage Monitoring and Risk analysis Tool (SMART), the tool for automated data analysis, is available to authorised users from the NCAs and also will be used to aid further communication to the European Commission, as it will be merging the data received from the MAHs with data on demand that EMA received from the NCAs. It will be used to support further decision-making processes on an EU level, and it is tailored to the crisis/MSSG-led preparedness situation. MAHs will not have access to the ESMP-SMART.

EMA handles confidential data from MAHs with the utmost care and does not make confidential data publicly available. Please also consult the ESMP data access policy.

3.4. Does an MAH need to have both: an appointed i-SPOC and the ESMP access roles?

As of 2 September 2022, and according to Regulation (EU) 2022/123, all MAHs in the EU/EEA regardless of authorisation route, indication, product type, or marketing status are required to appoint an industry single point of contact (i-SPOC) and keep the contact information updated. The i-SPOC facilitates rapid communication between EMA and MAHs to detect, report, and prevent or manage

supply and availability issues of medicines included in a list of critical medicines for a 'public health emergency' or a 'major event' and preparedness thereof. More information: Call for companies to register their i-SPOC on supply and availability and Industry contact points for supply and availability of critical medicines.

MAH representatives appointed with ESMP roles do not necessarily need to be the same person as the i-SPOC of the MAH. Equally, the person who is the company i-SPOC does not necessarily need to be the person who is reporting in the ESMP. The i-SPOC should be a person who has a high-level overview of the entire company's supply chain, all the shortages and potential mitigation measures. The person submitting the shortages in ESMP may or may not be the i-SPOC. There is no limit to the number of people who have ESMP user roles in a company. Whether the reporting is done centrally within the MAH or not, is a decision of each MAH. However, EMA advises companies to ensure full internal coordination and allocation of responsibilities to ensure accurate and streamlined reporting.

3.5. I have the Industry User role but I cannot see all the products of my organisation. What can I do?

If you would like to report shortages of CAPs to EMA for which the marketing authorisation is held by affiliates of your organisation, please request the ESMP Industry User role for the respective affiliates that hold the marketing authorisation for those CAPs, which can be requested in the EMA Account Management platform (IAM).

For example, if your organisation has multiple affiliates across the EU/EEA that hold the marketing authorisation for different CAPs, a designated user must be associated with each affiliate organisation (which may be the same person across affiliates) with the appropriate ESMP role to ensure they are able to submit shortage reports for their organisation's products.

More information on how to obtain relevant ESMP user roles is available in the ESMP training for MAHs and the User guide for MAHs.

4. ESMP and other EMA systems

4.1. How does ESMP interact with other EMA systems like IRIS, PMS, OMS, and RMS?

ESMP integrates information from EMA's SPOR data management services: Substance Management Services (SMS), Product Management Services (PMS), Organisation Management Services (OMS) and Referential Management Services (RMS).

The MAH on whose behalf you will be acting needs to be registered in the EMA's Organisation Management Service (OMS). OMS is the single repository of organisational data maintained by EMA. Once you have an EMA account and your organisation is correctly registered in the EMA's OMS, you can request access roles for specific EMA applications, including the ESMP.

ESMP retrieves product information from PMS to pre-populate the relevant product information in the reporting templates and to facilitate data collection, validation, analysis, and management. If this information is outdated, MAHs need to update the information in XEVMPD/PMS. For more information about the product information contained within PMS, please consult: PMS Implementation of ISO standards for the identification of medicinal products (IDMP) in Europe.

The marketing status for CAPs in the ESMP templates is pre-populated using the information submitted by MAHs in IRIS. Please ensure that marketing status information of all your products is inserted correctly and is up to date within the IRIS platform, because marketing status data affects the possibility of reporting the required information in the ESMP. More information: Notifying a change of marketing status and IRIS guide for applicants.

In ESMP, MAHs are able to perform routine CAP shortage reporting and certain data submissions for crisis and MSSG-led preparedness only for products that have the marketing status "Marketed" or "Temporarily unavailable" in a particular country. It is important to note that you will not be able to submit information required in the ESMP for CAPs in countries where in IRIS the products are stated to be "Not marketed", "Never marketed" or missing. Entries for those particular product and country combinations will not be pre-populated in the data submission templates downloaded from the ESMP. If the information on the marketing status of CAPs is not populated or not up to date in IRIS, please perform the necessary changes in IRIS, after which the information will be reflected in the ESMP within approximately 5-15 minutes.

4.2. What is the source for the marketing status data the ESMP platform is using for CAPs and non-CAPs?

Information on the marketing status for **CAPs** needs to be submitted and kept up to date at all times via an existing process in the IRIS platform. This information for CAPs is used in the ESMP to aid the reporting requirements via the ESMP, but it cannot be modified via ESMP. If marketing status details for CAPs in IRIS are out of date or incorrect, changes need to be implemented directly in the IRIS platform, after which they will be automatically reflected in the ESMP. Please find more information here: Notifying change of marketing status and here: IRIS guide for applicants.

Information on the marketing status of non-CAPs will only be requested for a specific group of products in scope of crisis or MSSG-led preparedness reporting when this is triggered by the MSSG and will be submitted via a standalone reporting data flow directly in the ESMP.

EMA will also work on the long-term strategy for reporting the information on the marketing status of all products via a single submission flow.

4.3. When should I change the marketing status in IRIS and when do I need to report a shortage in the ESMP?

Marketing status information for CAPs is reported via IRIS according to the IRIS guide for applicants while the ESMP is used for reporting CAP shortages in normal circumstances and additional data elements during crisis and preparedness actions. The marketing status information on CAPs in IRIS should continuously be kept up to date. If MAHs find incorrect marketing status data for their CAPs listed in the ESMP, they should update it in IRIS. Shortage information must be submitted through the ESMP, but other reporting requirements for MAHs to the EMA are unaffected and continue to be submitted through other EMA portals, including IRIS.

Please note:

- A "Marketed" product may experience a potential or actual shortage as per the shortage definition in Regulation (EU) 2022/123. In this case the marketing status may remain as "Marketed" in IRIS and the shortage should be reported via the ESMP.
- If a temporary marketing cessation causes a potential or actual shortage of a product, in addition to the change of the marketing status in IRIS to "Temporarily unavailable" the shortage of the temporarily ceased product should be reported by the MAH via ESMP to EMA.

Shortages of marketed CAPs caused by issues that do not trigger a temporary marketing cessation should be reported via ESMP while the marketing status in IRIS should remain "Marketed".
For example, a CAP is marketed in a specific country and due to unexpected increased demand a shortage occurs in this market, the marketing status in IRIS should remain "Marketed" and a shortage notification via the ESMP should be done. If for example a quality defect triggers a temporary marketing cessation and causes a shortage, the marketing status in IRIS should be changed to "Temporarily unavailable" and a submission via ESMP should be done.

Therefore, the marketing status update depends on the circumstances and should be assessed on a case-by-case basis. For a step-by-step explanation, kindly refer to the flowchart in Figure 1 below.

Please note that the reporting of changes to the marketing status and in particular withdrawn products in IRIS, as well as shortage reporting via ESMP should not be understood as meeting the national obligations to report marketing cessations and shortages at national level to the relevant EU national competent authorities at the same time. The MAH should ensure they are following the guidelines of each EU national competent authority to inform the NCAs about changes in the marketing status and shortages of products according to national requirements.

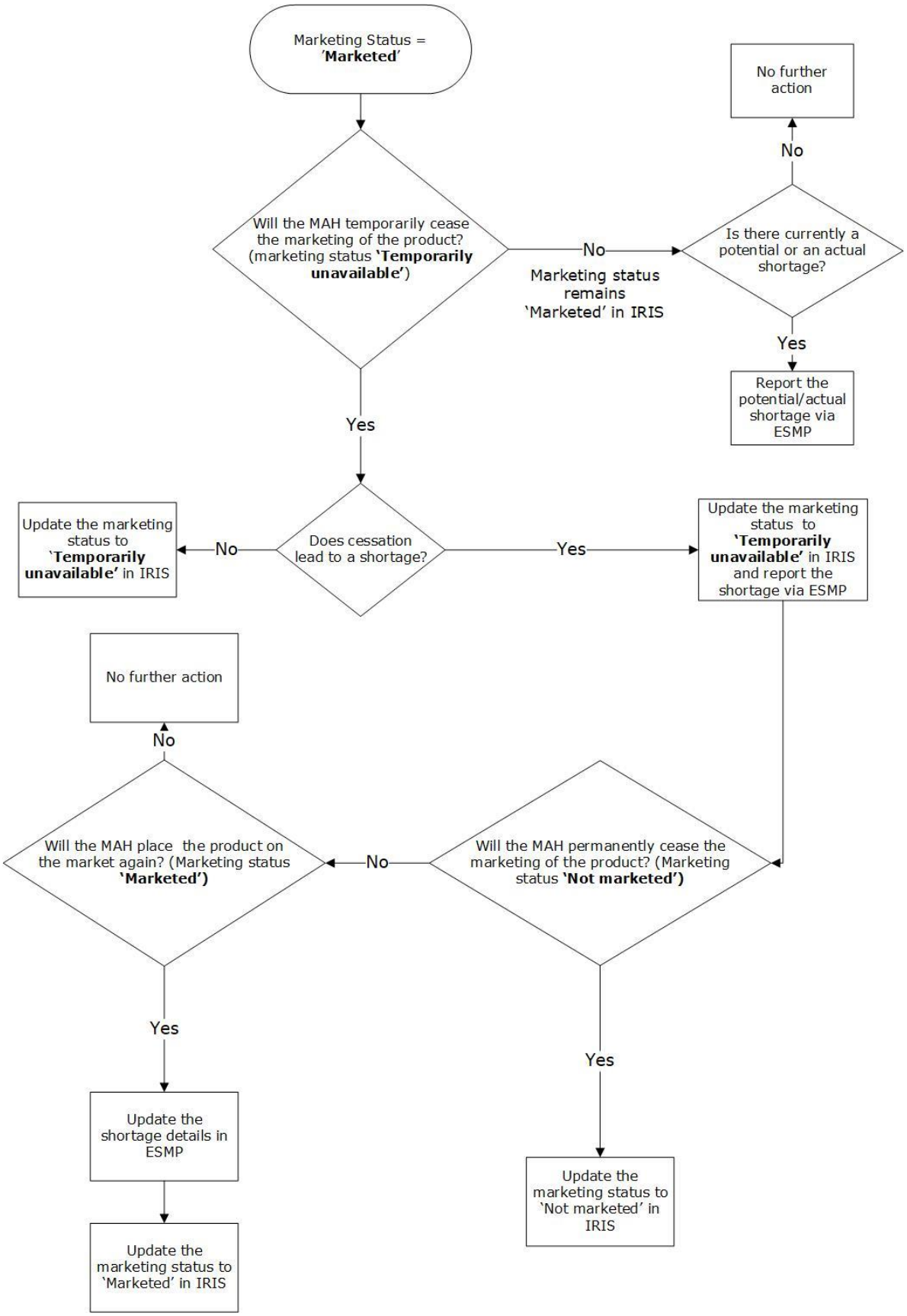

Figure 1: Process relation between the notification of the Marketing status via the IRIS platform and reporting shortages via the European Shortages Monitoring Platform (ESMP); MAH = Marketing authorisation holder

4.4. If the pre-populated product information in the ESMP templates for my products from PMS is outdated, can I correct that data by overwriting it in the Excel templates and submitting it in the ESMP?

It is not possible to overwrite pre-populated information from PMS in the ESMP. Please note the XEVMPD/PMS is the master data repository for product information on all medicines authorised in the EU/EEA and it needs to contain reliable, detailed and up to date information to therefore be used by all stakeholders for establishing the same data definitions on products across the EU/EEA. The ESMP will only be one of the consumers of this data. Information on product master data (including information on pack sizes and manufacturing sites) must be updated directly in PMS, as it will not be possible to override this data in the ESMP.

5. Platform development activities

5.1. How was the ESMP developed and when was it launched?

The development of the ESMP followed an incremental delivery in line with the Agile methodology adopted by the EMA. As of 29 January 2025, and ahead of the legal deadline, the ESMP is live with the full scope of functionalities of the minimum viable product (MVP) as per Agile methodology, fulfilling the legal requirements under Regulation (EU) 2022/123, to enhance shortages monitoring and preparedness across the EU/EEA. The routine CAP shortage reporting functionalities for MAHs were released already in November 2024.

5.2. Will further functionalities be added to the ESMP?

Following the launch of the MVP in January 2025, the platform will continue to undergo improvements and enhancements. In mid-2025, an ESMP expansion to include more functionalities was initiated. For more information, consult the ESMP webpage: development and milestones.

5.3. Are there any UAT or training sessions planned or is there a test environment for the ESMP?

User acceptance testings (UATs) for MAHs and NCAs have been conducted, with sessions in Q2, Q3 and Q4 2024, and in 2025. The ESMP Implementation guides for MAHs and NCAs and prototypes of the ESMP reporting templates for MAHs and NCAs are published on the ESMP webpage and can be consulted to understand the full scope of reporting requirements. The ESMP User guide for MAHs, with step-by-step instructions on how to use the ESMP for routine shortage reporting, has also been published. Trainings and on how to navigate the ESMP and other engagement initiatives are offered during the course of the second half of 2024 and in 2025. Please see the ESMP webpage's events section for links to all events and materials of webinars and trainings held.

While the ESMP team conducted UATs with industry volunteers, general access to the test environment cannot be provided due to technical and resource constraints. However, please note that MAHs can navigate the platform and familiarise themselves with routine shortage reporting functionalities while not finalising a submission. Additionally, users will find that the part of the data submission requiring most training is the population of the Excel file, which can be practiced with the downloaded data submission template.

Please consult the training materials, recorded trainings and follow the upcoming trainings.

All system demos of the ESMP are listed on the ESMP webpage and their recordings can be viewed on the respective event page that is linked on the ESMP webpage.