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European Medicines Agency

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

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

The European Medicines Agency (EMA) is setting up the ESMP as part of its extended mandate, in line with Regulation (EU) 2022/123 to gather information about medicine 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.

2. When is the launch of the ESMP foreseen?

The development of the ESMP is proceeding according to plan (see: development and milestones of the platform), following an incremental delivery in line with the Agile methodology adopted by the EMA. The functionalities for marketing authorisation holders (MAHs) will be launched in Q4 2024, while the functionalities for national competent authorities (NCAs) will be launched in Q1 2025. The complete minimum viable product (MVP) including also the public platform will be launched by 2 February 2025, in line with Regulation (EU) 2022/123. Following the launch of the MVP, the platform will continue to undergo improvements and enhancements.

3. 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.

4. Which is the scope of reporting for the ESMP?

The ESMP will enable EMA to monitor the supply, demand and availability of (critical) medicines 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 (NAPs). For more information, see: availability of critical medicines.
- **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.

Find more information here: ESMP informational brief.

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

The first reporting instance refers to MAHs' **routine shortage reporting of CAPs**, in which MAHs need to report all potential and actual shortages of CAPs in any EU/EEA country to EMA. Once ESMP is

launched in Q4 2024, this reporting will go through the ESMP, and MAHs need to ensure the 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 NAPs and will be made up *ad hoc* and tailored to the specific event.

The third reporting instance refers to **crisis reporting** by MAHs and NCAs 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 NAPs.

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 be submit to the ESMP during crisis, MSSG-led preparedness, or MAHs in normal circumstances for CAP shortages, is available in the ESMP Implementation guide for MAHs and the ESMP Implementation guide for NCAs that are published on the ESMP webpage.

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

Please note: There is a difference between the **Union list of critical medicines**, which has first been published in December 2023 with a second version to be published at the end of 2024, and the **specific lists of critical medicines** that will be defined by the MSSG and published by EMA in **crises** and/or **MSSG-led preparedness** exercises for that specific situation. These specific lists will define a subset of products (CAPs and NAPs) that will be in scope of mandatory reporting through the ESMP, when this reporting is triggered by the MSSG. MAHs have no immediate and direct reporting requirements to the ESMP for products in the Union list of critical medicines (except the requirement which is always valid for all CAPs to routinely report shortages to the EMA). Please also consult the Overview of medicine lists.

The **Union list of critical medicines** is not intended to replace existing national lists. 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 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.

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 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.

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

The tool for the automated analysis will be available to NCAs and also to further communication to the European Commission, as this will be merging the data received from the MAHs with the data on demand that EMA received from the NCAs and will be then serving for further decision-making processes on an EU level, and it will be tailored to the crisis/MSSG-led preparedness situation. MAHs will not have access to the data analytics platform.

8. What will be shared on the public platform?

When the minimum viable product (MVP) of the ESMP is launched in February 2025 (as per Agile methodology and the requirements set in the Regulation (EU) 2022/123) the public platform 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, and will show the information in EMA's shortage catalogue. With further developments of the platform later in 2025 and following years, the public platform may acquire further features.

9. What is the source for the marketing status data the ESMP platform is using for CAPs and NAPs?

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 will be used in the ESMP for CAPs in scope of the reporting requirements to the ESMP, but it cannot be modified there. 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 nationally authorised products (**NAPs**) 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 submitted via a standalone reporting data flow directly in the ESMP.

The 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.

10. Do MAHs need to submit shortages in IRIS or only in ESMP?

In IRIS and according to the IRIS guide for applicants, marketing status information for CAPs is reported, while the ESMP is used for reporting shortages and other data elements during crisis or preparedness exercises. 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.

11. If the pre-populated product information in the ESMP templates for my products from PMS is outdated, can data be submitted by overwriting in the Excel template generated?

It is not possible to overwrite pre-populated information from PMS in the ESMP. Please note the differences and purposes in the reporting requirements. 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 must be updated directly in PMS, as it will not be possible to override data in the ESMP.

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

Previously submitted data can be updated by submitting new information. The templates generated by the ESMP – to be downloaded per each submission – will be 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 and the newly updated file needs to be uploaded and submitted to the ESMP with the fresh information. This will be considered the latest source of information.

13. By when will the machine-to-machine communication be available?

At least one machine-to-machine dataset will be available with the launch of the ESMP MVP in February 2025. Then, depending on the usage of this API and depending on the interest to use more APIs, EMA will develop additional APIs. EMA engaged in numerous discussions with all relevant stakeholders about the messaging format and requirements and reached an agreement to use an open technology based on XML and HTTPS. This will be available from February 2025. EMA will inform relevant stakeholders when it becomes available. That option will be made available for MAHs who want to use the API and adapt internal systems to the API to submit data to the ESMP.

14. How about the reporting duplication for MAHs to the EMA and NCAs?

EMA is working on the interoperability of the ESMP with member states' and MAHs' systems and is constantly engaging with NCAs and MAHs to facilitate the interoperability by providing technical solutions. However, in parallel with the reporting requirements for the ESMP, national reporting requirements remain applicable. Steps on EU level for harmonisation are being undertaken. The prerequisite for a comprehensive harmonisation is for full interoperability to be established between the ESMP and national systems one on side, and a fully populated and reliable product data on pack sizes of all products in the EU/EEA in PMS on the other, to establish product data standardisation and mapping across national product systems and PMS.

15. Where can I find information regarding reporting requirements?

Further information for MAHs and NCAs regarding data elements, technical specifications, and clarification on data in scope are available in the ESMP Implementation guide for MAHs and in ESMP Implementation guide for NCAs, which are published on the ESMP webpage.

16. Are there any UAT or training sessions planned?

User acceptance testing (UAT) for MAHs and NCAs will be conducted in 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 as of July 2024. The ESMP User guide for MAHs, with step-by-step instructions on how to use the ESMP, will be published in Q4 2024. Trainings and on how to navigate the ESMP and other engagement initiatives will be offered during the course of the second half of 2024 and in 2025. A stakeholder engagement plan with an overview of the planned initiatives is published on the ESMP webpage, as of July 2024: ESMP webpage.

More information regarding last Quarterly system demo (Q2 2024) can be found here: Quarterly system demo (Q2 2024). All system demos of the ESMP are listed on the ESMP webpage and their recording can be viewed on the respective event page that is linked on the ESMP webpage.

17. 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)) templates as recently published here, 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 recently published ESMP Implementation guide for MAHs (that is 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 will start with a pilot, with a reduced number of products, in which SPMPs will be requested actively, submission via ESMP is not expected until it is fully operational. Further information will be available in late Q3 2024.

As per 2., **ESMP data element**: For the purposes of the ESMP, only very basic information on the shortage prevention and mitigation plans will be 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. More information on this data elements is available in the ESMP Implementation guide for MAHs available on the ESMP webpage.

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

The shortage needs to be reported when the MAH is made aware that the supply 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. 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).

19. 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), published in July 2019, a shortage should be notified as early as possible and no later than two months before the actual shortage. When routine reporting of shortages through ESMP starts in Q4 2024 (the exact date will be communicated), MAHs shall report shortages in 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 shortage, and provide sufficient information to EMA, who will work together with them to prevent, mitigate, or 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.

20. Will there be any specific access requirements for accessing the ESMP?

MAHs and NCAs will have to first 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. MAHs who do not have IRIS user roles assigned to their EMA accounts will need to request them (e.g. to submit i-SPOC data) as described in the relevant documentation. These are separate actions needed for access.

In the future, an ESMP user access role will be requested through IAM which will be approved by the organisations' User Administrator. For MAHs, multiple users can be registered for an MAH and submit on behalf of an MAH. Users submitting data in the ESMP can be different from the industry single point of contact (i-SPOC). Trainings for users will be organised before the launch of the ESMP for MAHs in Q4 2024. Additional information will be available closer to the launch in the ESMP User guide for MAHs (which will be published in Q4 2024) and in ESMP User guide for NCAs (which will be published in Q1 2025).

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

From November 2024 onwards, MAHs are encouraged to use the ESMP for the routine reporting of shortages of centrally authorised medicines. A transition period for MAHs to start performing these submissions via the ESMP is foreseen between November 2024 and February 2025. All MAHs need to be ready to use the ESMP from February 2025 for the reporting of information of medicines (as per the list of critical medicines that will be drawn up) during a crisis or a MSSG-led preparedness exercise.

For NCAs, from February 2025 the ESMP will be ready for submissions of data on national demand, stock and supply levels, patient estimations, and medicines usage to support crises or MSSG-led preparedness related activities.

For additional, more granular questions, please consult the ESMP Essentials Q&A document on the ESMP Essentials and Industry Reporting Requirement webinar event page, which gathers more than 130 questions raised from multiple stakeholders, mainly MAHs, during the ESMP Essentials and Industry Reporting Requirements webinar on 24 June 2024.