



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

European Shortages Monitoring Platform (ESMP) release notes

Version 2.0

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Acronym key and glossary terms

Abbreviation	Full name
ADO	Azure DevOps
API	Application Programming Interface
CA	Competent Authority
CAP	Centrally Authorised Products
RN	Release Notes
CSV	Comma-separated values
SMS	Substances Management Services
EAM	EMA Account Management
HF	Hot Fix
SIT	System Integration Testing
SPOR	Substances, Products, Organisations and Referentials
UAT	User Acceptance Testing
US	User Story
NCA	National Competent Authority
NP	National Procedure
OMS	Organisation Management Service
MAH	Marketing Authorisation Holder
MS	Member State
NAP	Nationally Authorised Products

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About this document

This document lists and briefly describes the new features, fixed issues and known issues included in each release of the ESMP. They are categorised per component/business process so that users can easily identify which issues are relevant for them. The most recent release appears first.

The components currently used are:

Component	Short description
ESMP	This component relates to the ESMP-website, i.e. the UI (user interface)
Template	This component relates to the pre-filled template files utilised for downloading and uploading data
CRM	This component is utilised to manage role-based access for EMA users and perform case management
SMART	This component is used to analyse supply and demand data submitted by MAH and NCA users during crises and MSSG-led preparedness phases.

If you encounter any issue that is not addressed in this document, please raise a ticket via the EMA Service Desk portal: <https://support.ema.europa.eu/esc>.

For more general information on ESMP, please visit: <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform>.

Version 2.0 (release date: 2025/01/29)

a. Overview

This is the latest version of ESMP, a major release, with release date of 29 January 2025.

Key functionality(ies):

ESMP release 2.0 will introduce enhanced functionalities for both marketing authorisation holders (MAHs) and national competent authorities (NCAs), including:

- Reporting of Availability information by MAH users in a crisis/MSSG-led preparedness phase,
- Reporting of the Marketing status for NAPs by MAH users in a crisis/MSSG-led preparedness phase,
- Reporting of Manufacturing information by MAH users in a crisis/MSSG-led preparedness phase,
- Reporting of Alternative therapies by MAH users in a crisis/MSSG-led preparedness phase,
- Reporting of Stock and supply by NCA users in a crisis phase,
- Reporting of Patient estimation by NCA users in a crisis phase,
- Reporting of Medicine usage by NCA users in a crisis phase,
- Reporting of National demand by NCA users in a MSSG-led preparedness phase,

- The ESMP's Shortage monitoring and risk analysis tool (SMART), analyses the data on supply and demand submitted by MAH and NCA users during crisis events and the MSSG-led preparedness phase. The tool provides critical insights and functionalities, including:
 - Comprehensive overview for NCAs
 - Supply and demand matching indicators for NCAs
 - MSSG-led preparedness event-level insights for EMA

b. New improvements from last version

Issue ID	Description	Component
220932, 162133, 227919, 226854, 227099, 166962, 227534, 196367, 196397, 196370, 224296, 231504, 180600, 209295, 21776, 168002230284	Routine shortage, Availability reporting Marketing status and Alternative therapies for MAH users: <ul style="list-style-type: none"> • Upload data functionality • Download template functionality • User experience optimisation • Core system improvements • General platform improvements • System-wide interface updates • Platform optimisation • Cookies banner and page 	ESMP
156319, 209577, 156320, 221082, 162133, 225781, 166962, 227534	Stock and supply, Patient estimation, Medicine usage, National demand for NCA users: <ul style="list-style-type: none"> • Upload data functionality • Download template functionality • Validation rules implementation • User experience optimisation • General platform improvements 	ESMP
215804, 215807, 222615, 208014, 208020, 227014, 212150, 227019	Shortage monitoring and risk analysis tool <ul style="list-style-type: none"> • Data model readaptation • Modification of matching supply and demand formula • Front-end adaptations with the latest changes • Validate access management • Row-level securities validations • Production deployments • End-to-end validations of the aggregation keys • Validations on list of key indicators 	SMART

c. Fixed bugs from last version

Issue ID	Description	Component
215232	In an upload process, the user can currently select and submit several files at once, instead of only being able to select/submit a single file at a time. If multiple files are uploaded, only the data from file that was uploaded last will be validated and submitted to the platform.	ESMP
221949	Routine shortage reporting for MAH users: the upload of a file containing deprecated RMS values in the 'Root cause of shortage' field from the 'Root Cause of Shortage' RMS list (i.e. the term IDs 200000028687, 200000028688, and 200000028683) are still being accepted.	ESMP

d. Known issues

Issue ID	Description	Component
230933, 231053	In the "My critical medicines" page table, the Marketing status of some CAPs may wrongly display UK (Northern Ireland) as a country. Also, the country column should be displayed first, followed by the CAP/NAP column.	ESMP
230284	In Availability information, the latest uploaded time series data is not entirely reflected in the download template functionality.	ESMP
N/A	After submitting data, in case of a failed submission status, the error messages displayed in the validation results table take some time to load. However, if the user attempts to download the validation results from a failed submission in an Excel file, the error messages will immediately be displayed there.	ESMP

Version 1.2 (release date: 2025/01/08)

a. Overview

This is the minor version of ESMP, with a minor release date of 08 January 2025.

Key functionality(ies):

- See Overview (v1.0)

b. New improvements from last version

Issue ID	Description	Component
166962	Routine shortage reporting for MAH users: <ul style="list-style-type: none"> • Improvements to the Submission status page 	ESMP

c. Fixed bugs from last version

Issue ID	Description	Component
N/A	N/A	N/A

d. Known issues

Issue ID	Description	Component
215232	In an upload process, the user can currently select and submit several files at once, instead of only being able to select/submit a single file at a time. If multiple files are uploaded, only the data from file that was uploaded last will be validated and submitted to the platform.	ESMP
180600	The ESMP cookies page is not yet available.	ESMP
N/A	After submitting data, in case of a failed submission status, the error messages displayed in the validation results table take some time to load. However, if the user attempts to download the validation results from a failed submission in an Excel file, the error messages will immediately be displayed there.	ESMP
221949	Routine shortage reporting for MAH users: the upload of a file containing deprecated RMS values in the 'Root cause of shortage' field from the 'Root Cause of Shortage' RMS list (i.e. the term IDs 200000028687, 200000028688, and 200000028683) are still being accepted.	ESMP

Version 1.1 (release date: 2024/12/09)

a. Overview

This is the minor version of ESMP, with a minor release date of 09 December 2024.

Key functionality(ies):

- See Overview (v1.0)

b. New improvements from last version

Issue ID	Description	Component
221961	On the Routine shortage reporting page, the table for Reported active shortages is to be sorted, by default on the Product name column, from A-Z.	ESMP

c. Fixed bugs from last version

Issue ID	Description	Component
N/A	N/A	N/A

d. Known issues

Issue ID	Description	Component
215232	In an upload process, the user can currently select and submit several files at once, instead of only being able to select/submit a single file at a time. If multiple files are uploaded, only the data from file that was uploaded last will be validated and submitted to the platform.	ESMP
180600	The ESMP cookies page is not yet available.	ESMP
N/A	After submitting data, in case of a failed submission status, the error messages displayed in the validation results table take some time to load. However, if the user attempts to download the validation results from a failed submission in an Excel file, the error messages will immediately be displayed there.	ESMP

221949	Routine shortage reporting for MAH users: the upload of a file containing deprecated RMS values in the 'Root cause of shortage' field from the 'Root Cause of Shortage' RMS list (i.e. the term IDs 200000028687, 200000028688, and 200000028683) are still being accepted.	ESMP
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Version 1.0 (release date: 2024/11/28)

e. Overview

This is the first version of ESMP, with a release date of 28 November 2024.

Key functionality(ies):

- Routine shortage reporting for MAH users, allowing MAHs to routinely report information on potential or actual shortages of CAPs for human use to EMA during normal circumstances. This includes the Submission history for MAH users, allowing MAHs to review their previous submissions along with associated metadata for individual entries, and,
- Case management for EMA users, enabling EMA staff to triage, evaluate, and manage shortage cases reported by MAHs through an integrated and highly automated case management system for the reported shortages.

Next expected major release date: February 2025

Expected new functionalities in the next major release: the upcoming ESMP release will introduce enhanced functionalities for both marketing authorisation holders (MAHs) and national competent authorities (NCAs), including:

- Reporting of Availability information by MAH users in a crisis/MSSG-led preparedness phase,
- Reporting of the Marketing status for NAPs by MAH users in a crisis/MSSG-led preparedness phase,
- Reporting of Manufacturing information by MAH users in a crisis/MSSG-led preparedness phase,
- Reporting of Alternative therapies by MAH users in a crisis/MSSG-led preparedness phase,
- Reporting of Stock and supply by NCA users in a crisis phase,
- Reporting of Patient estimation by NCA users in a crisis phase,
- Reporting of Medicine usage by NCA users in a crisis phase,
- Reporting of National demand by NCA users in a MSSG-led preparedness phase,
- Data analytics platform which will analyse the data on supply and demand submitted by MAH and NCA users in a crisis and MSSG-led preparedness phase.

f. New improvements from last version

Issue ID	Description	Component
134794, 149776, 161648, 161650, 185714, 187631, 37502, 136696, 136987, 167678, 188826, 207515, 223185	Routine shortage reporting for MAH users: <ul style="list-style-type: none"> • Upload data functionality • Download template functionality • Validation rules implementation • User experience optimisation • Core system improvements • General platform improvements • System-wide interface updates • Platform optimisation 	ESMP
133284, 133288, 133298, 133284, 133288, 133298, 133326, 133329, 145520, 149065, 186305	MAH Case management for EMA users: <ul style="list-style-type: none"> • Core case management implementation • Case creation system enhancement • Shortage updates integration • Communication and summary features • System-wide improvements • Advanced features implementation • Platform optimisation updates 	CRM

g. Fixed bugs from last version

Issue ID	Description	Component
N/A	N/A	N/A

h. Known issues

Issue ID	Description	Component
221961	On the Routine shortage reporting page, the table for Reported active shortages is to be sorted, by default on the Product name column, from A-Z.	ESMP
215232	In an upload process, the user can currently select and submit several files at once, instead of only being able to select/submit a single file at a time. If multiple files are	ESMP

	uploaded, only the data from file that was uploaded last will be validated and submitted to the platform.	
180600	The ESMP cookies page is not yet available.	ESMP
N/A	After submitting data, in case of a failed submission status, the error messages displayed in the validation results table take some time to load. However, if the user attempts to download the validation results from a failed submission in an Excel file, the error messages will immediately be displayed there.	ESMP
221949	Routine shortage reporting for MAH users: the upload of a file containing deprecated RMS values in the 'Root cause of shortage' field from the 'Root Cause of Shortage' RMS list (i.e. the term IDs 200000028687, 200000028688, and 200000028683) are still being accepted.	ESMP