

Product Management Service (PMS)



What?

The xEVMPD and SIAMED data have been migrated to PMS for CAPs (Centrally Authorised Products) and the data from xEVMPD to PMS for non-CAPs.



From when?

FOR NON-CAPs ULCM:

- **January 31st, 2025:** Submit pack sizes. Deadline extension: May 2025
- **End of 2025:** Submit manufacturers data and business operation + structured data.
- **End of 2026:** Submit rest of structured data of pack sizes and manufacturers data.



Applicable for

Human use medicinal products



Changes

FOR CAPs:

- The PMS data comes from the integration of SIAMED and xEVMPD.
- No need to submit updates for CAPs on pack sizes, as existing SIAMED information and it has been migrated to PMS
- Commercialization status is managed in IRIS, not PMS.

FOR NON-CAPs:

- Enrichment of structured data for pack sizes and manufacturers data through PUI (Product User Interface) or PMS API .



Action required

FOR CAPs:

- Check that the information migrated from SIAMED and xEVMPD is correct and if is not correct: send ticket to EMA. Highly recommended the Manufacturers and Business Operations.

FOR NON-CAPs:

- Check the information migrated from xEVMPD was correctly migrated and if is not correct: send ticket to EMA.
- Submit pack sizes from Union List of Critical Medicines to xEVMPD.
- Submit structured data for pack sizes and manufacturers for medicinal products under ULCM.

European Shortages Monitoring Platform (ESMP)



What?

Launch of the new ESMP to gather information about medicine supply in order to prevent and manage human medicine shortages in EU and EEA.



From when?

First full version of the platform from January 2025.



Applicable for

Human use medicinal products



Changes

New platform fed with product information data from PMS and from IRIS (for marketing status)

- Routine shortage reporting
- MSSG-led preparedness reporting
- Crisis reporting



Action required

Preliminary requirements for Industry before reporting

PMS data entry: Ensure that product information at pack size level and manufacturing site information are accurately recorded in the EMA's Product Management Service (PMS)

IRIS data entry: Ensure information on marketing status for CAPs is accurate and up-to-date in the EMA's IRIS platform

FOR CAPs:

Report shortages when exist a Potential or actual shortage of a marketing authorisation holder's product

List of medicines* to be monitored for MSSG-led crisis preparedness (CAPs and NAPs)

Close monitoring of a subset of medicinal products triggered upon request from the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

List of critical medicines* for a PHE/ME (CAPs and NAPs)

Monitoring of supply, demand and availability of medicinal products in scope of a list of critical medicines for a public health emergency or major event

IRIS - Regulatory Procedure Management (RPM)



What?

RPM is the new feature of IRIS that allows Management of post-authorisations product life-cycle procedures



From when?

January 2025.



Applicable for

CPs (also applicable for non-CAPs for procedures where EMA acts as the reference authority)



Changes

RPM platform will be used for all maintenance activities, including:

- Variations
- Article 61.3 notifications
- MA transfers
- Periodic Safety Update Reports (PSURs)
- Post-Authorisation Measures (PAM)
- Line Extensions
- Renewals
- Post-Authorisation Safety Studies (PASS)
- Referrals



Action required

- Use of personal mailboxes as product contacts
- Register all contacts in EMA Account Management System
- Request applicable IRIS Industry roles

Revision of the variation framework for medicines



What?

The European Commission has introduced the [Regulation \(EU\) 2024/1701](#), concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use, and amendments to the Variations Classification Guideline.

The Variations Guideline will be published in the Official Journal of the Union in all languages, expected end of August/beginning of September 2025.



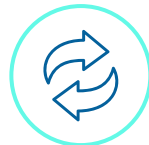
From when?

Variations Regulation: From 1st January 2025.
Variations Classification Guideline: From 15th January 2026.



Applicable for

Human use medicinal products



Changes

- Annual updates for minor variations of type IA
- Procedures for grouping and super-grouping of Type IA variations
- Mandatory (same MAH) and voluntary (different MAHs) use of the worksharing procedure
- Variations to human vaccines for public health emergencies



Action required

Variations implemented from January 2025 must follow the revised Variation Regulation. Variations submitted on and after the 15th January 2026 should also follow the new guidelines/classification system.