REGULATORY REQUIREMENTS

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 requiered

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.