



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12th Industry Stakeholder Platform meeting on the Centralised Procedure

19 June 2024



What is the justification for further development of XEVMPD (e.g. including pack size information) when this is not part of the future data architecture in which XEVMPD will be retired?

- EMA is **using XEVMPD capabilities**, in place since 2014, to address a time critical data enrichment need.
- Due to critical ESMP timelines and the need to provide Industry early notice, **XEVMPD submission** is the only solution available that **supports creation and maintenance of package data without jeopardising ESMP go-live**
- This is a **transitional measure** to enable PMS and meet deadlines which does not change the current or future data architecture.

Does EMA have a robust estimate on the number of datasets the additional granularity would generate? When and how will feasibility be demonstrated?

Industry deems unfeasible the update of data through XEVMPD within 14 days for critical MPs due to mismatch in granularity with PMS

- EMA requests **more information** and clarification on the “**mismatch in granularity**”
- When creating the product entity in XEVMPD, in order to report packages, a **matching product entity is created in PMS**. It will have the same level of granularity, i.e. the same number of packages will be listed in both databases
- The current requirements are to submit authorised medicinal products/packages to XEVMPD within 15 days of MAAs and within 30 days for variations.
- **In crisis situations** or if MSSG-led preparedness is triggered, due to the urgency of reporting availability and supply data, EMA expects that **within 14 days**:
 - **Only new packages are created in XEVMPD** - this is why EMA is asking industry to preemptively provide package details for the Union List of Critical Medicines through XEVMPD in anticipation of their possible relevance in a crisis. This ensures part of the time criticality concern is mitigated
 - **Structured package details are created in PUI** based on packages created through XEVMPD
 - The current requirement of 30 days continues to apply to updates to XEVMPD for existing packages as well as other updates i.e. variations, outside of a crisis

When will process discussions take place with industry and other agile working teams at EMA to ensure true interoperability of PMS data use and understanding of the impact on systems and processes at EMA, NCA, and the industry side?

- A straightforward, reliable way to correct data and clear roles and responsibilities for all actors should be part of the process
- Small changes in process can have large implications for industry and our ability to prepare on time for the submission of data to PMS
- A reliable roadmap/timeline and an impact assessment are critical for industry to be able to prepare.
- **EMA discusses the processes as they are implemented/changed**, as per priorities agreed at the quarterly PI.
- **Process discussions** involve POs and SMEs and where relevant SMEs from different teams are brought together as it has happened with PMS and ESMP.
- EMA is investing in the **harmonisation of its business architecture** and these discussions will likely fit in that context.
- EMA and the Network are investigating **how the Regulatory Optimisation group could be used** to facilitate this discussion and how it might involve industry.

What alternative, more pragmatic ways can the agency offer to industry to deliver the same data differently?

- EMA acknowledges the impact on Industry.
- To mitigate this, **EMA requests data only for the Union list of critical medicines** (~10% of medicinal products).
- Companies can **optionally use XEVMPD for all packages**, but EMA will only request data on non-critical medicines once PMS capabilities improve.
- EMA considered **alternatives to XEVMPD submission**, including a proposal from some MAHs (i.e. creation of product entities via PMS only to avoid pack size submission via XEVMPD) however these **cannot be accommodated**:
 - *Alternatives would **delay PMS work by three quarters**, making pack size updates impossible before Q2 2025.*
 - ***Matching NAPs with national systems** for critical medicines would **not be finalised** before the end of 2026.*

How will EMA work with the inconsistent content between PMS and EVMS in future as OTC products are not included in the EVMS repository?

Reuse of PMS data: All data available in PMS originate from applications/regulatory procedures; ***EMVS data will not be used in PMS*** (thus there is no impact of missing OTC).

- Past discussions between EMVS and PMS teams indicated the possibility for EMVS to reuse PMS data in a specific context where it would then be complemented by MAHs with additional information from the supply chain.
- Of interest:
 - *As of Q4 2024, MAHs can optionally populate data carriers (barcode/matrix) in PMS.*
 - *PMS Public API should be available in 2025 to enable access PMS public data, including any available package/data carrier info.*
 - *Once PMS public data is available any interested project team (including EMVS) should handle integration and could need to map data using the available PMS identifiers.*

How can the requirement to add information on manufacturers (needed for EVMS and shortages) be processed without any tools, sufficient access and without user rights to add/change data?

Reuse of PMS data to support ESMP scope:

- As of 31 May 2024, EMA has released the PMS Product User Interface (PUI) in read-only mode - CAPs only. Users can request their access via IAM to start reviewing and mapping their product data.
- At the beginning of Q3 2024 EMA plan to release PMS Application Programming Interface (PMS API) containing all CAPs and non-CAPs products in read-only mode. Users will be able to request the API access. Furthermore, at the same time PUI is expected to contain also non-CAPs.
- By Q4 2024, EMA will deliver the capability to create/manage manufacturer data via the PMS Product User Interface (PUI) and the PMS Application Programming Interface (PMS API).
- Adequate access and user roles have been developed to support these capabilities. Refer to EU IG Chapter 1 and On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services.
- Industry is expected to add the requested information on medicines, using the above tools/capabilities, for the products on the critical medicines list by December 2025.

No EMVS data will be used in PMS (for further information refer to Q5).