EMA
EUROPEAN MEDICINES AGENCY

Industry Standing Group
Update on Product Management Service (PMS) (H)

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Topics

- Key points from June ISG meeting
- Work in progress:
  PMS Working arrangements/ROG Feasibility study
- PMS development activities

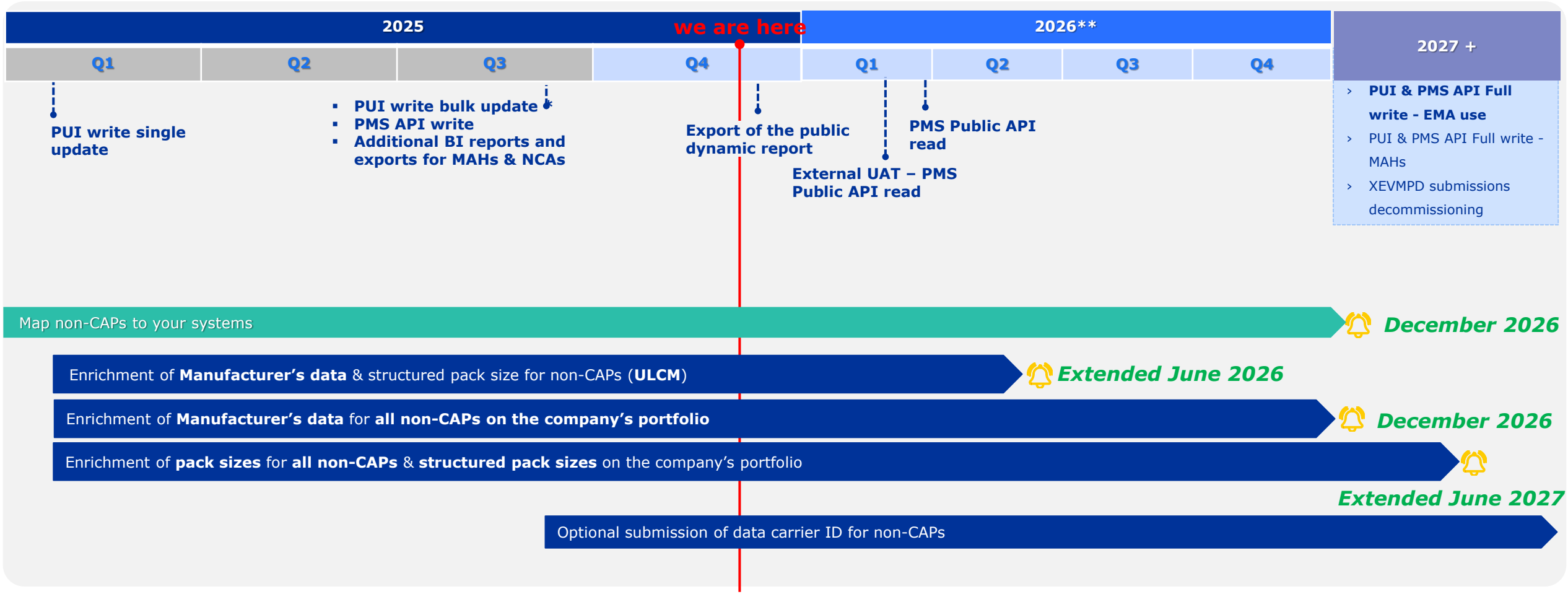
Key points from ISG meeting in June

- HMA/EMA publish recommendations for human Product Master Data implementation and data management from April 2025:
  - **Integrate PMS data with all regulatory processes** throughout the medicine's lifecycle, including the research and development phase.
  - Transition the **submission of both investigational and medicinal product master data from XEVMPD to ISO IDMP/FHIR format via the PMS API or User Interface** under the Article 57 legal basis**.**
- It is envisioned that there will be **no transition period**; XEVMPD will be decommissioned at a specified cut-off date.
- In 2026, we will **collaborate with industry stakeholders** to establish a timeline for the XEVMPD replacement.
- MAHs and sponsors will receive **frequent updates** through quarterly demos, PMS Info days, and other communications. Further impacts will be addressed through detailed engagement with MAHs and sponsors.
- Industry feedback: **Focus on PMS API** and allow a **minimum of 18 months for transition** once the cut-off date is published.

PMS Working arrangements - objectives

- **What is the purpose of his document**
  - Describe working arrangements across Sponsors, Industry and Regulators for the management of both **Investigational, Pending** and **Authorised** product master data in PMS
- **How will it do that**
  - Defines **operational governance** and **roles and responsibilities for EMA, NCAs and industry/sponsors** in managing PMS data:
    - Confirms that PMS becomes single point of entry
    - Recognizes this is transitional, not final state
    - Acknowledges NCA participation is voluntary in the transitional state
    - Defers technical details to EU IG Ch.4
- **Timeline**
  - Work has started and will incorporate input from ROG feasibility study
  - End of Q1 – finalised document for network endorsement
  - Industry consultation to follow

PMS development activities - roadmap overview



Acronyms

- **API:** Application Programming Interface
- **CAPs:** Centrally Authorised Products
- **MAHs:** Marketing Authorisation Holders
- **NCAs:** National Competent Authorities
- **PUI:** Product User Interface
- **UAT:** User Acceptance Testing
- **ULCM:** Union List of Critical Medicines

Legend

NCA action | MAH action | Milestone | Deadline

Q&A

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Thank you

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