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EUROPEAN MEDICINES AGENCY

Advancing Product Master Data – next steps

Strategic recommendations on PMS implementation

Industry Standing Group – 30 June 2025

NDSG recommendations for human Product Master Data implementation and data management

- Adopted by NDSG on 30 April 2025, the high-level paper includes guiding principles, operational recommendations to support effective and efficient execution, and a step-wise approach for delivery and benefits delivered by human medicinal product master data.
- HMA endorsed the recommendations paper for human Product Master Data implementation and data management on 2 June 2025 (via written procedure), followed by the EMA Management Board on 12 June 2025.
- The paper has been published on the EMA NDSG web page.
- These principles and recommendations will serve as the foundation upon which a model for the EMRN working arrangements for PMS data qualification and use can be agreed by end of 2025.

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Medicinal Product master data for better regulation and better health

NDSG recommendations for human Product Master Data implementation and data management

This paper provides the NDSG recommendations for human Product Master Data implementation and data management and includes operational recommendations from the Regulatory Optimisation Group (ROG) to support effective and efficient execution. A programme of work with Marketing Authorisation Holders (MAH) and Sponsors is being undertaken to understand their views and identify the steps they will need to take.

The goal is to achieve a **shared centralised repository** of human medicinal product information at EU level, supporting the product data lifecycle via a **unified entry point** for initial and subsequent product data submissions.

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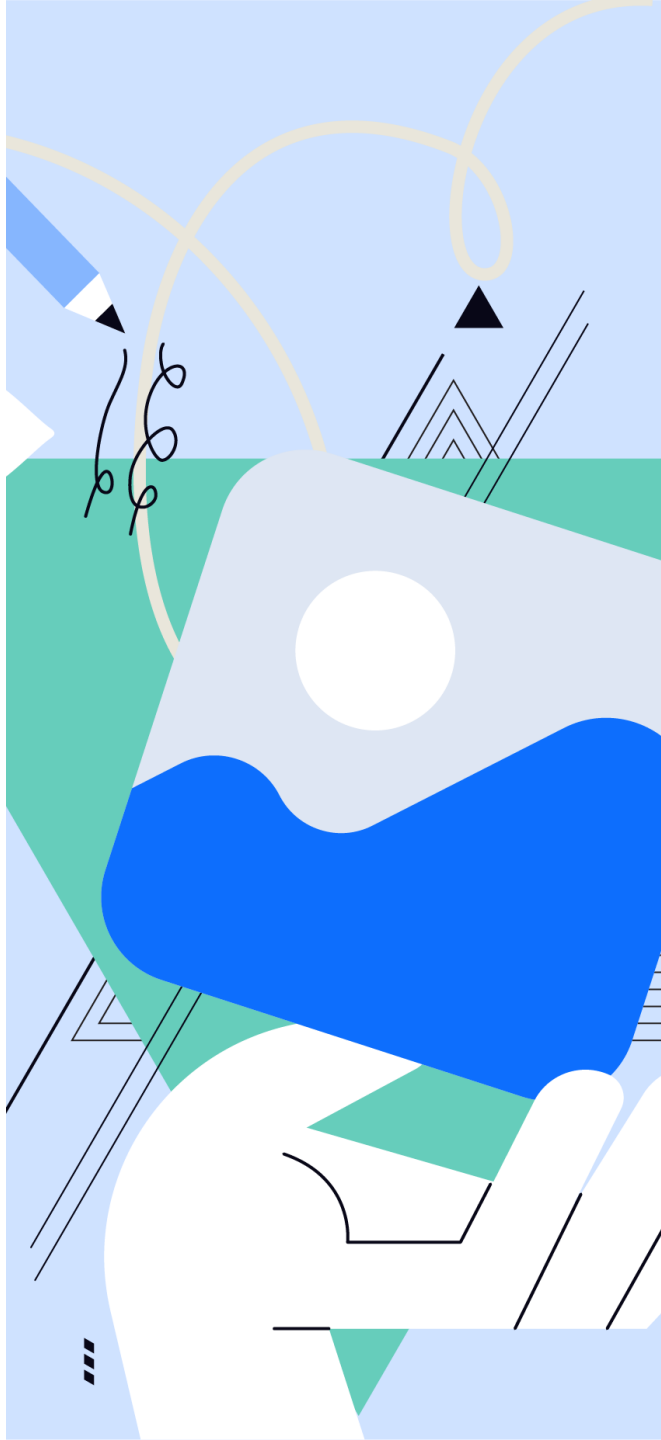
Background

- **Expanded use of Product Management Services (PMS) to support additional use cases** such as the eAF/variation procedures and the European Shortages Monitoring Platform (ESMP), **requiring a much closer collaboration on data quality between industry, NCAs and EMA.**
- **However, product data is submitted via multiple entry points in different formats across several systems,** leading to increased workload for the Network and industry stakeholders, high technical complexity, and suboptimal data quality.



Opportunity for change

- **Changes in the landscape** offer a chance to **rethink and accelerate the implementation of a centralized system**.
  - New Pharmaceutical legislation provides an opportunity to **reassess regulatory processes** and data needs, promoting a digitalized approach.
  - Key learnings **from the veterinary domain** on maintaining a centralized data repository.
- **Compelling use cases: European Health Data Space** (EHDS) Regulation presents the **need for a reliable structured product dataset** for cross-border healthcare.
- **Recent progress** in the EU network in implementing standards like ISO IDMP and SPOR, enable better data reuse and exchange.

Guiding principles

- Manage product master data as an asset to benefit medicine regulation, innovation, and patients.

- Implement and manage master data with a long-term vision for efficient regulatory processes and decision-making through consistent, standardized data.

- Create a trusted, shared repository of product master data for all EU human medicines to support regulation and healthcare decisions.

- Utilize Article 57(2) of Regulation (EC) No. 726/2004 as legal basis for data submission.

- Allocate multi-year resources at EMA and national authorities to realize the vision of product master data benefits.

- Collaborate within the regulatory network and with stakeholders, including MAHs, Sponsors, and healthcare data professionals.

Approach for delivery (1/2)

- Implemented in a **timely manner to support the implementation of the new pharmaceutical legislation (NPL)** for Europe, while driving tangible benefits for the Network and its stakeholders.
- The submission of **post-authorisation** structured medicinal product data is performed as per obligations set out in the Article 57(2) of Regulation (EC) No. 726/2004.
- Product data in the **pre-authorisation** stage is included in the scope of this work, with an aim to **cover the full product lifecycle.**

Scope and Timelines

- In preparation for the new pharmaceutical legislation (NPL)
- Covering entire Product Lifecyle i.e. Investigational, Pending and Authorised Medicinal Products

Approach for delivery (2/2)

- A first step enabling the submission of product master data in **ISO IDMP/FHIR format** via the PMS API or User Interface under the Article 57 legal basis, with **discontinuation of XEVMPD** once consuming systems had been repointed to PMS.
- Integration of PMS data in **regulatory processes via eCTD/eAF** is the goal, with structured medicinal product data submitted once throughout the regulatory lifecycle (and subsequently updated as needed). This should ensure data consistency and leverage, where appropriate, existing regulatory processes.
- **Data quality** is ensured following an **agreed validation process**, with a view to produce data that is 'fit for purpose'. Tailored models of NCA and MAH involvement to be considered to address the diverse demands, capabilities and capacities of the NCAs - *To be Informed by The EMA/HMA ROG feasibility study*

Benefits

- Trusted, publicly available human medicinal product repository, like for veterinary medicines.

- Simplified and harmonized submission process to reduce the burden on MAHs.

- Single source of quality product data enabling regulatory processes and ensuring data consistency across the EMRN.

- Reference data source enabling the reuse of data and improving data quality and analysis across stakeholders.

- Standardized data to prepare for future global data exchange with other international regulators.

- Adoption of emerging technologies such as AI requiring high quality data.

Key points for Industry

- The **goal is to integrate PMS data with all regulatory processes** throughout the medicine's lifecycle, including the research and development phase.
- A **first step** with **submission of both investigational and medicinal product master data in ISO IDMP/FHIR format via the PMS API or User Interface** under the Article 57 legal basis will be enabled, with the **discontinuation of XEVMPD.**
- It is envisioned that there will be **no transition period**; XEVMPD will be decommissioned at a specified cut-off date.
- In the coming months, 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.

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