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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.

Current status

The European Medicines Regulatory Network (EMRN) recognises the value of a shared centralised repository of medicinal product information, making fit-for-purpose structured product data together with the summaries of product characteristics, the package leaflet and the information shown on the labelling, available to its internal and external stakeholders, that is reusable and interoperable. Structured product data is a core asset for many regulatory processes and strengthening its use is in alignment with the recently published European Medicines Agencies Network Strategy to 2028, focusing on advancing data-driven decision-making and strengthening the network's digital capabilities.

Opportunity for change

Over the past years, the Product Management Service (PMS) extended its support to additional use cases, e.g. providing master data to variation procedures, providing data to European Shortages Monitoring Platform (ESMP), while maintaining the good functionality of established EU IT systems and processes, within the limitations of resource and budget constraints. In turn, this has led to a current operating model where product data is entered via multiple submission points in several systems, triggering unnecessary complexity, suboptimal data quality, maintenance costs in the long run, and an increased burden on the Network and stakeholders involved in the structured product data lifecycle.

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Several changes in the landscape surrounding the implementation of PMS currently offer an opportunity to rethink this strategy and accelerate the implementation of a centralised system managing structured product information.

The prospect of the **new pharmaceutical legislation** for human medicinal products in Europe provides the opportunity to reassess current regulatory processes and their data needs across the product life cycle, enabling a more digitalised and data-driven approach to medicines regulation. From the veterinary domain lessons learnt are available how to maintain a centralised data repository (Union Product Database UPD).

Additionally, the recent publication of **European Health Data Space (EHDS) regulation** brings forward the need for a reliable structured product dataset for cross border healthcare.

The implementation of **international** standards (e.g. ISO IDMP) and SPOR at the national level has made good progress in the recent years, with varying levels of adoption across Member States, contributing to improved identification of medicinal products and advancing interoperability and harmonisation among regulators. The modernised tools to create electronic application forms supports IDMP and SPOR which enables additional opportunities for re-using and exchanging product data.

Implementing the proposed approach will lead to leaner processes and simpler data management, better data quality, reduction in costs associated with maintaining multiple systems and decrease burden on stakeholders. A more detailed view of the expected benefits is described later in this document.

Guiding principles for product master data implementation and data management

NDSG agreed on the following guiding principles for human product master data, to move towards an achievable solution within reasonable time limits:

- Product master data should be managed as an asset of the EMRN to deliver benefits for medicines regulation, for innovation and for patients.
- A long-term **vision** guides the implementation and management of human product master data; this vision sees the product data as enabling efficient regulatory processes and decision-making, through the delivery, exchange and flow of consistent, standardized, quality managed medicinal product data in the EMRN and beyond.
- While building on the work already started by PMS the first priority is to achieve a unique and **shared repository** of trusted product master data for all human medicinal products in the EU throughout their life cycle (development and authorised) to support the agreed use cases across medicines regulation and where possible to down-stream decision-makers and delivery of healthcare.
- The established **legal basis** for master data submission of Article 57(2) of Regulation (EC) No. 726/2004 should be leveraged.
- Delivering the vision of product master data delivering benefits for stakeholders, there is a need for **multi-year resource** allocation at EMA and national authorities.
- **Collaboration** within the regulatory network and with stakeholders including the regulated MAHs and Sponsors and those working with healthcare data.

Approach for delivery

The NDSG recommends the need for a lean, achievable approach that can be implemented in a timely manner to support the implementation of the new pharmaceutical legislation for Europe, while driving tangible benefits for the Network and its stakeholders.

The NDSG recommends a step-wise delivery approach that will include a first transitional step enabling the submission of product master data in ISO IDMP/FHIR format under the Article 57 legal basis, with discontinuation of XEVMPD once consuming systems had been repointed to PMS.

Later steps will see integration with PMS data. This should ensure data consistency and leverage, where appropriate, existing regulatory processes

As a starting point, the submission of **post-authorisation** structured medicinal product data is performed, following obligations set out in the Article 57(2) of Regulation (EC) No. 726/2004 via the PMS API or User Interface. Product data in the **pre-authorisation** stage is included in the scope of this work, with an aim to cover the full product lifecycle.

Integration with the regulatory processes via the **eCTD/eAF** is the goal, with structured medicinal product data submitted once throughout the regulatory lifecycle (and subsequently updated as needed). National systems would be connected incrementally, depending on individual member states requirements, needs and priorities.

The ROG recommends that **data quality** is ensured following an agreed validation process, with a view to produce data that is 'fit for purpose'. The NDSG recommends for various models of NCA involvement to be considered to address the diverse demands, capabilities and capacities of the NCAs. The EMA/HMA ROG feasibility study will inform on the data quality models for the NCAs and any involvement of MAHs and Sponsors.

The existing **live systems** relying on product data need to adapt to the changes introduced. The systems currently being developed (or planned to develop in the next years) should build in technical adaptability to the PMS data format (IDMP).

Benefits delivered by this proposal

The implementation of proposed solution would produce benefits for the EMRN and stakeholders:

- A **publicly available** medicinal product repository like for veterinary medicinal products: a widely accessible and interoperable medicinal product dictionary containing all EU approved medicines is a valuable and awaited publication by EMRN stakeholders, ranging from MAHs and Sponsors, academia, HTA payers to the general public and healthcare providers.
- Simplification and harmonisation of the submission process, **easing the current burden** on **MAHs** and ensuring data consistency across the EMRN.
- Product data is core to many of EMRN systems and processes. Consuming data from a unique source is a major step forward towards **unlocking the value of data.**
- Published data is **reusable** by systems in the EMRN and the general public; new systems being developed would adopt a readily available product data repository, strengthening the usability and quality of data and, ultimately facilitating analysis cross-platforms.
- **Standardisation** - implementation of ISO IDMP and Fast Healthcare Interoperability Resources (FHIR) messaging allowing for a future integration and data exchange with other regulators in an international context.

- Moving forward towards a live system hosted by up-to-date technology allows adaptability to incorporate **new technologies**, making use of progress in AI, machine learning in the process.

Adopted by NDSG at their meeting on 30th April 2025.

Endorsed by HMA by written procedure on 11 June 2025.

Endorsed by EMA management board at their meeting on 12 June 2025.