

## EMA PMS: Capitalising on Centralised Medicinal Product Data – Which Way Now for Regulatory Leaders?

By 2026, IDMP compliance will become more challenging for all pharmaceutical companies operating in the EU, due to the broader adoption of the IDMP data model. Now, all eyes are on the EMA Product Management Services (PMS) – or they should be. EMA PMS is essentially a centralised platform, designed to streamline the management and exchange of medicinal product information across the EU, and beyond. MAIN5's Michiel Stam considers the pharma industry's best next steps.

The “bigger picture” benefits of the ISO Identification of Medicinal Products (IDMP) - international standards for uniquely identifying and describing medicinal products - have been well articulated over the years. Yet it is through the imminent rollout of Product Management Services (PMS) by the European Medicines Agency (EMA) that this wider reality will begin to take shape – in the European Union at least. After much grappling with intricate vocabulary standardisation and compliant data structuring, pharma companies marketing products in the EU will start to glimpse the potential (ultimately) of more tightly linking authorised medicines, product pack and data carrier IDs with the latest marketing status details, electronic patient information and summaries of product characteristics.

As a centralised European resource, holding extensive information on both EU-wide and nationally authorised products, EMA PMS is designed to streamline the management and exchange of medicinal product information across the EU and beyond. Like the older and more established eXtended EudraVigilance Medicinal Product Dictionary (xEVMPD), PMS (its successor) will form a comprehensive database enabling the consistent and accurate identification of medicines internationally. It will also support pharmacovigilance and assist in regulatory activities. Crucially, PMS will manage product data based on the ISO IDMP standards, ensuring greater harmonisation and richer detail in the information registered and maintained.

For pharma companies/marketing authorisation holders (MAHs), being ready for and compliant with PMS is paramount, yet continues to present several challenges. Many of these are linked to data preparation, most notably enrichment of existing data through xEVMPD or the PMS user interface to ensure quality, completeness and accuracy and consistent use of IDMP-compliant terms.

### Where We Are Now

EMA's current timescales specify use of PMS for data enrichment related to critical medicines by the end of 2025, and the end of 2026 for non-critical products, so there isn't long to bring data in line. Already, EMA is encouraging submissions of information on the ingredients and strengths in product compositions based on Module 3 of the registration dossier, rather than on local Summaries of Product Characteristic (SmPCs) which can vary in their terminology. Meanwhile submission of data carrier identifiers is supported as of Q2 this year.

Up to now, much of the data enrichment work to existing submissions has had to be done manually however, via EMA's

Product Lifecycle Management (PLM) Portal. Once EMA has established a fully operational application interface (API), registered industry and network users will be able to view and edit medicinal product data directly via their own database systems. Currently the API is available in read-only mode, allowing users to view (but not edit) data. EMA is gradually rolling out edit functionality, allowing registered users to modify specific datasets related to non-centralised marketing authorisation.

Until the full specifications have been finalised (full “write” capabilities are due sometime from 2026 onwards, with a minimum viable product expected towards the end of this year), both software vendors and the pharma industry remain somewhat in limbo. Yet, as with previous phases of EMA's IDMP rollout and associated guidance, waiting for concrete requirements is risky, so companies will need to take a middle ground and progress as and where this makes sense.

### Knowing Where to Aim: Scale and Scope

What is known is that the scale of companies' compliance capabilities will be critical, globally. Beyond the EU and Europe more widely (including Switzerland), the national health authorities in the US, Brazil and Canada are among those that have committed to embracing ISO IDMP standards with a view to harmonised global medicines definitions and information exchange. Global harmonisation was the original vision for the standards, after all. The closer and “truer” MAHs can stay to pure ISO standards, then, the better their chance of large-scale interoperability, automation and seamless compliance down the line (versus having to cater for multiple variations in requirements by region or country).

The other safe assumption is that inter-departmental collaboration will become increasingly important to realise the ultimate scope of IDMP's ambitions. It is well accepted that, for IDMP to succeed and deliver appreciable value, associated efforts must be seen as more than a regulatory undertaking. So, while most IDMP data is currently derived from Regulatory source documents as a legacy of document-driven processes (an approach that fulfils most of the needs of EMA Iteration 1), this is not a sustainable strategy.

Achieving IDMP data's full potential, and delivering real business value, requires a company-wide effort. Much of the core data originates in other domains, such as R&D, Clinical, PV, Medical Affairs, and Industry. Not least for the sake of efficiency, it follows that data should be managed at the source within the function that generates it (rather than extracted from documents retroactively).

Making this change will demand strong cross-functional data governance, and technical- and semantic interoperability. Starting with data domains that show visible cross-functional impact is a good approach. These successes can then serve as positive examples of what is possible, to demonstrate progress and justify ongoing collaboration.

### PMS & Internal Data Alignment Challenges

At a more technical level, there are other data challenges beyond



the current lack of API connection, the absence of software support, and of a holistic view across product data. As companies begin to navigate the initial transition to PMS, they are encountering a data mismatch between xEVMPD, SIAMED (EMA's internal database), and evolving PMS data – discrepancies resulting from migration and from pack-size splitting, for instance. A general lack of control over data quality and sources is compounding the issue, in addition to the EU centricity of the immediate IDMP implementation.

A lack of current compliance with the FHIR standard (standing for Fast Healthcare Interoperability Resources – designed to facilitate reliable exchanges of healthcare information between different systems) is also presenting complications. Currently, FHIR messages extracted through the PMS user interface are not FHIR compliant, requiring manual workarounds to ingest them. This situation is likely to persist until the PMS API FHIR v5 upgrade, which isn't due until 2026 at the earliest.

Moreover, is the reality that nothing is set in stone. EMA is known to be updating some of the reference terminology in the controlled vocabularies in the Referentials Management Services (RMS) system, for instance – around special precautions for storage and shelf life for materials, with an expectation that this will be ready for PMS implementation. This ongoing evolution of PMS's scope, added to system changes, migration and synchronisation challenges, service desk dependency and ongoing life cycle management in different source systems, add further data alignment challenges.

Finally, reliance on transitional xEVMPD/SIAMED-based processes and a short-term PMS roadmap (which lacks a defined 'To-Be' Target Operating Model) could present a barrier to companies looking to progress with strategic planning and effective data enrichment.

An "IDMP readiness" survey commissioned by Pistoia Alliance last year confirmed pharma's perceptions about barriers to fully harnessing the benefits of the standards.<sup>2</sup> It found that manual data collection; data silos; and a lack of data integration across systems present the biggest hurdles in product data management.

Companies' intentions are clear though. The same respondents (senior Regulatory professionals) highlighted the importance of overcoming cross-functional data integration issues, where long-term plans included integrating regulatory data with supply chain

and manufacturing systems – typically within the next year or two – underpinned by IDMP standards adherence.

### Working Around Obstacles that Persist

Given all the potential, yet the remaining practical barriers to progress, the pharma industry needs to balance the strategic with the tactical in planning its next steps.

In its broadest definition, ISO IDMP promises extensive benefits for all, and that applies as much to internal pharma efficiencies as to healthcare providers and patients who can expect a safer and more convenient experience following extensive harmonisation and enrichment of medicinal product information. Strategic and practical operational benefits for pharma include enhanced data quality; simplified, centralised compliance; improved operational efficiency (via robust, centralised data management); risk mitigation; and future readiness. PMS will play a significant role in enabling all of this, making it imperative to put in the groundwork now.

### REFERENCES

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