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From XEVMPD to PMS:

How ISO IDMP Standards are Revolutionizing Medicinal Product Data Management

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TRENDING TOPICS

For over a decade, Marketing Authorization Holders (MAHs) have been required to submit electronic information on authorized medicinal products for human use to the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD). XEVMPD plays a crucial role in supporting pharmacovigilance activities within the EU/EEA by providing a comprehensive and up-to-date medicinal product repository. This enhances the EudraVigilance system's ability to timely detect and assess safety signals, thereby safeguarding public health.

XEVMPD aids in maintaining the European Union Reference List and supports the planning of pharmacovigilance inspections by National Competent Authorities (NCAs). Additionally, it facilitates effective communication with relevant stakeholders, including regulatory authorities, healthcare professionals, and pharmaceutical companies, and is used for identifying medicinal products when handling Adverse Drug Reactions (ADRs).

While XEVMPD is essential for managing regulatory and pharmacovigilance activities, there is a need for global standardization of the effective exchange of medicinal product information. This can be achieved by implementing ISO IDMP standards.

ISO IDMP, developed by the International Organization for Standardization (ISO), is a set of standards designed to uniquely identify and describe medicinal products. The standards are divided into five parts, covering data elements and structures for the unique identification and exchange of regulated medicinal product information; pharmaceutical product information; substances; dose forms, units of presentation, packaging, and measurements. These standards provide a framework for the consistent identification of medicinal products, ensuring clear communication and interoperability between different systems and stakeholders in healthcare and regulatory environments worldwide.

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The adoption of ISO IDMP standards is anticipated to bring significant benefits across various regulatory settings, such as:

Pharmacovigilance

Adverse event reports will be based on a harmonized set of product definitions, enhancing the quality of data used for signal management and expediting communication, decision-making, and regulatory actions.

Regulatory Submissions

A consistent standard for capturing and managing data will allow medicinal product information to be shared and reused across different procedures and among various regulators, while maintaining confidentiality.

Clinical Trials

Stakeholders will access clinical trial data using agreed and well-supported standards, improving the assessment and scientific evaluation of medicines, as well as enhancing communication and transparency.

Good Manufacturing Practice

Inspections of manufacturing sites will be based on accessible information, streamlining the process, especially in urgent situations involving defects. Consistent data standards will also aid in the faster detection of falsified medicines.

The European Medicines Agency (EMA) is leading the transition to ISO IDMP standards by implementing four domains of master data: Substance, Product, Organization, and Referentials (SPOR). The Product Management Service (PMS) and Substance Management Service (SMS) build on the data foundations established by the Referentials Management Service (RMS) and Organizations Management Service (OMS), which the EMA launched in June 2017.

The implementation of PMS and SMS is iterative. The first iteration covers a subset of ISO IDMP data fields, with subsequent iterations to fully implement the standards in the EU.

The initial iteration of the SMS in 2019 enabled users to request the registration of new substance terms or updates to existing ones through the EMA Service Desk, allowing EMA to manage substance data. Future iterations of SMS will include synchronizing with the European Substance Reference System (EU-SRS) database and delivering a user interface for SMS.

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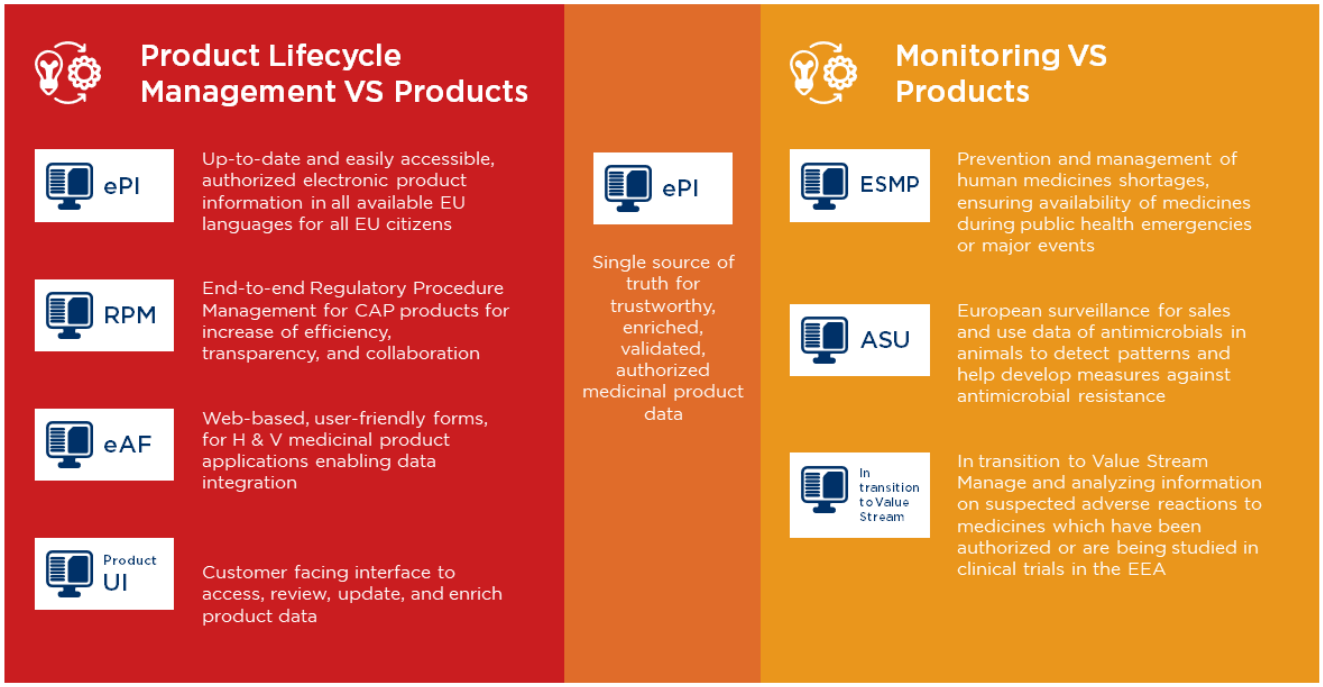
Within the European regulatory network portfolio, several products developed and maintained by the EMA are crucially supported by the Product Management System (PMS). These include the web-based electronic application form (eAF), electronic product information (ePI), the IRIS portal for regulatory procedure management, the European Shortages Monitoring Platform (ESMP), and the Antimicrobial Sales and Use platform (ASU).



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The transition to the Product Management Service (PMS) is a multi-year process involving multiple stakeholders. Currently, the EMA has migrated all data from SIAMED and XEVMPD, covering both centrally and nationally authorized products, into the PMS in an ISO IDMP compatible format.

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Example of Benefits in Implementing ISO IDMP Standards for Pharmacovigilance

Adverse Drug Reaction (ADR) Reporting

Scenario: A patient experiences an unexpected adverse reaction after taking a prescription medication.

Process:

1. Identification:

- **ISO IDMP Standard**: The healthcare provider uses ISO 11615 to identify the specific medicinal product involved.
- The product is identified by its unique identifier, which includes details such as the brand name, active ingredient, strength, dosage form, and packaging.

2. Data Entry:

- **Pharmacovigilance System**: The adverse reaction is reported to a pharmacovigilance system using the unique identifiers from ISO IDMP standards.
- This ensures that the report accurately captures all relevant details about the medicinal product.

3. Analysis:

- **Regulatory Authority**: The regulatory authority uses the standardized data to aggregate and analyze reports of similar adverse reactions.
- This helps in identifying patterns or trends that may indicate a broader safety issue with the product.

4. Action:

- **Risk Management**: Based on the analysis, the regulatory authority may decide to update the product's labeling with new safety information, issue a warning to healthcare providers, or even initiate a recall if necessary.

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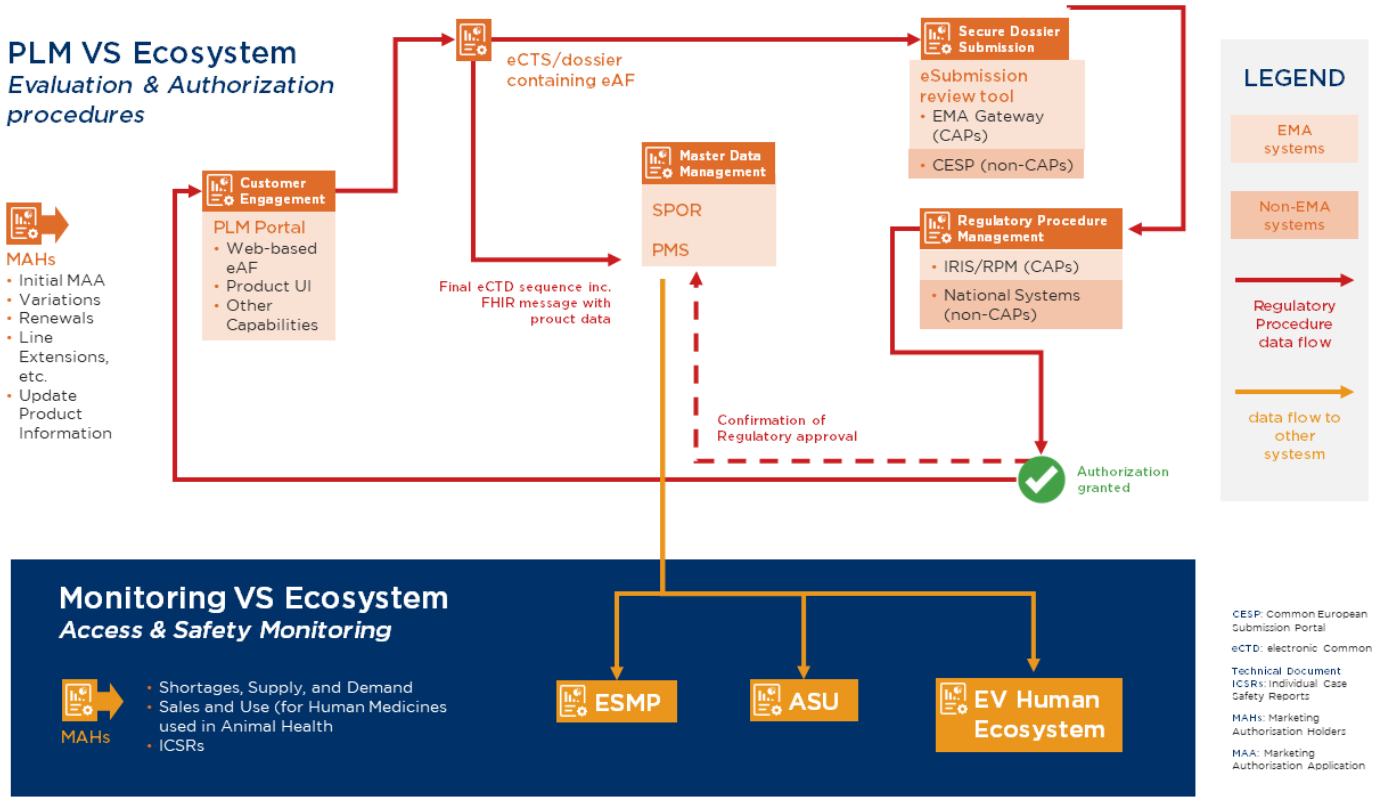
Since the end of May 2024, Marketing Authorization Holders (MAHs) and National Competent Authorities (NCAs) have read-only access to product data in PMS. MAHs are encouraged to review their medicinal products in PMS. This review will be followed by a data enrichment process to collect missing and incomplete data from MAHs.

At present, we are dealing with legacy systems that contain duplicate information, such as XEVMPD, SIAMED, application forms, dossiers, and national systems that are not yet fully integrated with the newly developed systems.

The target state of the regulatory data path is illustrated in the graphic below.



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Example of Benefits in Implementing ISO IDMP Standards for Pharmacovigilance

Medication Recalls

Scenario: A batch of a medicinal product is found to be contaminated during manufacturing.

Process:

1. Identification:

- **ISO IDMP Standard**: The manufacturer identifies the affected product batch using ISO 11615 and ISO 11239 standards.
- Each batch has a unique identifier, including specific manufacturing details and packaging information.

2. Notification:

- **Pharmacovigilance Network**: The manufacturer notifies regulatory authorities and healthcare providers using the standardized product information.
- This ensures that everyone is referencing the same product and batch, preventing confusion.

3. Tracking and Tracing:

- **Healthcare Providers and Pharmacies**: Using the ISO IDMP identifiers, healthcare providers and pharmacies can quickly identify and remove the affected batch from their inventory.
- Patients who have received the medication can be informed promptly using the standardized data.

4. Follow-Up:

- **Adverse Event Monitoring**: Regulatory authorities monitor for any adverse events related to the recall.
- Using the ISO IDMP identifiers, they can track and analyze if the contamination has led to any health issues.

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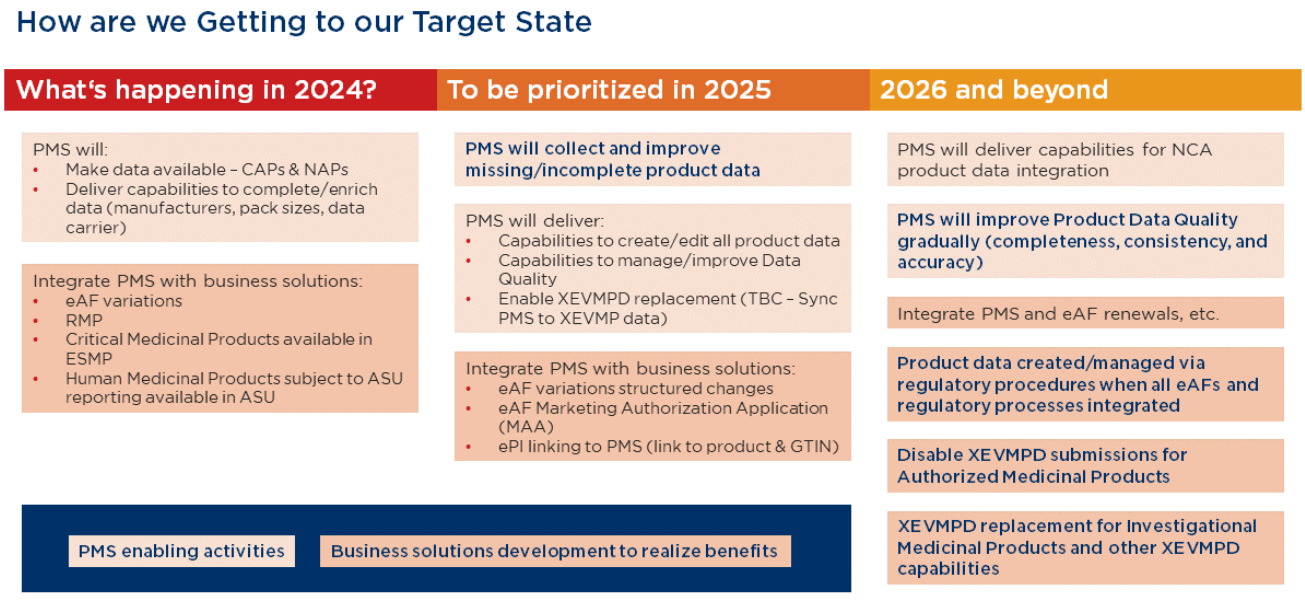
In the target state, Marketing Authorization Holders (MAHs) or applicants will submit applications through PLM customer engagement tools, such as the web-based electronic application form (eAF) and electronic product information (ePI). The eCTD/dossier will then be submitted via the EMA gateway or CESP and processed by regulatory procedure management solutions until authorization is granted. Once data is approved and centrally stored, it will be shared with consuming systems such as the European Shortages Monitoring Platform (ESMP), the Antimicrobial Sales and Use (ASU) platform, and the EudraVigilance (EV) Human Ecosystem.

The target state offers several benefits, including ensuring data quality through integrated processes and seamless integration with National Competent Authorities (NCAs) systems. It supports both regulatory and non-regulatory procedures by providing enriched and validated data sets, leading to better and faster decision-making due to increased data availability. Additionally, it enhances operational efficiencies for regulators and the industry, adheres to the once-only principle where data is submitted only once and then reused, and streamlines business and IT structures for simpler operation.



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Example of Benefits in Implementing ISO IDMP Standards for Pharmacovigilance

Cross-Border Data Exchange

Scenario: A new drug is approved in multiple countries, and there is a need for international pharmacovigilance collaboration.

Process:

1. Regulatory Submission:

- **ISO IDMP Standard**: The pharmaceutical company submits the drug's information to regulatory authorities in different countries using ISO 11615 and ISO 11616 standards.
- This ensures that each regulatory authority receives the same standardized data about the drug.

2. Adverse Event Reporting:

- **Global Pharmacovigilance Database**: Adverse events are reported in different countries and entered into a global pharmacovigilance database.
- The use of ISO IDMP identifiers ensures that all reports about the drug are linked correctly, regardless of the country of origin.

3. Data Analysis:

- **International Collaboration**: Regulatory authorities can collaborate internationally to analyze the data, identifying any emerging safety concerns.
- The standardized data format facilitates seamless integration and comparison of data from different sources.

4. Regulatory Action:

- **Coordinated Response**: If a safety issue is identified, regulatory authorities can coordinate their response, issuing warnings or restrictions simultaneously in multiple countries.
- This ensures a consistent and effective approach to managing the risk associated with the drug.

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Conclusion

In conclusion, MAHs must proactively prepare for the implementation of ISO IDMP in their systems and processes. As of May 2024, they began reviewing product data in the PMS, migrated from XEVMPD and SIAMED, to ensure accuracy and proper use of standard terms. According to current timelines, starting November 2024, MAHs will need to enrich product data for both centrally and nationally authorized products, with a completion target of December 2025. Beyond following EMA recommendations, MAHs should also scrutinize their internal processes and data flow to identify areas for efficiency improvement. Developing a strategy for data cleansing and enrichment is crucial to maintaining data quality, alongside investing in training for relevant stakeholders to navigate these changes effectively.

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