Preparing – at Last – for IDMP Adoption: How Life Sciences Should Ensure Readiness

The fact that the EU will soon be implementing global product identification standards created by the Organization for Standardization (ISO) is hardly breaking news. The life sciences industry has known about the impending adoption of Identification of Medicinal Products (IDMP) for nearly a decade. However, the implementation timeline has been a moving target and for many companies this has meant that preparations for IDMP, originally begun in earnest, have understandably been deprioritised.

Publication of version 2 of the IDMP implementation guide by the EMA earlier this year makes it highly likely that in 2022 companies will be able to begin their IDMP iteration 1 submissions, with this becoming mandatory for centrally approved products the following year.

Providing and maintaining standardised IDMP data will have a far-reaching impact across life science companies and is one of the most challenging changes that companies with products approved in the EU must address.

With the deadline finally on the horizon, life sciences companies need to regroup and ensure their data is ready for submission. Amidst numerous delays which have occurred over the last decade, extensive data quality assessments and revisions, and project scoping and budget requests, it is easy to forget what the original intention and purpose of IDMP was.

A Worthwhile Initiative, a Long Time in Coming

The suite of five standards that compose IDMP have been developed in response to pharmacovigilance legislation enacted in the EU in 2012 (EU No 520/2012, articles 25 and 26). The legislation represented the biggest change to the legal framework for human medicines in a generation. The pharmaceutical industry and regulatory authorities went into the implementation planning fully aware that this would take years to deliver.

Under the legislation, all life sciences companies are required to submit detailed product data for all medicinal products approved in the EU so that descriptors are common across jurisdictions. The standardised identifiers will eventually provide a complete picture of every aspect of every product on the market – the indications approved, the marketing statuses, all product ingredients and manufacturers involved, down to the batch IDs.

The standards are designed to support the exchange of unambiguous and accurate product information across global regulatory and healthcare communities. The overarching goal and driving force behind IDMP is to *improve patient safety through stronger pharmacovigilance and risk management.* Adverse event reports will be based on "a harmonised set of product definitions, improving the quality of data used for signal management and speeding up communication, decision-making and regulatory action."[1] The whole system will be built on a data-centric approach using structured content so that trends in safety issues will be easier to spot and sources traced more rapidly. Safety alerts will be easier to disseminate.

Full implementation of the PV legislation was estimated to save save up to 5910 lives per year and savings to society between 237 million and 2.4 billion Euros per year.[2]

Above and Beyond XEVMPD

IDMP represents a substantial evolution of existing pharmacovigilance reporting requirements in the EU. In addition to the data points required by the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD), the following will be required:

- Manufacturing functions, processes, and registered sites for the active ingredient(s), intermediates, and finished product
- Details on the administrable dose forms and strengths for each medicinal product
- The manufactured item describing the authorised pharmaceutical form of the product and, where applicable, before transformation into the administrable pharmaceutical form
- Packaging details including the packaged item container, quantity, and material for the inner and outer packs
- Marketing status at the pack level, identifying which products/packs are on the market across the EU
- Legal status of supply (Rx or OTC) at the product level where the same status applies across all packs; at the pack level where the status differs

Once fully implemented, IDMP will enable products to be tracked from regulatory approval through to every market. The ability to mine and understand this data will allow organisations to flag potential challenges and, ideally, circumvent issues.

Key Aspects of Compliance

Full coverage of the compliance requirements is beyond the scope of this piece, although the EMA has published several guidance documents explaining what will be required. The fundamentals are that:

- The EMA will create and maintain a product management service (PMS), and information already residing in XEVMPD for marketed products will be migrated into the PMS. The product information will need to be enriched to comply with IDMP requirements prior to any submission.
- When an application for marketing approval and subsequent lifecycle variations are submitted to regulators via the EU Centralized procedure, the IDMP data elements must be submitted as a fast healthcare interoperability resources (FHIR) message in the working documents folder of the electronic common technical document (eCTD). *This means that submitting the IDMP information is on a product's critical path to regulatory approval.*
- Having to provide the structured data at the time of submission is a significant shift from submitting XEVMPD data following receipt of approval as we do today. What this means in practice is that the regulatory authorities will have additional structured data to support their review of dossiers. Thus, marketing authorisation holders (MAHs) need to ensure their regulatory information management (RIM) system is up to date at all times and reflects data pending approval in addition to approved details. Aligning dossiers and data will be critical to companies moving forward.

A Thought on IDMP and COVID-19

The last 12 months in the COVID-19 pandemic have highlighted the criticality of structured data. With shortages in the drug supply and a dire need for global information sharing as the world has struggled to beat the virus, we can start to appreciate the value that IDMP will bring. Imagine the power of a common data repository on adverse drug reactions related to virus treatments and vaccines... or the benefit of being able to analyse the data you are collecting for EMA to better manage the drug supply and avoid the kind of shortages experienced during the pandemic. IDMP is just one of the structured data initiatives driven by EU Telematics, but the size of the data set and the cross-functional sources spanning regulatory, pharmacovigilance, manufacturing, and drug supply positions it for optimum impact. COVID-19 has proven the catalyst for change. Utilising IDMP to drive structured data governance across the industry will have far reaching benefits, the most important of which is patient safety.

The Time to Prepare Is Upon Us

In February 2021, EMA published the second version of the IDMP implementation guide, which makes it highly likely that compliance for centrally approved products (CAPs) will be mandatory in 2023 (the option to start transitioning will begin no earlier than February 22, 2022). The first step of the targeted operating model (TOM) 'currently being finalised and will cover CAPS only. The second step of the TOM will encompass non-centrally approved products.

Life sciences companies that have grown jaded over the subject of IDMP or that have put off preparations should dust off their plans and recommit to readying their organisation. Developing a comprehensive readiness plan will entail (Figure 1):

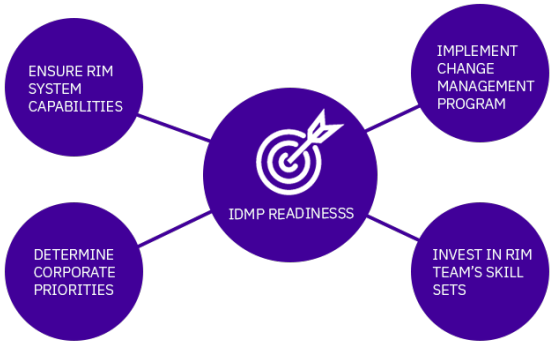

Figure 1: A comprehensive IDMP readiness plan involves multiple components

- Engaging with the company's RIM system vendor to ensure that the system will be capable of accommodating IDMP requirements over a product's lifecycle. Specifically, the RIM system will need to be upgraded to:
  - Capture all the required Iteration 1 IDMP information, in logically presented fields
  - Integrate automatically with source systems, according to their application programming interface (API) needs
  - Cross-reference data points so that information can be entered once and populated elsewhere as needed
  - Create the IDMP data elements as an FHIR message and include them in the working document folder in the eCTD for submission to the agency and where appropriate, support direct submission to PMS.
- Determining the company's priorities for enriching the data that already exists in XEVMPD on products in their portfolio (there will be at least a one-year transition period for centrally approved products). Which products and data elements should be addressed first?
- In advance of updating RIM systems, MAHs can identify complex CAPs and map these to the IDMP requirements. This will be a valuable exercise to help ensure data owners across the organisation are identified.
- Developing and implementing an organisational change management programme with cross-functional representation, to encompass:
  - Agreeing on data ownership and responsibilities
  - Assessing significant changes to business processes
  - Assessing the impact on outsourced work and external partners
  - Delivering focused stakeholder education (to include third parties as needed)
- Investing in the RIM team's skillsets so that team members are equipped to serve as the company's lynchpins in complying with the regulation. They will need to work across the organisation to ensure that all stakeholders are aware of their responsibilities. The RIM team must also be capable of coordinating an effective quality control process, engaging with those planning submissions and preparing dossiers, and providing input into the evolving support model.

Conclusion

Picking up the adoption of IDMP standards will be a significant undertaking requiring careful planning and coordination across many internal functions and external partners. The objective of IDMP – to save patient lives – bears repeating, especially given the years that have elapsed since its conception: IDMP will make it easier to mine product data to safeguard patients. With that goal – and a looming compliance deadline – in mind, it is time for life sciences companies to resume their preparations accordingly.

REFERENCES

1. EMA website accessed at: (https://www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview)
2. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2671:FIN:en:PDF

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