Beyond standard procedure: how to take advantage of new rules on medical product data

Getting ready for the Identification of Medicinal Products

Summary

Beginning in mid-2016, life sciences organizations operating in Europe as well as selling medicinal products in Europe will be required to adhere to a new set of regulations that govern the way their products must comply with industry standards. The Identification of Medicinal Products (IDMP) regulations will require all pharmaceutical products to be identified according to a set of data standards defined by the International Organization for Standardization (ISO).

The ISO data model was defined in 2012, but final guidance related to the implementation of these requirements remains unpublished. Europe will be the first region to implement IDMP standards; the European Medicines Agency (EMA) will publish the full implementation guidelines for IDMP in 2015, leaving those who wait little time to respond. Life sciences organizations will be expected to demonstrate compliance by 1 July 2016, creating an urgency to initiate planning activities now.

We anticipate that other regions will be quick to follow Europe’s example, but history warns us not to expect that IDMP implementation requirements will be consistent everywhere. This means that it will be critical for life sciences organizations to develop and implement a robust, flexible and sustainable approach to medicinal product master data standardization.

That said, embracing standardization of product information as mandated by the new regulations is viewed by some, including EY, as an opportunity to drive process and other efficiencies, thereby creating competitive advantage across the value chain. There is no doubt that leveraging product master data across R&D, manufacturing, supply chain and commercial divisions will increase operational effectiveness in those organizations that take a strategic view of IDMP requirements.

In this article, we explain how organizations can prepare for the implementation of the IDMP requirements — and, importantly, how they can turn it to their advantage by leveraging their product master data assets and capabilities and ensure that they can effectively manage the uncertainty caused by lack of clear regulatory direction.
Introduction to IDMP and the challenges it presents

A clear trend is emerging in medical regulatory affairs. All around the world, policymakers have implemented a raft of new regulations, aimed at improving patient safety, allowing greater transparency and securing the supply chain.

Life sciences organizations are well aware of this trend and the desire of regulators to standardize medicinal product data. Organizations are just starting to emerge from a long period of adapting to demands created by customer master data initiatives in Europe, the US and other countries in order to comply with Healthcare Professionals and Organization (HCP/O) transparency reporting requirements. Implementing those standards and assuring their compliance required significant investment, but life sciences organizations are now seeing efficiency and cost benefits from streamlining their customer master data.

Standardization of medicinal product data is not new. In recent years, life sciences organizations have conducted activities that satisfied the EudraVigilance Medicinal Product Dictionary (EVMPD) pharmacovigilance legislation, known as Article 57. The most recent update of EVMPD, known as XEVMPD, required marketing authorization holders to submit information on all human medicines authorized in Europe by July 2012, using a format defined by the EMA. With the initial submission phase for the XEVMPD now complete, IDMP is the next step in an evolution towards global standardization in identifying and reporting on medicinal products.

Although analogous to the customer transparency reporting requirements, the standardization of product master data, as per the IDMP regulations, is expected to be less complex due to the nature of the data model. But that will depend on the current circumstances of individual organizations with regards to their product master data entities, processes, systems and governance mechanisms.

European regulators have expressed a desire to harmonize directives for product master data, requesting the ISO to develop a set of standards that can be applied across the life sciences industry. The ISO has developed five IDMP standards (see below) designed to uniquely and with certainty identify medicinal products for human use. EMA is the first regulatory agency to require life sciences organizations to comply with these standards. Others, including the U.S. Food and Drug Administration (FDA) and the Japanese Pharmaceutical and Medical Devices Agency (PDMA), are expected to follow suit. Organizations are anticipated to face substantial financial penalties for noncompliance.

**ISO 11615: Medicinal products - regulatory information**

**ISO 11616: Pharmaceutical product (scientific composition)**

**ISO 11238:** Substance

**ISO 11239:** Pharmaceutical dose forms, units of presentation, routes of administration and packaging

**ISO 11240:** Units of measurement
The implementation of the IDMP standards presents organizations with a number of challenges, including:

- An ambitious regulatory implementation schedule. The final EMA implementation guidelines are not likely to be available until late 2015. Although the agency is working towards the development of a draft in the first half of 2015, this leaves life sciences organizations with limited time to respond to the requirements prior to the July 2016 deadline.

- The need to collaborate between business units. The product master data required to satisfy the IDMP standards is present in a wide set of functions and systems within life sciences organizations, and their partners/suppliers. This means that business and IT will need to collaborate to modify systems, definitions and data sourcing capabilities. The modifications will range from simple to extensive, but will likely be pervasive across the entire organization and include business functions beyond regulatory affairs.

- The need to keep abreast of different regulatory agencies’ evolving regulations and requirements as other Regulatory Regions come on board with the ISO standards.
Viewing IDMP as an opportunity

Despite these challenges, it should also be apparent that implementing the IDMP standards also presents life science organizations with a host of opportunities, including:

- Improving visibility and maintenance capabilities of product data across the entire enterprise will reduce data duplications and inconsistencies.
- Improving cross-functional information flows and cross-system reporting will better enable IT activities to support and complement those being performed by the business.
- Conducting meaningful analytics in key areas, enabled by a consistent set of product master data. This should deliver new insights in areas including post-marketing surveillance, competitor analysis, supply chain and return on sales and marketing spend.
- Creating process and operational efficiencies.
  - Increase operational effectiveness by improving internal business process efficiencies associated with product master data.
  - Reduced costs associated with managing, maintaining, integrating and reconciling data across functions and sites.
- Improving data compliance and reducing risk of adverse audit findings.
IDMP is associated with significant risks

There are a number of risks associated with implementing IDMP. Equally, however, there are also clear steps to take in order to mitigate these risks.

<table>
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<tr>
<th>Regulatory risks include:</th>
<th>Operational risks include:</th>
<th>Organizational risks include:</th>
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<tr>
<td>• A delay in the finalization of the EMA implementation guidelines, leading to uncertainty and tight implementation timelines.</td>
<td>• Conflicting and overlapping activities with ongoing and/or completed master data initiatives that were not previously aligned with the IDMP requirements.</td>
<td>• Misalignment across the various business and IT functions and stakeholders.</td>
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<td>• Inconsistent implementation requirements across different regulatory jurisdictions.</td>
<td>• Insufficient or inadequate operating models to enable the IDMP requirements to be met.</td>
<td>• There are multiple resource constraints.</td>
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In response, life sciences organizations can:

• Use the time from now until the end of 1H 2015 to complete a gap analysis based on what is currently known about the ISO data model, and your current product master data definitions. The gap analysis should include an assessment of all current and completed initiatives related to product master data management MDM, creating a plan for alignment and integration.

• Ensure that the right level of governance is in place – and that IDMP is not viewed as an IT-only initiative.

• Factor the timing of final guidance into the implementation program in order to achieve as much as possible in advance of final guidelines.

• Maintain a watching brief on regulatory discussions in all regions to ensure implementation trends are understood and the impact of regional variations are evaluated as guidance emerges.

• Plan and design flexibility into the IDMP, to enable regional extensibility in the future.

• Ensure engagement, contribution and buy-in from all impacted stakeholder groups and system owners who use, create or disseminate product master data.

• Ensure the appropriate level of sponsorship to enable resolution of issues at the executive level.
Essential capabilities for a successful IDMP implementation

To achieve successful implementation of the IDMP standards and to reap the wider benefits of opportunities, life sciences organizations need to be proficient in seven distinct capabilities. Some of these capabilities may already exist in parts of the organization, but they are often focused on specific functions. If they are to be harnessed to address IDMP regulations, life sciences organizations will need to boost the level of integration on these capabilities to a greater extent than for either XEVMPD or HCP/O transparency.

- **IDMP and legal interpretation**
- **ISO implementation and certification**
- **Product MDM and data governance**
- **Framework for delivery of evolving regulations**
- **Change management of associated business impact**
- **Project management methodologies for delivering complex programs**
- **ISO review and audit**

What can be done now  
Those to be addressed in the future
Two of these capabilities – product MDM and data governance and change management of associated business impact – can be prioritized and addressed even before the EMA and other regulators define and finalize their implementation guidelines. By conducting an “as-is” landscape assessment to understand the impact of IDMP standards on product and other master data initiatives, life sciences organizations will gain valuable insights into their data maturity capabilities across divisions and stakeholders, as well as process and organizational responsibilities, and highlight areas that require urgent action. This will, in effect, enable an accelerated response and enable companies to meet the timescales imposed by regulators. There is no doubt that the quicker an individual organization can improve its IDMP readiness, the quicker it will realize the tangible benefits offered by IDMP.

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<tr>
<th>Capabilities</th>
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<tr>
<td>IDMP requirements</td>
<td>Detailed knowledge of the IDMP standards and the legal interpretation of the associated regulations.</td>
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<td>ISO implementation and certification</td>
<td>Knowledge and experience of ISO certification requirements and options, including understanding of certification readiness and implementation of requirements.</td>
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<td>ISO review and audit</td>
<td>Knowledge and experience of ISO validation; ongoing maintenance and assurance of standards.</td>
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<td>Product MDM and data governance</td>
<td>Knowledge and experience of implementing MDM and data governance processes, operating models, data models, architecture and MDM systems into a pragmatic delivery road map.</td>
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<td>Project management methodologies for delivering complex programs</td>
<td>Tried and tested project management capabilities for delivering complex programs that require involvement and contribution from multiple business functions, stakeholder groups and geographies.</td>
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<td>Change management of associated business impact</td>
<td>Change management capabilities to ensure business engagement, opportunity realization and readiness for the change associated with IDMP. This includes the ability to assess the impact and define and implement stakeholder engagement, communication, training and talent management as required. This includes the execution of a gap analysis of the current and target state of organization, process, systems and data.</td>
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<td>Framework for delivery of evolving regulations</td>
<td>Ability to rapidly respond to changes in the global regulatory environment.</td>
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Applying MDM leading practices to IDMP

Fundamentally, the IDMP standards present an additional compliance requirement for product MDM. Life sciences organizations have different paths to compliance depending on their current state, and on previous investments they may have made in master data systems and processes. Regardless of their current state, life sciences organizations can build an IDMP strategy and initiate implementation activities using a defined methodology and structured approach.

Leveraging tried and tested approaches to MDM makes it possible to re-use prior MDM assessments, tailoring outputs as appropriate. The IDMP data architecture should be considered as part of an overall corporate architecture. Again, this presents an opportunity to leverage what already exists, while ensuring that the critical elements specific to the IDMP regulations are identified and addressed. Areas of conflict, overlap and duplication must be clearly identified and resolved to ensure compliance.
Why act now?

The IDMP standards will not only impact Europe-based life sciences organizations, but all organizations that market medicinal products in Europe. Currently, the life sciences industry does not have a consistent view of what needs to be done now in readiness for compliance with IDMP. Waiting for more detail from the EMA on the nature of the implementation guidelines will allow organizations to be more informed as they move forward. Time, however will be lost. On the other hand, a number of organizations are moving ahead, evaluating their product master data capabilities against the (already defined) data model, and conducting in-depth gap analyses. The outcome of these analyses can be quickly incorporated in implementation plans once the EMA guidelines are known and other regulatory agency requirements are published.

Waiting idle is not an option. Experience has shown that MDM implementations can be complex, not least because of the variety of stakeholder groups and systems involved. However, valuable experience has been gleaned from global master data alignment and the implementation of European Federation of Pharmaceutical Industries and Associations (EFPIA) HCP/O transparency reporting regulations, which have delivered a sustainable reduction in program and operational issues related to key master data as well as ensuring that regulatory requirements are met. This experience can and should be leveraged now to lay the groundwork for the implementation of the IDMP standards.

How EY can help

EY is actively involved with several life sciences organizations to leverage their existing product and customer master data assets. We can provide advisory, regulatory and legal input, support and direction to:

- Interpret the IDMP requirements and their legal implications as the requirements are finalized.
- Identify, evaluate and prioritize enhancements to MDM and data governance business processes, IT systems, assets and capabilities, to support streamlined adoption of IDMP requirements.
- Anticipate and adapt to future needs and changes to compliance regulations beyond the initial EMA requirements.
- Provide a risk-based approach to guide the IDMP implementation program, and a framework for helping to ensure ongoing compliance in steady state.
- Identify successful and sustainable ISO implementation and certification.
- Embed pragmatic change management and program management that take into account the complexity of the landscape and the stakeholder groups that will be affected by IDMP.
### Glossary

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<th>Description</th>
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<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<td>EVMPD</td>
<td>EudraVigilance Medicinal Product Dictionary</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>HCP/O</td>
<td>Healthcare Provider/Organization</td>
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<td>IDMP</td>
<td>Identification of Medicinal Products</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>MDM</td>
<td>Master Data Management</td>
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<td>XEVMPD</td>
<td>Extended EudraVigilance Medicinal Product Dictionary</td>
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For more information, please visit ey.com/lifesciences or email global.lifesciences@ey.com. You can also connect with us on our Changing Business of Life Sciences blog at lifesciencesblog.ey.com.
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