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A Modified Implementation Plan for IDMP

Since the publication of the EU's 2012 pharmacovigilance regulation, MAHs have been required to provide specific registered, labelled, and more recently supply information for all approved medicinal products in the EU. The EU's implementation of the Identification of Medicinal Products (IDMP) is designed to further increase patient safety by supporting the exchange of unambiguous and accurate product information across regulatory and healthcare communities.

Throughout 2021 The European Medicines Agency (EMA) with numerous industry, vendor, and National Competent Authority (NCA) stakeholders continued to work on the finalization of the data and process requirements for the submission of ISO compliant data for all medicinal products approved in the EU.

At the end of October 2021, the EMA communicated a change in the implementation strategy for IDMP having adopted a more agile and datacentric approach, with a focus for 2022 on replacing the e-Application Forms with digital forms that will integrate and be partially populated by the product data from Product Management Services PMS.

Previously the priority for 2022 had been the transition of EU centrally approved product information from the Article 57 database to PMS with a requirement to enrich the data and then submit future changes in the form of a Fast Healthcare Interoperability Resources (FHIR) message located in the working folder of the eCTD or directly via API.

THE AMENDED PLAN

Following an EMA Data Access and Interoperability (DADI) Webinar in mid-January 2022 additional information is now available

Submissions to Article 57 'XEVMPD' will continue to be required for the foreseeable future for all EU approved products.

The EMA's revised strategy for 2022 will be to digitize the submission process under the DADI project. The goals are to 1) rely more heavily on structured data to support evidence-based regulation of medicines, 2) create a modern interface and a simplified end user experience, and 3) gain efficiencies.

The current e-application form will be replaced by a new DADI form. The plan for the initial phase is to replace the current iteration of the variation form by 3Q 2022. The DADI form will be populated by structured, ISO-compliant data derived from PMS; populated with XEVMPD data migrated from Article 57 for all products and data from the EMA Siamed database for Centrally Approved Products.

Once the DADI form is completed, it will be downloaded in a PDF and FHIR format and submitted with the electronic common technical document (eCTD). The DADI form will provide capability to enter SPOR structured data in scope of the variation to PMS as well as provide the narrative required for the application form. The DADI Form will be populated via a portal, at the initial go live planned for the third quarter 2022 a largely manual data entry process will be implemented; there will be no direct machine to machine integration. It is hoped over time that the relevant data stored in Regulatory Information Management (RIM) systems will be leveraged such that population of the DADI forms can be supported and therefore reduce duplication of effort and the risk of misalignment of data.

WHAT TO EXPECT IN 2022

The coming year will be a busy one for MAHs and regulators alike in the EU. To keep the momentum going and to ensure readiness for each stage of implementation, companies will need to:

- Continue to submit XEVMPD data to Article 57, as before.
- Perform UAT of the data migration from XEVMPD and SIAMED to the PMS to ensure that the data transfers correctly.
- Develop processes for correcting and enriching the ISO-compliant data within PMS; it is yet to be confirmed if data in RIM systems will be used to directly update PMS via FHIR.
- Watch for updated/additional information on IDMP progress, particularly in the form of an updated project roadmap from the EMA and the IDMP Implementation Guide v2.2.
- Attend future EMA Webinars to be cognizant of the implementation plans as they evolve
- Engage users to understand the data and process changes that will be required.