Technical Webinar: Regulatory Procedure Management for PLM in IRIS for Network Users (27 February 2024) – Questions & Answers

Date: 27/02/2024

Location: Online, 14:00 – 16:00 Amsterdam time (CET)

Link: https://www.ema.europa.eu/en/events/technical-webinar-regulatory-procedure-management-plm-iris-network-users

Disclaimer

This document contains a direct record of questions asked through Slido.com during the Technical Webinar on Regulatory Procedure Management for PLM in IRIS for Network Users which were not answered live during the session. The answers to the other questions are available in the recording of the webinar.

In principle this document will not be updated.

The responses represent the expert view of the Product team at the time of the webinar and are not official statements by the European Medicines Agency nor its partners.

Acronym key and glossary terms

API	Application Programming Interface
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
EU	European Union
IAM	Identity Access Management
MAH	Marketing Authorisation Holder
NCA	National Competent Authority
PLM	Product Lifecycle Management
RBAC	Role-Based Access Control
RPM	Regulatory Procedure Management
SIAMED	Sistema de Información Automatizada sobre Medicamentos
SLA	Service Level Agreement

#	Question	Reply
1	Will Industry users have access to their documents on SharePoint in IRIS?	Yes, Industry users can access all documents exchanged with EMA via IRIS Industry portal.
2	What is the timeline for decommissioning SIAMED?	SIAMED decommissioning is part of the delivery roadmap. The PLM architects started analysis to list the items that are needed to formulate a plan for the SIAMED decommissioning. At this point in time, it is forecasted to have all post-authorisation regulatory procedures transitioned into IRIS by the end of 2024. Then, the marketing authorisation procedure, together with connected activities, are targeted to be moved out of SIAMED within 2025.
3	Marketing status (if product is launched or not in a country) is part of IRIS. To report shortages, MAH sends an email to EMA. Will this shortage reporting also be replaced by IRIS? Or will it replaced by the ESMP that will go live in 2025?	The question does not fall under the scope of the webinar. For more information, please contact Sofia Zastavnik - product owner of European Shortages Management Platform (ESMP)
4	What is the SLA for IRIS?	The incidents raised in IRIS are classified by impact and urgency. The items with the highest priority have a resolution time of 4 hours, up to the items with the lowest priority with resolution time of 5 days.

5	Will EMA share the code for IRIS on GitHub?	If the question is about opening our source code for contribution, it should be in line with transparency and open-source code policies at Agency and EU level. In any case, it must be a conscious decision supported by strong reasons. It also brings significant effort.
6	Is it correct that a generic product has the same product number of the originator product?	No, the generic product does not have the same product number of the originator product. They have distinct product numbers issued in IRIS.
7	Will Network users have the two numbers (PRD & SIAMED) in the notification until their internal systems change?	The list of authorisation products managed in IRIS now includes the PRD numbers along with EMA SIAMED numbers. EMA SIAMED number will be added to the email template where it is still missing.
8	Will stages of development of RPM be related to the go-live of the New Fee Regulations, early 2025?	The compliance with regulatory demands is a priority across the value streams. RPM is focused around the implementation of regulatory pocesses, some of which are incurring fees. The goal is to have those fees adhere to the new fee regulation target in January 2025.
9	How will IRIS deal with submissions that are not applied for via the Gateway or Common Repository – i.e. not based on an eCTD submission? How will cases then be communicated, case number, correspondence etc.?	The same communication model is applied through all procedures in IRIS in regardless of the submission format.
10	Access control in SharePoint is not very granular. How are the files/ documents secured in SharePoint?	IRIS SharePoint implement 4 main document libraries: the submissions library (for the Industry to upload submission related documents), the case library, the Committee Library and the Product Library. • The Industry users do not have direct access to any library, they can only see individual files in the Portal, and upload new files to the Submission Library. • EMA and Network users have read-only access to the submission library. If EMA users need to copy an outcome document to an industry folder in the Submission Library, they have to use an automated procedure. • The NCA users have Read/Write access to the Case, Committee and Product libraries, and read-only access to the submission library. NCA users cannot rename, delete or move documents, but they can edit them.
11	Access is in Dynamics and SharePoint is not synchronised. Are you basing the access on the RBAC method? And how are you handling access to files and cases in SharePoint?	The access control in Dynamics, SharePoint and Portals is handled via security role assignment derived by EMA IAM role configuration. There is no sync between Dynamics and SharePoint.
12	Is there ongoing work for IRIS API for NCAs?	Up to this point in time, no implemented work has been initiated regarding IRIS API for NCA.