



12 February 2024
Information Management

Agenda: Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS

13 February 2024, 10:00 – 11:30 (CET)

Webinar: WebEx meeting

EMA is continuing working on the onboarding of **Regulatory Procedure Management (RPM) for Product Lifecycle Management (PLM)** for medicinal products on IRIS. The **1st roll-out occurred on 23 January 2024**, covering Variations, Article 61.3 Notifications, and Marketing Authorisation Transfers procedures for a subset of 67 human generic products and 44 veterinary products. MAHs for the selected products were individually informed.

The onboarding of regulatory procedures on IRIS will lead in the long term to **process simplification and standardisation for MAHs**.

This virtual event is designed to provide a **comprehensive overview of RPM plans** for the year 2024, offering a glimpse into the strategic direction, key objectives, and upcoming milestones. Moreover, a focal point of the webinar is also a **live demonstration of the Industry Portal**, allowing participants to explore its lately developed features and functionalities.

The event is primarily dedicated to **all interested pharmaceutical industry companies** (especially individuals with expertise in regulatory affairs). Do not miss this valuable opportunity to enhance your understanding and stay informed about the latest developments in this area.

The **registration form** is available [here](#).

Registration is open until the start of the meeting.

#	Item	Speaker	Mins
1.	Welcome	Madalina Duta-Mare <i>Regulatory Procedure Management for PLM Product Owner</i>	10:00 – 10:05 (5 min)
2.	Progress of Regulatory Procedure Management (RPM) for Product Lifecycle Management (PLM) transition to IRIS	Madalina Duta-Mare <i>Regulatory Procedure Management for PLM Product Owner</i>	10:05 – 10:15 (10 min)



#	Item	Speaker	Mins
3.	RPM Roadmap	Madalina Duta-Mare <i>Regulatory Procedure Management for PLM Product Owner</i>	10:15 – 10:20 (5 min)
4.	1st roll-out impact on pharmaceutical companies	Simona Griniene <i>Regulatory Procedure Management for PLM Subject Matter Expert</i>	10:20 – 10:30 (10 min)
5.	IRIS Industry Portal Demo	Sonja Nolte <i>Regulatory Procedure Management for PLM Subject Matter Expert</i>	10:30 – 10:45 (15 min)
6.	Next steps	Simona Griniene <i>Regulatory Procedure Management for PLM Subject Matter Expert</i>	10:45 – 10:50 (5 min)
7.	Q&A Session	Moderator: Caterina Scarpati <i>RPM Change Management Team</i>	10:50 – 11:25 (35 mins)
8.	Closing	Madalina Duta-Mare <i>RPM for PLM Product Owner</i>	11:25 – 11:30 (5 mins)