13 June 2024
Information Management

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

13 June 2024, 10:00 – 11:30 (CEST)

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 the strategic direction, key objectives, and upcoming milestones of RPM for PLM, **including key impacts for the pharmaceutical industry and key actions** to be carried out by marketing authorisation holders throughout 2024 and 2025. 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** *Regulatory Procedure Management for PLM Product Owner*	10:00 – 10:05 (5 min)
2.	**Progress and roadmap of Regulatory Procedure Management (RPM) for Product Lifecycle Management (PLM) transition to IRIS**	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*	10:05 – 10:15 (10 min)

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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3.	**Key impacts and actions on pharmaceutical industries**	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*	10:15 – 10:25 (10 min)
4.	**Periodic Safety Update Reports (PSURs)**	**Sara Santos** *Regulatory Procedure Management for PLM Subject Matter Expert*	10:25 – 10:35 (10 min)
5.	**IRIS Industry Portal Demo**	**Sara Santos** *Regulatory Procedure Management for PLM Subject Matter Expert*	10:35 – 10:50 (15 min)
6.	**Next steps**	**Sara Santos** *Regulatory Procedure Management for PLM Subject Matter Expert*	10:50 – 10:55 (5 min)
7.	**Q&A Session**	Moderator: **Caterina Scarpati** *RPM Change Management Team*	10:55 – 11:25 (30 mins)
8.	**Closing**	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*	11:25 – 11:30 (5 mins)