



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2023
Information Management

Agenda: Update on Human Variations web-based electronic Application Form implementation on Product Lifecycle Management Portal

6 November 2023, 13:30 – 15:00 Central European Time (CET)

Webinar: WebEx

The web-based electronic Application Forms (eAFs) in the new Product Lifecycle Management (PLM) portal will replace the current interactive PDF eAFs used for regulatory submissions. This is a first step towards making the form-filling and submission-handling process more efficient.

The web-based Variations eAF for Human medicinal Centrally Authorised Products (CAPs) was released on 4 November 2022. Following the Product Management Service (PMS) data release, the form will support all types of EU variation procedures, CAPs and Nationally Authorised Products (NAPs).

This is a joint eAF-PMS webinar intended for business and technical audiences working for industry and national competent authorities that are interested in the use of Human Variations web-based eAFs.

The event aims at providing interested parties with comprehensive insights into the implementation progress, challenges, and future prospects of the web-based eAF within the PLM Portal. This session also offers an invaluable opportunity for participants to ask questions on pertinent matters.

One of the highlights of this webinar will be the live demonstration of the features currently under development on the PLM Portal for eAF.

[Register for this webinar.](#)

A video recording will be made available after the event.

Item	Agenda	Time	
1.	Introduction <i>Kristiina Puusaari, eAF Product Owner, EMA</i>	13:30-13:35	5 mins
2.	Update on NAPs release and next steps <i>Kristiina Puusaari, eAF Product Owner, EMA</i> <i>Noel Diamant, eAF Product Owner, UNICOM</i> <i>Marcos Fernandez Gomez, PMS Product Owner, EMA</i>	13:35-14:00	25 mins
3.	Update on Product Data Management UI & PMS API (Application Programming Interface) implementation <i>Veronica Lipucci Di Paola, PMS Product Owner, EMA</i>	14:00-14:15	15 mins

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4.	Demo on features currently under development <i>Noel Diamant, eAF Product Owner, UNICOM</i>	14:15-14:30	15 mins
5.	General Q&A session <i>Moderator: Cristina Pepato, eAF & PMS Change Manager</i>	14:30-14:55	25 mins
6.	Closing <i>Kristiina Puusaari, eAF Product Owner, EMA</i> <i>Veronica Lipucci Di Paola, PMS Product Owner, EMA</i> <i>Marcos Fernandez Gomez, PMS Product Owner, EMA</i>	14:55-15:00	5 mins