

11 May 2023 Information Management

Agenda: Webinar on Nationally Authorised Products (NAPs) release on Product Lifecycle Management (PLM) Portal electronic Application Forms (eAFs)

8 June 2023, 10:00 - 11:30 Central European Summer Time (CEST)

Webinar: WebEx

The web-based electronic application forms (eAF) 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 form 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 webinar is intended for business and technical audiences working for industry and national competent authorities that are interested in the use of eAFs for NAPs following the PMS data release in the PLM Portal between the end of Q2 2023 and beginning of Q3 2023.

Register for this webinar.

A video recording will be made available after the event.

Item	Agenda	Time	
1.	Welcome / Introduction	10:00-10:05	5 mins
	Kristiina Puusaari, eAF Product Owner, EMA		
	Veronica Lipucci Di Paola, PMS Product Owner, EMA		
	Marcos Fernandez Gomez, PMS Product Owner, EMA		
2.	NAPs Data Release in Product Management Service	10:05-10:20	15 mins
	Veronica Lipucci Di Paola, PMS Product Owner, EMA		
	Marcos Fernandez Gomez, PMS Product Owner, EMA		
3.	NAPs Data Release in PLM Portal eAF	10:20-10:45	25 mins
	Kristiina Puusaari, eAF Product Owner, EMA		
4.	Frequently Asked Questions on NAPs Data Release	10:45-11:00	15 mins
	Kristiina Puusaari, eAF Product Owner, EMA		
	Veronica Lipucci Di Paola, PMS Product Owner, EMA		
	Marcos Fernandez Gomez, PMS Product Owner, EMA		



5.	General Q&A session	11:00-11:25	25 mins
	Moderator: Cristina Pepato, eAF & PMS Change Manager		
6.	Closing	11:25-11:30	5 mins
	Kristiina Puusaari, eAF Product Owner, EMA		
	Veronica Lipucci Di Paola, PMS Product Owner, EMA		
	Marcos Fernandez Gomez, PMS Product Owner, EMA		