

New Variation Classification in eAF – Q&A Clinic

08 January 2026, 10:00 – 11:00 (CEST)

Webinar: WebEx

Agenda



EUROPEAN MEDICINES AGENCY



1

Introduction
10:00 – 10:10

Kristiina Puusaari
eAF Epic Owner, EMA

2

Q&A Session
10:10 – 10:55

Moderator:
Francesco Stella
eAF Change Management Team

3

Next steps & Closing
10:55 – 11:00

Kristiina Puusaari
eAF Epic Owner, EMA

For Questions: www.slido.com code: #EAFQA0801

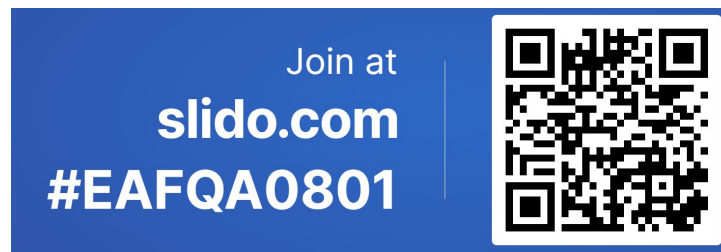


Send your questions via Slido

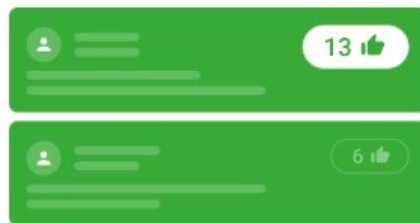
The session **is recorded** and will be shared



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1. Join via the QR code or link



2. Send or upvote the questions you want to hear answered



3. Questions will be shown on the screen and managed live in the Q&A session

Introduction

Kristiina Puusaari, eAF Epic Owner,
EMA

Join at www.slido.com #EAFQA0801



Human variations eAF – **New variation classification**



- *The revised Variations Regulation applies since 1 January 2025 for variation applications implemented and submitted to the European Medicines Agency (EMA) from 1 January 2025.*
- A single cut-off date for the entry into application (i.e., **15 January 2026**) is set out in the **final** version of the **Variations Guidelines**.
- [Guidance on the application of the revised variations framework | European Medicines Agency \(EMA\)](#) and [Heads of Medicines Agencies: Revised Variations Framework](#)

Human variations eAF – **New variation classification**

– **When to submit**



- Applicants are reminded that **new** variation applications using the **January 2026** version or the **v1.28.0.0** of the variation application form **should be submitted** to the EMA from **15th January 2026 CET 00:00**.
- Applications received **before** the 15th January 2026 will be **rejected**, and the application must be resubmitted on or after the 15th January 2026.
- Please note that **new** variation applications using the **September 2021** version or the **v1.27.0.1** must be **received** by the EMA **before 14th January 2026 CET 23:59**. Variation applications for new variation procedures using the old classification guideline received by the EMA on or after 15 January 2026 will be rejected.
- Ongoing variations should continue using the previous versions of the form and as always, the form version must not be changed for ongoing variations unless requested by the regulator.

New variation classification in PLM Portal eAF



- Where to find it: <https://plm-portal.ema.europa.eu/>

Create new application

1 Select Application Details 2 Add Co-Author

Application form type

Variation Form Human

Form version *

Lookup records

Search

Choose one record and click Select to continue

Version name
☐ September 2021
☐ January 2026

Select Scope

e

Choose one record and click Select to continue

✓	↓ Short Name	Description
☐	E.1.a	E.1.a - Administrative Changes - Change in the (invented) name of the finished product - For centrally authorised medicinal products
☐	E.1.b	E.1.b - Administrative Changes - Change in the (invented) name of the finished product - For nationally authorised medicinal products
☐	E.2	E.2 - Administrative Changes - Change in name of the active substance, excipient, medical device (part), or packaging components
☐	E.3	E.3 - Administrative Changes - Change in ATC Code
☐	E.4.a	E.4.a - Administrative Changes - Change in the name and/or address of the marketing Term name: E.4 authorisation holder, packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging material

New variation classification in PLM Portal eAF



- How to identify the version used



New variation classification in interactive PDF eAF



- How to access it
- <https://esubmission.ema.europa.eu/eaf/index.html>

Version 1.27.0.0
Human Variation

Form	Notice to Applicant Revision	Electronic Forms version	Release Notes version
MAA-Human	Revision 15 September 2021	MAA-Human Form 1.26.0.0 (06-12-2023)	MAA-H Release Notes 1.26.0.0 (06-12-2023)
Variation Human	Revision September 2021	Variation Form 1.27.0.1 (06-05-2025)	Variation Release Notes 1.27.0.0 (27-11-2024)
Renewal	January 2026	Variation Form 1.28.0.0 (25-11-2025) New	N/A
MAA-Vet *	Revision February 2018	Renewal Form 1.26.0.0 (05-12-2024)	Renewal Release Notes 1.26.0.0 (28-11-2023)
Variation Veterinary	Version 1	MAA-Vet Form 1.26.0.1 (10-04-2024)	MAA-Vet Release Notes 1.26.0.1 (12-04-2024)
	Version 1	Variation Form 1.26.0.0 (05-12-2024)	Variation Release Notes 1.26.0.0 (28-11-2023)
Summary of eAF changes in current release			Summary of changes 1.26.0.0 (28-11-2023) Summary of changes 1.26.0.1 (12-04-2024) Summary of changes Human Variation 1.27.0.0 (27-11-2024)

*Application form for marketing authorisation for veterinary medicinal products according to Regulation EU 2019/6 and for specific variations requiring assessment¹



- How to identify the version used

eAF Version Number: 1.28.0.0

 **EUROPEAN COMMISSION**
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Health Systems and products

January 2026

NOTICE TO APPLICANTS

**APPLICATION FOR VARIATION TO
A MARKETING AUTHORISATION**

3. TYPES OF CHANGE(S)

Variations included in this application: Please follow instructions below to add variation *fill Section 1 of the form first, so as for the proper variations to be loaded. Navigate through the dropdown lists, in order to show the variation.*
You can select the variation by clicking the relevant checkbox of the variation box.
Note: Any change in Type of Application in Section 1, will delete any selected variation!

Variation	Selected
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Show Selected Variations

Show Variation Lists

Grouping of variations is being selected. You may choose variation changes of types that are selected on section 1.

C. Safety, efficacy, pharmacovigilance changes
E. Administrative Changes
M. PMF/VAMF
Q. Quality changes

Q&A Session

Kristiina Puusaari
eAF Epic Owner, EMA

Francesco Stella
eAF Change Management Team

Join at www.slido.com #EAFQA0801



Next Steps & Closing

Kristiina Puusaari

eAF Epic Owner, EMA

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Upcoming eAF events



Training on interactive PDF form change - MAA Human

February 2026 – Date to be defined



Training on changes and improvements in eAF Webform - Human variations

February 2026 – Date to be defined



Training on interactive PDF form change - MAA Veterinary

March 2026 – Date to be defined



PLM Portal: [Link](#)

[eSubmission Website: Link](#)

[Training Videos on PLM Portal: Link](#)

[User Guidance on PLM Portal: Link](#)

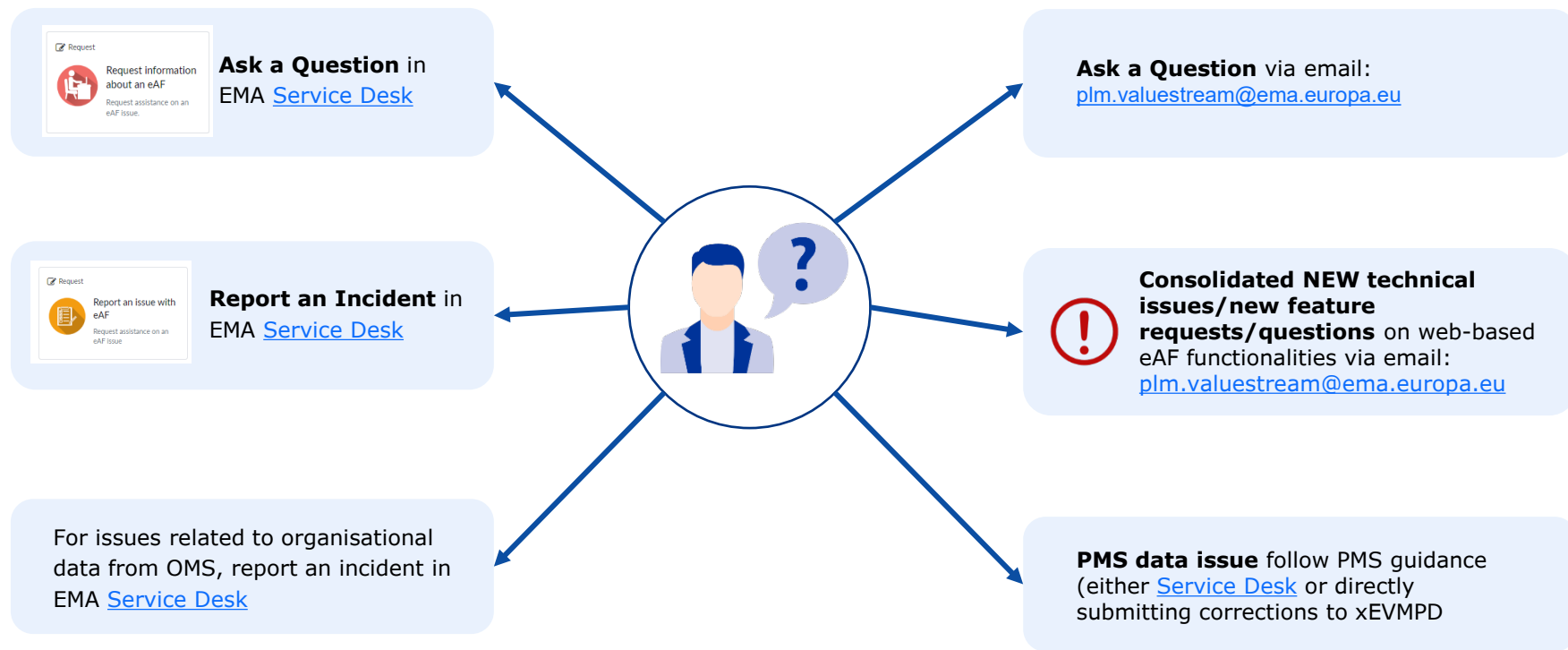
[Q&A Document on PLM Portal: Link](#)

[eAF News on PLM Portal: Link](#)

[PLM Newsletter: Subscribe Here](#)



How can EMA be notified of eAF technical issues?





EUROPEAN MEDICINES AGENCY



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Thank you

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