Agenda – New variations guidelines: webinar for marketing authorisation holders (human)

Tuesday, 13 January 2026, 13:00-15:00, Online, Live broadcast

Event summary

Following the amendment of the Variation Regulation, applicable since 1 January 2025, the European Commission (EC) has adopted and published an updated version of the EC guidelines on the details of the various categories of variations and operation of the procedures (EC Variations Guidelines (2025)).

The Guidelines apply from 15 January 2026. To support stakeholders on the upcoming changes resulting from the EC Variations Guidelines (2025), the Agency is hosting this session.

The event is broadcast live. A video recording will be made available after the event.

Item	Preliminary draft agenda	Time	Duration
1.	Welcome and introduction	13:00-13:10	10 min
2.	Overview of the new EC Variations Guidelines • Procedural aspects • Chapter E (Administrative changes) • Chapter Q & M (Quality and PMF/VAMF changes) • Chapter C (Safety, Efficacy, PhV changes)	13:10-14:00	50 min
3.	EMA/CMDh Q&A and Guidance	14:00-14:35	35 min
4.	Q&A session and closing remarks	14:35-15:00	25 min

The presentation and recording will be published on corporate website. Please check back on the EMA event page New variations guidelines: webinar for marketing authorisation holders (human) | European Medicines Agency (EMA)

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