



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Regulatory Perspectives on Herbal Medicinal / Botanical Drug Product Development - Joint FDA/EMA Workshop

25 September 2026 10:00 – 13:00 (CEST)

Hybrid meeting/EMA, Amsterdam

Facilitating Herbal Medicinal/Botanical Drug Product Development.

Public interest in the therapeutic potential of herbal medicinal/botanical drug products continues to grow, driving increased efforts to develop such products as regulated medicinal products. Recognising both the promise of these complex products and the unique challenges they pose, the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have existing guidance to facilitate their development. While both regulators share core principles, there are meaningful differences in their respective regulatory frameworks.

To advance shared understanding and support pharmaceutical developers navigating this evolving landscape, we are organising a workshop offering a practical exploration of regulatory considerations for herbal medicinal / botanical drug products intended for medicinal use.

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Chaired by Marta Sokolowska, Deputy Center Director of Substance Use and Behavioral Health, Center for Drug Evaluation and Research, FDA and Steffen Thirstrup, Chief Medical Officer, EMA

25 September 2026, 10:00 – 13:00 (CEST) - Room 1A

09:30 **Joining and technical checks**

10:00 **Welcome and opening remarks**

10:35 **Session 1: Setting the scene Public Health Need for Treatment, Messaging, and Regulation**

10:35 **Session 2: EMA and FDA Regulatory Framework**

11:15 **Coffee Break**

11:30 **Session 3: Panel Discussion**

12:55 **Wrap up and key messages**
