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)
In person and virtual 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.

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

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

Marta Sokolowska, FDA
Steffen Thirstrup, Chief Medical Officer, EMA

10:05 Session 1: Setting the scene Public Health Need for Treatment, Messaging, and Regulation

Moderator: *Menglu Yuan, FDA* **30 min**

Panellists
Stefan Gafner, Chief Science Officer, American Botanical Council
Jorge Batista, European Community Pharmacists (PGEU)
Dominique Hamerlijnck, European Lung Foundation
Traugott Ullrich, Executive Vice-President Innovation and Market Access, Schwabe-Group

10:35 Session 2: EMA and FDA Regulatory Framework

Presenters **20 min**
Carmen Purdel, HMPC
Cassandra Taylor, FDA

Case Studies
Presenters **20 min**
Jacqueline Weisner, HMPC
Charles Wu, FDA

11:15 Coffee break

11:25 Session 3: Panel Discussion

Moderators: Carlos Aicardo, EMA, Shannon Thor, FDA **90 min**

Panellists

Holly Johnson, Botanical Safety Consortium
Stefania Donadoni, Chiesi Global Rare Diseases
Susan Winckler, Reagan-Udall Foundation for the FDA
Christelle Anquez-Traxler, Association of the European Self-Care Industry (AESGP)
Angela Mueller, Chair of the Association of the European Self-Care Industry (AESGP)
Herbal medicinal Products Committee

Reactors
Steffen Thirstrup, EMA
Marta Sokolowska, FDA

12:55 Wrap up and key messages

Steffen Thirstrup, Chief Medical Officer, EMA **5 min**
Marta Sokolowska, FDA

13:00 Lunch