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**

Emer Cooke, EMA's Executive Director

10:05 **Opening remarks**

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

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

Moderators: *Shannon Thor, FDA, Carlos Aicardo, EMA* **35 min**

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

10:45 **Session 2: EMA and FDA Regulatory Framework**

Presenters **25 min**
Cassandra Taylor, FDA
Carmen Purdel, HMPC

Case Studies
Presenters **25 min**
Charles Wu, FDA
Jacqueline Wiesner, HMPC

11:35 **Coffee break**

11:50 Session 3: Panel Discussion

Moderators: *Menglu Yuan, FDA, Olga Palomino, HMPC* **1h 15 min**

Panellists

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

13:05 Wrap up and key messages

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

About the speakers

Emer Cooke

Executive Director of the European Medicines Agency

Emer Cooke has been the Executive Director of the European Medicines Agency, based in Amsterdam, since November 2020. She served as Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) for five years, from the beginning of her EMA mandate until the end of October 2025.
Between November 2016 and November 2020, she was the Director responsible for all medical product related regulatory activities at the World Health Organization in Geneva.
Ms Cooke is a pharmacist with Master's degrees in Science and Business Administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and held management positions at the EMA as Head of Inspections and Head of International Affairs respectively from 2002 until 2016. Between 1998 and 2002 she worked in the Pharmaceuticals unit of the European Commission, where intra-alia, she was responsible for international collaboration, EU enlargement and the orphan medicines regulation. Prior to this, Ms Cooke worked at the European Federation of Pharmaceutical industries and Associations (EFPIA) (1992–1998), in the Czech Republic as an independent pharmaceutical policy advisor (1996–1998) and in the Irish pharmaceutical sector (1985–1990).

Starting her mandate as EMA's Executive Director in November 2020 amid a public health crisis of unprecedented scale she announced "My number one priority will be to drive forward EMA's response to the pandemic and the work already ongoing to support the development and approval of safe and effective COVID-19 vaccines and treatments." Doing precisely that, has earned her various awards including the 'European of the Year 2022' award by European Movement Ireland and Honorary Doctorates in Science (Royal College of Surgeons in Ireland – 2023 and National University of Ireland - 2025).

Prof. Steffen Thirstrup

Chief Medical Officer of the European Medicines Agency

Prof. Steffen Thirstrup is a medical doctor, board-certified clinical pharmacologist, and adjunct professor in pharmacotherapy at the University of Copenhagen. He has extensive experience in clinical medicine, medicines regulation, and regulatory strategy.
Throughout his career, he has held senior roles at the Danish Medicines Agency, served as the Danish member of the EMA's Committee for Medicinal Products for Human Use (CHMP), and led medicines assessment and clinical trials activities in Denmark. He also held leadership positions at NDA Group, providing regulatory and scientific advice to the pharmaceutical industry

Since June 2022, Prof. Thirstrup has been Chief Medical Officer at the European Medicines Agency (EMA) in Amsterdam, the Netherlands.

Marta Sokolowska, Ph.D

Deputy Center Director for Substance Use and Behavioral Health in FDA's Center for Drug Evaluation and Research (CDER).

She serves as the center's executive-level leader responsible for advancing FDA's public health response to the non-medical use of substances with abuse potential. With expertise in science-based assessment and management of drug abuse risks, Dr. Sokolowska advises senior FDA officials on shaping scientific and policy interventions and executing strategies pertaining to the use of controlled substances and behavioral health programs.

Dr. Sokolowska joined CDER in 2018 as Associate Director for Controlled Substances in the Office of the Center Director. In 2020, she began leading the Controlled Substances Program (CSP), which comprises the Controlled Substance Staff (CSS) and the Controlled Substances Initiatives (CSI) group. CSS provides consultation throughout FDA on evaluation of abuse potential of drugs and advises on all matters related to domestic and international drug scheduling. The strategy group pursues activities and policies to identify, mitigate, and manage emerging issues with controlled substances to minimize risks associated with problematic use while enabling appropriate access to these products for medical use. Dr. Sokolowska is a recognized expert in drug abuse liability and scheduling strategies. She has facilitated numerous initiatives to improve public health by advancing the science of assessing drug abuse liability. Prior to joining FDA, Dr. Sokolowska held senior clinical and medical leadership roles in the pharmaceutical industry. She earned her doctoral degree in psychology from McMaster University in Canada.

Shannon Thor

FDA's Liaison to the EMA

Shannon facilitates and support technical and regulatory convergence for the purpose of global medical product development to the ultimate benefit of public and animal health. The Liaison Program supports alignment across the total product life cycle. Alignment enables efficient use of resources, avoids unnecessary duplication, and creates synergies. Regulatory certainty across the two regulatory regions de-risks product development for companies and increases trust in regulatory processes, leading to earlier development and global access to innovative products. The Liaison Program enables early and frequent communication between the Agencies. These communications include a wide range of activities such as ad-hoc and structured information sharing, formal bilateral and multilateral workgroups, and external public-facing publications, workshops, conferences, and events.

I have served for more than a decade in senior policy advisor and management roles at the FDA, and for two decades in public health leadership roles in the U.S. government. A pharmacist with roots in patient engagement, I approach my work with patients and clinicians in mind. As an active-duty officer in the U.S. Public Health Service, I have deployed with medical teams in various U.S. government agencies during public health emergencies, most notably to support the national COVID-19 pandemic response. Before reporting to EMA, I was the Regional Deputy Director for the FDA Europe Office in Brussels, Belgium, leading engagements with European counterparts across all FDA-regulated commodity areas to advance FDA's public health mission. During my FDA tenure, I have provided leadership and technical expertise on international public health initiatives and U.S.-European relations, with a particular focus on maternal health projects such as improving information on the safe use of medicines in pregnancy and during breastfeeding. I have advised on cross-cutting issues such as the U.S.-EU Mutual Recognition Agreement, parallel scientific advice, and clinical evidence generation.

Carlos Aicardo

International Affairs Officer, European Medicines Agency

Carlos currently holds a position as International Affairs Officer at the International Affairs Department of the European Medicines Agency managing technical and policy collaboration initiatives in the America's Region.
Previously, Carlos has worked as Committee Manager of the Committee of Human Medicinal Products (CHMP) being the main contact point for a wide range of regulatory or scientific topics channelling towards the Committee during the Covid pandemic.
Prior to his work at CHMP, Carlos worked in products assessments managing regulatory procedures and focusing on the provision of regulatory and procedural guidance on applications to both Scientific Committees and applicants from the Pharmaceutical Industry. He has also acted as Business Lead for the Product Management Systems (PMS) of SPOR where he led the drafting and publication of the first two versions of the EU Implementation Guide for Medicinal Product Data requirements.
Carlos holds an MSc in Biotechnology and Business Management obtained at the University of Warwick, United Kingdom and a Bachelor in Life Sciences and Biomedical sciences from Universidad de Vigo, Spain.

Stefan Gafner

Chief Science Officer of the American Botanical Council (ABC)

The American Botanical Council (ABC), a nonprofit research and education organization. Stefan is also director of the ABC-AHP-NCNPR Botanical Adulterants Program, a collaborative program initiated by the ABC, the American Herbal Pharmacopoeia, and the National Center for Natural Product Research at the University of Mississippi to educate members of the herbal and dietary supplement industry about ingredient and product adulteration. Prior to working for ABC, Gafner served as a Director of Analytical Chemistry in the R&D department of natural personal care products company Tom's of Maine.
Gafner received his degree in pharmacy at the School of Pharmacy, University of Berne, Switzerland. He obtained a PhD in pharmaceutical sciences, with a focus on the chemistry of medicinal plants, from the University of Lausanne in Switzerland, and conducted postdoctoral research on cancer chemopreventive natural products at the University of Illinois – Chicago. Gafner is author or co-author of over 85 peer-reviewed scientific publications and holds 5 patents. He is a member of the advisory board of the Society for Medicinal Plant and Natural Product Research (GA) and of the editorial boards of the Journal of Ethnopharmacology and Planta Medica.

Traugott Ullrich

Executive Vice-President Innovation and Market Access, Schwabe-Group

Dr. Traugott Ullrich is a medical doctor who holds a degree in business administration. He combines profound medical knowledge with extensive commercial expertise being responsible for Innovation and Market Access as EVP for Dr. Willmar Schwabe a multinational pharmaceutical company focusing on natural health solutions in Medicines, Medical Devices but also Food supplements. Working for many years successfully as Vice President of the Board of National (Pharma Deutschland) and European Pharmaceutical Associations (AESGP) he can complement this with a sound understanding of the political and regulatory framework in Europe.

Jorge Batista

European Community Pharmacists (PGEU)

Jorge Batista is the Senior Professional Affairs Advisor of the Pharmaceutical Group of the European Union (PGEU), representing the voice of community pharmacists in Brussels. He represents PGEU and European Community Pharmacists in different international fora and is a member of the European Medicines Agency (EMA) Healthcare Professionals Working Party. As a qualified pharmacist, he holds a MPharm Degree in Pharmaceutical Sciences.
Before joining PGEU, Jorge served as Secretary General of the Portuguese Pharmaceutical Society. He also held the roles of International Affairs Lead and Pharmacist responsible for the Professional Development Programme in the same organisation.
He is currently a PhD candidate in International Health at the Portuguese Institute of Hygiene and Tropical Medicine, specializing in Health Policies and Development.

About PGEU

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 33 European countries. In Europe over 470.000 community pharmacists provide services throughout a network of more than 190.000 pharmacies, collectively serving more than 500 million people.

Dominique Hamerlijnck

European Lung Fundation

Dominique Hamerlijnck, MPhil (Ethics), MBA, EUPATI fellow, patient expert. Background in business, especially change management. As patient expert involved in several patient organisations: the Dutch Lung Foundation (since 2005), Patient Federation Netherlands, European Lung Foundation, European Federation for Airways and Allergy Diseases Patients' Association. Member of several scientific advisory boards for ZONMW (organisation for knowledge and innovation in health, healthcare and well-being) on research applications. Involved in the development of national and international research agendas and guidelines. Member of ISPOR. Working as a patient advisor with Novartis and GAAPP on patient engagement and development of clinical trials. Founding member of the European Clinical Research Collaboration on Severe Heterogeneous Asthma Research collaboration, Patient-centred (SHARP registry project). I am a member of several patient advisory boards in international research projects.

Carmen Purdel

Chair of the Herbal Medicinal Products Committee

Carmen Purdel is a senior pharmacist and European Registered Toxicologist with a PhD in Toxicology and extensive expertise in analytical toxicology, risk assessment, and regulatory science. In 2015, she was appointed Associate Professor of Toxicology at the Faculty of Pharmacy, Carol Davila University of Medicine and Pharmacy, Bucharest, and was awarded the Habilitation in Medical Sciences in 2025.
Since 2003, she has served as a quality assessor at the Romanian National Agency for Medicines and Medical Devices, bringing more than two decades of experience in evaluating and regulating medicinal products.
At the European level, she has been actively involved in the work of the Committee on Herbal Medicinal Products (HMPC), serving as the Romanian alternate member from 2011 to 2017 and as a full member since 2017. She was also a member of the HMPC Working Party on Community Monographs and Community List (MLWP) from 2014 to 2018 and served as Chair of the Quality Drafting Group (QDG) and as a member of the Quality Working Party (QWP) between 2023 and 2026.
Since January 2026, she has been elected Chair of the HMPC

Cassandra Taylor

Public Health Advisor at FDA

Cassandra Taylor, Ph.D. is a Public Health Advisor at FDA within the Center for Drug Evaluation and Research's Office of the Center Director and leads CDER's cannabis science and research portfolio. She serves as a cannabis subject matter expert (SME) across FDA, concentrating on the botanical and quality aspects of cannabis. Dr. Taylor leads and coordinates a variety of cannabis initiatives and research projects within FDA. She has evaluated over 150 botanical drug submissions across CDER's clinical divisions, with a focus on reviewing cannabis submissions and was the technical lead on the FDA guidance for industry titled "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research." Dr. Taylor collaborates with federal partners to help close substantial knowledge gaps about the science, safety, and quality of cannabis and cannabis-derived products and has published multiple cannabis manuscripts. She is a recognized expert in the botanical and cannabis communities. She received her B.S. in Chemistry from St. Francis University, and her Ph.D. in Analytical Chemistry from the University of Maryland.

Dr. Jacqueline Wiesner

Head of Unit "Vitamins, Minerals, Complementary and Traditional Medicinal Products"; Federal Institute for Drugs and Medical Devices

Dr. Wiesner is an expert in pharmacology, toxicology, and the regulatory assessment of herbal medicinal products. From 2001 to 2016, she served as a Preclinical Assessor in the Herbal Medicinal Products and Traditional Medicinal Products Unit at BfArM. Since 2010, she has been a member of the European Medicines Agency's Committee on Herbal Medicinal Products (HMPC), having previously served as its alternate member, and has represented the HMPC as an observer in several EMA working parties. She studied Biopharmacology at the University of Greifswald, specializing in Pharmacology and Toxicology, and earned her Ph.D. in Pharmaceutical Biology from the same institution. In addition to her regulatory work, she lectures in the postgraduate Toxicology and Environmental Protection program at the University of Leipzig, contributes to international initiatives on herbal medicines through WHO, IRCH, and ECIHP, and serves on several EFSA working groups focused on botanicals and botanical safety. She is also a reviewer for leading scientific journals in the fields of ethnopharmacology and phytomedicine and a member of the German Society for Experimental and Clinical Pharmacology and Toxicology (DGPT).

Dr. Charles Wu

Master Reviewer in Pharmacology/Pharmacognosy

Dr. Charles Wu, Ph.D., is Master Reviewer in Pharmacology/Pharmacognosy and served as the Botanical Review Team Lead in the Office of Pharmaceutical Quality (OPQ) of the Center for Drug Evaluation and Research (CDER), the United States Food and Drug Administration (FDA). Dr. Wu trained in Clinical Medicine including Traditional Chinese Medicine (TCM) for his MD and earned his Ph.D. in Medical Science from the Medical Center of University of Amsterdam, the Netherlands.

Dr. Wu began his career at FDA in 2001 as a product reviewer in the Center for Biologics, Evaluation and Research (CBER) and then as a senior Pharmacology/Toxicology reviewer in CDER. In 2013 Dr. Wu joined the Botanical Review Team (BRT) and was promoted to the BRT lead since 2017. Charles has also served as the FDA's Focal Information Contact (FIC) to the WHO-IRCH (International Regulatory Corporation for Herbal Medicine) since 2019 and becomes the Steering Group (SG) Member and Vice-Chair (2021-2024), as well as serving as an Expert for Regional Consultation of Traditional Medicine to COVID-19 Response in the African Region.

During his tenure at FDA, Dr. Wu has gained extensive regulatory experience and scientific knowledge in pharmaceutical product research/development and published over 30 peer-reviewed journal articles including SCIENCE and scientific book chapters.

Menglu Yuan

Program and Change Manager within the Office of Global Policy Strategy (OGPS)

In this role, she designs and leads global strategies to strengthen public health outcomes. Prior to OGPS, Dr. Yuan served as a Senior Consumer Safety Officer in the Center for Drug Evaluation and Research (CDER) Office of Compliance, where she developed public health initiatives for portfolios spanning supply chain security, controlled substances, and GLP-1s. Dr. Yuan also served as a Science Policy Advisor in CDER's Controlled Substances Program, where she managed CDER's opioids portfolio and led public health initiatives that addressed substance use and overdose prevention. Dr. Yuan holds a Ph.D. in Pharmacology and Toxicology from the University of California, Irvine and a Bachelor of Science in Biochemistry and Molecular Biology from Boston University.

Olga Palomino

Vice-chair of the Herbal Medicinal Products Committee

Olga Palomino holds a doctorate in Pharmacy and is a Full Professor and Head of the Department of Pharmacology, Pharmacognosy and Botany, Faculty of Pharmacy, University Complutense of Madrid, Spain.

At European level, she is Member of Groups of Experts 13A and 13B of the European Pharmacopoeia (European Commission). She has been Member of the Working Party on European Union Monographs and European Union List (MLWP) and the Organisational Matters Drafting Group – (ORGAM DG) from the Committee on Herbal Medicinal Products (HMPC), European Medicines Agency (EMA) between 2011 and 2021. She's also Member of the Quality Drafting Group (QDG) and the representative of HMPC at the Healthcare Professionals Working Party (HCPWP) at EMA.

Since March 2026, she has been elected as Vice-Chair of the HMPC

Christelle Anquez-Traxler

Senior Regulatory Science and Strategy Lead at AESGP

Christelle Anquez-Traxler is Senior Regulatory Science and Strategy Lead at AESGP, which is the European Association representing the Selfcare Industry. Her focus has always been on regulatory and scientific aspects of non-prescription medicinal products. She has always been passionate about herbal medicines and she has been overseeing the AESGP Herbal Medicinal Products Committee since her start at AESGP more than 20 years ago.
She worked for the US FDA, in the office of the Commissioner, on international affairs and harmonisation programmes including the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) from 2000 to 2004.

She is a pharmacist by training with Master's Degrees in Regulatory Affairs and Health Economics.

Angela Müller

Chair of the Association of the European Self-Care Industry (AESGP) Herbal Medicinal Products Committee

Angela Müller is the Chair of the Association of the European Self-Care Industry (AESGP) Herbal Medicinal Products Committee which represents the Herbal Medicinal Products in Selfcare Industry. She has over 20 years' experience in the field of Regulatory Affairs for both herbal and chemical medicinal products with sound knowledge of the European Medicines Regulatory Network.
Being a pharmacist by training, she lectures at the University of Freiburg in a M.Sc. Regulatory Affairs program.

Holly Johnson

Pharmacognosist and the Chief Science Officer for the American Herbal Products Association (AHPA)

(AHPA), an alliance of over 400 member companies doing business in the natural products industry. She provides individualized scientific guidance to AHPA members and contributes to advancements in applications of science and technology for research and compliance with botanicals. Dr. Johnson has worked in remote jungles, research & testing laboratories, botanical gardens, and in the drug and dietary supplement industries. Holly is an active expert volunteer in standards setting for AOAC in foods, dietary supplements, and botanicals and also at the United States Pharmacoepia (USP) where she is Vice Chair of the Expert Committee for Botanical Dietary Supplements & Herbal Medicines and a member of the USP Cannabis Expert Panel. She serves on the Advisory Boards of the American Botanical Council and the American Herbal Pharmacoepia, and also on the Steering Committee & Pharmacognosy working group for the FDA's Botanical Safety Consortium. Holly has over 25 years of experience in botanicals research and spent many happy years giving courses at the University of Hawaii.

Susan Winckler

Susan C. Winckler is CEO of the Reagan-Udall Foundation for the Food and Drug Administration; the non-profit organization created by Congress to advance the mission of the FDA.

Prior to accepting the Foundation post in May of 2020, Winckler served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. She directly advised C-suite executives on public policy/regulation, business strategy, investments, and other matters. A pharmacist and attorney by training, she was, earlier, CEO of the Food & Drug Law Institute.
As Chief of Staff for the FDA (2007-2009), Winckler managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges, and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association.
Ms. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her law degree magna cum laude from Georgetown University Law Center. She is an APhA Fellow, a member of the Purgo Scientific, LLC board, and served as an elected member (2015-2020, 2020-2025) and Chair (2018-2025) of the United States Pharmacopeial Convention (USP) Board of Trustees. In 2023, she received the Distinguished Alumni Award of the Food and Drug Administration Alumni Association and, separately, was awarded the Osterhaus Medal for Lifetime Achievement by the Univ. of Iowa College of *Pharmacy.*