

FREE IFAPP WEBINAR

New provisions in the pharmaceutical legislation - will they solve the future challenges concerning pharmaceuticals?

15 APRIL 2026

12:00 - 01:00 PM CEST

TIME SCHEDULE

06:00 - 07:00 AM EST

11:00 - 12:00 AM BST

12:00 - 01:00 PM CEST

07:00 - 08:00 PM JST



Speaker

Prof. Dr Christa Wirthumer-Hoche
Former Head of the Austrian
Agency for Medicines and Medical
Devices and Chair of the EMA (1)
Management Board

Content

The general pharmaceutical legislation adopted on 11 December 2025 represents a major modernisation of EU pharmaceutical law addressing several critical issues such as access, regulatory efficiency, innovation incentives and supply security.

Individual provisions are discussed and their impact on healthcare supply with medicines is outlined. An overview will be presented.

However, this general pharmaceutical legislation alone cannot solve all the challenges in the pharmaceutical sector; supplementary legislation is needed, such as the Critical Medicines Act, European Health Data Space and AI (2) tools. The interaction between these regulations is also examined.

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CV of Prof. Dr Christa Wirthumer-Hoche

Prof. Dipl. Ing. Dr Christa Wirthumer-Hoche studied biochemistry and graduated at the Technical University, Vienna, in 1981, and wrote her doctoral thesis at the Institute for Medical Physiology, graduating in 1983. She joined the Austrian National Institute for Quality Control of Drugs, afterwards the Austrian Federal Ministry of Health and Women and from 2006 to 2023 the Austrian Medicines and Medical Device Agency, always in a leading role. In October 2013, she was appointed Head of the Austrian Agency for Medicines and Medical Devices.

At a European level, from 1994 to 2023, Prof. Wirthumer-Hoche has been involved in different European committees and working groups and, in 2016, she was the first woman to be elected Chair of the EMA's Management Board and was re-elected for a second term in 2019. Also at international level, within ICH (3) and ICMRA (4) she was an active member.

Since 1 April 2023 Prof. Wirthumer-Hoche has been retired but is still active as a lecturer on the subject "regulatory affairs and cooperation of different stakeholders in Europe in the field of marketing authorisation and life cycle activities of medicinal products", at different universities. During the review of the general Pharma legislation, she was a consultant to the Ministry of Health of Austria. She was and is involved in EC (5) projects that support the establishment of national regulatory authorities in countries with less developed regulatory systems.

Abbreviations

- 1) EMA: European Medicines Agency
- 2) AI: Artificial Intelligence
- 3) ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
- 4) ICMRA: International coalition of Medicines Regulatory Authorities
- 5) EC: European Commission