

Market Developments of Herbal (Medicinal) Products in Europe

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Herbal medicinal products (HMPs) remain an important pillar of self-medication and continue to be highly valued by patients across Europe. Nevertheless, innovation and regulatory development in this field have become increasingly challenging. This presentation examines the current European market situation for herbal medicinal products, discusses the changing interpretation of innovation in phytopharmaceutical development, and explores why traditional therapeutic systems require regulatory frameworks that adequately reflect their specific characteristics. It highlights the growing imbalance between increasingly stringent pharmaceutical legislation for HMPs and the comparatively limited regulation of competing product categories like dietary supplements/botanicals, contributing to a declining number of authorised herbal medicines despite sustained patient demand.

A central theme is the concept of *cultural heritage*. The presentation argues that phytotherapy is a scientifically supported, safe, and evidence-based component of modern healthcare when used appropriately, while also representing an important part of Europe's medical tradition. International comparisons with Traditional Chinese Medicine (TCM) and India's AYUSH system illustrate how traditional therapies can be successfully integrated into national healthcare systems.

Finally, the presentation discusses upcoming European regulatory developments, including the revised Pharma Package and the new Variation Classification Guideline, identifying several provisions that may disproportionately affect herbal medicinal products because they were primarily designed for chemically defined active substances. It concludes with a call for a regulatory environment that both safeguards public health and enables sustainable innovation, thereby preserving phytotherapy as an essential and culturally valuable component of European healthcare.