Self-Medication with Herbal Medicinal Products in Europe: Bridging Industry Market Data and Independent Prevalence Research

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Self-medication with herbal medicinal products is a substantial and growing component of self-care across Europe, regulated in the EU mainly via the Traditional Herbal Medicinal Products Directive (2004/24/EC) and HMPC monographs, alongside both industry market data and independent population-based research. The European self-care market reached €250 billion in 2025, according to a 2026 IQVIA analysis commissioned by AESGP [1]. Independent epidemiological data from the European Health Interview Survey indicate that 34.3% of the EU population practiced self-medication within a two-week period [2]. Herbal medicine use specifically shows even greater heterogeneity: a systematic review of national surveys reports traditional and complementary medicine use, including herbal products, ranging from 24% to 71.3% across European countries [3]. A recent review of clinical studies on herbal medicines approved in Europe concludes that they are generally well tolerated with a favorable benefit-risk profile for non-life-threatening ailments [4], and qualitative research suggests that users often perceive them similarly, using them as a first-line option before considering conventional medicine [5]. By integrating industry market data, independent prevalence data, and evidence on user motivations, this presentation aims to characterize current patterns and drivers of herbal self-medication in Europe, revealing sustained consumer demand alongside considerable cross-country variability. Combining these market, epidemiological, and qualitative perspectives, together with the regulatory context, offers a more complete evidence base for understanding herbal self-medication as an expression of self-directed health care in Europe.

[1] IQVIA Consumer Health. Self-Care Medical Devices Market Insights – EU Region and Country. Final Report, commissioned by AESGP, 2026
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[3] Lee EL, Richards N, Harrison J, Barnes J. Prevalence of use of traditional, complementary and alternative medicine by the general population: a systematic review of national studies published from 2010 to 2019. Drug Saf 2022; 45: 713-735
[4] Salm S, Rutz J, van den Akker M, Blaheta RA, Bachmeier BE. Current state of research on the clinical benefits of herbal medicines for non-life-threatening ailments. Front Pharmacol 2023; 14: 1234701
[5] Welz AN, Emberger-Klein A, Menrad K. Why people use herbal medicine: insights from a focus-group study in Germany. BMC Complement Altern Med 2018; 18: 92

Unlocking the Regulatory Potential of Secondary Health Data for Herbal Medicinal Products

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Over the past 25 years, regulatory requirements for medicinal products, including herbal medicinal products (HMPs), have become increasingly evidence-driven. While randomized controlled trials remain the cornerstone of initial marketing authorization, there is growing recognition that high-quality real-world data (RWD) and real-world evidence (RWE) can complement clinical trials by addressing questions on effectiveness, safety, and drug utilization in routine care. This is particularly relevant for HMPs, where long-term use in large populations provides valuable opportunities for secondary data analyses.
We present our experience from multiple research projects evaluating the effectiveness, safety, and real-world utilization of HMPs using diverse secondary health data sources, including the German National Cohort (NAKO), the pharmaco-epidemiological database PhytoVIS (Koop Phytopharmaka), private and statutory health insurance claims, pharmaceutical sales data (Insight Health and IQVIA), data from the German Research Data Centre (FDZ), and the Robert Koch Institute. Each data source offers distinct strengths and limitations. We emphasize that the formulation of a precise scientific research question is the essential first step, as it determines the appropriate study design. Depending on the objective, approaches such as cohort studies, case–control studies, cross-sectional analyses, and target trial emulation can be applied to secondary data.
The regulatory value of RWE depends on selecting fit-for-purpose data and robust epidemiological methods. We conclude by proposing a set of desirable characteristics for future secondary health data infrastructures that would better support regulatory decision-making, facilitate evidence generation throughout the product lifecycle, and unlock the full potential of RWD for the evaluation of HMPs.

How to reinstall phytotherapy in the European health system?

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Phytotherapy in Europe, has transitioned from traditional folk practice to a regulated, well accepted branch of complementary medicine. Currently is a legally recognized, regulated medical discipline that integrates plant-based remedies with modern scientific standards following the quality control through European Pharmacopoeia and safety monitoring and standards as all conventional medicines. Moreover, all final herbal medicinal products are following obligatory, both good agricultural and collection practice (GACP) as well as good manufacturing practice (GMP), harmonized labelling and assessment across Member States. Regulatory and Scientific Landscape at the EU for herbal medicines is governed by the Committee on Herbal Medicinal Products (HMPC) in European Medicines Agency (EMA).
Herbal medicines are widely used as first-line or complementary/adjuvant treatments for mild-to-moderate conditions. Germany and France appear as market leaders accounting for the largest share of the European phytotherapy market, with widespread over-the-counter (OTCs) availability in pharmacies. Additionally, EU market offers plenty of herbal preparations with significant differences in classification, out of herbal medicinal products, under the categories of medical devices, cosmetics and/or food supplements.
Even though there is a high general acceptance for herbal medicines, formal training in phytotherapy is low among 27 countries in EU, while it varies significantly by country. So, there are countries with better (Germany and Austria) -established pharmaceutical and medical societies dedicated to naturopathy, while other member states treat phytotherapy almost informally and based only as part of self-care.
Due to this fact of unbalanced European teaching and training programs on herbal medicines for pharmacists and medical doctors, there is an urgent need to reinstall, harmonise, follow up and implement an interoperable system for PHYTOTHERAPY in general. Certain ideas, proposals/plans towards this direction will be presented and discussed

Herbal medicinal products – current status, challenges and future developments

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Herbal medicinal products are clearly defined in the European Union pharmaceutical legislation. This sounds rather formal, but in a global context it is worth emphasizing. The authorization of finished herbal medicinal products requires assessment of data on quality, efficacy and safety. The indications of most authorized herbal medicinal products in the EU cover therapeutic areas allowing self-medication. However, during the last two decades only few herbal medicinal products with new herbal substances have been introduced.
Moreover, there are existing and new challenges, which will influence the future environment for herbal medicinal products:
- There is a competing market for herbal medicinal products, medical devices, food products and cosmetics containing similar substances and addressing similar target populations.
- Health care and management are increasingly including prevention.
- A new pharmaceutical legislation is under implementation in the EU, now.
- New knowledge in toxicology and environmental sciences will affect the use of well-known herbal medicinal products.
- Recent scientific developments – such as omics-technologies, molecular methodology, data analysis and real-world evidence – are not applied systematically in the field of herbal medicinal products development.
To step further into the future there is a demand for pharmaceutical and related life sciences to apply modern technology to generate high-level knowledge on the therapeutic potential of herbal medicines and to extend the set of tools for assessment. This will need visions, scientific input from academia and as well a continuous communication and cooperation at the interface of research and regulatory science.

HMPC's view on utilization of RWD for herbal medicinal products

Olga Palomino

The use of Real World Data (RWD) as a source of valuable information for regulatory activities for Herbal Medicinal Products (HMP) represents nowadays an increasingly valuable, highly strategic tool. The HMPC has actively embedded RWD into its regulatory roadmap and work plans for the upcoming years with the objective of updating, establishing or revising the EU herbal monographs for both Well-Established Use (WEU) and Traditional Use (TU) products. Nevertheless, there are still challenges limiting the potential of RWD in the regulatory field, such as the lack of adequate description of the herbal ingredient and herbal medicinal product or the existing regulatory category fragmentation across the European Union states. Thus, it is of paramount importance to have access not only to the information regarding the HMP quality, but also its regulatory classification and prescription status, among other, this leading to a better integration of these products into electronic records.

An Expert Perspective on the Future of Herbal Medicinal Products in Europe

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Herbal medicinal products (HMPs) in Europe are entering a period of substantial regulatory transformation. The new European Union pharmaceutical legislation, the implementation of the revised variations framework, and the growing integration of real-world data (RWD) and real-world evidence (RWE) into regulatory decision-making present both challenges and opportunities for the herbal medicines sector. These developments require adapting existing regulatory paradigms to enable greater flexibility, regulatory efficiency, and evidence generation throughout the product lifecycle.
In parallel, emerging opportunities for international regulatory collaboration, including increased engagement with global regulatory authorities, have the potential to promote greater convergence of scientific and regulatory standards, foster innovation, and enhance the global competitiveness of HMPs.

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.