

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

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Abstract

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.