



Role of Real-World Data and Real-World Evidence for Self-Care Products

BACKGROUND

Real-World Data (RWD) and Real-World Evidence (RWE) not only play an increasingly significant role in the pharmaceutical sector, but also the consumer health industry.

It has become recognized that important product information can be garnered during routine practice and not only in highly controlled clinical trials. The utility of RWD and RWE was originally demonstrated for prescription drugs and until recently there has been comparatively little focus on the potential role of RWE for self-care products (viz. non-prescription medicines and food supplements). This can be attributed to the nature of their purchase by consumers sometimes without the intervention of health care professionals (HCPs), that prescription, reimbursement, and electronic health records, etc. are not routinely captured. With the advent of new data mining technologies, some of these challenges have been overcome and real-world methodologies are gaining traction as promising approaches to optimize the development, marketing, and usage of self-care products (non-prescription medicines & food supplements).

Indeed, RWD and RWE have the potential of versatile applications within the consumer health industry, serving both regulatory and non-regulatory purposes and some of the areas where they could provide powerful insights include:



1. CLAIMS SUBSTANTIATION

Evidence that underscores the effectiveness, safety, and consumer-perceived benefits of self-care products in the real-world settings could guide marketing strategies. The generated evidence could be translated into tailored communications and non-label claims to HCPs and consumers – obviously while still adhering to local regulations and advertising rules.



2. REGULATORY DECISION MAKING

RWD and RWE can be leveraged for Rx-to-OTC switches to demonstrate their safety profile and extend their indications and effectiveness claims.



3. COMPARATIVE PRODUCT EFFECTIVENESS

Comparative real world effectiveness research could be leveraged and used to recommend products to HCPs and consumers influence their buying decisions.



4. CONSUMER BEHAVIOR AND PREFERENCE

The ability of RWD and RWE to decode consumer behavior and preferences is unique. Real world studies may provide a detailed understanding of how consumers use self-care products, including adherence to dosage recommendations, and overall product satisfaction. Such insights can inform the development of new products, shape marketing strategies, and contribute to effective consumer and HCP education initiatives.



5. SAFETY

RWE is a vital tool in post-marketing surveillance of self-care products and is perhaps the area in which RWD has been used most frequently. It offers the means to closely monitor trends in drug use, potential misuse, or abuse, and identify new safety issues that may not have been apparent during clinical trials. Timely identification of safety signals allows for swift intervention and effective life cycle management.



6. NEW INNOVATION

RWE could be used to identify unmet medical needs and market opportunities, allowing companies to make informed decisions and drive innovation in the self-care products landscape.

RECOMMENDATIONS

The consumer health industry stands to gain enriched perspectives on consumer behaviors, product effectiveness, safety, and market dynamics opening new horizons for self-care products research and utilization. **To leverage these potentials for the benefit of society and consumers alike, the following recommendations are put forward:**

**01**

Systematic or consumer-specific data are the most relevant sources for real world studies. They are also fast and cheap to run when based on EHRs and EMRs. To benefit from them, it is important to drive discussions on:

- a. Establishing routine collection of health data on self-care products.
- b. Using innovative data collection approaches such as symptom- and treatment-tracking apps.

**02**

Harmonized terminologies lead to effective pooling of data, leading to collection of good quality data and conclusive analysis. In order to get there, it is important to:

- a. Advocate for common data standards.
- b. Promote robust data governance practices to improve data quality.

**03**

Regulatory convergence on documentation requirements for regulatory decision making such as concrete proposals and study protocols between national regulatory authorities. Key elements for this advocacy towards streamlining requirements include:

- a. Facilitating knowledge exchange between stakeholders relevant to the consumer health industry to share their success stories.
- b. Promoting publications on RWE studies conducted by the consumer health industry.
- c. Establishing standardized methodologies for self-care products in collaboration with academia and other learned societies.