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Need for RWE in Consumer Health and Its Impact in Managing Lifecycle of Consumer Health Products

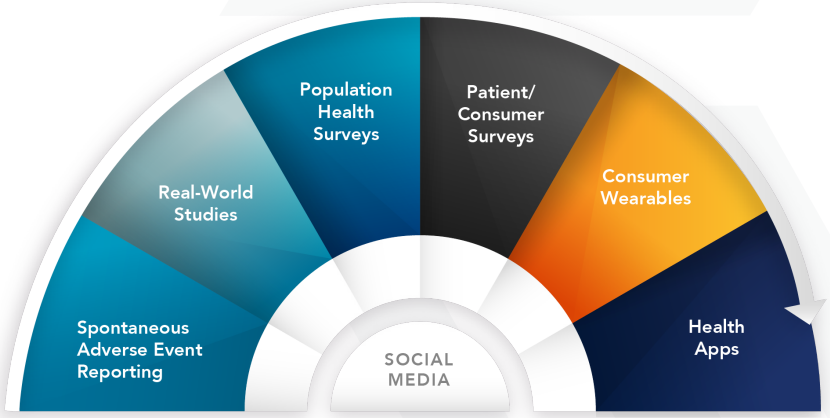
Content for this article was contributed by the EVERSANA Asia Pacific team

Healthcare has never been more important to the world than in the past two years and it will remain central during the economic recovery. The pandemic's impact on medical and healthcare systems has emphasized the value of real-world evidence (RWE). This value is now becoming apparent in consumer health, as well as its traditional applications in prescription (Rx) medicines.

Using real-world data (RWD) and RWE to support decision-making is not new. It is increasingly used to support regulatory approvals and market access decisions for prescription (Rx) medicines. RWE has formed the basis of safety profile evaluation, risk management, and ongoing benefit-risk assessment for decades. RWE is used during Rx product development as part of new drug applications, line extensions, comparative efficacy evaluations, and reimbursement decisions. A review published in May 2020 highlighting the application of RWD in regulatory approvals showed 27 examples (dating from 1998) leveraging RWD to seek approvals for new drug applications or line extensions for Rx medicines. However, there have been limited efforts to date to apply RWE within the non-Rx or over-the-counter (OTC) and consumer health sector.

RWE offers enormous potential in consumer health. OTC medicines have established safety and efficacy profiles and are used without healthcare professional (HCP) supervision by a broad population to manage a wide variety of health conditions. Therefore, in theory, these products would be the most suitable for real-world research. Across the consumer health industry, randomized clinical trials (RCTs) are still the primary source of data for developing new product claims. However, in this setting, RWD can be generated through alternative study designs, including pragmatic trials and observational studies (prospective and/or retrospective) to help address data gaps. While conventional RCTs have high internal validity and are necessary to demonstrate efficacy in controlled conditions, RWE's higher external validity can complement evidence derived from RCTs. As a result, claims generated based on real-world studies integrate the consumer perspective precisely.

Principal Real-World Data Sources for Non-Rx Medicines



The consumer health market is crowded with me-too products. Maintaining the growth of established brands requires managing their product lifecycles, including expanding claims and communicating their value and benefits, either on the package leaflet or through marketing or promotional materials that influence consumers. Real-world studies are the most important application of RWE here, but the lack of routinely collected data compared with Rx medicines where electronic health records (EHR) and claims data are available, offer a challenge. By contrast to Rx-only medicines, the wealth of information on the real-world use of non-Rx medicines is largely uncaptured. Using RWD may also change throughout the lifecycle of a product, particularly post-authorization.

Evidence generation under real-world settings, where consumers use health/OTC products in unrestricted and unguided conditions can offer more immediate and novel outcomes demonstrating products' benefits. Yet there seems to be a reluctance to fully exploit the potential to undertake such studies, even while consumers and regulators demand more evidence of value, efficacy, and safety than ever. Data-driven, scientifically valid claims are becoming vital to gain consumer trust in the crowded me-too field of consumer health.

An emerging source of RWD is patient-generated health data (PGHD), which offers significant potential to be utilized for RWE. Using analytics tools that leverage artificial intelligence and machine learning (AI/ML), collecting continuous data in natural settings over a long period, and automated data collection are possible. Mobile phone sensors, electronic apps, and consumer wearables already exist to generate RWD relevant to non-Rx medicines. More importantly, consumers are becoming more open to sharing their health data, personal preferences, knowledge, and experience via digital media. However, the application and demonstrated value of PGHD has been mostly confined to Rx-drugs in therapy areas outside the remit of self-care. Also, the heterogeneity of data types and modes present a challenge when managing data across multiple platforms. Capturing and utilizing PGHD that requires effort, time, and resources from consumers is an additional challenge. Despite the existing challenges with PGHD use, its potential value is enormous, and it is likely to play an increasingly important role in healthcare decision making in the future.

Planning RWE studies is not easy, and novel concise study design tools should be leveraged to guide decision steps through considering research objectives, product approval status, study setting, outcomes of interest, data availability in routine practice, need for primary data collection and/or randomization, study type and methodology, and applicable regulatory standards. In determining the value and potential application of RWE to non-Rx medicines, it is important to consider those areas where either conventional RCTs cannot address data requirements, or where RWE may present a more intuitive or efficient way of generating data to inform decision making. Three general areas where RWE may play an important role are: Rx to OTC switch, addressing post-marketing safety concerns, and investigating real-world effectiveness/updating the benefit profile.

Johnson & Johnson, a leading company in this space, is conducting an RWE study on sunscreen compliance and photodamage perception among consumers and dermatologists. There is strong literature-based evidence that sunscreen is safe to use and, when applied correctly, reduces the risk of skin cancer. Several studies have been performed globally, especially in Australia and the US, regarding knowledge and use of sunscreen. Australia has one of

Potential areas where RWE may aid decision-making for Non-Rx medicines

the highest rates of cutaneous malignancies globally, of which melanoma is the fourth most common. The Therapeutic Goods Administration (TGA) has published regulatory guidelines for sunscreens emphasizing government's important role in establishing skin cancer prevention policies and long-term funding arrangements. Consumer health/OTC product manufacturers should proactively assess the value of their products and their likely application in therapeutics. This can be done by defining within their research objectives where an RWE study can enhance the value of their product and where it might prove to be a prophylactic treatment.

The importance of RWE in the non-Rx sector is likely to increase as new sources of RWD emerge. PGHD is a key emerging source of RWD, which may be used to generate RWE across a spectrum of settings ranging from prospective clinical trials to retrospective observational studies. Other data sources include population health surveys, patient/consumer surveys, social media, where although the opportunity is untapped, relevant, high-quality data to support decision making should not be underestimated. As authorities become more open to accept and release guidance on the use of RWD, there is a huge OTC opportunity to use more robust data to support label claims.

EVERSANA's APAC HEOR and RWE team are experts in evidence synthesis, economic modeling, data analytics, value communication, reimbursement strategy, and more. Together we help biopharma, device and digital medicine clients demonstrate and communicate value to key stakeholders at every phase of the product lifecycle. We engage with many multinational consumer health companies to address their business questions around OTC or nutraceuticals products and generate evidence of their effectiveness/safety to substantiate the claims. EVERSANA has successfully delivered many RWE studies, including evaluating the effectiveness of an Integrated Personalized Diabetes Management (iPDM) concept using integrated glucometer meters with a mobile application in T2DM patients in India. Multiple RWE studies are at different stages for one of the leading health food drinks companies in India. We are assessing different variants of the food drink to establish their effectiveness, safety, and compliance across consumer age groups in the health conditions for each of these are indicated.

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