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PAGB Digital Week, Day 2: Real-World Evidence And Its Potential In Consumer Healthcare

by Tom Gallen

Day two of PAGB's Digital Week explored potential applications for real world evidence in the consumer healthcare industry, such as generating new claims for established products and to help support prescription-to-OTC switches.

Session 1 – Real-World Studies And The Self-Care Industry

The first session of the day was opened by the PAGB's acting senior regulatory manager, Christina Gkouva, who presented the association's latest guidance on the use of real-world data (RWD) and evidence (RWE) in relation to self-care products.

RWD/E had been used in the Rx side of the pharmaceutical industry for a while now, Gkouva pointed out, but within OTC it was still relatively new.

While definitions of RWD/E exist, for example those put forward by the UK's Medicines and Healthcare products Regulatory Agency (MHRA), European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), these definitions did not take account of the potential for data generated by OTC-specific distribution channels, such as through pharmacy or general sales outlets like supermarkets and drugstores.

RWD/E had "huge potential" for OTC product innovation, Gkouva argued. For example, for Rx-to-OTC switch, especially for first in category switches. In addition, RWD/E had many possible applications for traditional herbal medicinal product self-care medical device registrations.

However, generating new advertising claims is an area where RWD/E was currently being used most, which is why PAGB had developed key principles and reminders for RWE in advertising claims.

After pointing briefly to an RWE study used by Teva Pharmaceuticals in collaboration with Orbital Media to create new claims for Sudocrem, senior advertising policy and operations manager Laura Kelly ran through the key advice for firms thinking about using RWD/E in advertising. Establishing clear objectives, asking the right research questions, getting the sample size right and timing were all good practices for successful RWE generation.

The session was closed by Bayer Consumer Health's director of clinical development, Andreas Ehret, who began by saying he had a "great interest in how RWD/E can be used in the fight for the self-care industry."

Echoing PAGB's position, Ehret insisted that RWD/E was "not new," having been used for safety signal evaluation and risk management and in the Rx sector for "quite some time." However, the lack of agreed definitions and appreciation of the lifecycles of OTC medicines had held back its use in consumer healthcare, Ehret noted.

To accelerate its use in self-care, RWD/E should be "defined more broadly by regulators," he argued, and "should include data generation from real world studies, as very few data are routinely available and can be used for generating RWE."

While RWD/E offered ways to complement traditional evidence such as that from randomized clinical trials – which remained the "gold standard" in industry – there were some limitations that needed to be addressed, Ehret insisted.

Firstly, the data generated by consumers was "subjective in nature," he pointed out. This raised questions about the generalizability of such evidence, and whether it could be applied to diverse populations.

RWD/E from wearables and mobile health apps was more objective, he noted, but without access to the proprietary algorithms, it was difficult to judge the reliability and quality of the data they generated. Nevertheless, "given right fit for purpose framework," Ehret said that RWD/E was a "fast and cost-conscious tool that has the potential to satisfy industry and regulatory needs," and to avoid "missed opportunities for consumers and their health."

Session 2 – RWD/E; Future Opportunities In The Digital World For The OTC Industry

IQVIA Consumer Health's global senior director R&D services, Dr Volker Spitzer, opened the session by highlighting the opportunity for industry to use RWE to "generate new and consumer relevant claims" for their OTC products.

Real world studies enabled companies to understand the effectiveness of their product in "live use," Spitzer pointing out, giving insights into consumer behavior and experience.

By using apps and wearables, large volumes of RWD could be collected, recording digital biomarkers, such as cough and sneezing frequency, sleep patterns, physical activity and stress levels. "Measuring these will bring new insights even for established products," he insisted.

Spitzer highlighted the example of the Hyfe app which measures the acoustic signature of a cough and records cough frequency. Such an app could be utilized by an OTC company to show how using their product improved a consumers cough over a 14-day period, he suggested.

With so many possibilities for RWE, why has it not been more widely adopted by industry? Spitzer suggested this was due to a number of factors, including the concerns of regulators, questions over whether apps are reliable sources of information and how to accurately interpret recorded data.

For RWE to deliver its potential, industry needed to be open, Spitzer argued, to collaborate early with regulators and experts and to ensure their studies were scientifically sound, while putting the consumer first.

Building on this point, Nicholas Hayhoe, research project manager at Orbital Research, highlighted why industry couldn't afford to ignore RWE.

The "big issue of the day" for OTC firms was how to justify the premium cost of their brands to consumers over cheaper generic alternatives, Hayhoe explained. This was difficult, he noted, as the claims used in the marketing of many brands did not show actual product differentiation.

Therefore, firms needed new claims to increase the perceived value of their product by consumers. Orbital's Digital RWE methodology could achieve this, he argued, by taking the standards of randomized controlled trials (RCTs) and applying them to RWE.

Hayhoe explained how Orbital looks at the evidence needed, agrees a clinical protocol, with ethics and standards like a RCT, and agrees the questions which will be used to gather the data. The study is then promoted through digital methods, like social media, to attract participants. After the data is collected it goes through a medical peer review as though it were a clinical trial paper, which, once it has been reviewed, can be used to support enhanced claims.

Using this process, Orbital had generated new claims for Teva's Infacol and Sudocrem brands, he pointed out. These claims expanded the marketability of both products, Hayhoe insisted, and were used in advertising on social media, on television and on-shelf in-store.

Noting that perceived consumer value was now more critical than ever, Hayhoe asked participants whether they could afford not to use RWE "to get ahead of your rivals with new and reinforced claims."

Dr Alison Carr, epidemiologist and clinical director at Hamell Communications, presented at a different possible application of RWE: to help support prescription-to-OTC reclassification.

RWE from a number of sources could help demonstrate that the incremental benefits and risks of switching a medicine were minimal and could be managed, Carr explained, which is a key requirement of reclassification.

Consumer studies could help to mitigate fears of misdiagnosis by showing patients could identify a health issue based on symptoms, she noted, while a study of data from electronic health records could address fears around delayed diagnosis.

Carr highlighted how Pfizer had effectively used RWE to tackle key regulatory concerns to secure the switch of Viagra Connect, first in the UK and later in other EU markets.

Pfizer conducted a real-world study using patient records to show how many men would have a delayed diagnosis of cardiovascular disease or diabetes if they used Viagra OTC to address their erectile dysfunction. Carr explained that the study had shown that for men with serious underlying disease, their doctor diagnosed them with erectile dysfunction after their CVD or diabetes had already been identified.

It was clear RWE could help dispel concerns about risk, Carr argued, and therefore play a "really important role" in switch applications.

Concluding the session, Matthew Carpenter, analytics team leader at Nielsen IQ, gave an overview of the growing importance of the online channel in the consumer health market.

In the year ended March 2021, the online health category had grown by 90%, compared to 15% growth in the previous year, he noted.

Despite this phenomenal growth, online sales still only represented 15% of sales in the category, Carpenter pointed out, with the vast majority still conducted in bricks-and-mortar stores. However, a growing number of consumers – 29% – now purchased some health products online.

Convenience, access to a wider range of products, and looking to save time were some of the reasons why more people were now shopping online, Carpenter observed.

For the consumer health industry, there was an opportunity to go further to engage consumers online, he argued, by expanding distribution options, such as utilizing apps for fast delivery.

Don't forget to enter your OTC brand launch, marketing campaign, packaging change and/or pharmacy training to the OTC Marketing Awards 2021.

The OTC Awards entry deadline is 1 September 2021. *More information and entry instructions can be found here*.