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AESGP Meeting: Real World Evidence Could Drive Rx-To-OTC Switch, If Regulators Embrace It

by David Ridley

Real-world data and evidence, for example generated by digital consumer health technology like apps and wearables, could provide crucial support for Rx-to-OTC switch applications, argues Sanofi Consumer Healthcare's Penny Glover at the Association of the European Self-Care Industry's 60th Annual Meeting in Brussels, Belgium. Recent research by Sanofi indicates that regulators are actually already using RWD and RWE in many cases when assessing switch applications, even if they do not call it that.

The OTC industry has for a number of years pointed to the potential of real-world data (RWD) and evidence (RWE) to support Rx-to-OTC switch applications.

Regulators, however, have been slow to embrace it, favoring traditional clinical evidence instead – even though recent research by Sanofi Consumer Healthcare shows that in reality they draw on a variety of different sources.

Digital technology, such as apps and wearables, could help generate RWD and RWE that could be used in reclassification applications, argued Sanofi Consumer Healthcare's Penny Glover at the recent Association of the European Self-Care Industry's 60th Annual Meeting in Brussels, Belgium.

"It's already being used, right?" said Glover, who is global switch science lead at Sanofi Consumer Healthcare.

"I understand that in some cases, there are concerns about the robustness or validity of the data," Glover acknowledged. However, if this data is generated by approved medical devices,

then the potential is there to demonstrate that a product can be used safely, she argued.

"These digital tools could play a really significant part in demonstrating what consumers actually do. Real world data should be, I think, a key part of the package of justification for Rx-to-OTC switches."

Regulators want reassurance that the drug in question will be suitable as an OTC product, Glover noted. "We can use this data to demonstrate that, but they need to accept it."

Sanofi Study

A recent study by Sanofi Consumer Healthcare found that, when a broader definition is adopted, including for example label comprehension and actual use studies, regulators do actually accept RWD and RWE as part of Rx-to-OTC switch applications.

Published in the peer-reviewed journal Clinical Therapeutics, the Sanofi-funded study – undertaken by Clarivate Analytics – looked at "which circumstances and to what extent RWD and RWE were used in regulatory decisions when switching products from prescription-only to OTC status with the aim of extracting learnings that could be applied in future switches."

Examining information in the public domain from the European Medicines Agency, the German Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), the US Food and Drug Administration (FDA), and the UK Medicines and Healthcare products Regulatory Agency (MHRA), the researchers found only two specific mentions of RWD and RWE in documentation associated with a switch application.

In one of these instances – the rejection by the FDA of cholesterol lowering drug lovastatin in 2000, 2004 and 2007 – "real world experience" was mentioned in relation to concerns regarding self-selection: "consumers were not believed to make appropriate decisions in the OTC setting."

Wider Definition

However, by abandoning the strict filters of RWD and RWE, the researchers found that regulators applied a "rather pragmatic approach, drawing information from a wide range of sources, most of which were not classical randomized clinical studies but in many instances could be regarded as RWD or RWE also when applying the definition of regulators."

The most important kinds of RWE supporting switch applications, they discovered, are those "corroborating the safety of the drug, drawing on repositories with recorded adverse events of the Rx-approved drug."

"Next to corroborating the safety profile, it proved successful to demonstrate that the patient is capable of self-diagnosis and will understand which drug to use, but also how and when to use

it," they continued.

"Rx-to-OTC switching presents complex challenges for both regulators and sponsors but can be appropriately addressed in a regulatory environment with a transparent and standardized regulatory framework with regard to RWD and RWE," they concluded.

UK Leading

In the UK, the government is looking to work with manufacturers to identify medicines that could be made available without a prescription, as part of its plans to relieve pressure on the country's primary care system. (Also see "*UK Government Wants To Work With Industry To Identify OTC Switch Candidates*" - HBW Insight, 6 Jun, 2023.)

"The MHRA, the Department of Health and Social Care and NHS England will work together with suppliers to identify medicines which could be reclassified from 'available only on prescription (POM)' to 'available in a pharmacy (P),' based on international practice and real-world evidence of safety," NHS England explained, in its recently published *Delivery plan for recovering access to primary care*.

Haleon also recently used a real world study to explore whether its UK Otrivin nasal spray could not only help unblock consumers' noses but also improve various aspects of their daily life. (Also see "*Haleon Real-World Study Shows Quality Of Life Improvement With Otrivine Use*" - HBW Insight, 15 Apr, 2024.)

Participants in Haleon's decentralized, longitudinal, open-label study used the firm's Otrivin 0.1% xylometazoline hydrochloride nasal spray as needed for seven days, recording quality of life (QoL) measures assessed using the validated Wisconsin Upper Respiratory Symptom Survey-21 tool, with additional QoL questions added. The results from the study – which involved 102 UK adults and is published in the scientific journal Therapeutic Advances in Respiratory Disease – showed overall QoL scores improving by over 70% with Otrivin use, as well as significant improvements in nasal congestion, strongly correlated with breathing easily.