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Longer Exclusivity Periods For EU Centralized Rx-To-OTC Switches? Commission Says No

by [David Ridley](#)

One way to revitalize interest in the EU's centralized switch procedure would be to introduce longer data exclusivity periods or market exclusivity for successful applicants, concluded an AESGP expert switch panel presenting at the association's 59th Annual Meeting in Paris, France. However, a European Commission representative told another panel that this was not under consideration as part of the EU pharmaceutical legislation revision.

Offering longer periods of data exclusivity or additional periods of market exclusivity for European Union centralized Rx-to-OTC switches would help revitalize interest in the process, reclassification experts argued at the AESGP 59th Annual Meeting in Paris, France.

“The single action that would make the biggest difference in revitalizing switch is introducing automatic market exclusivity for innovative switches,” suggested James Walmsley, a consultant at Snakestick Ltd, who was reporting on the results of a recent AESGP switch advisory board meeting. Companies who successfully navigate the centralized route to secure a reclassification are currently rewarded with just one year of data exclusivity for their efforts.

Designed primarily for innovative, or “first-in-class” switches – those involving new active ingredients, combinations of active ingredients or indications – the centralized procedure is widely thought by industry to have failed to live up to expectations so far, with just six reclassifications approved since its introduction in 2005. (Also see [“EMA’s Frias Defends EU Centralized Switch Procedure Despite Only Delivering Four Reclassifications In 10 Years”](#) - HBW Insight, 26 Mar, 2019.)

Not Looking Good

But this situation looks unlikely to change anytime soon.

During an earlier session, AESGP director general Jurate Švarcaite asked the European Commission's Olga Solomon whether the regulator had considered extending the exclusivity period for centralized switches as part of the proposed revision of the EU pharmaceutical legislation.

“We considered it,” responded Solomon, who is head of the EC's DG Sante unit, Medicines: Policy, Authorization And Monitoring. “But we didn't see any evidence that there is any particular problem” with the existing legislation.

While the ongoing revision the EU pharma legislation aims to reward innovation and investment by manufacturers, Solomon explained that it also seeks to increase competition by creating opportunities for other products to come into the market earlier.

“Of course, there is an investment in Rx-to-OTC, and this is certainly something we want to see more of, where there is evidence,” Solomon conceded. However, the EC's evaluation “didn't see that this isn't rewarded in the current framework.”

“That's why we kept the one year, as a reasonable reward,” she added. “At the same time, we increase the possibilities for competition from other products.”

RWE And Switch

Speaking at the same panel as Solomon, Bayer Consumer Health's Christine Eising asked if the Commission would consider accepting real-world data and evidence (RWD, RWE) as part of applications for the one-year exclusivity period in future.

“Looking at the regulation right now, it is really strictly linked to clinical studies,” noted Eising, Bayer CH's head of regulatory affairs, EMEA. “Would you also consider RWD and RWE to help us

The centralized procedure has delivered six switches:

Haleon's Alli (orlistat) weight-loss drug, 2008

Takeda's Pantoloc Control (pantoprazole) proton-pump inhibitor, 2009

Haleon's Nexium Control (esomeprazole) PPI, 2013

HRA Pharma's EllaOne (ulipristal acetate) emergency contraceptive, 2015

Ratiopharm GmbH's Desloratadine Ratiopharm (desloratadine) antihistamine, 2020

Recordati SpA's Fortacin (lidocaine/prilocaine) premature ejaculation treatment, 2020

to get this one-year exclusivity, in other words, to expand the scope rather the duration?”

“We’re moving into an era where we want to facilitate the use of RWD and RWE,” Solomon replied. The issue is still being evaluated, she said, but exclusivity will be given if RWD/RWE can be shown to be as robust as that generated by clinical trials.

AESGP’s switch advisory board has spoken about RWD/RWE extensively, according to Walmsley. “There was a genuine feeling from the panel that real world evidence is the best tool for showing that consumers can use OTC drugs safely.”

“There’s an opportunity for a framework to be agreed between industry and regulators in terms of how real-world evidence could be used to address this question,” he added.

Passion And Partnerships

In addition to thinking about RWD/RWE, the AESGP switch board also wants companies to nurture the next generation of reclassification experts and to consider possible partnerships with pharmaceutical companies now that some major consumer health businesses are moving to a standalone business model.

“There’s a generation of who have lived through a golden era of switch and our passion needs to be passed down to the to the younger ones joining industry at the moment,” Walmsley reflected. “It’s important that we don’t lose that expertise and we don’t lose that passion.”

Due to the changing nature of the consumer healthcare sector, it’s also important that standalone OTC companies start thinking about strategic partnerships with pharma companies, he explained. “Because otherwise, the only switches we’re going to see are going to be generic switches.”

Such strategic partnerships, Walmsley said, would bring together the companies that have the capability to commercialize non-prescription medicines and companies that have a pipeline of products that could be switched.

Switch Is Not Dead

Despite the barriers to switch in the EU currently, Walmsley concluded on a positive note.

The AESGP switch board was “clear,” he said, “that even though switch is not dead, switch will look different in the future. And it will look different in terms of both the types of products and indications but also the type of companies pursuing switch projects.”

“We’ve already seen some interesting companies getting involved in switch, some specialist switch companies and some pharma companies that don’t have a consumer healthcare division.

So, switch is already starting to look different to how it used to.”