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Future Still Looking Bright For UK Switch, Even After Brexit – Q&A With PAGB's Michelle Riddalls

by [David Ridley](#)

The UK has for decades been considered a European Rx-to-OTC switch leader. A combination of regulatory openness and a strong retail infrastructure will enable the country to remain so even if it leaves the European Union in October, insists the Proprietary Association of Great Britain's senior director of Regulatory Affairs, Michelle Riddalls, in an exclusive interview.

The UK has for a long time been considered a 'go to' market for prescription-to-OTC switches within the European Union.

A unique combination of regulatory openness and strong retail infrastructure has made the country very appealing for firms looking to extend the life of their prescription brands, or to widen access to OTC medicines by switching them to general sales list (GSL) status.

In an exclusive interview with HBW Insight, the Proprietary Association of Great Britain's Michelle Riddalls points to the "forward thinking" approach to switching by the UK's Medicines and Healthcare products Regulatory Agency, as well as the scientific advice offered by the agency to prospective switch applicants, as specific factors that make the country appealing for switch.

Riddalls – who in June became PAGB's new senior director of Regulatory Affairs after spending over five years at Pfizer, where she was involved in one of the most high-profile switches in recent years, erectile dysfunction drug Viagra Connect (Also see "[Switching Can Help Normalize Self-Care – PAGB's Michelle Riddalls](#)" - HBW Insight, 13 Aug, 2019.) – also notes the important role British pharmacists play in creating a positive switch environment in the country.

The existence of a pharmacy (P) category between prescription and general sales list status and the use of checklists over complicated pharmacy protocols are two aspects of the UK's switch system that enable pharmacists to act as enablers for switch, she argues.

These factors will enable to the UK to continue leading European switch even if the country leaves the EU in October, Riddalls insists.

Q Is the UK still a 'go to' market for switch?

A Definitely. Looking at the MHRA website, I counted 11 switches in total since [Pfizer Inc.](#)'s prescription-only to pharmacy reclassification of Viagra Connect. That's quite a lot in less than two years. It's perhaps true that these switches were not necessarily as high profile as Viagra, which created a whole new OTC category, as did [Glenmark Pharmaceuticals Ltd.](#)'s Maloff Protect. But that doesn't negate the importance of these switches because they still widened access to medicines and enabled consumers to self-care more easily in all of these established categories. High-profile, ground-breaking switches like Viagra, by their very nature, occur less often, one every few years rather than two or three every year.

Q Have all the easy switches been done now?

A No switch is easy. People might say 'oh, that was an easy switch,' but I can tell you from experience that nothing about a switch is easy or predictable. There are often unexpected hurdles that you have to go through even with switches that might be seen as simple and easy. This is because the reclassification process in the UK is rigorous, as it should be, to make sure that the safety of the patient is paramount. But that's what makes switching an exciting area to be involved in.

Q How important is the MHRA as a "forward thinking" regulator in making the UK an attractive country for firms to switch in?

A We very much see the MHRA as a forward-thinking regulator and the sheer volume of switches that go through the UK system shows that it is staying that way. In my experience with Pfizer and [Johnson & Johnson](#), I found that MHRA worked very collaboratively with industry to support the appropriate reclassifications. For

example, MHRA provides very good scientific advice before a company submits a switch application. That's part of the switch model in the UK. I think that's really important because MHRA talks to applicants about its concerns and also advises them what they can do to address these concerns.

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This makes the UK a very positive environment to switch in. I think the legal framework in the UK also helps. The fact that you have a pharmacy (P) category means that the MHRA can be assured that a switched medicine will be used appropriately, as pharmacists can advise consumers on its safe use. By contrast to other countries, pharmacists in the UK can also actually choose not to supply an OTC medicine to a consumer if it is not appropriate.

Q Does it make a difference that pharmacists in the UK can use checklists rather than complicated protocols when advising consumers?

A I think the move away from protocols to checklists has made it a lot easier for pharmacists to advise consumers on OTC medicine use and has also helped pharmacists become trained and confident in dealing with switched OTC products. Pharmacists need to feel confident in their decision of whether or not to supply an OTC medicine, and checklists are a good tool to enable them to do that. By taking away the requirement to use them every time also helps pharmacists feel more confident and have more natural conversations with their customers about OTCs.

Q Where do you see the next generation of UK switches coming from, in terms of categories or conditions?

A Women's health is an obvious one, with the World Health Organization recently saying it would like to see more countries switching the oral contraceptive pill from prescription to OTC. (Also see "[Global Industry Welcomes World Health Organization's Call For Widespread Oral Contraceptive Rx-To-OTC Switch](#)" - HBW Insight, 22 Jul, 2019.) I think this is very positive and would be potentially a sensible option, given that you've already got the morning after pill out there non-prescription ([HRA Pharma SA](#)'s ulipristal acetate-based EllaOne). If used sensibly, what's the risk of having the daily contraceptive pill as P with a pharmacist overseeing its supply? As I said before, having a P category opens up the ability to explore switches you might not have thought about, as you can balance the safety by using the pharmacist, which increases the chance of switches being successful.

Q How will Brexit affect the UK's status as switch leader?

A To be clear, PAGB believes that it is in the best interest of the public and the industry is to remain aligned with the EU and the European medicines system to ensure consumers continue to have timely access to OTC medicines. However, there is one area of opportunity presented by Brexit which we wouldn't say ruled out all the negatives of regulatory divergence but could make some aspects of switching easier.

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licenses for new medicines rather than having to go through EU's centralized procedure, which would mean that in the future firms would also not need to navigate this procedure also to switch these medicines to OTC status. Medicines that were granted marketing authorization through the centralized procedure – which currently would need to also be switched through this system – would also be potentially open to be switched in the UK first. This would mean that one of the constraints for firms looking to switch in Europe would be removed and would potentially allow the UK to carry on trailblazing as it has in the past. But irrespective of Brexit, it is important that the MHRA should carry on taking a proactive stance towards switching. (Also see "[Brexit Could Open Up Rx-To-OTC Switch Opportunities In UK, Says MHRA](#)" - HBW Insight, 8 May, 2019.)

Q Aside from switching, how will Brexit affect OTCs?

A Obviously, OTC medicines are part of the UK government's no deal Brexit contingency plan. (Also see "[Supply Of 'Important' OTCs From EU Prioritized In Event Of No Deal Brexit](#)" - HBW Insight, 26 Feb, 2019.) Prescription medicines are important, no one is going to say anything different from that, but if consumers can't get OTC medicines, there will be a knock-on impact on the UK National Health Service. This is because if people can't get OTCs then they will go to a doctor or to a hospital. But the healthcare system is under huge pressure already. So, from that point of view, OTCs are actually really important. We are pleased the government has recognized this and is including them in the contingency plans.