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Prescription-To-OTC Switch Of Daily Contraceptives And High-Dose Statins In The UK?

by [David Ridley](#)

Daily contraceptives and high-dose statins are two OTC categories that have future switch potential, according to UK self-care industry association CEO John Smith.

Prescription-to-OTC reclassification is the “holy grail” for many pharmaceutical firms, representing a way to extend the life of blockbuster prescription drugs or the possibility of dominating a new OTC product category established via a switch.

With its forward-thinking medicines regulator, the MHRA, and self-care savvy consumer base, the UK has always been a “go to” market for firms looking to switch their products, according to British self-care industry association, PAGB. (Also see "[Future Still Looking Bright For UK Switch, Even After Brexit – Q&A With PAGB's Michelle Riddalls](#)" - HBW Insight, 27 Aug, 2019.)

In this final part of an exclusive interview series, PAGB chief executive officer John Smith tells *HBW Insight* where he thinks UK switch might be heading in the next few years.



PAGB CEO

ptives and high-dose statins are two es that have future switch potential, he also posed some interesting challenges healthcare firms in terms of persuading mers to pay for such products, which are ilable for free via the UK's National

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Health Service.

Q How does prescription-to-OTC reclassification fit into PAGB's "Strategy to 2024"?

A It is absolutely one of our key areas. I think for me it's one of the things that PAGB can do really well. It is about evaluating different switch models and pathways to reclassification – working with the UK medicines regulator, MHRA – to increase access to self-care products, whether that be via prescription-only to pharmacy-only (POM-to-P), pharmacy to general sales list (P-to-GSL) or straight from prescription to self-selection (via POM-to-GSL switch).

Q Are there any product areas or indications in particular that you see have potential for switch in the UK?

A We've had some internal meetings to discuss areas with potential for switching. Women's health was one of the areas identified by our new switch expert Michelle Riddalls, for example, as having great potential.

Q Recently the World Health Organisation said they wanted to see the daily contraceptive pill become available OTC in as many countries as possible in the future. (Also see "[Global Industry Welcomes World Health Organization's Call For Widespread Oral Contraceptive Rx-To-OTC Switch](#)" - HBW Insight, 22 Jul, 2019.) Would you say that this provides a boost to switching in these categories?

A Yes, it is a boost. However, the challenge with switching oral contraceptives is finding a regulatory pathway that makes it possible and that also makes such a switch commercially viable. If you think in the past, there's been some great switches that have had the regulatory pathway but weren't commercially viable, for example tamsulosin or triptans. There are a number of different reasons that switched products may be commercially unsuccessful, such as not meeting a consumer need, the consumer wasn't ready for it so the demand wasn't there, or the switched product was too complicated. There have also been issues in the past with regard to protocols,

which have now been alleviated by the use of a non-mandatory checklist which is less time consuming but also provides the pharmacists with a tool to ensure they feel confident to supply newly switched products, as this is another critical success factor.

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I do think oral contraceptives have great switch potential, but the question is: how to make the switch commercially viable? Because at the moment it's available for free via the NHS, so is a consumer going to pay for it? Could there be an approach whereby the pill is switched but it's still free to the consumer? So, in a sense the government would still pay for it from a company point-of-view but then it would be easier to access for the public. That's something we are going to look at. But then again there may be a way that consumers could pay for the contraceptive pill that does not represent a price barrier. So, consumers may pay for the convenience of buying contraceptives OTC from pharmacy, rather than waiting for a GP or practice nurse appointment.

Q You mentioned before that the UK medicines regulator, MHRA, is very pragmatic and forward thinking when it comes to widening access to medicines. Does this help with switching in the UK?

A As I said before, if the UK was to have a sovereign regulator after Brexit, we could become the leading light for switch in Europe. (Also see "[UK Industry Hit By Brexit Uncertainty, Spies Opportunity](#)" - HBW Insight, 11 Nov, 2019.) I think they are the type of regulatory agency that could do that. They are one of the most pragmatic, forward-thinking regulators and one that supports widening access to medicines. If you think about our NHS, it's really struggling to keep up with demand and faces increasing financial pressures. How can we widen access to medicines on the part of

consumers to take some of the burden away? We want people to go to the pharmacy, to the supermarket, for products that are appropriately safe as OTC medicines. This way they're not going to the doctors or to the Accident & Emergency services of hospitals when they have self-treatable conditions. That's got to be the way forward in the future.

Q Are there any other categories that you think might have potential for switch in the UK?

A The other category in which I would personally like to see a successful OTC product is statins. NHS England has recently said it would like to make more high-dose statins available OTC, to reduce the incidence of heart disease and stroke. (Also see "[High-Dose Statins Could Go OTC In UK](#)" - HBW Insight, 6 Sep, 2019.) This is the only other category that jumps out at me at this point in time as having the potential to see a successful high-profile prescription-to-OTC switch.

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One of the key drivers to ensure success of any future OTC statin is consumer education, ensuring that people understand the need for the product and that it needs to be taken long term without having the positive feedback loop of an immediate visible response. Furthermore, the use of checklists rather than protocols, would ensure the pharmacist's interaction with the patient would be efficient and help make the supply of the medicine much smoother. Equally, there would need to be the support of all key stakeholders, including GPs, pharmacists and relevant health charities, to ensure that if there was another switch in this category it would

be commercially viable.