

The benefits & challenges

Healthcare systems around the world are in a state of crisis. The accelerating rise in non-communicable diseases like cardiovascular disease, cancer, diabetes and respiratory conditions like asthma is putting healthcare under increasing pressure. One of the ways to relieve this pressure is self-care.

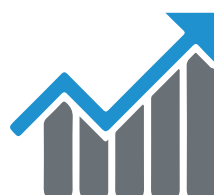


Consumers need more self-care tools, and the pipeline of new tools comes largely via Rx-to-OTC switch.

As well as significant healthcare cost savings, Switch brings multiple benefits:

- Increased consumer access to treatment
- More self-reliant consumers
- New business for companies
- Enhanced science for regulatory decisions
- Chance to launch a new consumer brand & create new consumers
- Give a great Rx brand a second and longer life as an OTC

The challenge for companies is that Switch requires a senior leadership commitment, many resources and a high-performing team combining the best talent in marketing, regulatory & medical. It is a long-term commitment, requiring support from senior sponsors. In addition, companies that want to Switch must have strategies to compete with Rx generics, particularly in the US, as prescription is one of the main competitors of switched brands.



Switch is challenging but the rewards are great. The benefits of success are transformational growth for the company, as well as the chance to create and lead a new consumer healthcare category.

USA – the land of Big Switches



The biggest financial successes in Switch come from the US. The Top 10 US switches since 2000 (including Claritin, Flonase, Mucinex, Nexium and Zyrtec) generated US\$3bn (in

a US OTC market worth US\$32bn) in the 12 months to June 2017.

A liberal regulatory environment in the USA has seen a number of Rx-to-OTC switches in recent years, of which three were first in class: Differin, Nasacort and Oxytrol. Other switch activity has been mostly in existing categories, mainly Gastrointestinals and Allergy remedies. The FDA is encouraging more switches but requesting conditions of safe use to aid selection, with its latest comments opening the prospect that new technology will be taken into account for actual self-selection / actual use trials.

Case study: Flonase (GSK)

- Flonase Allergy Relief (fluticasone propionate spray) was the second intranasal steroid to launch in the USA (Feb 2015), taking the allergy category by storm
- It created a point of difference by establishing efficacy for itchy, watery eye relief, an indication not offered by competitors
- Awarded three-year period of OTC exclusivity for the eye relief claim
- Heritage as Rx market leader plus innovative A+P (“This changes everything”) drove growth
- Launch of Children’s version in 2016 and Sensimist spray (plus children’s) in 2017 cemented its position



(photo: Flonase.com)

Exciting developments beyond USA

Despite the dominance of USA in the Switch landscape, it is often smaller, more liberal markets such as the UK, Poland and New Zealand that drive groundbreaking switches.

Erectile dysfunction has flourished via switch, seeing non-prescription availability for Silvasta in New Zealand, MaxOn Active and others in Poland, and most recently Viagra Connect in the UK.

The UK is among the most liberal markets, with a high level of switched ingredients, and ongoing trend towards extending mass market (GSL) distribution. Its latest world-first switch was antimalarial Maloff Protect launched in August 2017.



What’s next for Switch?

Regulatory hurdles for future switches are higher now than a decade ago, not least because the medicines and conditions are more complex. Meanwhile, switches in traditional OTC categories are reaching saturation point. Chronic conditions that are symptom-free (such as high cholesterol) require consumers to know their own health data and medicines. New technologies offer ways to support consumer selection and use that were not possible just 3-4 years ago.

Future switch pioneers will look to new OTC categories, avoided in the past owing to challenging safety and self-selection requirements. Some of the switch opportunities evaluated in the report include Migraine, Topical NSAIDs in the US, Daily Oral Contraceptives, Erectile Dysfunction, Cholesterol Reduction and Overactive Bladder, among many others.



This paper contains selected highlights from the report *Rx-to-OTC Switch: Success Strategies & Opportunities* by **Nicholas Hall’s OTC Reports** in collaboration with industry switch expert Joseph McGovern of Everything Health. For more information about this report, please contact owen.hartnett@NicholasHall.com