MINI GUIDE TO THE OPTIONS FOR SWITCHING MEDICINES FOR SELF CARE

SWITCH POTENTIAL

This chapter considers the different options available for switching medicines and is designed to stimulate thinking around switch.

Given the challenges of running switch projects in Europe and the cost of launching a switch in the US, this chapter also explores the possibility of piloting switch projects in the UK where the regulator is switch friendly and the consumer is sophisticated and distribution channels well defined.

7 SWITCH OPTIONS

There at at least seven different options for switch illustrated in this chapter.

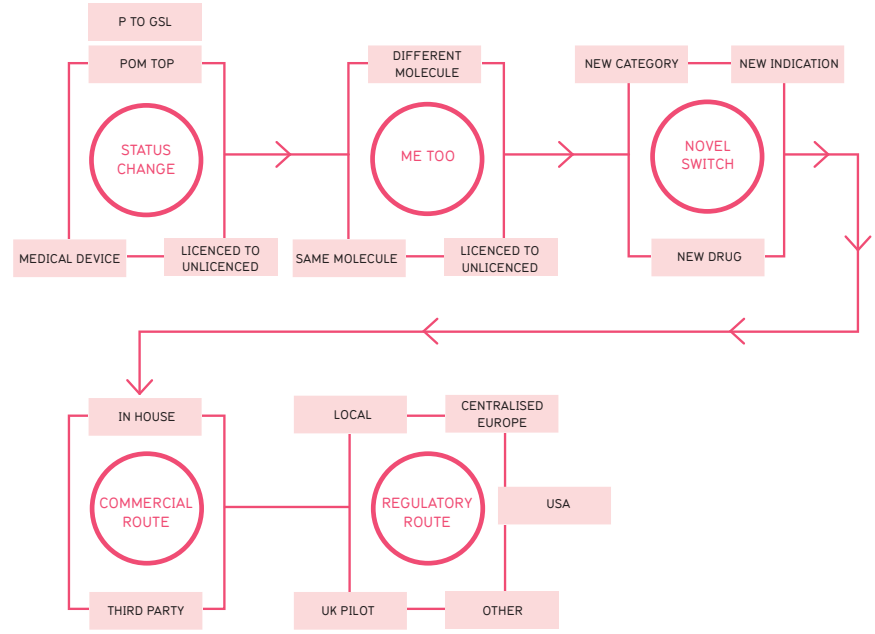
1. Status change.
2. Me Too.
3. New Molecule.
4. New Supply Model.
5. New Indication.
6. New strength or format.
7. Switching a molecule you don't own.

THE SWITCH POTENTIAL

We are now working in an era where it is said that most of the easy switches have been done - but there are still possibilities for simple switches when companies mine for them. There are around 2000 prescription-only molecules in the UK compared to 500 pharmacy-only molecules and 900 GSL molecules[16].

DIFFERENT TYPES OF SWITCH

Thinking laterally, there are many options for evolving switch projects and some of the options are outlined in the table below. I use this type of framework when mining a portfolio for switch candidates: -



1. STATUS CHANGE

In the UK there are a number of routes possible for changing the status of a medicine. The route chosen depends upon the start point of the molecule, ie the current legal status of the product (see Table Page 18).

a. POM to P Switch – this is where a molecule with a prescription-only status is converted into a pharmacy-only status which can then be supplied by the pharmacist. This type of switch involves the submission of a relevant application to the regulatory body. Sometime it is the indication that has to be switched, eg thrush (see point 5 on page 74.)

b. P to GSL Switch – when a product moves from a pharmacy-supervised status to a General Sales List (GSL) status that enables self-selection and the opening up of new distribution channels such as supermarkets. This type of switch involves the submission of a relevant application to the regulatory body.

Note: In the US, switches are made from Rx to OTC. There is presently no P category and therefore products switch from prescription-only straight to self-selection over the counter (OTC). This type of switch involves the submission of a relevant application to the US Food and Drug Administration (FDA).

c. Licensed to medical device status – In Europe, the regulation of Medical Devices[17] is different to medicines in that a CE mark is required, which is obtained from a competent authority. There are specific controls around manufacture, supply and labelling that must be followed.

One benefit of a medical device route is that the labelling has to include a medical claim. This has the potential of making the medical device a stronger proposition than it would be if a food or cosmetic and almost equivalent to a Marketing Authorisation status. An example of this type of switch is GSL to medical device, eg skin barrier creams.

Note: Medical devices have no pharmacologic effect, metabolic or immunological effect. They prevent or treat conditions through physical, mechanical, thermal, physico-chemical or chemical action, for example barrier creams, weight management products.

d. A medicine status to unlicensed cosmetic[18] or food[19] product – Moving a product from licensed to unlicensed status saves the costs

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of managing and keeping updated the marketing authorisation which companies are obliged to do with a licensed product; however, the strength of the claims are diluted and marketing becomes more challenging. This type of switch is simple to undertake without reference to the medicines authority. Examples of this type of switch are GSL to food supplement, eg certain vitamins, GSL to cosmetic, eg mouthwashes.

2. ME TOO

Where the molecule has already been switched and the new product is a copy of an existing switched product, eg cetirizine for a private label or omeprazole as a brand extension.

3. NEW MOLECULE

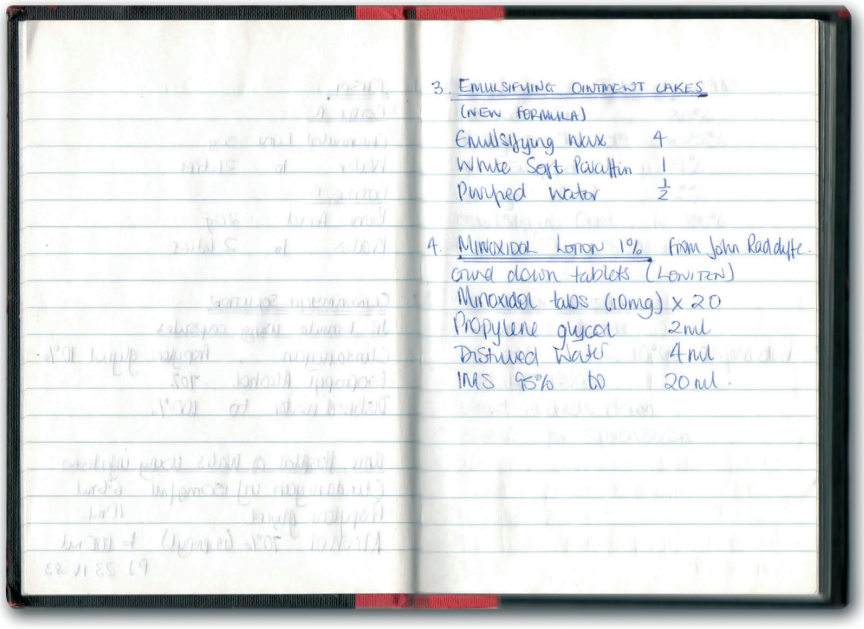
Where the indication has already switched and the new molecule is a better clinical option or has a better efficacy or safety profile or just a different molecule to that was the first to switch in the category, eg fexofenadine/hayfever.

4. NEW SUPPLY MODEL

Where the molecule has already been switched but a new supply model is developed that is an enhanced version of the first generation model, perhaps simplifying the process for the sale, the label, or enables the pharmacist consultation to be done in a different way, eg a revised pharmacy protocol for tamsulosin or sumatriptan.

5. NEW CATEGORY OR NEW INDICATION

Where the switch of the molecule opens up a new opportunity for self-medication or prevention of disease, such as prevention of osteoporosis or over-active bladder. Companies may also be able to employ the use of the molecule in a different way such as exploiting a known side effect, eg sleep, or promoting an off-label use, eg hair re-growth, thus inventing new self-medication possibilities.



Early recipe for minoxidol lotion 1% (Regaine) to treat male pattern baldness as an off label indication, minoxidil is a cardiovascular drug for hypertension. I frequently made this up in the pharmacy in Oxford where I worked during my early career as a pharmacist.

6. NEW STRENGTH OR FORMAT

Where the proposed switch is a different strength or delivery format to the current switch version, eg Orlistat 120mg (Rx) and Alli 60mg (OTC)

7. COMMERCIAL ROUTE

The commercial route adopted may also give further options:

(i) In-house Switch – Switching a molecule that the company already owns.

(ii) Third-party Licence – Switching a molecule that is owned by someone else and licensed in for the purpose.

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Option ii. may have significant benefits in that the third-party molecule may be competitively advantaged compared to the in-house option, eg higher up the treatment algorithm, better safety profile, bigger potential, different category.

One example of a third-party licence is when The Royal Pharmaceutical Society of Great Britain rather than the brand owner Bayer brought about the clotrimazole switch. More details on this case study can be found at www.dynamicswitch.co.uk.

THE UK AS A TEST MARKET?

Why not consider the possibility of piloting the switch in the UK? If you can make a switch work in the UK then there may be a platform to build a case for switch in other countries. In any case it is an opportunity to build some sales and generate some metrics in a real-life setting in a territory and get the proof of principle ironed out. Evidence of use on the OTC setting from other markets is very useful in determining the risks and benefits of switching medicines and now regulatory agencies worldwide want to see this information if it exists.

The UK's National Health Service offers free healthcare provision, thus making it probably one of the hardest markets in which to persuade people to self-medicate. When it was set up in the late 1940s, the NHS was designed to be free at the point of need, yet it has become free at the point of delivery, ie to everyone who accesses it. So it doesn't have a value to most who use it until they develop a serious life-threatening condition, need an operation or lose their mobility and independence. With an ageing population and increased life expectancy of the nation going forward, the numbers don't stack up and something has to change. I believe that switch should be part of the NHS re-engineering process.

In light of this economical situation with the NHS, the UK regulatory authority MHRA is very receptive to widening access to medicines and increasing the choice for patients; because of this, the UK is viewed as a world leading country in switch. MHRA are receptive to conversations about the possibilities for switch and this can easily be arranged in the early stages of switch evaluation before any significant investment is committed.

MHRA also has a clearly defined process for switch (which is used by other countries as a basis for their switch framework) available at www.mhra.gov.uk.

The benefits of running a switch pilot in the UK are:

- It has a sizeable population, the third-largest self care business in Europe. [20]
- There are large and small pharmacy chains and networks that can be partners in the delivery of the switch programme.
- There is advanced technology to capture sales data.
- Internet pharmacy is well established for mail-order supply.
- The legislative environment is receptive to switch.
- There is reduced complexity associated with a UK switch compared to a centralised European one.
- It is quicker.

20:20 HINDSIGHT

How different could it have been for Pfizer if a UK pilot had been possible for sildenafil (Viagra) instead of a centralised European procedure?