PHARMACEUTICAL INDUSTRY WHITEPAPER

Why Rx to OTC switch is a viable off-patent strategy

Developed by

Oz Pharma Contracting & Consulting Inc.

Introduction

As 2011 unfolds, the pharmaceutical industry is headed into an unprecedented period of drug actives losing patent protection, including many 'blockbuster products'. Companies facing the 'patent cliff' challenge will already have or be in the midst of planning strategies to minimize the critical sales losses that this situation causes. Some of the strategic options for extending the product life cycle of Rx products include launching new indications, formulation variants, extended/controlled released versions; switching users across to a new, improved version of the product, or the option of releasing a company–owned or licensed generic. Some or all of these strategies are likely to be assessed by most companies with expiring patents. Another strategy though is to **switch the product from prescription (Rx) to over-the-counter (OTC)**. This white paper discusses what advantages an OTC marketing environment can offer to a suitable 'off-patent' product and some of the basic success factors required.

OTC Brand Advantages

Why consider an OTC environment? An OTC switch offers an opportunity to rejuvenate an off-patent brand into a new life-cycle growth phase by moving to a new market segment where self-selection and professional recommendation drive sales, rather than a doctor's prescription. A new OTC market segment will potentially contain users of other competitor Rx brands, existing OTC brands, recurrent sufferers that may not consistently seek physician help and non-treating patients.

The appeal of this opportunity is to introduce a new OTC treatment to consumers, often with superior benefits versus existing OTC treatments available, while leveraging from established Rx brand awareness and equity among key professional audiences (pharmacists and physicians) and some consumers. New non-switch OTC brands are usually launched without existing brand awareness and need years of substantive promotional investment to gain the advantage that Rx heritage lends to OTC switch brands. Previous studies have shown this advantage is one of the factors that contribute to achievement of OTC switch sales levels higher than original Rx sales levels. Other key drivers explaining the higher OTC sales phenomenon include increased access for patients (convenience) and the potential to provide more accessible treatment to previous non-treaters who do not visit doctors.

> ***"..Most of Zyrtec OTC switch sales (84%) came from other OTC products and only 27% of Zyrtec prescription patients moved to Zyrtec OTC..."***
>
> ***Nielsen HealthScape™ Research 2008.***

Although it is a common misperception about OTC switches, sales are not always derived primarily from current Rx brand users changing from doctor- to pharmacist-led use. Research data from 2008 (Nielsen; HealthScape™ research, November 2008) on the Zyrtec OTC switch showed that most of Zyrtec OTC switch sales (84%) came from other OTC products and only 27% of Zyrtec prescription patients moved to Zyrtec OTC. Many users were new to the allergy category or hadn't purchased any product in the last two years.

Given that most successful OTC switch launches either maintain or increase brand awareness, it can be argued that a secondary benefit to OTC switch is the potential for a positive halo effect on any remaining Rx parts of the brand, This is an added bonus that can help strengthen the Rx brand, assisting in maintaining sales or decreasing sales losses when it is facing generic threat after patent expiration.

Key Factors influencing a decision to proceed with switch

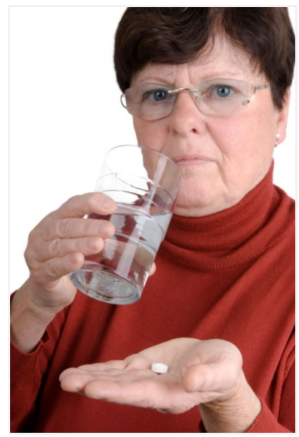
The decision to move ahead to switching a product from Rx to OTC status is a major strategic move, regardless of what markets a company serves. Several key factors need to be assessed to determine its success potential, including whether:

- The active is a suitable self-medication candidate
- The active is going to be first in a Rx category to switch (creating a new OTC category),

- There is exclusivity once switched
- The product has a recognizable point-of-difference versus existing treatments
- The product has potential for modification into different forms to increase differentiation
- There is an unmet consumer need
- The Rx brand has adequate market equity to achieve a successful switch

Is your product suitable for OTC switch?

Is the product actually suitable for consumers to appropriately self-diagnose, self-select and then self-treat? Products that have serious side effects or require medical intervention or assistance with administration would not fall in this category. The product requires a proven safety record, usually having been marketed pre-switch for at least two-three years, and an adequate volume of patient usage for it to be assessed by health authorities.



For OTC usage, a suitable product has to be available; perhaps a lower strength or a smaller number of doses versus the existing Rx use of the active. The indication too, will often be a short-term or milder condition versus the one approved for Rx use in most cases, and will need to be something suitable for consumer self-medication. Past OTC switch products have been largely therapies for symptomatic and non-serious conditions, usually for time-limited conditions. However, treatments for chronic and more complex conditions are now also being reviewed for suitability as switch products, at least in some categories.

Consumer research and label testing are also often required to verify OTC suitability in a regulatory switch application, by demonstrating consumer capabilities and understanding with the proposed OTC active. Broader consumer research is also extremely useful to identify the type of claims required for OTC success.

OTX or 'Dual Brand' strategy

An extended version of OTC switch strategy is known as **OTX or Dual Brand strategy. This is a planned dual channel approach for a single brand, simultaneously marketing both Rx and OTC brands under the same umbrella**.

This strategy entails a broad channel approach where a brand starts its life as a Rx product and at some stage part of the brand moves into an OTC environment so that the brand has strategic presence in both channels. Planning for a long-term successful OTX strategy often requires that new Rx line extensions are available in the planning pipeline to be added over time to maintain the Rx brand presence, at the same time as certain parts of the existing Rx brand (lowest strengths, doses etc) are moved into OTC status.

This can be a particularly powerful strategy as it ensures continued brand innovation at both channel levels but maintains the powerful heritage lever that helps drive OTC sales in pharmacy. Additionally, consumer advertising of OTC brands that have an Rx component can help maintain physician as well as patient awareness of the brand name overall, providing a positive effect in both channels.

An Rx-OTC switch of a product can be an attractive strategy for many reasons besides patent protection. Launching the first OTC switch product of an active into the OTC market can provide the foundation for not only a potentially large consumer brand in its' own right but also for extensive brand growth through the addition of bigger pack sizes, higher doses, new indications or further brand extension into combination formulations of existing OTC products. Eventually the possibility of licensing out the active for store brand generics may also present a strategic opportunity that is sensible.

Seven Switch Success factors

1. Regulatory success is measured by strong claim approval

Stage One: Launching an Rx brand into OTC requires firstly gaining health authority approval to deregulate the Rx status of the relevant pharmaceutical active to a less regulated or OTC status. This process varies in different regions however the application will usually require a nominated strength or number of doses of the active proposed for a particular indication. Regulatory authorities will assess the likely suitability of the proposed product for self-selection and treatment. An acceptable safety profile is the cornerstone of gaining OTC switch approval so product safety is a key focus. They will review the active's adverse event profile as a Rx product, potential for overdose and habit-forming use, safety margin in case of overdose, potential to mask underlying conditions, normal side effect profile (any serious potential effects) and ease of administration.

Aside from providing a well-argued safety case, the application will also need to provide a clear rationale explaining:

- The proposed use of the active for a defined medical condition(s),
- How the condition would be diagnosed and treatment selected/recommended in an OTC environment;
- How consumers will manage self-medication (what education and assistance is required to move them to an acceptable position of effective self medication if not there currently); and
- What the limitations are for success in achieving this – including when professional intervention at physician level may be needed, and how this will be managed.

Evidence may be required of OTC use of this active in other markets, if available.

Once approval is achieved, then a company can apply to register their OTC brand containing the deregulated active.

Stage Two: Even if switch approval of an active is obtained, in most regions, the new OTC product must be registered with health authorities. As a self-medication product, the claims and wording presented on labeling are crucially important for communicating directly to end-users who are reviewing product choices at the point-of-purchase but also for developing effective DTC (direct-to-consumer) advertising. Without claims that adequately support the intended positioning and product superiority versus competitors, the switch launch will not be maximized.

It is important to note also that claims accepted by Rx health authorities are not automatically accepted by OTC health authorities. As such, an application must be well-planned and usually requires regulatory staff with switch application experience or use of a regulatory consultant with these skills.

2. Product differentiation is essential

A switch product needs to have a clearly defined point-of-difference in the OTC market where it will compete and is only likely to be successful if it can fill an unmet need of existing consumers. For switch products that are first in a category to go OTC, this is not usually a hurdle as they entail either a new technology or class of agent that provides superior benefits versus what is already available in an OTC market.

The strength of product differentiation will rely heavily on what claims have been approved for promotion and labeling, and underlines the importance of the regulatory effectiveness at earlier stages in the switch launch process. Claims integral to OTC success need to be identified in market research with consumers well before regulatory applications are submitted. Claim approval also requires appropriate clinical data available to support OTC claims. Companies who plan a switch with an Rx product well ahead can ensure that there is published data that supports use for the product for the OTC indications and uses sought.

> ***"Consumer brands focus on translating emotional benefits rather than the functional benefits traditionally communicated to physicians…..thus require an entirely different approach & competencies…."***

OTC switch products effectively become new consumer brands and require communications suited to self-selection and treatment. Consumer brands focus on translating emotional benefits rather than the functional benefits traditionally communicated to physicians. Effective DTC advertising of OTC switch products thus require an entirely different approach and competencies than those usually found in traditional mainstream Rx companies. Defining a clear 'consumer' proposition and translating this into effective communication is a task requiring experienced OTC marketers. Ideally though, these marketers can also understand the ramifications from an Rx sales point-of-view as well to ensure overall sales optimization.

While such marketers are not found easily, this capacity to understand both channels and the ramifications of a switch strategy can be an influencing factor in achieving an integrated campaign and sales success.

Other points of differentiation that can contribute to long-term success for OTC switch include packaging design: inclusion of recognizable elements that highlight key product positioning, benefits and link these to the Rx heritage. Strong, long-term planning can ensure that the Rx product starts to communicate these through packaging at a much earlier phase than when switch is imminent. This enables a smooth transition from Rx to OTC with packaging changes reflecting an evolution of communications rather than an abrupt change.

Product differentiation in OTC can also be strengthened by providing different formats for consumer use e.g. different pack sizes, liquid versus tablets etc.

This requires a well planned product pipeline that may or may not entail Rx-OTC switch for these formats.

Whatever differentiation approach is chosen, the strategy needs to be clear and integrated for external audiences as well as amongst internal parties involved. Long term planning is essential to ensure that there is sufficient time to achieve an integrated, holistic brand approach that is well thought out.

3. First-to-market is best

> ***" Ideally any switch product should aim to be the first in category launched into OTC….For switches not first-in-category, it is often harder unless they have a superior benefit that is well marketed versus the already switched products….."***

Ideally any switch product should aim to be the first-in-category launched into OTC. Historically, these switches are most likely to gain long-term advantages by launching first. For switches not first-in-category, it is often harder unless they have a superior benefit that is well marketed versus the already switched products. Although Teldane (Seldane) was the first OTC non-sedating antihistamine launched, achieving market leadership as a result; Claratin subsequently took market leadership by taking advantage of safety issues relating to Teldane at the time. Even so, first-to- market for an OTC switch can provide a strong head-start that can be difficult to penetrate for later switch products from the same category, despite the fact that they have superior benefits.

4. Build a robust demand model

One of most important tasks for a company pre-launch is estimating product demand. A demand model will need to be developed which makes assumptions about the sources of new product sales e.g. predictions about what sales volumes will be achieved from other Rx or OTC products and new users. This assessment will also include the proportion of current Rx brand sales that will be gained as part of new OTC sales, through cannibalization of sales. This will vary depending on the indication that is being promoted in OTC; and on organizational and marketing effectiveness of the company involved.

Other key modeling factors to consider may include the frequency of symptoms and treatments per year, units of product used per episode and how patients will use the treatment provided (full course, some or none of what is recommended). The demand model will need to reflect assumptions on consumer need for the new OTC product, their reactions to price and the impact on consumers of visiting a pharmacy for treatment versus a physician.

"*.. **Without DTC branded advertising, any new OTC product will be mostly reliant on pharmacist and physician recommendation to generate sales…..**"*

An understanding of professional recommendation behavior of pharmacists and physicians with the new product will also be critical to developing a robust model that covers all parameters. Development of any such model will rely heavily on qualitative and quantitative research. Aside from helping to establish veracity of modeling assumptions, research will be needed to gain a comprehensive understanding of the market and its dynamics, even more so if the OTC market is new or not well understood by the company.

The availability of DTC brand advertising is another key determinant in success and market development. Without DTC branded advertising, any new OTC product will be mostly reliant on pharmacist and physician recommendation to generate sales.

5. Professional Audiences should be consulted early

While it is assumed in most cases that pharmacists will be open to the idea of a new switch product, this is not always the case. In Australia, when the first emergency contraceptive product was switched to OTC, there was mixed reaction from pharmacists about its appropriateness in pharmacy and the issues surrounding its OTC scheduling. In addition, some switch products that were welcomed as new therapy options for pharmacist use, have been adopted slower than expected, due to reticence by pharmacists in changing current recommendation approaches or poor understanding of where the new therapy fits in. As key stakeholders, pharmacists should be consulted early by companies planning an OTC switch to identify any salient issues and to partner with key pharmacy bodies in developing effective pharmacy education programs. Previous successful switch programs have often included thorough pharmacist training on the product and category, prior to or in very early stages of the switch being launched. Orlistat (Roche), for example, provided intensive training pre-switch and post-switch which contributed to a fast adoption of the product by pharmacists as their first choice of treatment.

Physicians are also key stakeholders in the OTC switch process including both general practitioners as well as specialists. It is recommended to engage with both doctor groups early on in the planning process to assess their reactions to switch, gain endorsement for OTC use, and partner with to communicate appropriately to all involved health bodies about the OTC product's role in the therapy area indicated.

Specialist endorsement may be a critical factor in gaining switch approval in early stages by providing key opinion leader support to health authorities but their support may also be needed post-launch to mobilize other healthcare practitioner buy-in.

At general practitioner level, there will need to be clear communication about the roles of the new OTC product, where it fits into the remaining Rx portfolio (if one exists) and how the self-treatment approaches being implemented will address any concerns they may have about misuse, incorrect diagnosis or similar issues resulting from pharmacist recommendation and consumer self-selection and treatment.

6. Use an experienced, professional OTC sales force

For an established medium-large size OTC company switching a product Rx-OTC, selling and promotion can be handled usually by their own fieldforce. However, for an Rx only company planning an OTC switch, the decision can be much more complex. There are several possible fieldforce selling options some of which include establishing a licensing or distribution partnership with an OTC pharma company, starting up their own OTC business so they can market the OTC product themselves or using an external contract fieldforce. Each of these can also have numerous alternative scenarios. Some of the considerations for an Rx company may include whether:

- they want OTC switch sales reported in their business
- they are confident about allowing a third party marketing/selling organisation to have control of the same active they may be promoting to physicians
- an internal OTC division makes good strategic and business sense
- the switch is a one-off
- Suitable resourcing is available to support an OTC switch

OTC fieldforce competencies need to be sufficient to sell product benefits that may require technical explanation and provide category education to pharmacists. Selling OTC products into pharmacy also relies on having an established reputation with pharmacists and relationships that can be leveraged, to gain support for the new switch product. These factors are often hurdles for a new OTC division setup within a traditional Rx company, to launch a switch product.

The Rx salesforce also have a role to play in repositioning the OTC product to physicians versus other therapeutic options including the prescription part of the brand.

7. Build a team approach internally

Other factors that contribute to a successful OTC switch revolve around company culture and organizational effectiveness. In companies where the OTC switch is managed internally and the brand sits across multiple channels, there needs to be an integrated vision of the overall brand throughout the organisation.

Table One – OTC switch: seven success factors

Switch Success Factors	Key Actions Needed
Regulatory approval	• Safety data • Well-argued switch case • Claim approval • Clinical data to support OTC
Product differentiation	• Start when product has Rx status • Brand design elements linked to positioning • Identify point-of-difference for consumer market • Different product formats for product extension later • Unique consumer proposition
Timing	• Be first-to-market where possible • If not, need exceptionally strong point-of-difference
Estimating product demand	• Robust model • Research to validate assumptions
Professional audiences	• Seek input early • Identify potential issues • Comprehensive pharmacist training pre & post-launch • Selling programs that provide an integrated therapeutic approach
Fieldforce distribution	• Utilize both Rx & OTC salesforces • Technical training for OTC salesforce • Use experienced OTC salesforce
Integrated internal approach	• Set up Rx-OTC switch taskforce • Communicate internally about need for integration • Set combined goals & incentives • Plan well ahead

This requires a positive, ongoing relationship between Rx and OTC divisions and is a pre-requisite for successful Rx-OTC switch co-ordination in marketing and sales particularly. One approach to managing this is to form an Rx-OTC switch taskforce that has representatives from all involved areas and which is charged with integrating all aspects of the switch. Other methods to improve team approaches include developing shared goals and incentive programs, and to provide senior management endorsement by communicating company-wide on the need for an integrated approach to achieve success.

Reasons for failure with OTC switch

While there are myriad examples of successful Rx-OTC switches, there also exist examples of OTC switch failure or those that achieved below-expected results.

Many of these can be attributed to a few common factors either singly or in combination:

- The OTC switch occurred with no prior pharmacy training or education programs in place.

- There was no perceived need by consumers for the product as a self-selection treatment. This is particularly a risk with conditions where there is no visible or outward sign of symptoms or problems occurring from the condition; or when the ramifications of non-treatment are not well understood by consumers.
- Rx product switched to OTC had a small base of Rx users and declining equity as it was being switched.
- The third-party OTC company chosen for the switch launch did not provide adequate or effective promotional support for the product.

- The company launching the product did not have an understanding or experience in OTC and underestimated sales and promotional requirements.
- Individual OTC and Rx marketing & sales divisions were not integrated in launch approaches e.g. they focused on maintaining channel sales of their own brand instead of proactively promoting new sources of business.

Why OTC is not always the first option

Companies with patent expiration challenges may well decide that OTC is not a suitable strategic move for them for justifiable reasons. However, OTC switch is a life-cycle extension opportunity that is sometimes overlooked by traditional "Rx" dominated pharma companies as it is beyond their current paradigm. Marketing polarization towards one type of professional channel or another is still strongly embedded in some pharmaceutical company cultures, such that a brand is often only envisioned by marketing business units within their own area of expertise. Such silo thinking is not new and occurs regularly when a brand is deregulated in some way that results in a shift in brand guardianship to another division in charge of a different channel. Despite common belief to the contrary, an OTC switch does not always have negative consequences at the physician level. Usually, the original Rx product is unaffected by the switch regulatory changes – the product continues to be available to physicians without limitation. It is the potential switching of customers seeking a solution, from visiting the physician to the pharmacist (or supermarket in some places), and thence where the sales for this get credited, that creates internal company angst. Concerns on the part of Rx sales divisions about losing significant sales to another channel are often over-inflated.

However, negative feedback from physicians, alarmed at losing professional control of the medication, can also help sour the attractiveness of switching Rx-OTC to incumbent brand guardians within corporations. Instead of avoiding discussions with physicians about the product they have 'lost', a more positive approach for the Rx fieldforce is to proactively manage physician expectations and include them in providing the best therapeutic solution for their patients. Developing physician recommendation for the OTC product can also increase pharmacist comfort in using a new OTC product at the same time as reinforcing the superior efficacy of the existing Rx range that is still physician-only.

Well planned and integrated Rx-OTC tactical programs can help position the existing Rx products more clearly for serious conditions, while still allowing a doctor to recommend a low-strength or a short-term dose for a milder condition which a pharmacist can dispense. In this way, the Rx-OTC combined efforts can work synergistically to reap benefits for the entire brand, regardless of sales channel.

Summary

OTC switch is a viable alternative for many off-patent medicines including some that facing the patent expiry in the current financial climate. Launching an OTC product though is a specialized task, and one that will be more effectively implemented by experienced players in sales, marketing, regulatory and other key personnel. Although it is not always possible, planning should be made as far ahead as possible to implement the most integrated and optimized switch launch. Success factors for an effective OTC switch include:

- Gaining successful approval of critical claims for labeling and promotion
- Developing a healthy brand extension pipeline and effective communication platforms that clearly differentiate the new product for consumers versus existing treatments.
- Developing a robust demand model including all relevant influences
- Working proactively pre-switch with health professional bodies to identify hurdles and achieve a smooth launch
- Being first to OTC market wherever possible
- Use a professional OTC fieldforce that can handle technically sophisticated products and has established relationships they can leverage in pharmacies
- Integrate combined divisional sales and marketing approaches in a cooperative taskforce approach with senior management support

As healthcare costs continue to rise, the opportunity to move Rx status actives into deregulated markets will continue. It remains to be seen whether prescription pharmaceutical companies will be adopting OTC switch more often as one effective approach to extending brand life-cycle rather than accepting sales declines as part of the inevitable fallout from generic competition.

ABOUT OZ PHARMA CONTRACTING & CONSULTING

Oz Pharma Contracting & Consulting is a leading pharmaceutical marketing consultancy, based in NJ USA that provides **services** for the Pharmaceutical industry in the USA, Australia and other regions.

We work with clients to provide **Contracting Services** (Temporary Marketing help) for short term projects, vacancy gaps or **Consulting Services** such as feasibility studies, business plans, launch plans, divisional set-up etc. Our experience covers both OTC and prescription channels. Rx-OTC switches are just one area in which we are highly experienced. For more information on us visit: **www.ozpharmagroup.com**

ABOUT THE AUTHOR

Anne-Marie Watson is Senior Marketing Consultant and Principal of Oz Pharma Contracting & Consulting Inc. After a successful career in marketing and sales management across several blue-chip pharmaceutical/healthcare companies in Australia, Anne-Marie set up Oz Pharma to meet the short-term needs of pharma companies for urgently needed marketing resources. After seven years in Australia, Anne-Marie has relocated to New Jersey, where she has launched her US branch of the company called Oz Pharma Contracting & Consulting Inc. Anne-Marie writes regular articles and whitepapers and is a keen follower of social media. Her other interests include her family, reading, walking, archaeology and running two small businesses.

Contact Details: Oz Pharma Contracting & Consulting Inc.

Address: P.O. Box 5, Glen Ridge, NJ, 07028, USA.

Office Phone: 1-973-744-0297

Website: www.ozpharmagroup.com

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