Rx-to-OTC Strategies: Maximizing the Commercial Potential of an Rx-to-OTC Switch

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Providing you with:

• Overview of the Rx-to-OTC strategy, analyzing why, when, where, what and how to implement such a switch strategy

• Identification of drivers and resistors of Rx-to-OTC switching across the seven major pharmaceutical markets

• Case study analysis of the most recent Rx-to-OTC switches

Use this report to...

Identify the recent trends in the Rx-to-OTC market, including which are the most popular OTC indications, and who is implementing Rx-to-OTC switches
Introduction

With the growing cost of developing novel drugs, combined with the fact that fewer such drugs are gaining regulatory approval, the use of lifecycle management is playing an ever-more important role in the increasingly cost-conscious pharma industry. Rx-to-OTC switching is one such strategy employed to either enhance existing franchise revenues or protect branded revenues from generic competition.

Several key factors need to be considered before the implementation of an Rx-to-OTC strategy. Manufacturers need to carefully identify what products are suitable for an Rx-to-OTC switch, when in the lifecycle of the Rx product the switch should be initiated, and how to differentiate, price and position the OTC product.

Key findings and highlights

• For Rx-to-OTC switches to succeed, there needs to sufficient differentiation between the existing Rx drug and the new OTC product. However, differentiation must meet a genuine unmet need. Differentiation for the sake of it is unlikely to produce a winning Rx-to-OTC switch strategy.

• The volume of the OTC market is declining in the majority of the seven major markets. If this trend continues, it will not only impact the profits of OTC manufacturers, but also national cost-containment measures to reduce ever-escalating healthcare costs.

• At present, Rx-to-OTC switches in the five major EU markets are decided at a national level. However, despite ongoing discussions, there are numerous barriers to harmonized EU Rx-to-OTC switches. Consequently, it is unlikely that in the EU harmonization will happen at least in the foreseeable future.

Reasons to buy

• Identify the recent trends in the Rx-to-OTC market, including which are the most popular OTC indications, and who is implementing Rx-to-OTC switches

• Gain insight into the drivers and resistors of implementing Rx-to-OTC switches across the seven major markets

• Recommendations on how to maximize the commercial success of an Rx-to-OTC switch
**EXECUTIVE SUMMARY**

**Scope of the report**

**Key findings**

**OVERVIEW OF RX-TO-OTC SWITCHING**

- Why implement lifecycle management strategies?
- Classification of medicine types
- What is Rx-to-OTC switching?
- Why switch? - Drivers and resistors of Rx-to-OTC switching
  - Pharmaceutical companies - Drivers
  - Pharmaceutical companies - Resistors
  - Consumers - Drivers
  - Consumers - Resistors
  - Payers and Governments - Drivers
  - Healthcare professionals - Drivers
  - Healthcare professionals - Resistors
- What to switch? - Which products are targeted for Rx-to-OTC switching?
- Who is switching? - Which companies are the leading Rx-to-OTC switchers?
- What are the likely future Rx-to-OTC switches?
  - Zyrtec-D enters a crowded market
  - Trial run of Viagra OTC
  - Schering-Plough files for OTC Zegerid in the US
- When to switch? - When is the optimal time to implement an Rx-to-OTC switch?
- How to switch? - What are the US and EU regulatory processes?
  - Rx-to-OTC regulatory processes in the US
  - Rx-to-OTC regulatory processes in the EU
  - Marketing and promotion of switched products
  - The cost of switching
  - Selecting a price
- Summary of key Rx-to-OTC switch success factors

**RX-TO-OTC SWITCHING ACROSS THE SEVEN MAJOR MARKETS**

- Declining OTC usage across the seven major markets
- Overview of the US OTC market
  - US medicines classification
  - Market assessment of Rx and OTC classifications in the US
  - Drivers and resistors in the US market
  - BTC - A future switching option in the US?

**RX-TO-OTC CASE STUDY ANALYSIS**

- Overview of the Japanese OTC market
  - Japan's medicines classification
  - Market assessment of Rx and OTC classifications in Japan
  - Drivers and resistors in the Japanese market
- EU approach to Rx-to-OTC switching
- Overview of the UK Rx-to-OTC market
  - UK medicines classification
  - Market assessment of Rx and OTC classifications in the UK
  - Drivers and resistors in the UK market
- Overview of the German OTC market
  - Germany's medicines classification
  - Market assessment of Rx and OTC classifications in Germany
  - Drivers and resistors in the German market
- Overview of the French OTC market
  - France's medicines classification
  - Market assessment of Rx and OTC classifications in France
  - Drivers and resistors in the French market
- Overview of the Italian OTC market
  - Italy's medicines classification
  - Market assessment of Rx and OTC classifications in Italy
  - Drivers and resistors in the Italian market
- Overview of the Spanish OTC market
  - Spain's medicines classification
  - Market assessment of Rx and OTC classifications in Spain
  - Drivers and resistors in the Spanish market

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As healthcare costs continue to rise, the use of OTC medications will become an increasingly important part of healthcare systems, as payers look to contain costs by shifting the cost of medicines to the patient...
Rx-to-OTC Strategies

Maximizing the Commercial Potential of an Rx-to-OTC Switch

With the growing cost of developing novel drugs, combined with the fact that fewer such drugs are gaining regulatory approval year-on-year, the use of lifecycle management (LCM) is playing an ever-more important role in the increasingly cost-conscious pharma industry.

Rx-to-OTC switching is one such strategy employed to either enhance existing franchise revenues or protect branded revenues from generic competition. However, execution of the switch is crucial to the future success of the OTC product.

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Classification of medicine types

In the US, Japan, France, Germany, Italy, Spain, and the majority of other global pharmaceutical markets, two main classifications of medicine exist, as summarized in Figure 2:

- prescription medicines (Rx) – also referred to as prescription-only medicines (POM);
- over-the-counter medicines (OTC).

However, at present time in the US, there is ongoing discussion regarding the introduction of a new classification referred to as behind-the-counter (BTC) medicines. It is proposed that BTC products should be dispensed without prescription but under the direct supervision of a pharmacist. For more information on the proposal of the BTC classification, please refer to BTC – A future switching option in the US? in Chapter 3.
Table 2 summarizes the Rx-to-OTC switches in the US since 2001 by date of approval.

<table>
<thead>
<tr>
<th>OTC brand</th>
<th>Molecule</th>
<th>Company</th>
<th>Purpose</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monistat 3</td>
<td>miconazole</td>
<td>J&amp;J (McNeil)</td>
<td>Vaginal antifungal</td>
<td>February 2001</td>
</tr>
<tr>
<td>Monistat 1</td>
<td>miconazole</td>
<td>J&amp;J (McNeil)</td>
<td>Vaginal antifungal</td>
<td>June 2001</td>
</tr>
<tr>
<td>Lotrimin Ultra</td>
<td>butenafine</td>
<td>Schering-Plough</td>
<td>Topical antifungal</td>
<td>December 2001</td>
</tr>
<tr>
<td>Nicotrol TD</td>
<td>nicotine patch</td>
<td>Pfizer (now J&amp;J)</td>
<td>Smoking cessation</td>
<td>March 2002</td>
</tr>
<tr>
<td>Mucinex ER</td>
<td>guaifenesin</td>
<td>Adams Respiratory Therapeutics</td>
<td>Expectorant</td>
<td>July 2002</td>
</tr>
<tr>
<td>Claritin Syrup</td>
<td>loratadine</td>
<td>Schering-Plough</td>
<td>Antihistamine</td>
<td>November 2002</td>
</tr>
<tr>
<td>Claritin Reditabs</td>
<td>loratadine</td>
<td>Schering-Plough</td>
<td>Antihistamine</td>
<td>November 2002</td>
</tr>
<tr>
<td>Claritin-D</td>
<td>loratadine</td>
<td>Schering-Plough</td>
<td>Antihistamine/</td>
<td>November 2002</td>
</tr>
<tr>
<td>Claritin-D 24-hour</td>
<td>loratadine</td>
<td>Schering-Plough</td>
<td>Antihistamine/</td>
<td>November 2002</td>
</tr>
<tr>
<td>Prilosec</td>
<td>omeprazole</td>
<td>AstraZeneca</td>
<td>Acid reducer/PPI</td>
<td>June 2003</td>
</tr>
<tr>
<td>Pepcid AC Maximum Strength</td>
<td>famotidine</td>
<td>J&amp;J/Merck &amp; Co</td>
<td>Acid Reducer/H2 blocker</td>
<td>September 2003</td>
</tr>
<tr>
<td>Claritin Tablets</td>
<td>loratadine</td>
<td>Schering-Plough</td>
<td>Antihistamine</td>
<td>November 2003</td>
</tr>
<tr>
<td>Mucinex DM ER</td>
<td>guaifenesin + pseudoephedrine</td>
<td>Adams Respiratory Therapeutics</td>
<td>Expectorant/cough suppressant</td>
<td>April 2004</td>
</tr>
<tr>
<td>Mucinex D ER</td>
<td>guaifenesin + pseudoephedrine</td>
<td>Adams Respiratory Therapeutics</td>
<td>Expectorant/</td>
<td>June 2004</td>
</tr>
<tr>
<td>Zantac 150</td>
<td>ranitidine</td>
<td>GlaxoSmithKline</td>
<td>Acid reducer</td>
<td>August 2004</td>
</tr>
<tr>
<td>Lamisil Derm Gel</td>
<td>terbinafine</td>
<td>Novartis</td>
<td>Topical antifungal</td>
<td>July 2006</td>
</tr>
<tr>
<td>Plan B</td>
<td>levonorgestrel</td>
<td>Duramed</td>
<td>Emergency contraceptive</td>
<td>August 2006</td>
</tr>
<tr>
<td>MiraLAX</td>
<td>polyethylene glycol</td>
<td>Schering-Plough</td>
<td>Laxative</td>
<td>October 2006</td>
</tr>
<tr>
<td>Zaditor</td>
<td>ketotifen</td>
<td>Novartis</td>
<td>Antihistamine eye drop</td>
<td>October 2006</td>
</tr>
<tr>
<td>Alii</td>
<td>orlistat</td>
<td>GlaxoSmithKline</td>
<td>Weight loss aid</td>
<td>February 2007</td>
</tr>
<tr>
<td>Zyrtec</td>
<td>cetirizine</td>
<td>J&amp;J (McNeil)</td>
<td>Allergy</td>
<td>November 2007</td>
</tr>
<tr>
<td>Zyrtec-D</td>
<td>cetirizine + pseudoephedrine</td>
<td>J&amp;J (McNeil)</td>
<td>Allergy</td>
<td>November 2007</td>
</tr>
</tbody>
</table>

J&J = Johnson and Johnson; PPI = proton pump inhibitor

Source: Datamonitor adapted from Rx-to-OTC Switch List, 2007; [www.fda.gov](http://www.fda.gov) and [Ingredients & Dosages Transferred From Rx-to-OTC Status (or New OTC Approvals)](http://www.chpainfo.org) by the Food and Drug Administration Since 1975, 2007; [www.chpainfo.org](http://www.chpainfo.org)
Sanitation Council (PAFSC), part of the MHLW, proposed the implementation of a scheme to improve and speed up the Rx-to-OTC product transition. Figure 35 summarizes the key proposals set out by the PAFSC. This guidance should encourage and promote the implementation of Rx-to-OTC strategies in Japan.

**Figure 26: Enhanced Rx-to-OTC switch scheme proposed by the PAFSC, March 2007**

- **Rx status**
  - Academics from the pharmaceutical arena assess the applicability of products selected for an Rx-to-OTC switch
  - The summarized information is publicized and presented to HCPs of an academic society in the relevant medical field, who then assess the appropriateness of that switch
  - The summarized information and HCP opinion is presented to the PAFSC, which makes the final decision on whether to approve the switch

- **OTC status**

Source: Datamonitor adapted from JSMI Newsletter, 2007; [www.jsmi.jp](http://www.jsmi.jp)

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**Increased access to OTC products drives uptake**

In June 2006, a bill was passed to update the Pharmaceutical Affairs Law (PAL), revising the marketing system for OTC products, specifically improving the safety and risk management of these products. By April 2007, OTC drugs were classified into
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Boots
Bristol-Myers Squibb
Cantab
Caremark International
Chiesi
Chiron
Chugai
Daichi
Deutsche Morgan
Grenfell
Elan
Eli Lilly
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Flamel
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Genzyme
Gilead
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LEK
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Lundbeck
Merck KGaA
Merck & Co
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Nabi Biopharmaceuticals
Novartis
Novo Nordisk
Pfizer
Pharmachemie
Pierre Fabre
Pliva
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Ranbaxy
Recordati
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Schering AG
Schering-Plough
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