

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

Published: Jun-08

Product Code: DMHC2399

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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

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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

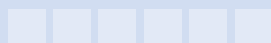


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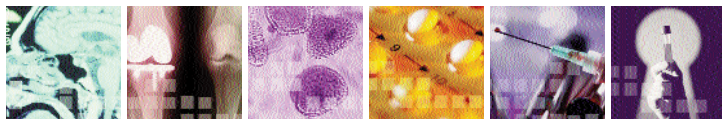
- **The varying success of GlaxoSmithKline's EU triptan Rx-to-OTC/pharmacy-only strategies**

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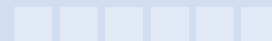
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"...As healthcare costs continue to rise, the use of OTC medications will become an increasingly important part of healthcare systems, as payers look to contain costs by shifting the cost of medicines to the patient..."



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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.

Reference Code: DMHC2399

Publication Date: 06/2008

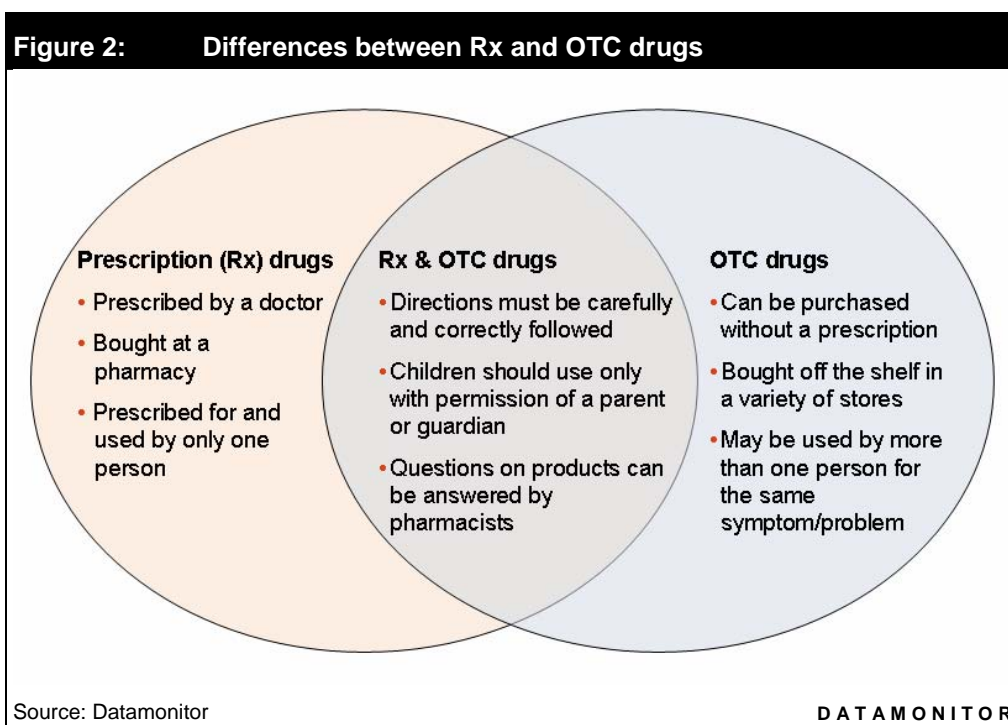
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Classification of medicine types

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.



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Table 2 summarizes the Rx-to-OTC switches in the US since 2001 by date of approval.

Table 2: Rx-to-OTC switches in the US since 2001				
OTC brand	Molecule	Company	Purpose	Approval Date
Monistat 3	miconazole	J&J (McNeil)	Vaginal antifungal	February 2001
Monistat 1	miconazole	J&J (McNeil)	Vaginal antifungal	June 2001
Lotrimin Ultra	butenafine	Schering-Plough	Topical antifungal	December 2001
Nicotrol TD	nicotine patch	Pfizer (now J&J)	Smoking cessation	March 2002
Mucinex ER	guaifenesin	Adams Respiratory Therapeutics	Expectorant	July 2002
Claritin Syrup	loratadine	Schering-Plough	Antihistamine	November 2002
Claritin Reditabs	loratadine	Schering-Plough	Antihistamine	November 2002
Claritin-D	loratadine	Schering-Plough	Antihistamine/ decongestant	November 2002
Claritin-D 24-hour	loratadine	Schering-Plough	Antihistamine/ decongestant	November 2002
Prilosec	omeprazole	AstraZeneca	Acid reducer/PPI	June 2003
Pepcid AC Maximum Strength	famotidine	J&J/Merck & Co	Acid Reducer/H2 blocker	September 2003
Claritin Tablets	loratadine	Schering-Plough	Antihistamine	November 2003
Mucinex DM ER	guaifenesin + pseudoephedrine	Adams Respiratory Therapeutics	Expectorant/cough suppressant	April 2004
Mucinex D ER	guaifenesin + pseudoephedrine	Adams Respiratory Therapeutics	Expectorant/ decongestant	June 2004
Zantac 150	ranitidine	GlaxoSmithKline	Acid reducer	August 2004
Lamisil Derm Gel	terbinafine	Novartis	Topical antifungal	July 2006
Plan B	levonorgestrel	Duramed	Emergency contraceptive	August 2006
MiraLAX	polyethylene glycol	Schering-Plough	Laxative	October 2006
Zaditor	ketotifen	Novartis	Antihistamine eye drop	October 2006
Alli	orlistat	GlaxoSmithKline	Weight loss aid	February 2007
Zyrtec	cetirizine	J&J (McNeil)	Allergy	November 2007
Zyrtec-D	cetirizine + pseudoephedrine	J&J (McNeil)	Allergy	November 2007

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

Source: Datamonitor adapted from Rx-to-OTC Switch List, 2007; www.fda.gov and Ingredients & Dosages Transferred From Rx-to-OTC Status (or New OTC Approvals) by the Food and Drug Administration Since 1975, 2007; www.chpa-info.org

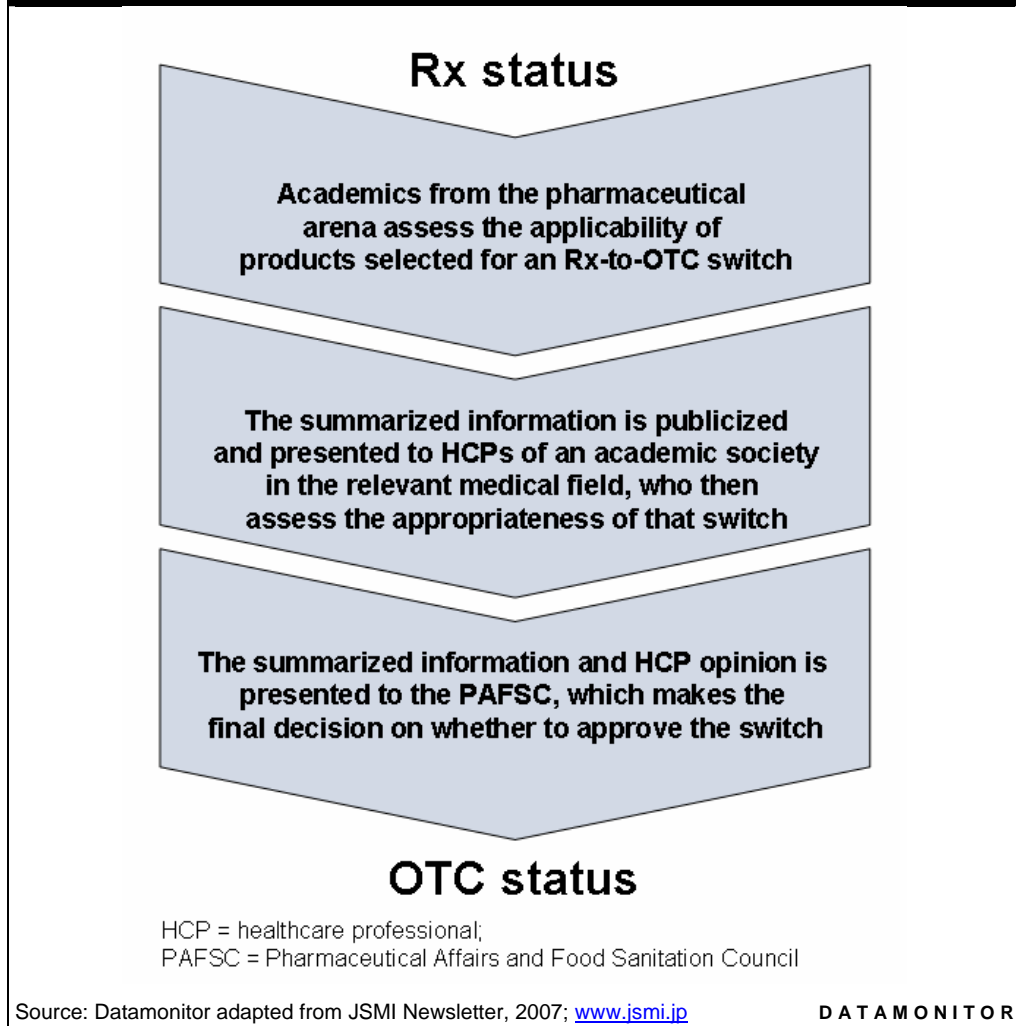
Rx-to-OTC switching across the seven major markets



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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



Increased access to OTC products drives uptake

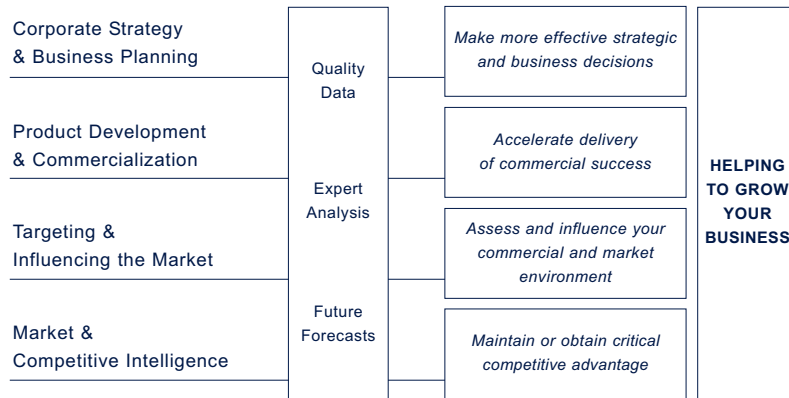
In June 2006, a bill was passed to update the Pharmaceutical Affairs Law (PAL), revising the marketing system for OTC products, specifically improving the safety and risk management of these products. By April 2007, OTC drugs were classified into

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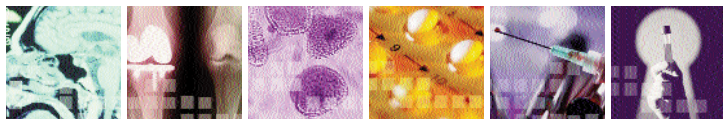
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