

# **Rx-to-OTC Switch Success Strategies & Opportunities**

**(252 pages)**

Definitions & methodology

**Foreword by Joseph McGovern** (2 pages)

**Introduction** (3 pages)

**Switch Learnings** (19 pages)

Reasons to Switch (5pp)

Switch is critical for growth of consumer health

9 of the world's Top 20 are switched products

*Global Top 20 OTC brands 2016*

Switch increases access to treatment

Potential stages in an Rx-to-OTC switch

Switch increases healthy outcomes

Healthy outcomes for NRT's self-care availability

Switch is a vital part of healthcare

Switch drivers (4pp)

Rising cost of healthcare

Pharmacy Point of care

Collaborative care

The rise of technology

Better educated consumers

Barriers to successful switch (4pp)

A challenging time for switch

Navigating the stages of access

The pros & cons of BTC status

Potential stages in a switch

Dual status

Lessons from difficult switches (5pp)

Zocor Heart-Pro

Flomax Relief

Oxytrol for Women

Zegerid OTC

Lipitor (did not switch OTC in US after failure of Actual Use Study)

Key lessons from difficult switches

**Switch Strategies** (28 pages)

The key to switch (1pp)

Switch checklist

Types of switch (2pp)

Different forms of switch

Complete switch: all indications and doses move from Rx to OTC

Dual status (a medicine is both Rx and OTC)

Collaborative care

The potential of pharmacies (2pp)

Community pharmacies may hold key to next generation of switches outside of the US

Geographical disparity in switch (1pp)

The big geographical divide

The issue of responsibility

Choosing the right brand to switch (4pp)

What to switch?

Researching the potential consumer

Evaluating the brand's OTC attractiveness

Consider the regulatory perspective

Commercial potential

Competitive landscape presently

Category growth potential

Ease of in-licensing

Competitive landscape in future

OTCs form a vital part of the healthcare system (1pp)

Building the case for switch – key points

Key strategies for successful switch (6pp)

Environmental management

Gain advocates / stakeholders

Case study: Alli Advisory Committee meeting (a regulatory success)

Make the public health case

Reach out to private healthcare providers

US Managed Care is a critical partner for switch

Consumer support programmes

Alli (GSK)

Nicorette (GSK)

Ten recommendations for switch (2pp)

Ten recommendations for switch (according to the EU)

Building a switch team (2pp)

Team setup

Core team

Regulatory & medical team

Marketing team

Supply team

Professional marketing team

Go-to-market team

The importance of marketing in switch (5pp)

Creating & building brands

Focus on claims or status?

Pepcid

Tagamet

Targeting the retailer

Launch and beyond (1pp)

Key steps before and after launch

## **Region by Region Analysis** (76 pages)

### Regional differences (2pp)

USA

Europe, Japan, Canada, Australia

Rest of world

Understanding your country system

### North America – Canada (3pp)

Canada

*Canada OTC sales mid-2016 & mid-2017*

Overview

OTC classification

Distribution

Switch process & developments

Recent switches in Canada

### North America – USA (5pp)

USA

*USA OTC sales mid-2016 & mid-2017*

Overview

OTC classification

Distribution

Switch process & developments

Recent switches in USA

FDA's PARADIGM SHIFT TO EXPAND NON-PRESCRIPTION ACCESS?

*USA Top 10 Rx-to-OTC switches since 2000 by sales mid-2017*

### Fundamentals of switching in the US (10pp)

A switch programme in the US must prove the consumer can...

Early communication is vital

Label development

Agreeing messages and how to communicate

Consumer studies

Label comprehension study

Self-selection study

Actual use study

Issues and challenges of actual use studies

Key principles of actual use studies

### Europe (2pp)

EU's Centralised Procedure for switch

Key centralised switches in the EU

### Western Europe – France (3pp)

France

*France OTC sales mid-2016 & mid-2017*

Overview

OTC classification

Distribution

Recent switches in France

Switch process & developments

### Western Europe – Germany (3pp)

Germany

*Germany OTC sales mid-2016 & mid-2017*

Overview

OTC classification

Distribution

Recent switches in Germany

Switch process & developments

Western Europe – Italy (3pp)

Italy

*Italy OTC sales mid-2016 & mid-2017*

Overview

OTC classification

Distribution

Recent switches in Italy

Switch process & developments

Western Europe – Spain (3pp)

Spain

*Spain OTC sales mid-2016 & mid-2017*

Overview

OTC classification

Distribution

Recent switches in Spain

Switch process & developments

Western Europe – UK (4pp)

UK

*UK OTC sales mid-2016 & mid-2017*

Overview

OTC classification

Distribution

Recent switches in UK

Switch process & developments

Patient Group Direction service allows pharmacist dispensing of certain Rx medicines

Western Europe (1pp)

Other regional developments

C&E Europe – Poland (4pp)

Poland

*Poland OTC sales mid-2016 & mid-2017*

Overview

OTC classification

Distribution

Recent switches (selected) in Poland

Switch process & developments

Analgesics

CCA

GIs

Derma

Lifestyle OTCs

C&E Europe – Russia (3pp)

Russia

*Russia OTC sales mid-2016 & mid-2017*

Overview  
OTC classification  
Distribution  
Recent switches in Russia  
Switch process & developments

Asia-Pacific – Australia (4pp)

Australia  
*Australia OTC sales mid-2016 & mid-2017*  
Overview  
OTC classification  
Distribution  
Recent switches in Australia  
Switch process & developments

Asia-Pacific – China (3pp)

China  
*China OTC sales mid-2016 & mid-2017*  
Overview  
OTC classification  
Distribution  
Recent switches in China  
Switch process & developments

Asia-Pacific – India (3pp)

India  
*India OTC sales mid-2016 & mid-2017*  
Overview  
OTC classification  
Distribution  
Recent switches in India  
Switch process & developments

Asia-Pacific – Japan (5pp)

Japan  
*Japan OTC sales mid-2016 & mid-2017*  
Overview  
OTC classification  
Recent switches (selected) in Japan  
Distribution  
Switch process & developments

Asia-Pacific – New Zealand (4pp)

New Zealand  
*New Zealand OTC sales 2012-16*  
Overview  
OTC classification  
Distribution  
Recent switches in New Zealand  
Switch process & developments  
Focus on Pharmacy Point of Care in New Zealand

Asia-Pacific – South Korea (3pp)

South Korea  
*South Korea OTC sales mid-2016 & mid-2017*  
Overview

OTC classification  
Distribution  
Recent switches in South Korea  
Switch process & developments

Latin America – Brazil (5pp)

Brazil  
*Brazil OTC sales mid-2016 & mid-2017*  
Overview  
OTC classification  
Distribution  
Recent switches in Brazil  
Switch process & developments  
*Ingredients proposed for switch to OTC status in Brazil 2017*

Latin America – Mexico (3pp)

Mexico  
*Mexico OTC sales mid-2016 & mid-2017*  
Overview  
OTC classification  
Distribution  
Recent switches in Mexico  
Switch process & developments

**Case studies of switched brands (86pp)**

**Abreva (GSK) (2pp)**

*Abreva OTC sales 2012-16*  
*Abreva OTC sales by market 2016*  
Key switch elements

**Advil (Pfizer) (2pp)**

*Advil OTC sales 2012-16*  
*Advil OTC sales by market 2016*  
Key switch elements

**Alesion (SSP / Sanofi) (2pp)**

*Alesion OTC sales 2012-16*  
Key switch elements

**Aleve (Bayer) (3pp)**

*Aleve OTC sales 2012-16*  
*Aleve OTC sales by market 2016*  
Key switch elements

**Allegra (Sanofi) (3pp)**

*Allegra OTC sales 2012-16*  
*Allegra OTC sales by market 2016*  
Key switch elements

**Alli (GSK) (3pp)**

*Alli OTC sales 2012-16*  
*Alli OTC sales by market 2016*  
Key switch elements

**Clamelle (Allergan) (2pp)**

Key switch elements

**Claritin (Bayer) (3pp)**  
*Claritin OTC sales 2012-16*  
*Claritin OTC sales by market 2016*  
Key switch elements

**Dexak (Berlin Chemie / Menarini) (1pp)**  
*Dexak OTC sales 2012-16*  
Key switch elements

**Differin (Galderma / Nestlé) (2pp)**  
Key switch elements

**Dovonex (Leo Laboratories) (1pp)**  
Key switch elements

**ellaOne (HRA Pharma) (2pp)**  
*ellaOne OTC sales 2012-16*  
*ellaOne OTC sales by market 2016*  
Key switch elements

**Flonase (GSK) (5pp)**  
*Flonase OTC sales 2012-16*  
*Flonase OTC sales by market 2016*  
The mechanics of Flonase's US Rx-to-OTC switch  
Key switch elements

**Formigran (GSK) (2pp)**  
*Formigran OTC sales 2012-16*  
Key switch elements

**Hascovir Control (Hasco-Lek) (1pp)**  
Key switch elements

**Lamisil (GSK) (2pp)**  
*Lamisil OTC sales 2012-16*  
*Lamisil OTC sales by market 2016*  
Key switch elements

**Loxonin S (Daiichi Sankyo) (2pp)**  
*Loxonin S OTC sales 2012-16*  
Key switch elements

**Maloff Protect (Glenmark) (2pp)**  
Key switch elements

**MaxOn Active (Adamed) (1pp)**  
*MaxOn Active OTC sales 2012-16*  
Key switch elements

**Meloxicam Adamed (Adamed), Mel (Hasco-Lek) (1pp)**  
Key switch elements

**MiraLAX (Bayer) (2pp)**  
*MiraLAX OTC sales 2012-16*  
*MiraLAX OTC sales by market 2016*  
Key switch elements

**Mucinex (RB) (3pp)**

*Mucinex OTC sales 2012-16*

Key switch elements

**Nasacort (Sanofi) (3pp)**

*Nasacort OTC sales 2012-16*

*Nasacort OTC sales by market 2016*

Key switch elements

**Nexium 24HR (Pfizer) (4pp)**

*Nexium 24HR OTC sales 2012-16*

*Nexium 24HR OTC sales by market 2016*

Key switch elements

**Nicorette (J&J, GSK) (2pp)**

*Nicorette OTC sales 2012-16*

*Nicorette OTC sales by market 2016*

Key switch elements

**Pepcid AC (J&J) (2pp)**

*Pepcid AC OTC sales 2012-16*

*Pepcid AC OTC sales by market 2016*

Key switch elements

**Plan B (Foundation Consumer Healthcare) (2pp)**

*Plan B OTC sales 2012-16*

*Plan B OTC sales by market 2016*

Key switch elements

**Prevacid 24HR (GSK) (2pp)**

*Prevacid 24HR OTC sales 2012-16*

Key switch elements

**Prilosec OTC (P&G) (2pp)**

*Prilosec OTC OTC sales 2012-16*

Key switch elements

**Rhinocort (J&J) (2pp)**

*Rhinocort OTC sales 2012-16*

*Rhinocort OTC sales by market 2016*

Key switch elements

**RiUP (Taisho) (2pp)**

*RiUP OTC sales 2012-16*

Key switch elements

**Silvasta (Douglas Pharmaceuticals) (2pp)**

*Silvasta OTC sales 2012-16*

Key switch elements

**Viagra Connect (Pfizer) (3pp)**

Key switch elements

**Volini (Ranbaxy / Sun Pharma) (2pp)**

*Volini OTC sales 2012-16*

Key switch elements



**Voltaren (GSK) (3pp)**  
Voltaren OTC sales 2012-16  
Voltaren OTC sales by market 2016  
Key switch elements

**Xenical (Roche) (2pp)**  
Xenical OTC sales 2012-16  
Key switch elements

**Xyzal (Sanofi, UCB) (3pp)**  
Xyzal OTC sales 2012-16  
Xyzal OTC sales by market 2016  
Key switch elements

**Zyrtec (J&J, UCB) (2pp)**  
Zyrtec OTC sales 2012-16  
Zyrtec OTC sales by market 2016  
Key switch elements

## **Looking Forward (26 pages)**

Introduction (1pp)

Potential switch areas – Analgesics (4pp)  
Migraine  
Osteoarthritis / rheumatism  
Others

Potential switch areas – Cough, cold & allergy (4pp)  
Allergy  
Cold & flu  
Topical decongestants

Potential switch areas – Gastrointestinals (2pp)  
Antacids  
IBS treatments

Potential switch areas – Derma (2pp)  
Antifungals  
Eczema & psoriasis  
Cold sore treatments

Potential switch areas – Lifestyle OTCs (12pp)  
Daily oral contraceptives  
Emergency hormonal contraception  
Erectile dysfunction  
Topical treatment of erectile dysfunction  
Cholesterol reduction  
Overactive bladder  
Opioid overdose  
Urinary tract infections  
Insomnia

**Conclusion (5pp)**

Key switch learnings  
10 key switch lessons