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
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 – Gastrointestinal (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