



11th Edition

# Rx-to-OTC Switch Pipelines USA: Competitive Assessment

Published: May 2015

Base Year: 2013 and 2014

Forecasts through: 2019 and 2020

Regional Coverage: ■ United States

This report provides subscribers with a comprehensive, objective assessment of Rx-to-OTC switch pipelines by company in the United States. This analysis includes assessments of prescription-only pharmaceutical companies, as well as pharmaceutical companies with both OTC and prescription units. The report provides details on recently approved switches and forecasts of future switches by company. Included in the forecasts are future switches in existing OTC categories and projected switches that would create new OTC categories.

## This Report Helps Subscribers to:

- Assess Rx-to-OTC Switch forecasts by company
- Analyze regulatory and retail paradigm shifts and implications for future switches
- Cast a wide-net analysis for uncovering potential licensing opportunities
- Benchmark one company's future switch potential against competitors

Features Kline's proprietary *FutureView* Forecasting model with sales forecasts by company.



# Report Contents

## Introduction

### Executive Summary

An executive briefing including the assessment of:

- Key trends and paradigm shifts
- Regulatory criteria for Rx-to-OTC switch
- Recent switches
- Corporate structures for Rx-to-OTC switch management
- Clinical study considerations
- Switch forecasts
- Conclusion

## Switch Pipelines by Company

Assessment of companies shown in Table 1 including assessments of future switches in existing OTC categories and those that may create new OTC categories, including overview of the condition, comparative analysis of prescription and OTC markets (where applicable), regulatory issues including patent expiration data, safety/efficacy, potential nonprescription indications and claims, likelihood of switch and expected timing, sales forecasts, expected competitive response from both branded and private-label products. Categories with potential switch candidates are shown in Table 2.

**Table 1: Companies Profiled**

Actavis
Astellas
AstraZeneca
Bayer Group
Boehringer-Ingelheim
Bristol-Myers Squibb
Chiesi USA
Galderma Laboratories
GlaxoSmithKline/Novartis
Johnson & Johnson
Meda Pharmaceuticals
Merck
Perrigo
Pfizer
Ranbaxy (Sun Pharmaceuticals)
Roche
Sanofi
Sunovion
Takeda
Teva
Valeant Pharmaceuticals

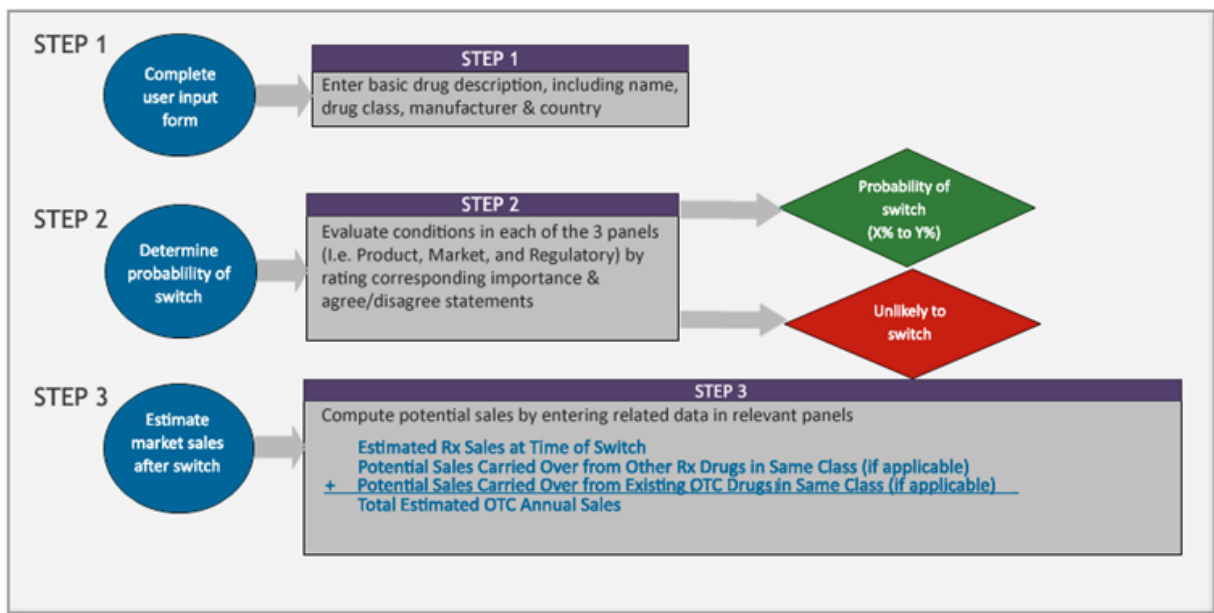
**Table 2: Categories with Potential Switch Candidates**

Acne	Erectile dysfunction
Allergy	Incontinence
Analgesics	Irritable bowel syndrome (IBS)
Antifungals	Migraine
Benign prostatic hyperplasia (BPH)	Oral contraceptives
Cholesterol	Osteoporosis
Digestives	Skin rash
Eczema	Sleeping aids



## FutureView Forecasting Model Contents

This report will include access to Kline’s proprietary and interactive *FutureView* forecasting model which is an Excel-based model accessed online. The model will provide Kline’s assumptions about the probability of switch and sales forecasts by company and therapeutic class. The assumptions in the model can be changed by users to revise sales forecasts or probabilities for companies and drugs included in this analysis or for other classes/drugs not profiled.



Rx-to-OTC Switch Pipelines USA: Competitive Assessment is the 11th edition in Kline's long running series of reports on Rx-to-OTC switch and seeks to examine future switch pipelines of OTC and prescription pharmaceutical companies. This report examines recent and future Rx-to-OTC switches by company in the United States. Each company's switch pipeline is analyzed on a case-by-case basis, and the forecast time horizon may differ for each.

For each company and drug class, this report provides:

- Prescription drug sales for 2013 and 2014
- OTC sales for 2013 and 2014 (where applicable)
- Assessment of market dynamics including patent expirations, generic competition, advertising and promotions, and regulatory issues
- Likelihood and timing of switches
- Likely OTC claims/indications
- Sales forecasts through 2019 or 2020; however, this may vary depending on various variables and are noted as such

## Key Benefits

Rx-to-OTC Switch Pipelines USA: Competitive Assessment is an extensive industry resource used by sales, marketing, and business development executives in the pharmaceutical industry for competitive analysis, market investigation, acquisition screening, business planning, and strategic purposes. The report provides a comprehensive, objective assessment of Rx-to-OTC switch pipelines by company in the United States, examines key issues and implications that switches can have on the existing OTC market, and identifies opportunities for future growth from switches. Accurately predicting Rx-to-OTC switches and assessing their competitive impact is crucial for maximizing business opportunities, minimizing threats, and successfully constructing long term strategic plans. Specifically, the report provides subscribers with the following key deliverables:

- Up-to-date primary research on switches conducted with knowledgeable industry participants
- An objective perspective on future switches by company
- Ability to cast wide net and uncover potential licensing opportunities
- Realistic assessment of paradigm shifts and future implications
- Identification of future switches by company, by identifying categories with high likelihood of switch, with what timing, and forecasting sales potential
- A tool to use to benchmark your business against those of competitors
- Access to Kline's proprietary and interactive *FutureView* forecasting model

## Methodology

Kline’s approach places principal emphasis on primary research techniques to ensure that the foundation of business intelligence and insight is accurate, current, and reliable. Building on our 50-plus years in the business and leveraging our worldwide network of offices, our teams of seasoned professionals draw upon pragmatic industrial and commercial experience to understand and interpret global impacts and local perspectives.

### Primary Research

#### We Know Who to Talk to. We Know How to Listen.



A high number of in-depth discussions are conducted by each analyst. All interviews are done with true industry insiders.

Kline’s analysts draw upon pragmatic experience to understand global impacts and local perspectives. Our interviews engage experts across all pertinent fields and sectors including:

- Executives in the OTC and prescription pharmaceutical industry
- Regulators
- Retailers
- Pharmacists
- Trade associations
- Consultants
- Attorneys

### Secondary Research

#### We Know Where to Look – Mining the Details.



Analysis is further supplemented by secondary research, consisting of constant tracking of regulatory information obtained from the FDA and trade associations, patent searches annual company reports, national statistics bureaus, trade/industrial/professional associations, and the like.

Relevant developments are diligently followed and their impact closely monitored. Reports also draw upon non-confidential data from Kline’s internal database, consisting of over half a century’s syndicated research.

### Comprehensive Market Intelligence

#### We Know How to Verify.



Data are rigorously analyzed, cross-checked, distilled, and validated. Kline’s proven methodology allows exceptionally effective, precise, and reliable market

intelligence procurement and assessment, giving subscribers a solid foundation on which to grow, refine, and expand their business with confidence.

## Kline Credentials

Kline is a leading global management consulting and market research firm offering the complete spectrum of services. The firm has served the management consulting and market research needs of organizations in the chemicals, materials, energy, life sciences, and consumer products industries for over 50 years.

#### A FULL SPECTRUM OF SERVICES



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