



## OTC Opportunities in Europe, the US and Japan

Key trends, leading players and  
future Rx-OTC switching



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## Report overview

The developed OTC markets such as the US and UK are heavily reliant on Rx-to-OTC switching of "new generation" products as a means of generating growth. Switching also plays an important role for less-developed markets (e.g. France, Spain, Italy, Japan), though in this case they are playing "catch-up" with the more developed markets.

The "Power of Switch" was brought into sharp focus in 2009 with the first ever use of the centralized procedure for switching products throughout the European Union. This comprehensive report provides background on market dynamics (including overall market size and therapeutic category size) for each of the core countries under analysis.

This report also examines products and categories that are likely to be switched in the future, regulatory changes that are likely to impact the OTC market, and provides growth forecasts to 2013. Included in the report are case studies for two of the most significant switches of recent years – i.e. Alli (orlistat) and Zocor (simvastatin).

**Pages** 125

**Figures** 16

**Tables** 13

This report provides a comprehensive analysis of recent trends and developments in the OTC markets in each of the selected major countries...

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## Key findings



**OTC market expansion is being fuelled by Rx-to-OTC switching** in the seven key markets.



**The success of new-generation switches often relies on a collaborative care model**, involving co-operation between consumers, doctors and pharmacists.



**The collaborative care model could potentially be used as a basis for switching products for treating conditions such as asthma, hypertension, hyperglycemia and osteoporosis.** There is also scope for switching products for treating conditions for which the timing of treatment is critical: for example, adrenaline injectors containing epinephrine and antivirals such as Roche's Tamiflu (oseltamivir).



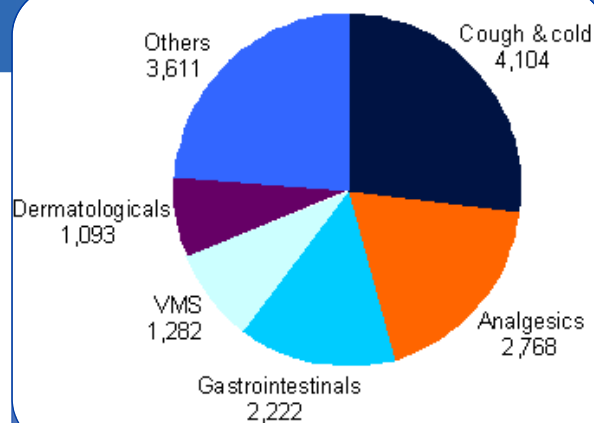
**Although each region is faced with its own regulatory challenges**, the situation is particularly complex in Europe owing to the problems involved in reconciling national laws with EU-wide regulations.



**Over the past couple of years, Japan's government has actively encouraged Rx-to-OTC switching**, as a means of cutting its national health insurance bill.



**Prevailing economic conditions are likely to dampen OTC sales throughout the seven main countries over the next few years.** For each of the countries under review, the annual growth rate over the next few years will struggle to rise above low single digits.



**Figure 3.10: US OTC sales (RSP \$m) by major therapeutic market, 2008**

"In terms of products, the US OTC market is characterized by a large number of private labels and generics, which have inevitably exerted a downward impact on prices. In keeping with this, mass market outlets account for over 40% of overall sales, which is a considerably higher proportion than in most other countries..."

## Use this report to...

- **Gain a clear and concise understanding** of the dynamics of the global OTC market.
- **Gain an understanding** on how the dynamics of the OTC markets in the various countries differ widely and how they relate to each other.
- **Identify and examine** examples of successful switches, which can be used as a model for future switches.
- **Discover switches that failed** and examine possible causes for failure.
- **Predict what switches are likely to take place in future;** and take into account other regulatory changes that are likely to take place.
- **Plan ahead**, in light of likely OTC market growth forecasts.
- **Gain insight into** stakeholder attitudes to switch (i.e. consumers, regulators, pharmacists and doctors).

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## Key issues...



**In 2008, the global pharmaceutical market grew by 4.8%**, while the global OTC market grew by 7.6%.

Although OTC growth in recent years has been driven by emerging markets such as China and Eastern Europe, the developed markets of North America, Western Europe and the Pacific Rim together account for over 50% of global OTC turnover.



**Although most Rx-to-OTC switches are driven by manufacturers;** governments around the world

increasingly view Rx-to-OTC switching as a means of relieving pressure on overburdened health insurance systems.



**Throughout the world, access to OTCs is increasing. In some countries, the increased access is**

**derived mainly from pioneering switches from Rx-to-OTC;** while, in others, the increased access is derived mainly from the opening up of distribution channels and from an easing of advertising restrictions.



**Many new switches are part of the so-called collaborative care model,** whereby consumers rely

heavily on the advice of pharmacists (or other healthcare professionals) in making their OTC purchases. On the basis of this collaborative care model, many new products and indications are likely to become available OTC.



**Japan has traditionally had a highly regulated OTC market, with all registered OTCs restricted to**

**pharmacy sale.** However, following a major regulatory shift in mid-2009, many OTC products are now permitted to be sold in the mass market. This has led to heavy discounting at the retail level, which has contributed to a decline in value sales.

## Discover...

- What opinion do various stakeholders (i.e. consumers, regulators, manufacturers and healthcare professionals) have on Rx-to-OTC switches?
- How will regulatory developments affect the development of the OTC market?
- What does the future hold for the global OTC market?
- What trends are emerging in the OTC market?
- What Rx-to-OTC switches might there be in the future?
- What lessons can be learned from previous Rx-to-OTC switches?
- Why have some previous Rx-to-OTC switches failed?

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