

Assessing the OTC market in France

While Rx to OTC switching has the potential to increase sales and lengthen life-cycles, experience in France suggests that success with this strategy may not come easily. Jean-Michel Peny explains.

As the pressure on reimbursed drug prices in most Western countries increases, the lure of a market where prices are generally free and volume growth is not limited has prompted many pharmaceutical companies to take a greater interest in over-the-counter products. Indeed, some major research-based companies such as Bristol-Myers Squibb, Smith-Kline Beecham and Roche have made acquisitions to reinforce their presence in this sector. But the absence of price and volume controls does not necessarily mean that the over-the-counter market is attractive in terms of profitability and sales prospects.

In common with the over-the-counter (OTC) markets of most other European countries, the French OTC market has not grown as rapidly as expected and prospects for the near future do not look much brighter. Pharmaceutical companies planning to enter this sector or to strengthen their position in it should therefore carefully assess its current attractiveness and future opportunities. In addition, before proceeding with prescription to OTC (Rx to OTC) switches of particular brands, they should ensure, firstly, that the move will pay off and, secondly, that they have the competencies to succeed in the OTC sector.

It is important to define clearly what OTC means in the French context. An OTC product is a registered drug that can be bought without a prescription and is not reimbursable by health insurers, even when it has been prescribed. OTC is in fact an improper term in the French market, since regulations require drugs to be kept behind the pharmacy counter. There is often a confusion between the OTC market as defined above and the self-medication market. The latter also

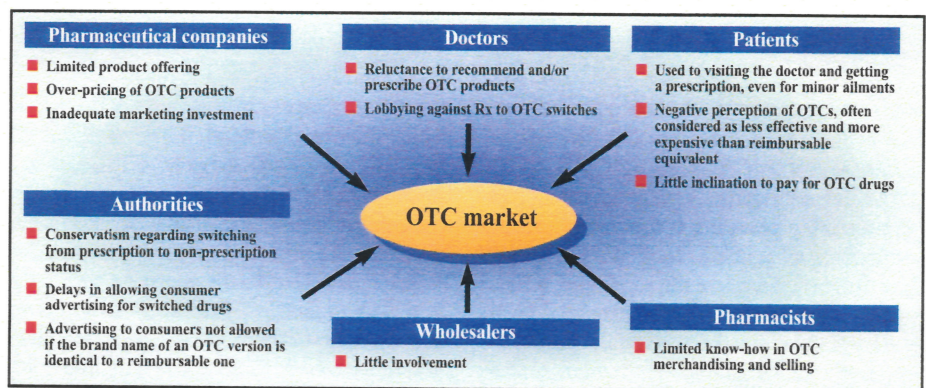


Figure 1: Major barriers to the development of the OTC market in France. Source: ADL analysis.

includes self-medicated semi-ethicals which, although they can be bought without a prescription, are reimbursable when prescribed.

Market attractiveness

In 1996, total sales in the French pharmaceutical retail market were US\$15.1 billion*, of which self-medication products accounted for US\$2.6 billion. Of the latter, sales of OTC products were US\$1.2 billion (46% of the total self-medication market) with self-medicated semi-ethicals accounting for the remaining US\$1.4 billion.

Both the total retail sector and the self-medication market as a whole grew by 2% in the 1995-1996 period while the compounded annual growth rate (CAGR) for 1992-1996 was 5% for the retail market and 4% for the self-medication segment. Within the self-medication market, however, the picture is less consistent. In 1995-1996, sales of self-medicated semi-ethicals rose by 1% and those of OTCs by 4% but for 1992-1996, the CAGR was 8% for self-medicated semi-ethicals while OTC sales remained stagnant.

There are various reasons for this lack of growth in the OTC sector. They are economic, regulatory and cultural in nature and

cover the whole spectrum of the healthcare system from the regulatory authorities through to the patient, as shown in Figure 1. Part of the problem is that pharmaceutical companies currently have only a limited range of OTC products on offer and their investment in marketing is usually inadequate. In addition, OTC players tend to overprice their products, which are often two to three times more expensive than the equivalent reimbursable semi-ethicals.

Compared with other European countries, the French authorities have been more conservative in granting permission to launch OTC versions of prescription-only drugs. For example, OTC ibuprofen only became available in France in 1992, nine years after it was launched in the UK. Moreover, after a product has been made available OTC it has often taken several years for permission to be granted for advertising on television and in newspapers or magazines. Loperamide, for example, obtained its consumer advertising licence in 1996, four years after it entered the OTC market. Another limiting factor is that companies are not allowed to promote an OTC product to consumers under the same name as the reimbursable form. Thus, in order to be allowed to com-

*Average exchange rate: US\$1 = Fr5.1.

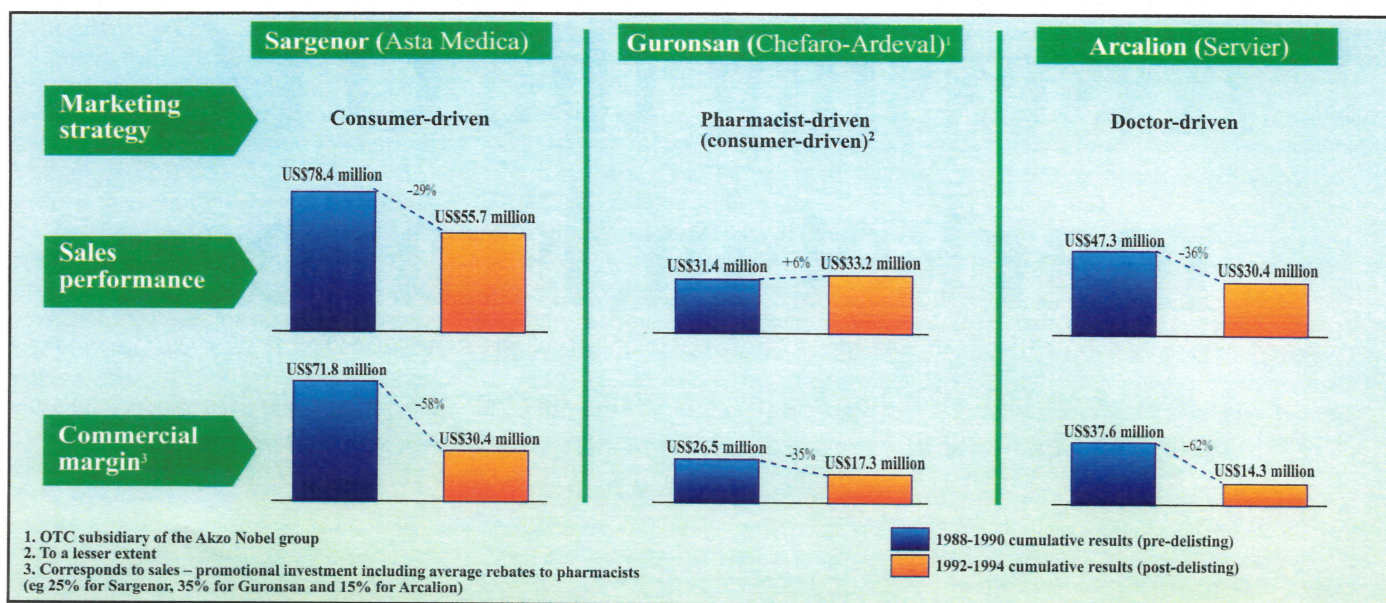


Figure 2: A comparison of the results of the marketing strategies used in the complete switching of three anti-asthenics. Source: IMS, Dorema, Secodip – ADL analysis.

communicate to patients, SmithKline Beecham had to launch its OTC version of Tagamet under the name of Stomedine.

As far as doctors are concerned, supporting OTC products is against their own interests. As French practitioners receive a fee for every consultation, their income suffers when patients self-medicate. There is certainly a link between this issue and the fact that a union of French gastroenterologists recently opposed the launch of OTC versions of H₂-antagonists. Moreover, doctors regard the great majority of OTCs as second-class medicines, with no real therapeutic value.

For their part, patients are used to visiting a doctor and being given a prescription, even for minor ailments. They have only a limited knowledge of self-medication and tend to regard non-reimbursable products as expensive and ineffective in comparison with reimbursable drugs, either ethicals or semi-ethicals. The development of a thriving OTC market has also been limited by pharmacists' lack of know-how in merchandising and selling these products.

Long-term development

The combination of these obstacles appears strong enough to prevent the OTC market from growing significantly before the year 2000. However, recent changes in the business environment may boost its development in the longer term.

For instance, the recent switching of some major prescription products has brought a number of new and effective products into the OTC sector, including Hextril, Zovirax/Activir, Imodium/Imossel, Tagamet/Stomedine and Pepidine/Pepcidac. And the budget cap imposed early this year

on doctors' prescribing of reimbursed drugs may make them more inclined to prescribe OTC products rather than reimbursed equivalents.

Both patients and pharmacists also now seem to be more receptive to OTCs. Patients are becoming more knowledgeable and appear to be eager to play an active role in the management of their health, within the limits of reasonable cost, while pharmacists have begun to appreciate that they have an economic interest in expanding their OTC business. Prices of OTC products are free, there is no ceiling on growth and, if rebates given by pharmaceutical companies are included, margins are two to three times higher than for reimbursed drugs. OTCs also offer pharmacists an opportunity to increase customer loyalty, provided they can deliver value-added information and advice for minor ailments.

The authorities also appear to be softening their stance. Since 1996, approval procedures for Rx to OTC switching have been relaxed and it has been easier for companies to gain permission to advertise to consumers in all media. This has applied to Stomedine, Pepcidac, Hextril and Activir.

In a move that could give a considerable boost to the OTC market, the government may be tempted to remove from reimbursement the categories of semi-ethicals recommended for less severe pathologies (phlebotonics, expectorants, laxatives, etc) or those whose efficacy is questionable. Such a measure would, in theory, be a very attractive way of curbing the drugs bill. Delisting of these products would save US\$1 billion a year with phlebotonics alone accounting for US\$370 million. However, such a measure has two major drawbacks which explain

why, since 1991, successive French governments have been reluctant to implement it. Firstly, past experience has shown that in these circumstances patients press doctors to prescribe a reimbursed substitute for the delisted drugs. Thus when psychostimulants were delisted in 1991, the consumption of high-priced anti-depressants such as serotonin re-uptake inhibitors increased considerably. Secondly, as drug delisting primarily affects low-income patients, governments are unwilling to adopt a measure that would inevitably be politically unpopular.

Rx to OTC switching

With 50% of the French OTC market controlled by ten pharmaceutical companies in 1996, the sector is fairly competitive. Roche is the current market leader with annual sales of US\$83 million, followed by SmithKline Beecham (US\$65 million) and Rhône-Poulenc Rorer (US\$63 million). But while the operating margin for prescription drugs averages 25%-30% of sales, for OTC products the margin is closer to 15% or even lower. This inevitably limits the attractiveness of the market and the situation is unlikely to improve significantly before the end of the decade. However, Rx to OTC switches do offer opportunities to extend the life-cycle of some ethical or semi-ethical drugs.

Rx to OTC switches are either complete or partial. In the first case, the product is completely transferred from the prescription to the OTC market. This type of switch may result from a delisting imposed by the authorities, as when tonics were delisted in 1991, or from a strategic decision made by a pharmaceutical company, such as Pharmacia-Upjohn's decision in 1996 to market

Nicorette gum as an OTC product. In the case of partial switches, companies voluntarily add to an existing prescription drug an OTC version which may have either the same brand name (eg Nurofen by Boots Healthcare in 1992) or a different one (eg Imodium/Imoscel by Janssen-Cilag in 1992 and Actifed/Sudafed by Warner-Wellcome in 1991). These variants of partial switching are known respectively as 'hybrid' and 'twin-track' switches. The success of the various types of switch can be assessed using case studies.

Complete switches

In 1991, when the French government deleted anti-asthenics from the reimbursement list, their sales dropped by 27% in value and 36% in volume. Four years after the delisting, the value of annual sales had been halved and sales volume had fallen by 75%. The pharmaceutical companies concerned reacted by adopting three different marketing strategies:

- The consumer-driven approach, oriented towards direct communication to consumers (eg Sargenor from Asta Medica).
- The pharmacist-driven approach, leveraging pharmacists' ability to counsel patients (eg Guronsan from Chefaro-Ardeval).
- The doctor-driven approach, capitalising on doctors' prescribing habits (eg Arcalion from Servier).

A comparison between the pre-delisting period (1988-1990) and the post-delisting period (1992-1994) shows that sales of Guronsan rose by 6% while those of Sargenor and Arcalion fell by 29% and 36% respectively (see Figure 2). In 1991, the year of de-reimbursement, the price of Sargenor

increased by 58% for drinkable ampoules and 20% for tablets, and subsequent annual increases averaged 2%-5%. Arcalion and Guronsan prices followed the same pattern with increases of 39% and 47% respectively in 1991, and 3% and 5% in subsequent years. During the 1992-1994 period, for one US dollar invested in promotion, Sargenor and Guronsan generated sales of US\$2.5, whereas Arcalion achieved only US\$2.0. The estimated commercial margins (ie annual sales minus promotional investment, including rebates to pharmacists) fell by 62% for Arcalion, 58% for Sargenor and 35% for Guronsan between the pre- and post-delisting periods 1988-1990 and 1992-1994.

Thus Guronsan, which was positioned mainly as a pharmacist-driven OTC, has performed better in terms of sales and profit growth than either Sargenor and Arcalion. This may be partly explained by the fact that, prior to delisting, a higher percentage of Guronsan's sales came from self-medication (54% against 37% for Sargenor and 27% for Arcalion). The doctor-driven approach, followed by Arcalion, appears to be more expensive and less productive than the other two alternatives. In the strict sense, the doctor-driven approach should not be considered as an Rx to OTC switch since the product remained positioned as a prescription drug.

Hybrid switches

A good example of a hybrid switch is the launch by Boots Healthcare in 1992 of an OTC version of its reimbursed prescription-only product, Nurofen (ibuprofen), under the same brand name. The move was part of a strategy to optimise Nurofen's life-cycle in France. To obtain OTC status,

the company had to market its 200mg tablets in packs of 20, whereas the prescription-only version is sold in packs of 30 tablets. The public price of the OTC pack was not significantly different from the prescription one (US\$3.76 against US\$3.51), but the price per tablet increased by 40% (US\$0.18 against US\$0.13). Authorisation to communicate directly to consumers was granted three years after the switch but, because both the OTC and the reimbursable ethical versions were being commercialised under the same name, Boots Healthcare could not take advantage of this.

Launching an OTC version enabled Boots Healthcare to generate extra sales which helped to widen Nurofen's advance over its major competitor, Advil (Whitehall-American Home Products). In 1991, before the switch, Nurofen's sales were US\$4.1 million, 26% higher than Advil; three years later they were 40% higher at US\$8.6 million. Between the pre-switch period (1989-1991) and the post-switch period (1992-1994), total Nurofen sales (prescription plus OTC) increased by 133%, from US\$9.4 million to US\$21.9 million, as shown in Figure 3. To achieve this, Boots Healthcare increased its promotional investment (including rebates to pharmacists) by just 39%. As a result, Nurofen's commercial margin has grown by a factor of six, from US\$2.0 million to US\$12.4 million.

Twin-track switches

Two types of twin-track switching can be identified (see Figure 3). The first is illustrated by Janssen-Cilag's (Johnson & Johnson) launch in 1992 of an OTC version of its anti-diarrhoeal product Imodium

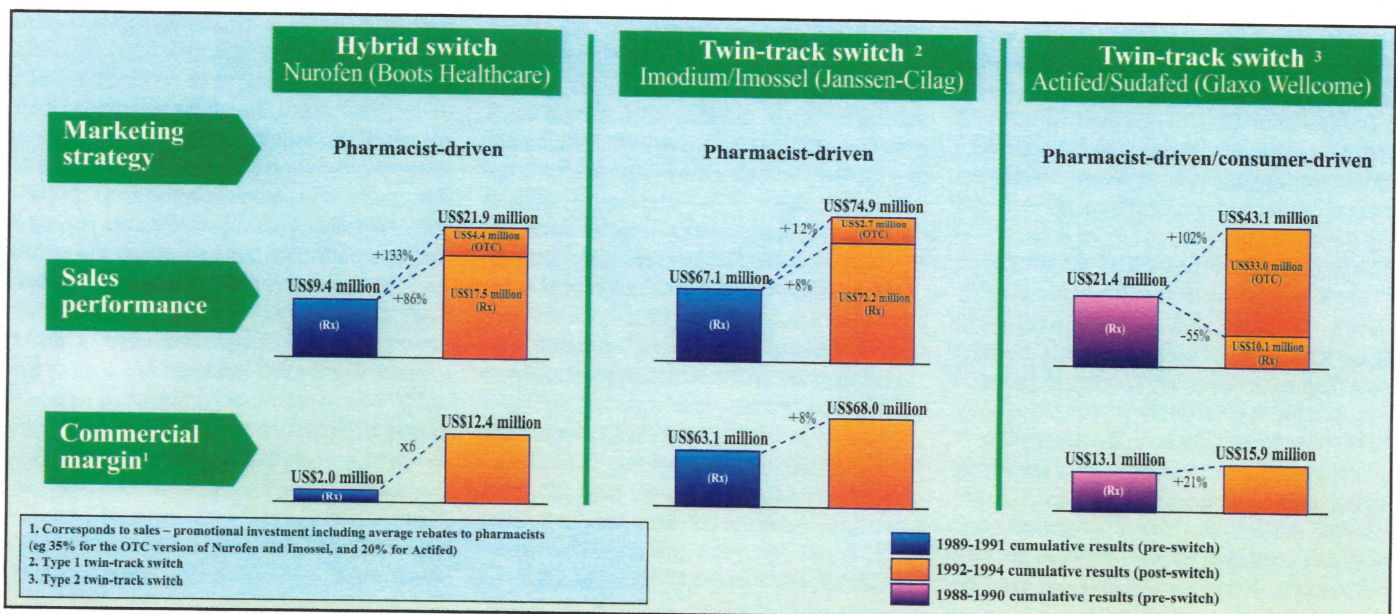


Figure 3: An analysis of the performance of the three types of partial switches. Source: IMS, Dorema, Secodip - ADL analysis.

(loperamide) under the name of Imossel. To obtain the right to enter the OTC market with this product, Janssen-Cilag had to reduce the number of tablets in each pack from 20 to 6. Both packs are marketed at a similar public price. Thus the price per tablet is three times higher for Imossel than for Imodium and many pharmacists have complained that they have difficulty in justifying this premium to their customers.

While total sales of Imodium and Imossel increased by 12% (US\$74.9 million against US\$67.1 million) between the pre-switch (1989-1991) and post-switch (1992-1994) period, the global commercial margin improved by only 8% (US\$68.0 million against US\$63.1 million). The modest results obtained by Imodium/Imossel, as shown in Figure 3, may be explained partly by the pricing difficulties and partly by a level of promotion that was inadequate to establish a new brand successfully.

The second type of twin-track switching is exemplified by Actifed. In this case, a complete switch was carried out with the simultaneous launch of a reimbursable semi-ethical, called Sudafed. Unlike Actifed, which contains pseudoephedrine, paracetamol and triprolidine, Sudafed contains only pseudoephedrine. In 1991, when Actifed was switched, its unit price doubled, but subsequent price increases remained below 5%. During the post-switch period (1992-1994), the combined sales of Actifed and Sudafed reached US\$43.1 million, which represented a 102% increase as compared with a pre-switch period (1988-1990). In 1992-1994, the cumulative promotional investment for Actifed amounted to US\$10.4 million compared with US\$8.2 million in 1988-1990.

To establish Sudafed on the prescription market, US\$16.9 million was invested during 1992 to 1994. However, the overall commercial margin of Actifed/Sudafed has improved by 21%, from US\$13.1 million to US\$15.9 million (see Figure 3). Actifed has benefitted from the extensive brand-name awareness built up when it was a semi-ethical.

Key success factors

The majority of OTC products introduced in France in the 1990s have come from Rx to OTC switches. However, these switches have enjoyed varying degrees of success and it is possible to identify a number of key factors that can influence this.

Success depends primarily on the ability of the pharmaceutical company to:

- Be first in the market, by good up-front planning and good coordination between the ethical and OTC divisions (eg development, registration, manufacturing, marketing, etc).
- Adjust the product offering (eg formula-

tion, packaging, pricing) to consumer needs.

- Capitalise on a strong prescription brand and/or product heritage (eg consumer communication).

- Maintain good commercial relationships with retail pharmacists in terms of service quality, competitive rebates, etc.

In the case of complete switches, resulting from government delisting, the 'doctor-driven' approach appears to be less successful than the consumer-driven or pharmacist-driven alternatives, although, as shown by the anti-asthenics case study, the pharmacist-driven approach may provide better short-term results.

As a rule, the voluntary transfer of a brand from reimbursable prescription status to non-reimbursable OTC status should be avoided given the deleterious impact on product sales and margins. There are however some cases where this strategy may make sense. For example, in 1981 SmithKline Beecham negotiated with the French authorities for a proactive delisting of Synthol in return for a free pricing agreement, in order to restore the product's profit margin, and in 1996 Pharmacia & Upjohn obtained approval to switch Nicorette gum from non-reimbursed prescription to OTC status. This allowed Pharmacia & Upjohn to use television and press advertising to maximise its brand awareness with customers, a strategy which led to a doubling of Nicorette gum sales in less than a year. There are good reasons to believe that the Drug Pricing Committee is becoming more willing to trade-off more favourable prices for new or existing products in return for complete switches.

For partial switches, the best performances have been achieved when companies have launched an OTC version with the same brand name as the existing prescription version, as in the case of Nurofen and Actifed. By entering the OTC sector through partial switches, either hybrid or twin-track, pharmaceutical companies expect to expand the market for their existing ethical or semi-ethical products. This approach can also form part of a generic defence strategy¹. However, as has been seen with Nurofen and Imodium/Imossel, the additional sales and profits generated by these OTC versions are in general limited and, consequently, switching is often difficult to justify in strategic and economic terms.

The most successful OTC players are characterised by their ability to build up strong brand names, and by their patience. The time required to establish a leading OTC brand name is very long. The top 20 brands in the French OTC market are on average more than 32 years old, compared with 16 years in the prescription market,

and household names like Procter & Gamble's Vicks Vaporub and SmithKline Beecham's Synthol were launched 47 and 72 years ago respectively. OTC companies therefore need to take a long-term perspective in setting their strategic objectives.

Uncertain prospects

Companies with the opportunity to switch products, but no operation in the OTC market, could either start from scratch or ally with an OTC company. But OTC and prescription competencies are too different, and brand-building too slow a process, for pharmaceutical companies to enter the OTC business on their own. The preferred approach seems therefore to subcontract the commercialisation of 'switchable' products to an OTC company. This is the option chosen by Glaxo Wellcome, whose Actifed and Activir (the OTC version of Zovirax) are currently marketed in France by Warner-Lambert.

While the OTC market in France does offer opportunities for companies to increase sales and extend product life-cycles, it must be recognised that this sector is around five times smaller and 40% less profitable than the retail prescription market. Moreover, the OTC market is unlikely to grow significantly before the year 2000 whereas retail prescription sales are expected to increase by an average of 3% per year. In addition, the payback time for an OTC company acquisition or new product introduction is around ten years, whereas five years is common in the prescription business (excluding generics).

Pharmaceutical companies contemplating entering or strengthening their position in the French OTC market cannot ignore the fact that this business is structurally less attractive than the prescription business. Consequently, any significant move, such as an acquisition or a joint venture, should be motivated by a firm strategic intent to play a leading role in the sector over the long term. Irrespective of the increasing economic constraints on public healthcare spending in France, as in all major markets, the fact remains that one dollar invested in the reimbursable prescription market will, for the foreseeable future, generate a better and faster return than a dollar invested in the OTC market. SM

Reference

1. J-M.Peny et al. 'Are generic defence strategies worth the effort?', *Scrip Magazine*, June 1996.

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