

Should big pharma

One major R&D-based player has already got out of the over-the-counter market. Should others continue to maintain a presence, or should they too focus their efforts on innovation? Jean-Michel Peny explains why big pharma needs to reassess the business rationale for its OTC activities

In July 2004, Roche announced it was selling its over-the-counter drug unit to Bayer. The management of Roche was motivated to take this decision by its strategic intent to remain focused on its innovation-driven pharmaceuticals and diagnostics businesses. In these two market segments Roche manages to grow at a fast pace and to generate high margins.

However, while companies like Roche are refocusing their activities on their prescription drug portfolio, others prefer to follow the Bayer strategy and spread their business risks by reinforcing their non-prescription drug business. To determine the best strategic option in general, individual pharma companies must first carefully evaluate the relative attractiveness of the branded ethical (innovative prescription) and over-the-counter (OTC) markets. Then they must consider the structure and performance of their current activities, and set their strategic business priorities accordingly.

A look at the future

There is no strong reason to think the years to come will be any more difficult for the branded ethical market than those of the past. The market drivers and limiters are well identified (see Figure 1), and their impact on market economics is well understood. Increasing populations in emerging markets like Latin America and Asia-Pacific, as well as the ageing population in developed countries, represent strong growth drivers for pharma. A large proportion of elderly people are treated with drugs for chronic conditions like cardiovascular risks or diseases, arthritis, osteoporosis and other degenerative pathologies. With continuing unmet medical needs in many diseases, demand for new and better pharmaceutical products will

keep growing strongly in the years ahead. And there are a large number of untreated patients in various therapeutic categories. For example, only one-third of those US citizens eligible for cholesterol-lowering drugs are actually treated with them.

Another important market feature is the stagnation of R&D productivity, with an average of 34 new active substance (NAS) launches a year between 1998–2003. Provided the attrition rate remains unchanged, the number of projects currently in clinical development stages suggests that the average number of NASs likely to be launched per year will fall even further, to about 30, during the next four years. Meanwhile, the number of blockbuster products on the market has greatly increased, from 20 in 1998 to 67 in

2003. According to IMS Health, the market should comprise 105 blockbusters in 2007.

This trend is explained by R&D-based companies' strategies to concentrate their efforts on the development of potential blockbusters, and by the huge marketing investment they allocate to new products to maximise sales growth before their patents expire. Since the late 1990s, it has not been unusual to see potential blockbusters launched onto major national markets with as many as eight to ten mirroring sales forces. In France earlier this year, for example, AstraZeneca launched its new statin, rosuvastatin (Crestor), with eight sales forces.

While generic competition is not a new phenomenon, the rate at which it erodes sales of original brands is growing apace. Even in

France, where generics account for only 6% of the market in value terms, Losec/Prilosec sales decreased by 50% within a month of generic omeprazole products entering the market in April 2004. It is certain that generic competition will continue to weaken and shorten the lifespan of ethical brands after patent expiry. This means R&D-based companies have no choice but to boost sales of their branded products as much and as quickly as possible.

Pricing pressures will also remain an issue in the coming years. In several European countries, governments continue to squeeze pharmaceutical prices with the aim of controlling drug budgets, although products that demonstrate added medical value will obtain relatively better prices. In Japan, the world's second-largest pharma market, with 12% of world revenues, annual sales growth is expected to remain at about 2%, reflecting the increasingly tough

Figure 1: Key market drivers and limiters 2003-2007

Branded ethical market	
Drivers	
• Population increase and ageing	
• Increasing number of blockbusters	
Limiters	
• Stagnation of R&D productivity	
• More intense generic competition	
• Maintenance of pricing pressure by governments	
OTC market	
Drivers	
• Population increase and ageing	
• Growing health awareness and confidence in self-medication	
• Delisting of drugs indicated for minor ailments	
• Public healthcare campaigns (eg smoking, obesity...)	
• Development of lifestyle drugs (eg for obesity, alopecia...)	
• Advisory OTC concept (treatment initiation by physician)	
• Rx-to-OTC switches of blockbusters (eg loratadine, omeprazole, simvastatin)	
• Brand extension (eg travel packs, chewable tablets...)	
Limiters	
• Deregulation of distribution (larger customer access and increasing price competition from private labels and generics)	
• Increasing competition from more efficacious prescription drugs	
• Negative impact of side-effects reported for certain well-established OTC products and dietary supplements	

Source: Smart Pharma Consulting analysis

sell its OTC business?

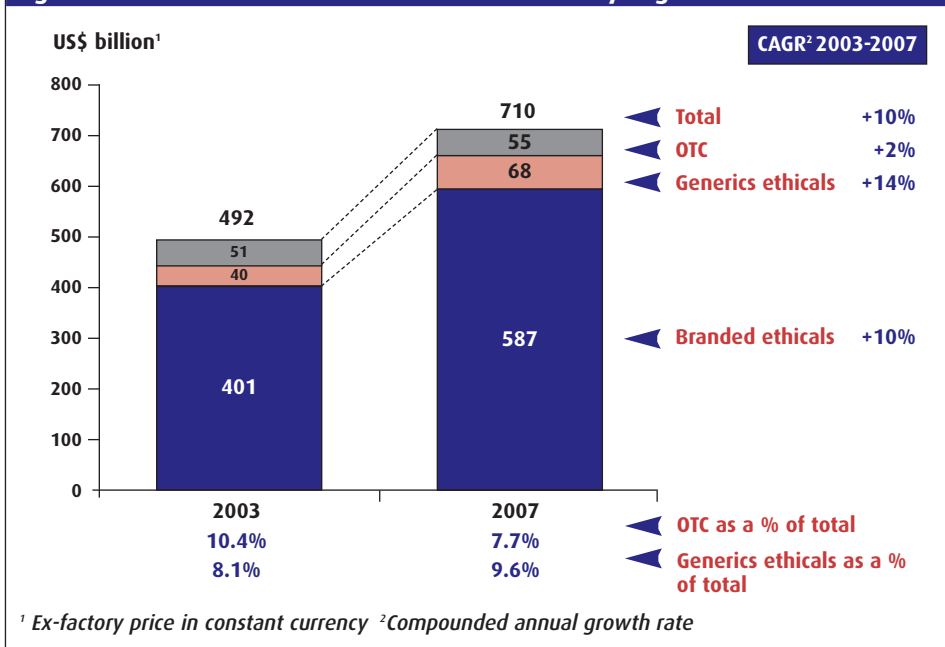
pricing environment. In the US, price pressure is also becoming more important – the Medicare reform bill signed in 2003 and due to be implemented in 2006 is expected to put pressure on the price of drugs purchased by senior citizens and people with disabilities. However, this negative impact may be offset, at least partially, by volume increases. The US branded ethical market could also suffer if unregulated parallel imports of lower priced drugs from Canada or other countries were authorised.

Globally, the net impact of these different forces on the branded ethical market should not be worse than in the recent past. Pharma companies will certainly need to keep adapting their strategies to the continuous evolution of the environment. Waves of mergers and acquisitions will continue because they generate economies of scale, force companies to rethink their organisational efficiency and, to a certain extent, increase the chances of potential blockbusters reaching the market. Further mergers may also contribute to redefining the competitive intensity in certain therapeutic areas, and even to eliminate certain competing products. It is also a means of ensuring better geographic market coverage. This point is particularly important for companies that are not well established in the US: the US market accounts for 47% of the world pharmaceutical sales in value, but is estimated to represent 70% of the total profits generated in this sector.

Thus it seems reasonable to forecast a compounded annual sales growth of 10% over the period 2003-2007 for the branded ethical market. The market should increase from US\$401 billion to US\$587 billion (see Figure 2). However, if pharma companies keep their organisations fit and if they are prompt in adapting their strategies to changes in the competitive environment, they should be able to maintain their operating profitability on the prescription market segment at around 27%, as it is today.

Just as with the branded ethical market, no major turnarounds are expected in the coming

Figure 2: Pharmaceutical market sales forecasts by segment 2003-2007



Source: Smart Pharma Consulting analysis after IMS Health data

years, so this sector should not change significantly in terms of sales dynamics or global profitability. Indeed, growing health awareness, confidence in self-diagnosis and a desire to prevent disease are all expected to sustain the continuing consumer trend towards self-medication. And, similar to the situation with branded ethical drugs, the ageing population will lead to a greater consumption of OTC products, especially analgesics, vitamins and mineral supplements.

The OTC market should continue to benefit from the spiralling public sector healthcare costs that will force governments to shift the financing of drugs for benign pathologies to patients. Simultaneously,

governments are likely to sponsor campaigns to enhance health education, increasing the take-up of self-medication. Smoking cessation aids, for instance, should continue to benefit from government bans on smoking in public places and from advertising on health damage.

Lifestyle drugs like hair restoration and anti-

obesity products are also a source of market growth. Certain therapeutic categories like anti-allergy and eye-care products will be driven by environmental factors such as urban pollution, air-conditioning and widespread computer use.

The new concept of advisory OTCs, which makes certain products available over the counter following initial prescription by a physician, should also expand over the next four years. However, the drugs that could be candidates for advisory OTC status are limited because of the risks of side-effects over the long

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term. Recent market withdrawals, such as the Cox-2 inhibitor Vioxx (rofecoxib) in September 2004 and the statin Lipobay/Baycol (cerivastatin) in August 2001 have made regulatory authorities more and more cautious. Meanwhile, the products most likely to benefit from advisory OTC status are influenza

treatments, oral contraceptives, migraine treatments and asthma remedies. However, if treatment continues to be initiated by a physician, it is likely that the marketing strategy will remain at least partly physician-focused.

Although Rx-to-OTC switches can contribute to expansion of the OTC market, such opportunities will remain rare because product categories suitable for self-medication are limited, too. On average, two or three molecules are switched annually and the number has declined over recent years. FDA and EMEA scrutiny of potential switches is high and the market potential restricted, apart from in the

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US and, to a lesser extent, the UK. However, the switches of some blockbusters, like the proton pump inhibitors for heartburn or the statins to lower cholesterol, should help to sustain the future growth of the OTC market.

For the foreseeable future, product launches will consist mainly of extending powerful brands through additional components, modification of composition, new delivery systems or more convenient packaging. This approach offers the advantage of leveraging the existing brand equity, reducing the advertising costs and increasing the rate of adoption by consumers.

The expansion of distribution channels through non-pharmacy outlets such as drugstores, convenience stores, mass merchandisers or direct sellers broadens consumer exposure to OTC products and favours volume growth. But the current deregulation of distribution also leads to a rise in generic and private label products that undermine OTC brands' sales value and profitability – the price advantage of these products has proved attractive to consumers and has reinforced the trend toward self-medication. Price competition is not only becoming fierce in mature markets like North America and Western Europe but also in younger promising markets like Latin America, Eastern Europe, China and India.

The competition from more efficacious prescription drugs may also erode OTC sales, especially in certain therapeutic areas like the analgesic and digestive market segments. With direct-to-consumer advertising becoming more

important in countries like the US, where it is permitted, patient preference for prescription drugs may be stimulated. The OTC market has also recently suffered from negative publicity with regards to the efficacy and safety of certain dietary supplements (for example St John's wort and echinacea) and vitamins C & E, which may slow the market dynamics down.

The high fragmentation of the OTC market, whereby the top ten manufacturers represented only a 25% market share in 2003, indicates the potential economies of scale that could be generated through further consolidations. In addition, with organic growth in the OTC market quite sluggish, only an acquisition-based strategy can offer dynamic growth by extending combined geographic reach. To reinforce their competitive position, OTC companies may consider acquiring brands rather than companies. This strategy has been followed by Boots, which acquired Clearasil from Procter & Gamble in 2001, in the medicated skincare segment. At the same time, Procter & Gamble bought the Clairol haircare brand from Bristol-Myers Squibb.

Considering the key market drivers and threats, the worldwide OTC segment is expected to grow from US\$51 billion to US\$55 billion between now and 2007, an average annual increase of only 2%. It is estimated that the operating margins of OTC companies will decrease on average from 15% to 13% by 2007, mainly as a result of fierce price competition and higher advertising costs required to reach consumers.

The prescription-focused strategy

It appears that the branded ethical market will remain significantly more attractive than the OTC market, seemingly supporting the decision made by Roche to divest its OTC business. At Roche, non-prescription medicines accounted for 8% of total company sales in 2003 and generated an operating margin of 15%, compared with 24% for its prescription business. In local currencies, the firm's OTC sales grew by 5% (excluding Chugai OTC sales) in 2003, against 23% for total prescription products.

Roche's strategy is to focus on therapeutic areas with high unmet medical needs where it has the core skills and competencies to make a difference, including oncology, virology, transplantation medicine and anaemia. The company began refocusing its activities in 2000 by selling its Fragrances and Flavours division, followed in 2003 by disposing of its Vitamins and

Fine Chemical business to the Dutch company DSM. At the same time the firm reinforced its position in the prescription-driven pharma business. In 1999, it increased its stake in Genentech and in 2002 acquired a controlling interest (50.1%) in the Japanese pharma company Chugai. Roche has also multiplied its partnerships with small innovative research companies.

The Roche strategy is strongly marked by a focus on innovative drugs and diagnostic solutions for life-threatening or severe diseases. Thus, Roche is adopting the same strategic direction as other leading companies like Merck & Co, AstraZeneca and Lilly, whose branded ethical sales account for more than 90% of their global revenues (see Figure 3 on page 29).

The diversified strategy

Should it then be concluded that Bayer made the wrong move? The company is not in the same situation as Roche. Bayer should be viewed as a conglomerate with strategic focus on three core businesses: crop science, material science and healthcare (its chemical business, now known as Lanxess, will be spun out in 2005). Within its healthcare segment, Bayer has operations in the branded ethicals (called pharmaceuticals), the OTC (called consumer care), the diagnostics, the biological and the animal health markets. Bayer's management recently stated that the company has repositioned its branded ethical activity as a stand-alone, mid-size European player. In 2003, Bayer's branded ethical sales amounted to US\$4.1 billion and contributed 41% of the healthcare division's revenues, compared with 16% (ie, US\$1.6 billion) for OTC sales, before the acquisition of Roche Consumer Health. Since this takeover, Bayer's overall OTC business has been estimated at US\$2.8 billion, equivalent to 25% of Bayer's healthcare division sales, versus 37% for branded ethical sales. In 2003, Bayer's OTC sales were as dynamic as branded ethical sales, showing 11% growth, while the operating profitability of the overall healthcare activity was as low as 3.8%. This particular situation alone would justify the strategic move made by Bayer management: the poor performance of the healthcare division should improve through this acquisition, which makes Bayer the third-largest OTC company worldwide, just behind Johnson & Johnson and GlaxoSmithKline. The enlarged Bayer portfolio has a number of well-known brands including Aspirin, Alka-Seltzer, Supradyn, Bepanthen and Rennie. In addition, these products have a strong market presence in Europe and the

Americas, which represent 70% of the worldwide OTC market sales. In the fast-moving Asia-Pacific region, they are consolidating their presence. The new Bayer OTC division benefits from a strong geographical position and an overall know-how that make it a partner of choice for future Rx-to-OTC switches.

Bayer has definitely chosen a different strategic orientation from Roche. This choice has been driven by the current structure and performance of its healthcare business. Like Bayer, other leading companies including Novartis, Johnson & Johnson and Wyeth have a relatively diversified

competitive position by acquiring brands and/or the OTC divisions of other players for which the consumer care business is not core.

The question-mark strategy

Among the top ten leading R&D-based pharma companies there is a third category of player. Companies like Pfizer, GlaxoSmithKline, Sanofi-Aventis and Bristol-Myers Squibb draw more than 80% of their revenues from branded ethical products, while the contribution of their OTC activity remains below 8%. In every instance the evolution of their OTC business was less favourable than their branded ethical

OTC market.

Assuming these four companies decide to sell their OTC operations, and considering the quality of their portfolio or of certain of their leading brands, they could be valued at 2.5 to 2.8 times their annual sales. Mid-size OTC players, for which this market segment is strategic, could strengthen their competitive position through such an acquisition.

Thus, the Pfizer and GlaxoSmithKline OTC portfolios could represent an attractive target for companies like Johnson & Johnson, Wyeth or even Novartis. In addition, considering the development of multi-channel distribution in

Figure 3: Top 12 pharmaceutical companies' business structure in 2003

Business structure	Total Revenues		Branded ethicals		OTC drugs		Others	
	In US\$ billion	Annual growth	% of total	Annual growth	% of total	Annual growth	% of total	Activities
Prescription-focused								
Roche ¹	20,140	+11%	73%	+14%	0%	-	27%	▪ Diagnostics
Merck & Co	22,486	+5%	100% ⁵	+5%	0%	-	0%	-
AstraZeneca	18,849	+6%	97%	+6%	0%	-	3%	▪ Astra Tech (devices-implants) ▪ Salick Health Care
Lilly	12,583	+14%	94%	+14%	0%	-	6%	▪ Animal health
Diversified								
Bayer Healthcare ²	11,173	-5% ⁶	37%	-1%	25%	+8% ⁶	38%	▪ Animal health ▪ Diagnostics – biological products
Johnson & Johnson	41,862	+15%	47%	+14%	5%	+14%	48%	▪ Medical devices and diagnostics ▪ Skin, women, baby & kids care
Novartis	24,864	+19%	64%	+18%	7%	+17%	29%	▪ Sandoz (generics) – animal health ▪ Ciba Vision – nutrition – infant & baby
Wyeth	15,851	+9%	75% ⁵	+8%	15%	+11%	10%	▪ Animal health ▪ Nutritionals
Question mark								
Pfizer ³	45,188	+40%	88%	+40%	7%	+20%	5%	▪ Animal health
GlaxoSmithKline	36,235	+1%	85% ⁵	+1%	7%	-2%	8%	▪ Oral care ▪ Nutritionals
Bristol-Myers Squibb	20,894	+15%	82% ⁷	+17%	2%	-6%	16%	▪ Nutritionals ▪ Conva Tec – medical imaging
Sanofi-Aventis ⁴	29,120	-1%	95%	-1%	5% ⁸	-2%	1%	▪ Winthrop (generics)

¹ Estimates after OTC divestment – ² Estimates including Roche OTC acquisition – ³ Includes Pharmacia sales – ⁴ Estimates after merger – ⁵ Includes vaccines – ⁶ Proforma evolution
⁷ Includes Oncology Therapeutics Network – ⁸ Estimates after IMS Health data.

Source: Smart Pharma Consulting analysis adapted from annual reports

healthcare business in which the OTC segment brings a significant sales contribution compared with the branded ethical activity. Thus, the branded ethical business of Novartis represents 64% of company sales and the OTC business 7%. For Johnson & Johnson the contribution of branded ethicals is 47% in total company sales, while the OTC products generate 5%. In the case of Wyeth the ratio is higher, with its OTC business contributing 15% of the total company sales versus 75% for the branded ethical products. These four companies could consolidate their

business in 2003, with sales declining, except in the case of Pfizer.

With respectively 2% and 5% of their sales generated by OTC products, Bristol-Myers Squibb and Sanofi-Aventis could reassess opportunities for divesting this activity, thus following the Roche strategy. The Pfizer and GlaxoSmithKline OTC businesses each represent 7% of the companies' total revenues, but are not essential for their future development, even if both companies benefit from a strong position on the worldwide

mature markets like the US and the UK, consumer goods companies already active in the OTC market such as Procter & Gamble or Reckitt Benckiser would be well positioned to leverage these OTC businesses or brands.



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