Entering the French retail generics market

In light of government initiatives designed to stimulate the development of generics in the French retail pharmaceutical sector, Jean-Michel Peny examines the attractiveness of this market and assesses the opportunities for market entry.

Senior executives of research-based pharmaceutical companies are only too aware of the deleterious effects of generics on the market share of original drugs. It was no wonder then that when the French government announced in 1994 that it was going to introduce measures to stimulate the development of generics in the retail pharmaceutical market, anxiety levels among French pharmaceutical executives began to rise.

Three years down the road, the generics explosion predicted by the great majority of industry experts has still not happened. But, with these same experts once more forecasting generic 'take-off', it is perhaps a good time to look at the current situation in the French pharmaceutical retail market and to try to find answers to the questions still worrying company managers. Is the business environment now favourable enough to guarantee success for generics? What entry and product portfolio strategies are being followed by the major generics companies already operating in the French retail market? And how can industry select the most suitable original brands to launch as generics?

Small market share

In 1996, generics accounted for less than 5% of the total French pharmaceutical market, estimated at US$17 billion[1]. Total generics sales in France stood at US$784 million, equally split between the retail and hospital markets. Generic penetration in the hospital market at this time was as high as 20%, due to price pressures by hospital pharmacists, who increasingly purchase drugs through contract tendering[2]. By contrast, generics held less than 2.6% of the retail sector.

Among the factors generally put forward to explain why generics play such a limited role in the French retail market, two are fundamental. Firstly, until 1995, the generics market was mainly composed of branded products with limited price discounts (5-10%), if any, and generics were promoted to physicians in the same way as original brands. Secondly, French physicians are culturally attached to branded drugs they know, and are therefore unlikely to prescribe new, less expensive generics on a widespread basis unless they receive strong financial incentives from authorities or are forced by them to do so.

As a part of its strategy to develop the generics market, the French government began to encourage pharmaceutical companies to enter this sector. A measure was initiated in 1994 whereby, under pricing contracts agreed between the Drug Pricing Committee and the pharmaceutical industry, major companies were asked to market generics at a minimum price discount of 20-30% compared with the original brand. In return, they were granted higher prices for their innovative drugs.

Although this move has contributed to a significant increase in generic offerings, it has not addressed physicians' reluctance to prescribe generics. However, the contract signed early this year between physicians'

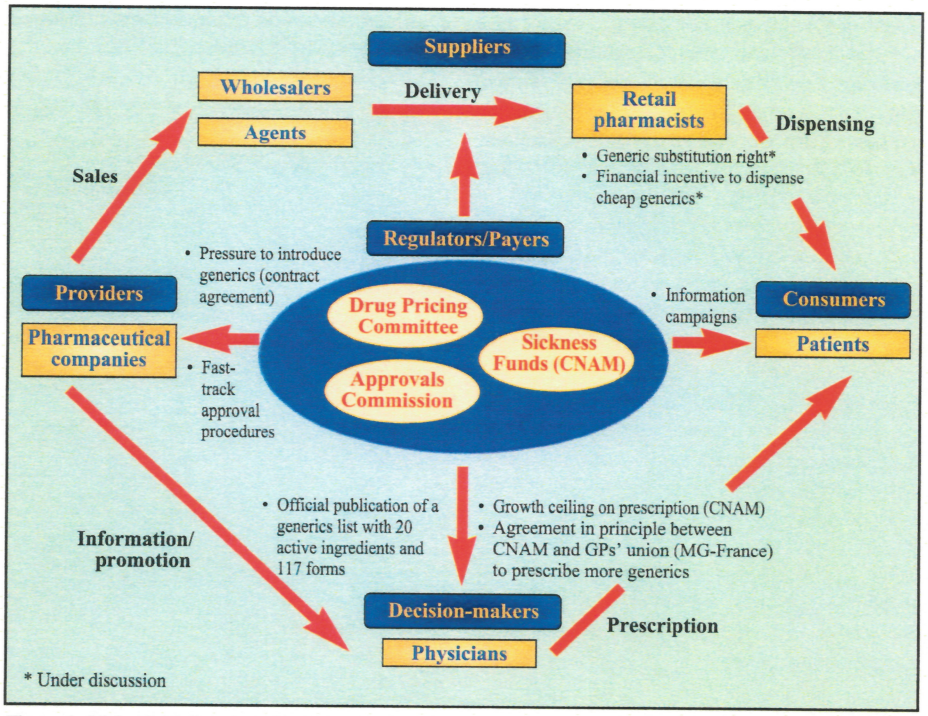

Figure 1: Major initiatives introduced by the French government to stimulate generics development in France. Source: Arthur D Little.

unions and the Sickness Funds should encourage more frequent prescribing of low-priced generics. Under the terms of this agreement, physicians are committed to limiting their annual prescription growth in value terms (1.3% for general practitioners and 0.5% for specialists in 1997). If these targets are met, physicians will obtain increases in their consultation fees, if not, they will have to pay a penalty.

As shown in Figure 1, the French government has a large number of initiatives aimed at different levels of the drug value chain in order to create a more favourable business environment for generics development. While some of these initiatives are in place, no decision has yet been taken about giving retail pharmacists the right to substitute. Although this measure might address a problem for pharmacists, who are currently obliged to stock an increasing number of generic versions, it is not a prerequisite for the generics market to take off. In Germany, where pharmacists are not allowed to substitute, generic penetration is as high as 20% in value terms.

In this context, and considering that 20 major original drugs will lose patent protection by the year 2000, the share of the retail market held by generics is likely to grow annually by 15% to US$686 million. Assuming that this market grows on average by 3% a year, generic penetration in France should be close to 4% by the year 2000, with corresponding annual savings of US$21 million.

The profit problem

One key issue governing the French generics market is its profitability. Today, only those branded generics that have been promoted for several years to physicians and sold at a minimum discount price are generating profits. Their profitability – expressed in terms of PBIT (profits before interest and taxes) – averages 13%, compared with 25% for an original drug. Generics launched since 1994 at a 20-30% discount rate, either branded or not, are unlikely to break even in less than three to four years. Even then, their average PBIT is not likely to exceed 5-6%. Once the French generics market has matured, price competition among generics will intensify and 'discounts' on original brands may exceed 60%, as is the case in Germany (eg 80% for ranitidine in 1995), the US (eg 90% for captopril in 1996) and the UK (eg 95% for captopril in 1997). Analysis of the performance of leading players in these markets shows that many of them are losing money. Consequently, in 1996 Rhône-Poulenc Rorer (RPR) sold its British generic subsidiary, APS-Berk, to Teva Pharmaceuticals because, although it ranked second in the British generics market with a 20% market share, the company was not profitable.

If the French government decides to grant retail pharmacists the right to substitute, the situation could become even worse for generic companies. In order to reduce their inventory costs pharmacists will seek to limit the number of equivalent generics they stock. To become a preferred supplier and secure their orders, therefore, generic companies will have to give discounts to the pharmacists. Discounts for reimbursed drugs are legally limited to 1.8% of the retail price, but there are good reasons to believe that 'unofficial agreements' will be struck.

Strategic objectives

In spite of the limited profit scenario, two main strategic objectives, which are not necessarily mutually exclusive, have recently led some pharmaceutical companies to enter the generics market. Firstly, companies can reinforce their negotiating power vis-à-vis the Drug Pricing Committee in order to obtain price increases for their branded drugs currently marketed and/or for their innovative products ready to be launched. The granting of a more favourable volume growth rate cap can also be achieved, as has been done by RPR, Sanofi, Merck & Co and Synthélabo, for example.

Secondly, entering the generics market enables companies to exploit an additional source of sales growth which, unlike the reimbursed original drugs, is not regulated by the Drug Pricing Committee in terms of growth and promotional expenditure. This approach has been adopted by global generics players (eg Merck KGaA, BASF-Knoll, Bayer Pharma), by certain small or medium-sized companies with few or no original products to launch (eg Lafon, Bouchara, Zambon) and by some new entrants to the pharmaceutical sector such as Biogyne.

Market entry modes

Once the decision to enter the market has been made, three modes of entry can be considered – strategic alliances, acquisition of a generic company, or a start-up company (see Figure 2).

A strategic alliance with a third party seems to be an option particularly suited to companies that do not intend to play a significant role in the generics market but have good reason to satisfy Drug Pricing Committee demands. This option was followed by SmithKline Beecham (SB), which has signed a marketing deal with RPR's generics arm (Biogalenique) to market a generic version of Tagamet (cimetidine). Another interesting example of partnership is the recent joint venture between the Canadian-based generic company, Apotex, and the French-based company, Expanscience (owner of a generic company called Biotherapie), to enter the French market.

Acquisition of a generic company is without doubt the quickest way to become a major player. RPR followed this route by taking over Biogalenique from Pierre

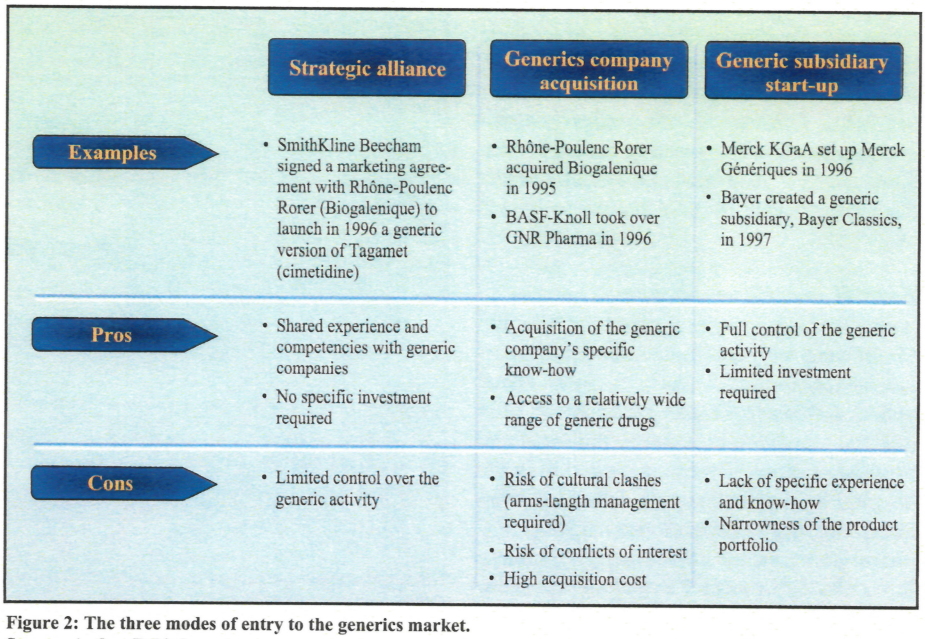

Figure 2: The three modes of entry to the generics market.
Source: Arthur D Little.

Fabre in 1995. In 1996 Biogalenique was number one in the generics retail market, with sales of US$23.1 million. However, pure French generic companies available for acquisition are few in number. Currently, most of the potential generics candidates have a mixed product portfolio including patented and non-patented original prescription drugs in addition to branded generics (eg Bouchara, DOMS-Adrian, Elerte). The acquisition prices now prevailing in France for a generic company, therefore, are in the range of two to three times annual sales. At such prices and considering the generics market forecasts, a payback period of less than ten years is unlikely.

The start-up alternative seems appropriate for new entrants that do not want to invest heavily, but wish to remain in control of their generics activities (eg Merck & Co, Merck KGaA, Bayer). A lack of specific experience in the generics business and a narrow product portfolio are often cited as the two major drawbacks of this entry strategy. However, the first argument has little validity in France because the market is embryonic and so there are limited competencies available. The second also does not appear to be an issue considering that Biogalenique (RPR) generated 92% of its 1996 sales with three branded generics (Bronchokod, Xenid and Keal). A variant of the start-up approach would consist of acquiring a selected number of established branded generics from different sources to build up a product portfolio. To speed up the launching of new generics it is also possible to acquire basic registration files at a cost of US$0.3-0.6 million.

Product portfolio strategy

Once a decision has been made on entry strategy, generic companies need to select a portfolio strategy. There are again three main options – the catalogue strategy, the range strategy or the product strategy.

The catalogue strategy is characterised by a wide range of products covering a large number of therapeutic areas. For example, Biogalenique offers 30 active ingredients and 85 formulations in 11 therapeutic areas. The assumption behind this strategy is that, out of greater convenience, physicians will generally prefer to prescribe generics belonging to the most comprehensive product range. However, the expected overall average profitability is generally low and the operational management fairly complex. If retail pharmacists were granted the right to substitute, they would tend to favour generic companies offering an extensive product catalogue from which they could obtain the best volume discounts. Pharmacists would therefore be in a position to reduce their supplier base, simplify their purchasing processes, reduce the inherent administrative costs and improve their inventory management.

The range strategy consists of building a comprehensive product offering, but in two or three therapeutic areas only. Lafon Ratiopharm, which seems to follow this approach, proposes three products for the treatment of hypertension: a diuretic, a calcium antagonist and a beta-blocker. This should again lead physicians to favour companies with the widest product range by therapeutic area. However, there is a certain degree of risk of cannibalisation between generics from the same therapeutic area, which could render the profitability uncertain.

In the product strategy, a limited number of products are promoted at a time, irrespective of the therapeutic area. Dakota Pharm (generic subsidiary of Sanofi) achieved sales of US$8 million with only two products. Merck & Co and Biotherapie have followed the same approach with a degree of success. In this case the investment required is low, the profitability generated reasonable and the operational management simplified. The weakness of the strategy lies in the difficulty in keeping the product name at the forefront of the physician's mind.

Generics launch assessments

When the product portfolio strategy has been decided, generic companies should analyse the original brands on the French market to assess which would offer the best generic opportunities (Figure 3). These products will have to pass an initial screening to identify those that can be 'genericised', in other words those that pass the legal (eg patent protection, supplementary protection certificate), technical (eg bioavailability, active ingredient sourcing) and regulatory barriers (eg preparation of a registration file including bibliography and bioavailability data). Products that pass this first test should then go through a second filter to determine their level of attractiveness as generics candidates.

One of the criteria used to determine this level of attractiveness is original brand performance. This can be illustrated with Feldene (piroxicam) which was, with five new generic entries, the most genericised original drug in France in 1996. As shown in Figure 4, overall 'genericable' piroxicam sales (Feldene plus existing branded and unbranded generics) at this time corresponded to US$24.7 million out of a total of US$39.2 million, the difference coming from the dispersible formulation still patented. An analysis of piroxicam by form shows that sales achieved by injectables (US$5.1 million) and suppositories (US$2.5 million) are far too low to attract generic competition. In addition, their sales declined in 1996 by 17% and 14% respectively. For capsules the situation is different. They achieved sales of US$17.1 million, of which US$3.1 million (ie 18%) came from six generic drugs (two branded and four unbranded). Capsules sales grew by 3%, with generic growth exceeding 350% and Feldene declining by 12%. In spite of a 12% growth in volume terms in 1996, the piroxicam capsules market segment seems too

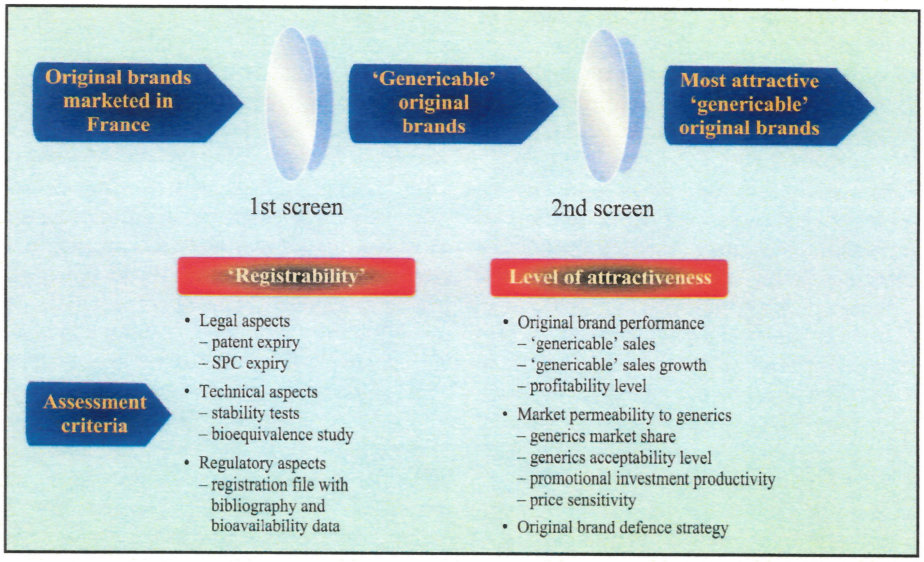

Figure 3: The methodology behind the assessment of generics launch opportunities.
Source: Arthur D Little.

small and already too crowded to represent an attractive opportunity for a new entrant.

Further analyses show that the number of generic piroxicam prescribers (20mg capsules) was limited compared with the same Feldene formulation. Olcam (Irex-Synthélabo), the best established generic piroxicam in 1996, was prescribed by just 1,300 physicians compared with 8,200 for Feldene. However, the prescription rate (average number of prescriptions per prescriber) of leading generic piroxicams was equal or superior to Feldene.

To reach a higher market penetration, generic companies have no choice but to extend their prescriber base and/or further augment their prescription rate. For this, they need to maintain a significant level of promotional investment. For example, in 1996, two years after launch, 133% of Olcam's sales were still being invested in promotion (ie US$1.2 million for a turnover of US$0.9 million). And an interesting comparison can be made between the two generic piroxicams, Inflaced (Biotherapie-Expanscience) and piroxicam GNR (Knoll-BASF) launched in early 1996. While the former company invested over four times more than the latter in promotion (US$1.8 million compared with US$0.4 million), it obtained sales results only twice as high (US$1.1 million against US$0.5 million). This performance gap could partly result from price sensitivity on the part of prescribers, since Inflaced was priced 40% higher than piroxicam GNR.

Another key element to be considered when assessing opportunities for generic introductions is the defence strategy implemented or likely to be introduced by the original brand companies. There are seven basic defence strategies that can, to a certain extent, limit the market penetration of generics[3]:

•The development of a new patentable formulation to reduce the size of the 'genericable' market (eg Feldene dispersible tablets by Pfizer).

•The multiplication of formulations, dosages and packaging sizes leading to market fragmentation, thereby raising the entry cost for generic companies (eg Voltaren by Novartis).

•An improvement in the quality of medical services offered to physicians to reinforce their loyalty to the original brand[4] (eg Ventolin from Glaxo Wellcome – the company provides services to physicians for their asthmatic patients).

•The introduction of an OTC version which, when allowed by regulatory agencies, enables the original brand company to transfer a share of sales from the prescription to the OTC market (eg Imodium by Janssen-Cilag).

•The launching of a defence generic which may be used either to deter competing generics from entering the market and/or to compete directly against them (eg atenolol, by Zeneca Pharma, which is the unbranded defence generic of Tenormin).

•A price reduction for the original product which can reduce or even eliminate the price difference with generics (eg Clamoxyl by SB).

•The launching of a new generation product that can make generics obsolete (eg prescriptions for Glaxo Wellcome's Zovirax are expected to be progressively replaced by its newly launched antiviral drug, Zelitrex).

The efficacy of these defence strategies will largely depend on the original brands, the quality of the implementation and the market characteristics of the country concerned.

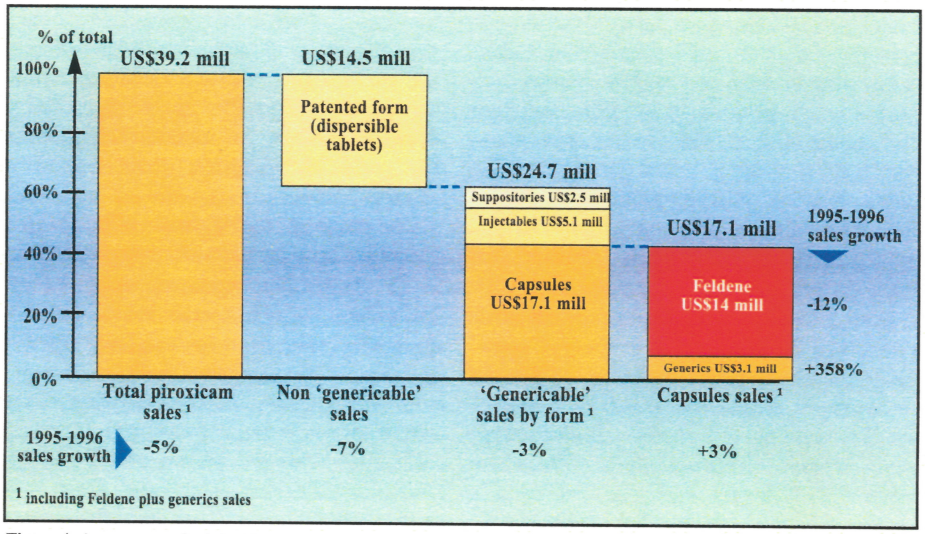

Figure 4: Assessment of original brand sales and growth of Feldene, the most genericised original drug in France in 1996. Source: LMP-IMS, Arthur D Little.

Low-investment options

It is clear from this analysis that the attractiveness of the French retail generics market is currently limited. There is, moreover, no strong argument to suggest that conditions will improve in the near term. However, given that a number of pharmaceutical companies will have decided, within the context of an agreement with the Drug Pricing Committee, to enter this market segment, there are some conclusions that can be drawn.

Companies should favour low-investment entry options such as strategic alliances or subsidiary start-ups. As a part of their longer-term strategy, global generic companies may also establish positions in France with a view to becoming leading local players. For these companies, the most appropriate option, in business and financial terms, seems to be the setting-up of a subsidiary with an entry portfolio of ten to 15 drugs belonging to two or three therapeutic areas. In this case, a virtual organisation, in which all or most of the business functions (eg registration, manufacturing, logistics, marketing, sales) are outsourced, would be particularly appropriate. With such a configuration, payback might be achieved within five to six years, whereas in the case of an acquisition it is likely to take at least twice as long.

Companies unwilling to contribute to the development of generics could alternatively propose to the Drug Pricing Committee that they relaunch, either directly or indirectly, some of their older products that have remained unpromoted for several years. These 'classic' brands are not necessarily obsolete and can often represent an economical substitute for more recent brands. And if market conditions improve in the future it would certainly not be too late for these companies to envisage entering the generics sector. SM

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