

Lighting fire from wet timber in French generics market

French government efforts to bolster the generics market have conspicuously failed. This is not surprising, says Jean-Michel Peny, because all the incentives to use generics ignore the fact that patients don't want them

It is quite amazing to observe the optimism that exists among both market players and experts regarding the future of the French generics market. It seems to be in complete denial of the facts. Despite the many initiatives by the French government to encourage the use of generics and the huge investment by generics companies over the past five years to develop new products, the market is not growing as expected.

A recent study, conducted by Smart Pharma Consulting into the sales and profit potential of the market from 2001-2006, confirms this view. The study involved in-depth interviews with representatives of all the various parties involved in French generics and found that the main reason why the market refuses to respond to repeated government stimuli to use generics is simply that there is no inherent demand for them. Not only do patients not want them but there is no incentive for physicians to prescribe them or wholesalers to distribute them. Only the pharmacists have some interest in dispensing generics.

But consider the ripples that have emanated from the move by the French government to give retail pharmacists the right to substitute a generic alternative when dispensing a prescription. This is thought to be by far the most effective of the government's series of measures to boost the generics market, which, at just 7% penetration in 2000, remains one of the smallest in Europe, along with Italy, Spain

and Portugal. But even this, one year after its introduction, has generated savings of only 76.2 million, much less than the 305 million that had originally been forecast.

The measure came into being when the Social Security Financing Law, passed in December 1998, allowed pharmacists to substitute an original drug with its generic equivalent or one generic for another, provided:

- The latter is not more expensive (within a limit of 0.08 per pack).
- The physician has not handwritten 'not substitutable' on the prescription.
- The substitution is made with a product that is 'strictly identical' to the prescribed one.
- The name of the product dispensed and the number of dosage units are clearly marked on the prescription.

Substitution actually began nine months later, in September 1999. And it was helped along by the fact that the government also reviewed the pharmacists' margin and discount systems to make it more profitable for pharmacists to use generics. It had been the case that pharmacists' margins were proportional to retail price. This meant that generics, being at least 30% cheaper than original drugs, generated less profits. The government agreed to grant pharmacists the same margin, in absolute terms, on generics as on original brands. They already received higher discounts on generics than original products in that they are legally entitled to receive discounts of:

- 2.5% of the wholesaler price for original brands.
- 10.74% of the ex-factory price for generic products.

In practice, pharmacists receive higher discounts, of as much as 50-60%, when they buy generics directly from the company, which can more than double their additional unit margin. The French authorities know pharmacists receive discounts that are way beyond the legal upper limit of 10.74%, but

have not yet taken any action to prevent it for fear of demotivating the pharmacists. They want generics to be used.

Unlike anyone else, it seems. The government, although it pulls virtually all the strings, has very little control over how the players interact on the market. Take the physicians. From 1996-1999, they had been 'invited' by health authorities and the umbrella insurance body, the Sickness Funds (CNAM), to prescribe generics. In November 1998, the CNAM even signed an agreement with the general practitioners' union, MG-France, which obliged subscribing GPs to commit themselves to ensuring that 15% of the value of their prescriptions was for generics. But, by early 2001, only one in ten practising GPs had subscribed to this agreement which, it is estimated, generated a maximum of 38 million in additional generics sales in 2000.

One factor limiting the effectiveness of this measure is the fact that since pharmacists have been entitled to make substitutions, many physicians have stopped prescribing generics, considering them to be the responsibility of the pharmacist. In a market survey carried out on 200 physicians in 2000, three-quarters said they were in favour of generics but that they now only prescribe them occasionally.

Barriers to substitution

But, contrary to expectations, pharmacists are not substituting. It is estimated that less than half of all retail pharmacists substitute and that 30% perform no more than ten substitutions per day. The chief

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barrier to substitution is the refusal by clients to accept a generic equivalent. Patients affected by chronic diseases and who have been treated satisfactorily with a given brand for some time are not willing to accept a generic equivalent. In a study carried out in January 2001, around 70% of the 130 pharmacists interviewed said they do not try to convince their patients to accept generics substitution, for fear of losing them. Only 30% persist in trying to convince patients of the value of generic substitution. And in the great majority of cases, pharmacists also tend to avoid confrontation with physicians, believing this to be in their mutual interest.

The actions of the R&D based companies in a generics market driven largely by

French generics

substitution are also interesting. It has been shown that R&D based companies can best limit or prevent generics market growth by reducing or even abandoning their promotion on original brands. This is because the absence of promotion results in less prescriptions for original brands, thus reducing the substitution basis for generics.

Generics firms are losing out

Generics companies are losing out on various fronts. Consider how retail pharmacists purchase their supplies. In 2000, 53% of the 22,600 retail pharmacies were members of formal purchasing groups that negotiate special discounts with pharmaceutical companies, mainly for generics and over-the-counter (OTC) products. These groups are not as powerful as their equivalent in the consumer goods sector because they are not particularly large (only five have more than 1,000 members) and because they have a propensity to purchase outside the reference lists, thus weakening the negotiating power of the group.

The largest purchasing groups have set up partnerships with two or three generics players, through which they get the large 50-60% discounts mentioned earlier. Since the introduction of the substitution right, purchasing groups have benefited at the expense of the generics companies because of the larger and larger discounts they get.

Generics companies also lose out to the wholesalers which tend to distribute the products of companies with whom they have signed a distribution agreement. Through these agreements, wholesalers offer 10.74% discounts to pharmacists. These discounts, which represent the wholesalers' margin, are then reimbursed by the generics companies.

The three leading wholesalers have all signed agreements with generics companies. OCP of the Gehe group, which leads pharmaceutical distribution in France with a 41% market share, is tied-up with Merck Génériques (Merck KGaA) and Biogaran (Servier Group). Alliance Unichem, the second largest wholesaler with 30% of the market, has signed alliances with RPG-Aventis and MSD Génériques (Merck & Co). The third heavy-weight, CERP France, which accounts for 25% of the market through its four regional branches, has partnerships with RPG-Aventis and EG Labo (Stada).

Generics companies which have not entered into agreements with wholesalers sell their products mainly direct to retail pharmacists. But retailers often prefer to use wholesalers because they do not impose minimal orders and can deliver at least twice a day.

Generics companies have had to adapt

to this new market. The three leading players – Merck Génériques, with 88 million sales in 2000, followed by Biogaran and Bayer Classics, with sales of 51 million and 35 million respectively – have done so by investing strongly in agreements with pharmacists' purchasing groups.

These three companies have portfolios made up exclusively of unbranded generics, that is the international non-proprietary name (INN) followed by the company name or acronym (eg, ranitidine Merck).

In France, where the market is driven by substitution, branded generics are at a disadvantage compared to unbranded versions. The former were once promoted to physicians but, with pharmacists receiving generous discounts to substitute branded generics with unbranded versions, branded generics companies are now focusing their promotional efforts on pharmacists.

The average number of representatives required to cover the 10,000 to 12,000 retail pharmacies which substitute generics is around 50. These representatives place orders to fill pharmacist shelves and thus are in a position to motivate them to substitute in favour of their generics. And their methods are working. In 2000, direct sales reached, on average, more than 60-70% of total sales for leading generics companies.

Interestingly, the marketing strategy adopted by MSD Génériques, to concentrate on physicians, prompted its sales to drop by 42% in 2000 to 3million. Whatever level of prescriptions the company was

able to secure from physicians, it was largely substituted by pharmacists afterwards, benefiting other generics companies.

This is why the leading players such as Merck Génériques, Biogaran and Bayer Classics have all decided to strengthen their agreements with leading pharmacists' purchasing groups. But while these groups have certainly contributed to their sales growth, this has come at a price that could be viewed as prohibitive considering the discount levels granted.

Analysis of the cost structure of generics companies shows that the break-even point on an annual basis is reached, on average, at sales of 35 million. This is one of the main reasons why only Merck Génériques and Biogaran generated profits in 2000. Such poor results are a direct result of the fierce competition on discounts and the low demand for generics.

Generics market potential

They are also a direct reflection of the government policy of encouraging substitution. In other respects, it has not been as effective as had been hoped. In 2000, the market was worth 984 million or, as stated previously, 7% of the total pharma market. Of course, its share is growing to some extent. Generics grew by 31% in 2000, compared with just 9% for the total pharma market.

The picture is, however, more complicated because the French generics market can be further broken down into:

Position of key players	Past (1996-2000)		Medium term (2001-2006)	
	Sales	Profits	Sales	Profits
Authorities/payers				
1. Right to prescribe by INN (2001)	NA	NA	+	■
Clients				
Pharmacists/purchasing groups				
2. Increasing substitution rate	+++	■	+	■
3. Increasing discount levels	+++	---	+	---
Wholesalers				
4. More active role in distribution	+	+	+	+
Patients				
5. Less resistant to generics and substitution	+	■	+	■
Physicians				
6. Less reluctant to prescribe generics	+	■	+	■
Competitors				
7. Decreasing promotion of off-patent brands	+++	■	+++	■
8. Defensive generics strategy	-	-	-	-
9. Concentration of generics market	+	+	+	+

NA not applicable ■ no impact +/- low impact +++/- moderate impact +++/- high impact

Figure 1: Impact of key players on the French generics market (1996-2006). Source: Smart Pharma Consulting

- Non-substitutable generics (581 million).
- Substitutable generics (403 million).

The substitutable generics market grew by 63% in 2000 versus 15% for non-substitutables, confirming the importance of substitution in the development of the generics market. It is for this reason that we have limited our analysis of how the generics market will evolve to the substitutable segment. Within this segment we have developed two scenarios:

- The base case scenario which considers the introduction of the right of physicians to prescribe all products by INN in early 2002.
- The 'reference pricing system' (RPS) scenario, that could be introduced in early 2003.

The base case scenario

The base case scenario considers how the behaviour of the different market players will evolve from 2001-2006 and what their respective impact will be on the sales and profitability of the generics market as illustrated in Figure 1. In this scenario, physicians have the right to prescribe all products by INN, a measure that can only have a limited effect because it simply legalises a practice to which the French authorities and Sickness Funds have long turned a blind eye.

The promoters of this measure claim that by prescribing amoxicillin, say, instead of the original brand, Clamoxyl, when the pharmacists will deliver amoxicillin Bayer, may reduce the reluctance of patients vis-à-vis substitution. Nevertheless, the impact of this measure will remain marginal at the generics market level.

According to this scenario, by the year 2006, the substitutable generics market should reach 1,170 million, thus increasing its penetration rate from 2.8% to 5.5%. While the compounded annual growth rate (CAGR) was 42% between 1998 and 2000, it should not exceed 19.4% between 2000 and 2006 (see Figure 2). Original products which lose their patent over the 2000-2006 period are the main source of growth. In 2006, generics introduced since 2000 should account for 58% of the total generics market.

At best, the average profit before interest and taxes (PBIT) of leading generics players would culminate at around 11% in 2005 and then stabilise at this level.

Since the end of 2000, the French authorities and Sickness Funds have been considering introducing an RPS. This would mean setting an identical reimbursement level for a given group of products, which could be defined as:

- Products containing the same active ingredient (eg, original products and corresponding generics).
- Products belonging to the same therapeutic class (eg, NSAIs, ACE inhibitors).

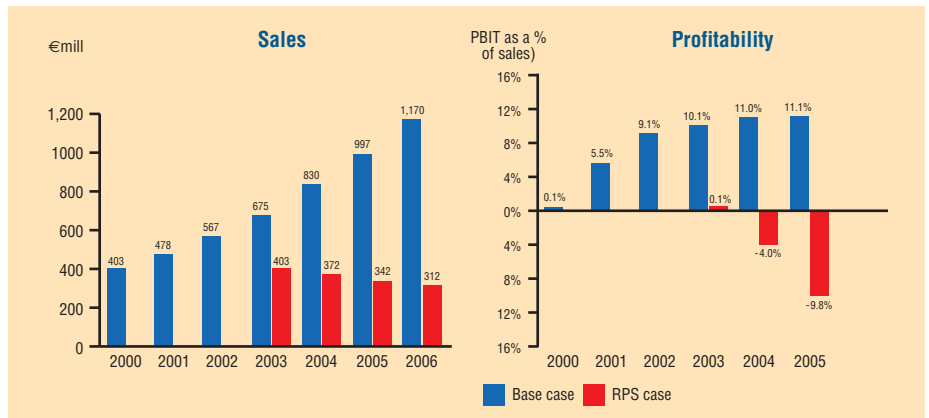


Figure 2: Generics market sales growth and profitability forecasts (2000-2006). Source: Smart Pharma Consulting

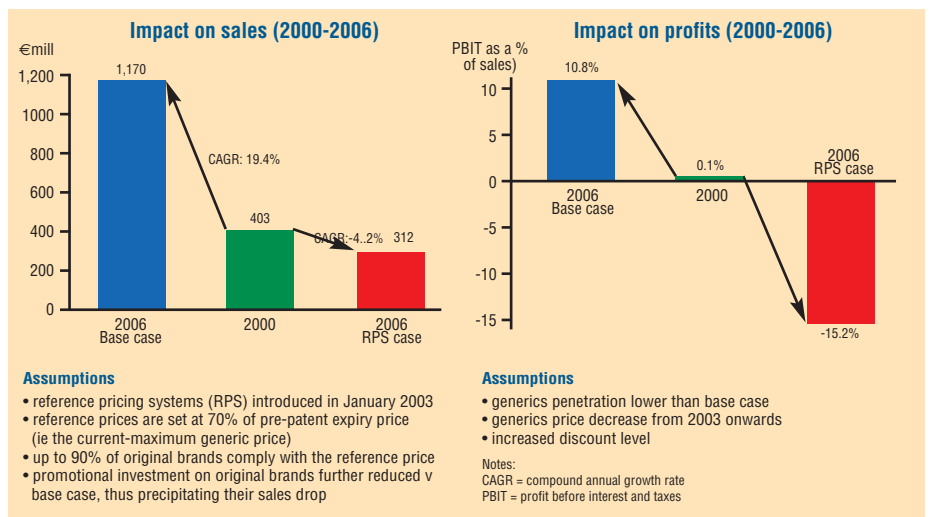


Figure 3: Impact of a reference pricing system on generics market sales growth and profitability (2000-2006). Source: Smart Pharma Consulting

- Products having the same indications (eg, antihypertensives, anti-ulcers).

In the French context, the groups would probably be the same as those on the Drug Agency list of substitutables. If an original product within the RPS was priced beyond the upper limit of reimbursement, patients or insurers would have to pay the difference.

This system is already in place in countries such as Germany and the Netherlands and has induced short-term reductions in drug expenditure but no long-term savings. Interestingly, more prescriptions in favour of patented products outside the RPS have been observed, resulting mainly from the fact that R&D-based companies have less incentive to promote products involved in the RPS.

If an RPS was introduced in France, the reimbursement price would be close to the current generics price, ie, 30-40% less than that for original products. If R&D-based companies behave as they do in Germany or the Netherlands, more than 90% will align their original product prices to the reference price, ie, to the average price of the generics.

Such a measure would be disastrous for the development of the generics market,

decreasing the market size significantly and making it almost impossible for generics companies to make a profit (see Figure 3).

But even if the RPS scenario seems improbable, the base case alternative offers no good reason for optimism for some years to come. Therefore, any generics company tempted to enter this market should do so cautiously. SM

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