Can generics really help to curb French healthcare costs?

by Jean-Michel Peny and Patrick Le Maire

The current French government, like its predecessors, is under pressure to reduce the structural deficit of the social security system. The accumulated deficit from 1995 to 1998 reached US$30 billion, of which the health insurance agency, the CNAM, accounted for US$17 billion, or 57% of the total.*

Not surprisingly the French government is focusing its attention on containing reimbursable healthcare expenditures in its efforts to cut the social security deficit. In line with this, the CNAM has proposed a strategic cost containment plan which could save US$10.5 billion annually from 2003 onwards. A key part of this strategy includes containing the drugs bill. In order to achieve this, since 1995, the government has launched a series of measures to promote the development of the generics market. These are outlined in Figure 1, with an estimate of their potential impact on generic market development.

The first strand of the strategy involves the use of incentives for R&D-based companies to enter the retail generics market. These were introduced between 1995 and 1997 and take the form of price increases for marketed original products and/or new products, in exchange for companies' commitment to developing the generics market. As a result, several R&D-based companies, such as Rhône-Roulenc Rorer, Sanofi, Merck & Co and Synthélabo either acquired or started generics businesses, contributing to a significant generic offering. The cost of the price increases for the CNAM is estimated at an average of US$100 million a year – so far this does not outweigh the savings generated by developing the generics market.

Authorities are also assessing the possibility of simplifying the reimbursement and pricing procedures for generic products. One proposal is that the transparency and pricing committee process could be bypassed, if the price requested by generics companies is at least 30% below that of the original product. This would reduce the time to market from ten months to six months on average and would cut the corresponding registration fees by 20%.

Regulatory measures	Short term (1999-2000)	Medium term (2001-2002)	Long term (2002 onwards)
Targeted at pharmaceutical companies			
1. Incentives to enter the generics market	NA	NA	NA
2. Fast-track approval procedures	0	0	0
3. Tax exemption on generics promotion	0	0	0
Targeted at physicians			
4. Growth limit on prescription[1]	NA/+	+	+
5. CNAM /GPs' union agreement	+	+	+
Targeted at pharmacists			
6. Generic substitution rights[2]	+	++	++/+++
7. Margin system revision[3]	+	++	++

[1]Implementation unlikely before the middle of 2000
[2]Implementation planned for May 1999
[3]Implementation in September 1999

NA Not applicable
0 No impact
+ Low impact
++ Moderate impact
+++ High impact

Figure 1: Relative impact of regulatory measures on retail generics market development. Source: ISO-Healthcare Group.

Further incentive

Another incentive to generics companies is a tax break. In 1997, the French Parliament introduced a progressive tax rate on the promotion of reimbursed drugs. The higher the promotion-to-sales ratio (P/S), the higher the tax – for example if it is less than 10% the tax is 9.5%, rising to 21% if the ratio is more than 14%.

If the sales of generic companies' products listed on the Drug Agency formulary are below US$17 million or their P/S ratio is less than 30%, they are exempted from promotional tax. R&D-based companies with generic activity are allowed to consolidate their promotional expenditures and integrate generics tax exemptions. However, generic sales are currently too low to make this a significant financial incentive.

Another strand of the strategy aims to promote the use of generics by tackling increasing prescribing costs. Since 1997, the CNAM has signed annual agreements with physicians to limit prescription growth in value terms. If these annual targets are not met, physicians must pay a collective fine – 5% of the excess amount in 1998 and 10% in 1999.

However, this payback system will only apply if physicians' spending exceeds 10% of the annual growth target, which was set at 2.6% in 1998.

The impact of this measure on physicians' behaviour is likely to be limited because the sanction is collective, not individual. As yet this measure has not been implemented because the French Constitutional Court ruled last December that the principle of a 'collective fine' was unfair. On the other hand, in early 1998, the Council of State annulled the 1997 agreement, which included an individual payback system, considering it to be discriminatory. The situation is therefore deadlocked.

The CNAM is also tackling healthcare costs through an agreement with the leading general practitioners' (GPs) union, MG-France. This 'gatekeeper' agreement commits GPs to:

- Follow-up each contracted patient and to keep his/her medical record.
- Apply a fixed consultation fee set by the CNAM (US$18.60).
- Prescribe 15% of drug volume as low-priced drugs (as per the 'therapeutic equivalents' formulary published by the CNAM), including 5% as generic products (as listed in the Drug Agency formulary)

*The exchange rate used throughout is US$1= FF5.9.

•Comply with a 'quality charter' and participate in prevention and epidemiology programmes.

In 1999, it is estimated that 20% of GPs will subscribe to the gatekeeper programme and 25% of their patients will accept registration. So the 15% of low-priced 'therapeutic equivalent' products prescribed would save up to US$2.4 million, while the 5% of generics prescribed would save only US$800,000.

Substitution rights

Another key group, pharmacists, have also been brought on board in the CNAM's effort to contain costs. The Social Security Financing law, passed in December 1998, allows pharmacists to substitute an original drug with a generic, or one generic for another, provided the latter is not significantly more expensive (less than US eight cents per selling pack).

However, physicians can prevent this by writing 'no substitution' on their prescription. In this case, they may be asked by local branches of the CNAM to justify their behaviour. The substitution rights will hold back pharmacists' increasing inventory cost resulting from the large number of generics recently launched (81 in 1998).

At the same time, the government has agreed to revise pharmacists' margins. With the current system, margins are partly proportional to retail price, so pharmacists make less profit in absolute terms when they dispense low-priced drugs or generic products.

The new system will include a two-tier mark-up: 26.1% on the pharmacy buying-in price for products costing up to US$25.40, and 10% above that level. In addition, pharmacists will receive a fixed dispensing fee of US 59 cents per pack, increasing to US 93 cents for certain products.

To ensure they do not lose out when substituting, pharmacists will receive the same mark-up in absolute terms for dispensing a cheaper generic as they would receive on the original product. In addition, they are entitled to receive a discount of up to 10.74% on the ex-factory price (versus 2.5% for original products) from wholesalers or generics companies.

By neutralising the negative impact of generics on pharmacists' margins, the government expects to limit 'wild substitution' in favour of more expensive brands; and convince more pharmacists to substitute generics for original products.

To benefit from this new mark-up system, which will cost the CNAM US$85 million in 1999, pharmacists have agreed to use their substitution rights in an average of 35% of cases – amounting to annual savings of US$170 million. However, if this objective is not achieved, the fixed dispensing fee of US 59 cents will be proportionately decreased.

The developing generics market with a high level of discounts is a significant business opportunity for pharmacists' purchasing groups

Key players' views

Surveys recently published show just how far the major players' position in the generic drug value chain has evolved over the past six months.

Most physicians claimed they were in favour of generic products, but strongly opposed the substitution rights granted to pharmacists. As a consequence, they felt less committed to prescribing generic products regularly. Surprisingly, less than a quarter of physicians said they would prevent substitution.

Wholesalers were very concerned by generic companies selling directly to pharmacists or via pharmacists' purchasing groups. Two major drug wholesalers operating in France, OCP and CERP, have recently signed deals with generic companies to limit and even reduce the volume of direct selling. Like pharmacists, wholesalers will receive the same margin in absolute terms for generics and original products – so now they have good reason to contribute to the development of the market.

Since 1997, pharmacists' purchasing groups, originally founded to increase their negotiating power with over-the-counter (OTC) companies, have started to sign exclusive or semi-exclusive deals with generics companies. It is estimated that 40% of the 22,590 French community pharmacies belong to a structured purchasing group. The development of the generics market along with the high level of discounts represents a significant new business opportunity for pharmacists' purchasing groups, which could become as attractive as OTC products, if not more so, in two or three years time.

And pharmacists recognise the potential of generic substitution – 87% are in favour. However, only one-third are willing to substitute a generic for an original product, while two-thirds would prefer to exercise this right only between generic products. Although 82% of pharmacists are willing to substitute treatments for acute diseases (for example, antibiotics), this drops to 10% and less for chronic treatments (such as antihypertensives, antidiabetics, antidepressants).

In addition, they are more inclined to substitute in favour of unbranded generics than branded ones[1]. In other words, pharmacists now realise they have a strong economic incentive to dispense generic products.

But what about patients' reactions to generic substitution? Most patients are now familiar with the definition of generic products and are either neutral or in favour of generic prescriptions. Regarding substitution, 80% of patients say they would accept it. However, their views differ according to the circumstances. For example, a young patient with a one-off prescription for an antibiotic is expected to be more receptive to a pharmacist's substitution than an elderly patient who has been taking the same antidiabetic brand for years.

Publicly, R&D-based companies are not opposed to generic development, however they have taken a strong stance against substitution rights. Their trade association, SNIP, is lobbying and taking legal action to prevent or limit the implementation of the substitution rights.

Not surprisingly, they favour prescriber-driven market development, claiming that this approach preserves a good quality of relationships between patients, physicians and pharmacists and, therefore, ensures better patient care.

R&D-based companies have several strategies to postpone the entry of generic competitors as well as to contain their impact on original brands[2,3]. For example, in January 1999, SmithKline Beecham aligned its Clamoxyl (amoxicillin) prices to the level of the cheapest generic product, representing a price cut of 17% on average. Previously, in October 1996, the company had adopted the same strategy by reducing the price of Clamoxyl by an average of 30% in order to retain market share.

Market size

What is the size of the French retail generics market and how much is its growth likely to reduce the social security deficit? Figures for this differ according the definition a 'generic'. The Drug Agency, whose formulary is targeted at pharmacists, defines generic products as only those having the same active ingredients, the same dosage and the same pharmaceutical form as the original products.

These generic products are bio-equivalent to original prod-

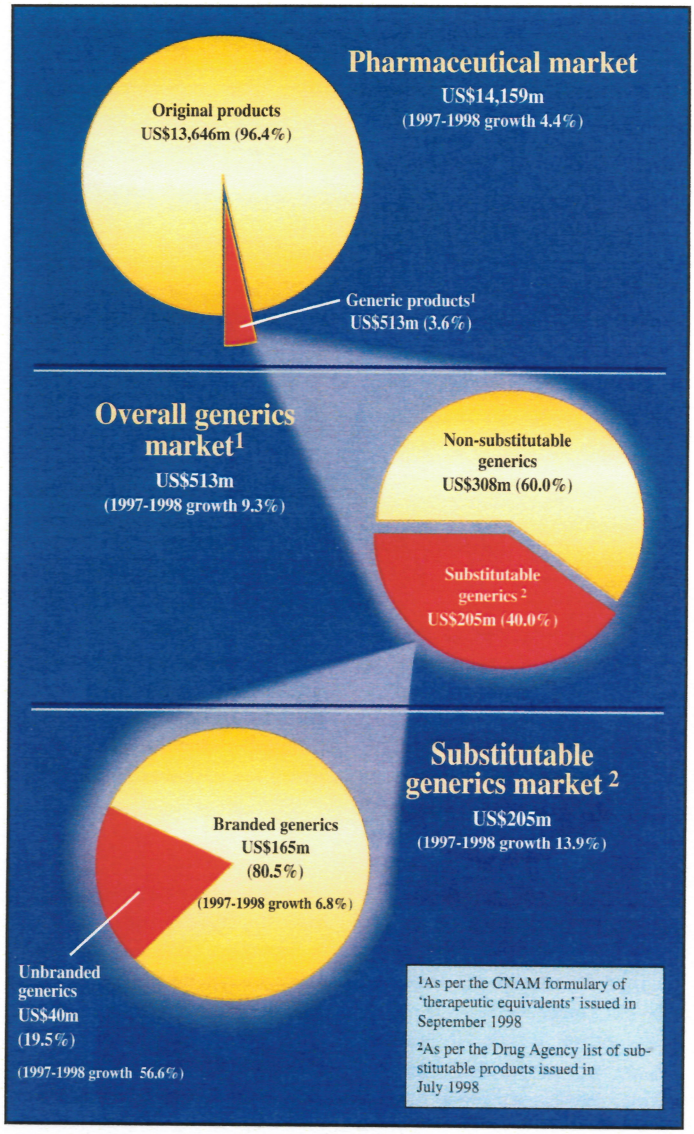

Figure 2: Structure of the French retail generics market (1998).
Sources: IMS Health, Generics database, MAT December 1998, ISO-Healthcare Group.

ucts and therefore legally substitutable. By contrast, the CNAM, whose formulary is designed for physicians, extends this to cover low-priced therapeutic equivalents. These products have the same active ingredients as original products but not necessarily the same salts, or presented in the same pharmaceutical forms and/or dosages.

A total of 77 product groups, 82 originals and 496 corresponding branded or unbranded generics are included in the Drug Agency's formulary. Not surprisingly, the CNAM's formulary is much larger – comprising 832 products.

In 1998, according to the CNAM definition of generics, the retail generics market reached US$513 million and grew by 9.3% (see Figure 2), of which substitutable generic products achieved US$205 million sales and increased by 13.9% over 1997.

Unbranded products accounted for 19.5% of the total substitutable generics market, with corresponding sales of only US$40 million. However, their 1998 sales growth rate is eight times higher than for branded generic products – 56.6% compared with 6.8%.

The growth of branded generic products has slowed down over the past three years because of price cuts imposed by the Drug Pricing Committee. The great majority of branded generics products already marketed and listed by the Drug Agency had to adjust their price to 70% at least of original products. In addition, physicians started to switch their prescriptions from branded to unbranded generic products. The higher growth of unbranded generic products is mainly due to an increasing number of marketed products by generics companies and prescription by physicians as well as to the rising rate of substitution by pharmacists.

Growth rates

Estimated potential growth in the retail generics market is very important. Sales represented by off-patent products in 1998 reached US$2,214 million, representing 15.6% of the total retail market and more than four times the current generic sales. Even though the substitutable market was smaller with sales of US$1,196 million, it represented almost six times the 1998 substitutable generic sales. The speed of development will depend mainly on physicians' and pharmacists' behaviour.

For example, doctors are unlikely to change their prescribing habits without strong financial or coercive incentives from government or encouragement from medical sales forces, which generics companies are cutting back on. And if pharmacists limit themselves to substituting one generic product for another, market growth will be limited. This limited substitution scenario would see the market reach US$850 million by year 2002, representing a market penetration of 5.2%.

By contrast, given strong financial incentives for doctors and willingness to substitute original products by pharmacists, the French retail generics market could reach as much as US$1,340 million by the year 2002, accounting for 8.2% of the market (Figure 3a).

If the recent agreement between pharmacists' unions and the government – on the new margin system and substitution rights – works, the latter scenario is more probable.

Levels of savings

French authorities and industry specialists estimate potential annual savings from generics market development of US$170 million to US$340 million. The CNAM estimates that the introduction of a 'reference price' system applied to the therapeutic equivalents formulary would generate US$576 million savings by 2001 on an annual basis. If this measure was restricted to the Drug Agency's generic list, savings should amount to US$331 million by the year 2000.

Independent analysis shows that the average annual savings from generic market development during 1999-2002 would range from US$227 to US$286 million depending on pharmacists' substitution (see Figure 3b). During the same period, considering the average annual increment only, the saving becomes more modest (US$39 to 75 million).

Compared with the CNAM's 1998 expenditure of US$103.2 billion, these potential savings are unlikely to contribute significantly to reducing the chronic deficit. Generic products probably will not contribute more than 6% to 7% of the total annual savings forecast in the strategic cost containment plan recently released by the CNAM.

The amount of effort being invested in boosting the retail generics market, including the cost of incentives granted to R&D-based companies, seems disproportionate to the expected benefits. Moreover, in a country like France, where reimbursed drug prices are directly controlled, these strategies do not seem to be the most appropriate approach for the government to take.

But what are the alternatives? A more effective way to curb the cost of drugs would be to introduce a 'reference price'

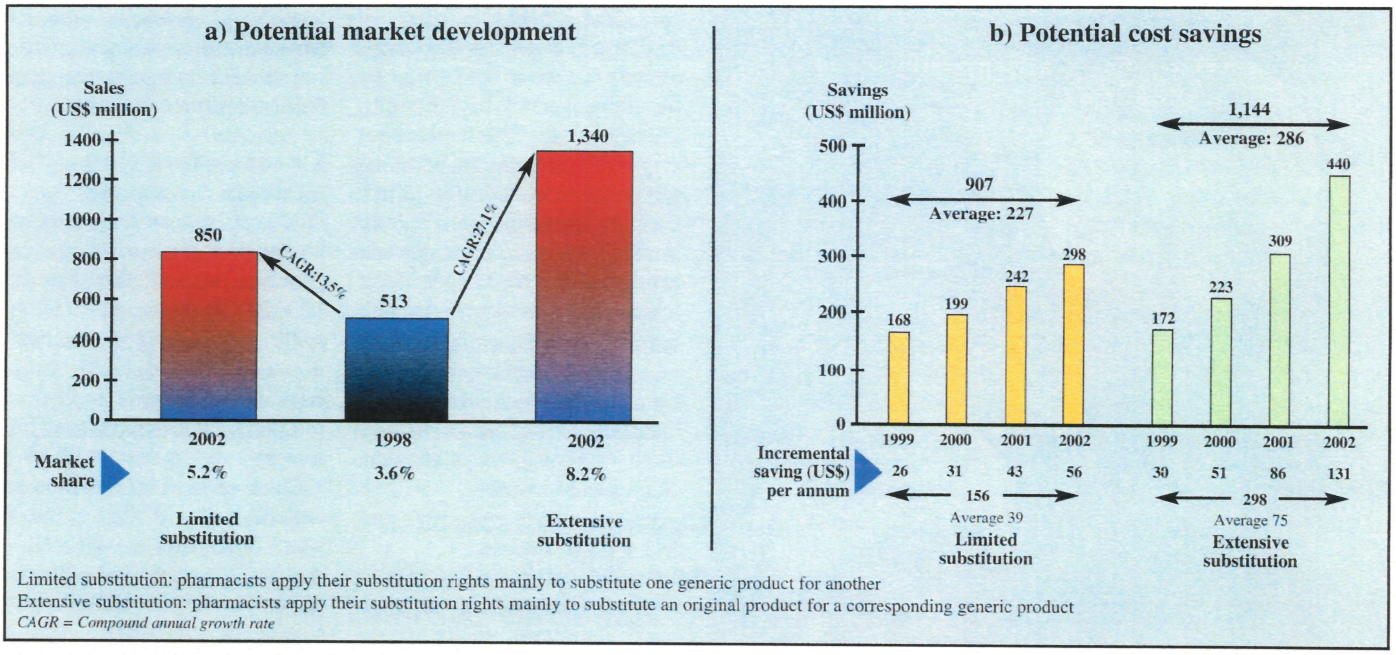

Figure 3: Potential development of the French generics market and estimated savings. Sources: IMS Health, Generics database, MAT December 1998, ISO-Healthcare Group.

system for off-patent products, as recently suggested by the CNAM.

However, this measure would be disastrous for original as well as for generic products. The former would see their price aligned to the cheapest generic and the latter would lose their only competitive advantage, that is their lower price. Under this system, most generics companies, if not all, would disappear.

An alternative would be for the government to impose a predetermined price reduction for all original products coming off-patent.

Assuming that all original products are subject to a 5% price cut the year their patent protection expires, the cumulative cost saving for this would be the same as those expected from generic products (Figure 3b). Even if a price cut of 20% was imposed, the net impact on R&D-based companies' performance would be far better than direct competition against generic products.

This option would be less disadvantageous to R&D-based companies than the other approaches mentioned. At the same time, this should limit the damage to generic companies, not least because most generics players operating in France are owned by R&D-based companies.

Clearly, the expected savings from developing the generics market will be insufficent on their own to significantly curb French healthcare costs.

Without an holistic approach to address the root causes of the structural dysfunction in the French healthcare system, the government has little chance of finding a sustainable solution to balance its social security and CNAM budgets.

In other words, it has no choice but to re-engineer the entire healthcare and social security systems, reducing complexity and increasing coordination between the various players. Such a reform will require a huge amount of determination and political courage – as the benefits will not be seen for at least five years. SM

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