Original Paper

Journal of Generic Medicines

Journal of Generic Medicines
0(0) 1–8

DOI: 10.1177/1741134315569554
jgm.sagepub.com
SAGE

What future for the French retail generic market? Can generic companies survive?

Jean-Michel Peny

Abstract

The worldwide generic market doubled, in volume, over the past 10 years. It appears, at first sight, very attractive. However, generic companies' profitability is on average lower than that of R&D-based companies and their future risk of deterioration higher due to stronger commoditisation. The attractiveness of generic markets being significantly different from one country to the other, thus, the author proposes an approach, that he has applied to the French market, to assess country-specific business opportunities and threats. The analysis of different stakeholders shows that the French generic market development has been driven by a series of governmental measures to encourage physicians to prescribe, pharmacists to substitute and deliver, and patients to accept generic products. Physicians, who did not play a major role so far, could be asked to prescribe significantly more generic products, or at least more genericized brands, so that pharmacists can substitute them. Retail pharmacists, who substitute more than 70% of genericized brands, have been instrumental in the development of generic products and will be asked to further increase their substitution rate. Patients, of whom almost two-third accepts generic products, are not expected to change their attitude over the short term. Generic companies, operating in France are in danger due to anticipated price cuts of the government in one hand, and the refusal of retail pharmacists to accept any decrease of their discounts, in the other hand. In such an increasingly unattractive environment, survivors will be the biggest generic companies which will manage to secure the lowest production costs and the highest Generic Preference Mix index.

Keywords

French generic market, generic companies' profitability, generic preference mix, generic substitution, market attractiveness assessment

Introduction

Generic products play a key role in the pharmaceutical market. In 2013, they accounted for 28% of the worldwide market and achieved USD 283 billion sales.[1] They represented 66% of the total number of drug packs sold.

Over the past decade, the worldwide generic market has more than doubled in value and volume.

It is expected to grow at a compound annual growth rate (CAGR) of 7% by the end of 2017 to achieve USD 368 billion.[1] Then, its market share in value and volume should reach respectively 33% and 70% of the total pharmaceutical markets. In terms of operating profitability, worldwide leading generic companies achieved 14–15% in 2013, compared to 21–22% for R&D-based companies in 2013.[1] Over the recent years, several of the major global R&D-based companies (e.g. Pfizer, Sanofi, Novartis, Abbott, etc.) have decided to enter or to expend their presence in the generic business segment. The analysis of generic markets at country levels shows very important heterogeneity in terms of attractiveness and of key success factors. To help investors evaluate them, we have developed a specific approach that has been applied to the French market.

French generic business model

The French generic market has doubled in volume over the past eight years, growing faster than the worldwide generic market, to reach a penetration rate of 28% in 2013.[2] However, when compared to the 66% of the worldwide market or the 75% observed

Smart Pharma Consulting, Paris, France

Corresponding author:
Jean-Michel Peny, Smart Pharma Consulting, 1 rue Houdart de Lamotte, Paris 75015, France.
Email:jmpeny@smart-pharma.com

in Germany or the UK, the potential for growth in France remains very important. The average price difference between original brands and generic products being on average lower in France than in the rest of the world, this explains, in value terms, why the 17% penetration rate is only 11 points below the worldwide average compared to a difference of 38 points in volume (Figure 1). To understand the drivers of the generic market, irrespective of the country considered, it is important to analyse the role and the position of:

1. Health authorities/government;
2. Payers;
3. Physicians;
4. Pharmacists;
5. Patients;
6. Generic companies.

The market sales growth and profitability will depend on the behaviour of these six stakeholders (Figure 2). Health authorities are the master piece that determines the behaviour of all the other stakeholders. In the French healthcare system, where 77% of expenditures are covered by the Sickness Funds, health authorities have a determinant power on health insurance policies while the influence of private insurers is negligible, especially on drug reimbursement.[3]

Physician behaviour

In 2013, 64% of physicians' prescriptions were patented original brands, 28% were genericized brands and 8% generic products. This means that if 100% of prescribed genericized brands and generic products were delivered by pharmacists as generic products, the French market could not exceed 36% in volume. To grow the market, one of the most effective measures is to encourage physicians with financial incentives or penalties to prescribe more genericized products, at the expense of patent-protected me-too products. Since 2012, ~75,000 French physicians of whom almost 51,000 general practitioners have signed a voluntary pay-for-performance scheme, called ROSP (Remuneration sur Objectifs de Santé Publique) whereby they received an additional payment for prescribing genericized brands or generic products. The government has also targeted certain specific drug classes (e.g. antibiotics, proton-pump inhibitors, statins, antidepressants, etc.). For statins, it has decided to go one step further. Since November 2014, physicians who want to prescribe patent-protected statins such as Crestor (rosuvastatin), Ezetrol/Zetia (ezetimibe) or the fixed combination Inegy/Vitorin (ezetimib and simvastatin), must obtain a prior authorization from the Sickness Funds. The objective of the public payer is to create an administrative barrier to stimulate prescriptions of genericized statins.

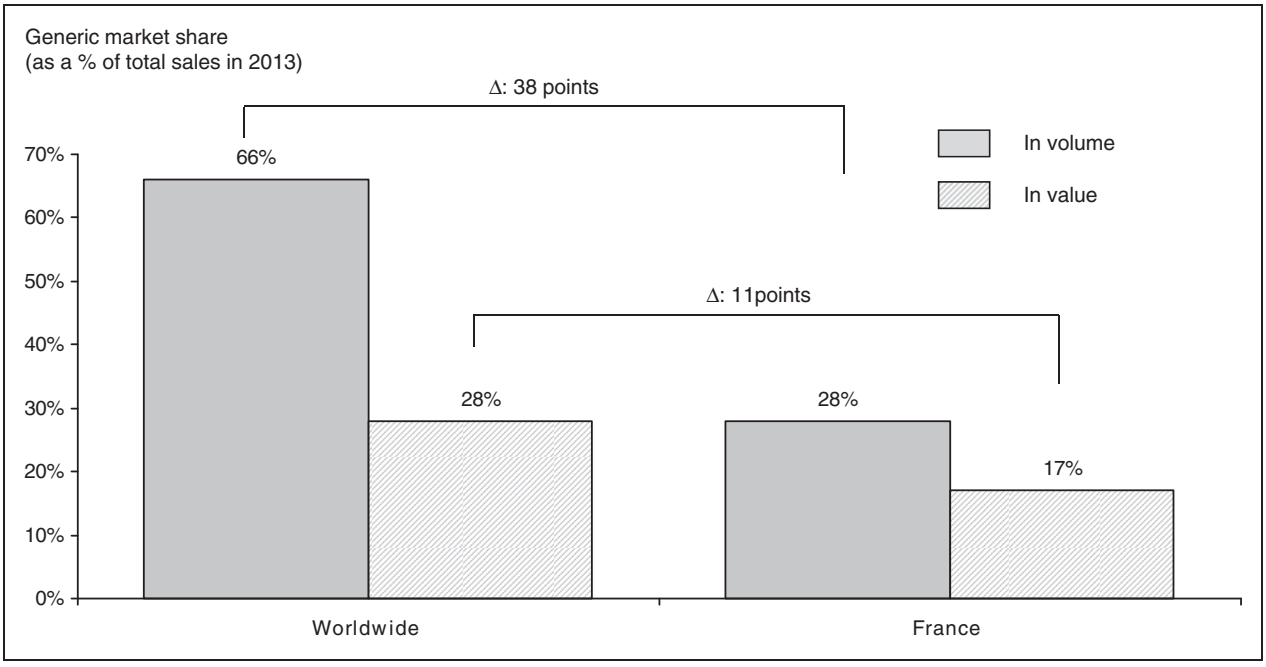

Figure 1. 2013 generic penetration in volume and value (based on ex-factory prices)
Source: GERS, IMS Health, Smart Pharma Consulting estimates.

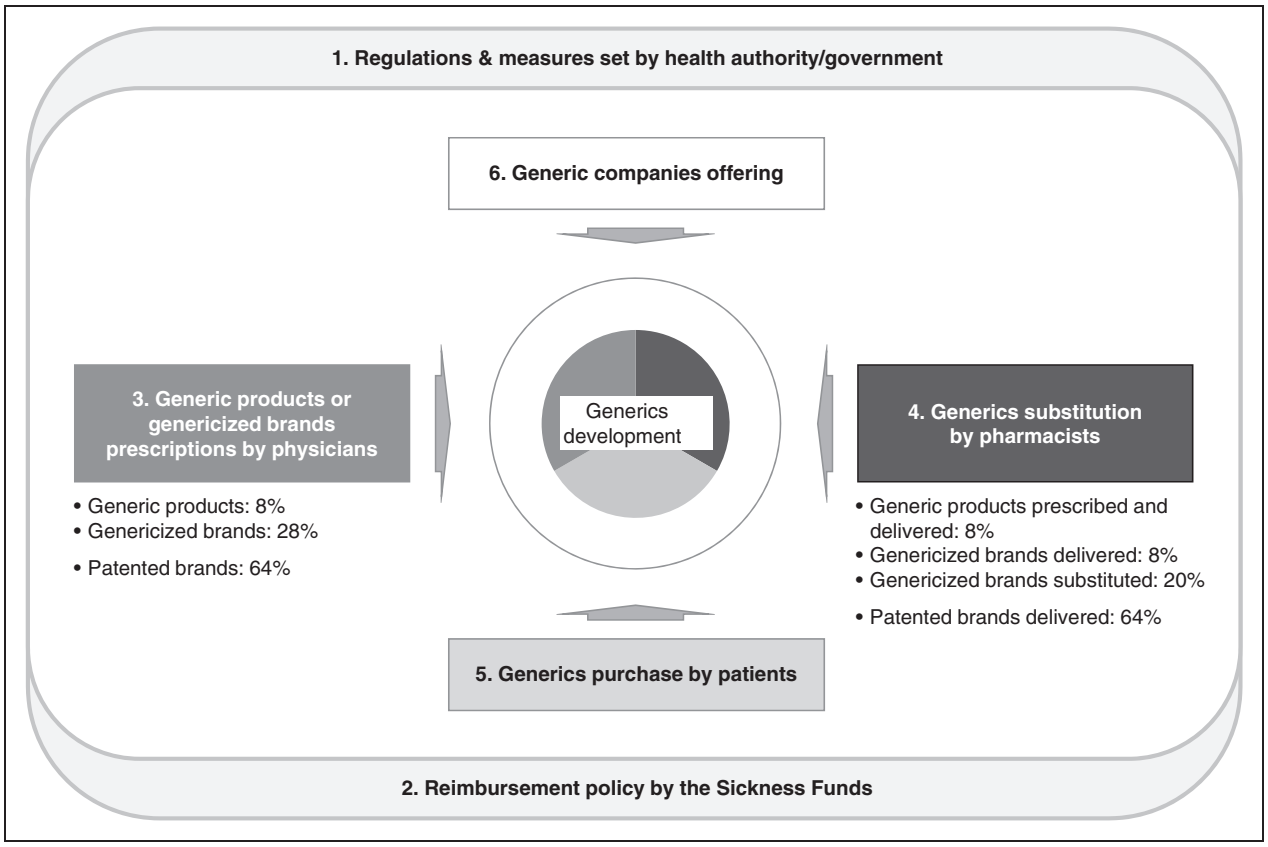

Figure 2. Stakeholders' behaviour vis-à-vis generic products in France.
Source: Smart Pharma Consulting

The weight of prescriptions in international non-proprietary name (INN) is 13% in France compared to 83% in the UK where generic entry can reach more than 95% market share in less than a quarter while in France it takes one year to reach an average of 71%. Actually, a higher rate of prescriptions in INN or generic name would speed up the penetration of generics and raise the level of plateauing by increasing the acceptance of generic substitution by patients. Prescriptions in INN are compulsory since 2009 for genericized original brands but only 25% of them comply with the regulation. In the absence of penalties, the law is not strictly enforced. From January 2015 onwards, this rule will be extended to all prescribed drugs, either genericized or patent protected. The impact of this measure will be progressive because neither penalties nor incentives have been planned; and moderate because it will mainly accelerate generic uptakes of original brands during the first four to six months following their loss of exclusivity. Besides, we can expect to raise the level of plateauing by three to five points, depending on the products.

According to a survey carried out by the Sickness Funds, less than 5% of prescriptions are associated with "non-substitutable" mentions. If for certain pathologies (e.g. epilepsy), or drugs with narrow therapeutic index (e.g. levothyroxine, fentanyl, buprenorphine, calcineurin inhibitors, etc.) the government accepts that physicians refuse their prescriptions to be substituted, for others they can be asked to medically justify their decision[4]. The rate of "non-substitutable" mentions remains low but could be reduced by one or two points through a tighter control, especially at those physicians who systematically refuse to see their prescriptions to be substituted.

Any measure, to be effective at French physician level, must be imposed and not only incentivized. A model similar to the one in place in Germany with either an annual drug budget per prescriber should foster the penetration of generic products. Alternatively, physicians could be imposed an individual rate of genericized brands and of generic products to be prescribed.

Pharmacist behaviour

Retail pharmacists have been instrumental in the strategy implemented by the French government to develop generic products. Since 2009, they have been authorized to substitute genericized brands by generic products. To encourage them to substitute,

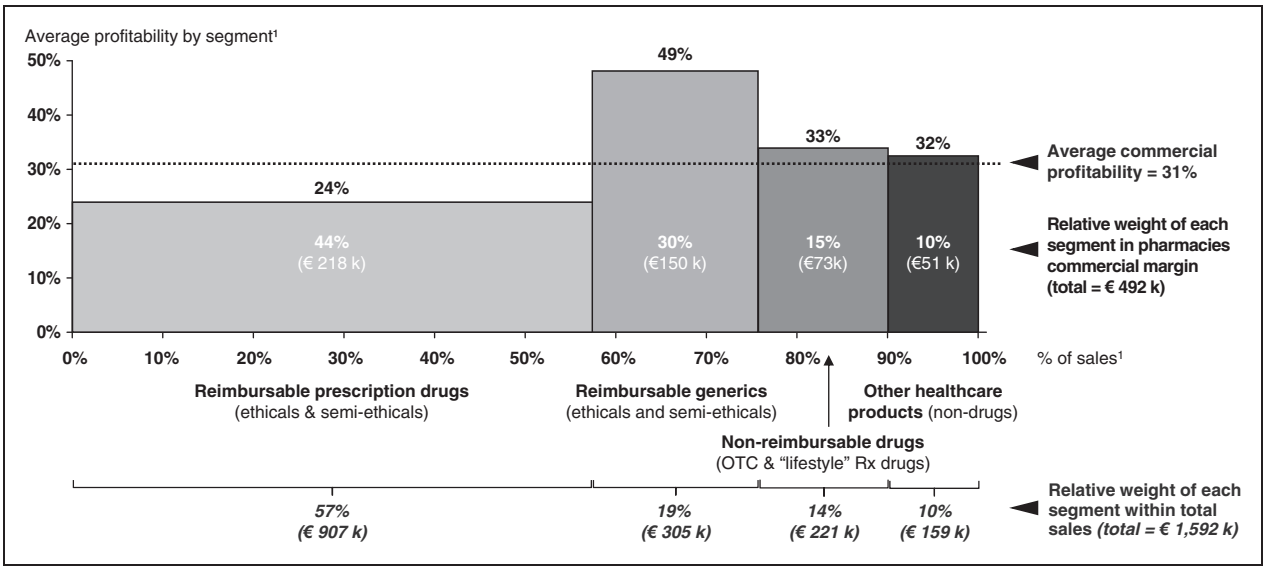

Figure 3. Economic structure of French retail pharmacies in 2013.
[1]Value based on ex-pharmacist price (i.e. sales at ex-wholesaler price inclusive of legal margin and discounts and commercial agreements, including VAT).
Source: KPMG, GERS, IMS Health, Smart Pharma Consulting anlyses and estimates.

they get the same margin, in value, for dispensing an original or a generic product and were authorized to receive, for the latter, discounts up to 17% of the ex-factory price. Since September 2014, discounts have been capped at 40%. For original brands, discounts are capped at 2.5%. By delivering a generic product, pharmacists make on average 40% more profits than with the corresponding genericized brand. The financial incentive associated with the delivery of generics is very significant for pharmacists. On average, generics account for 30% of retail pharmacies profits (Figure 3).

To stimulate the substitution by pharmacists, health authorities have set a national objective of 85% of the ANSM (French National Security Agency of Medicines and Health Products) generics directory. In 2013, the rate of substitution was estimated at 71%. In addition, objectives of substitution have been set for 29 molecules (e.g. 95% for amlodipine, 90% for atorvastatin, etc.). A bonus based on their individual substitution rate has been however granted to retail pharmacists who received on average 5,705 euros.

If one year after their launch the penetration of generics for one given product does not reach 60% in units, the government may introduce a reference pricing system (RPS) called TFR (Tarif Forfaitaire de Responsabilité) by which patients will be reimbursed for the prescription of a genericized brand on the basis of the price of their generic. In such a circumstance, the margin of the pharmacists for the generic product is reduced.

Thereby, the main initiatives to increase the rate of substitution are not at pharmacists' level, but at physicians' level as previously mentioned and at patients' level.

Patient behaviour

The level of confidence of patients in generics has not significantly improved over the past 10 years. Surveys show consistently that on average 60% of patients accept willingly generics when they are proposed by pharmacists. It is difficult to raise the confidence of patients considering the numerous articles or interviews of medical opinion leaders, including the French Academy of Medicine, which questions the quality of generic products, their bioequivalence, etc. The analysis of pharmacosurveillance case reports shows that there are no significant difference between genericized brands and their corresponding generics.

To reinsure patients, public campaigns are regularly launched regarding the quality of generic products and their equivalence to the original brands, in terms of efficacy, safety and convenience. They have been mainly carried out by the French government, the Sickness Funds, the French generic-maker association (GEMME) and by certain generic manufacturers (e.g. Mylan in 2014, Biogaran and Teva in 2013). However, these promotional campaigns have not proven to be very effective.

The most effective measure introduced by health authorities to increase the level of patients' acceptance of generic products has been the generalization of the

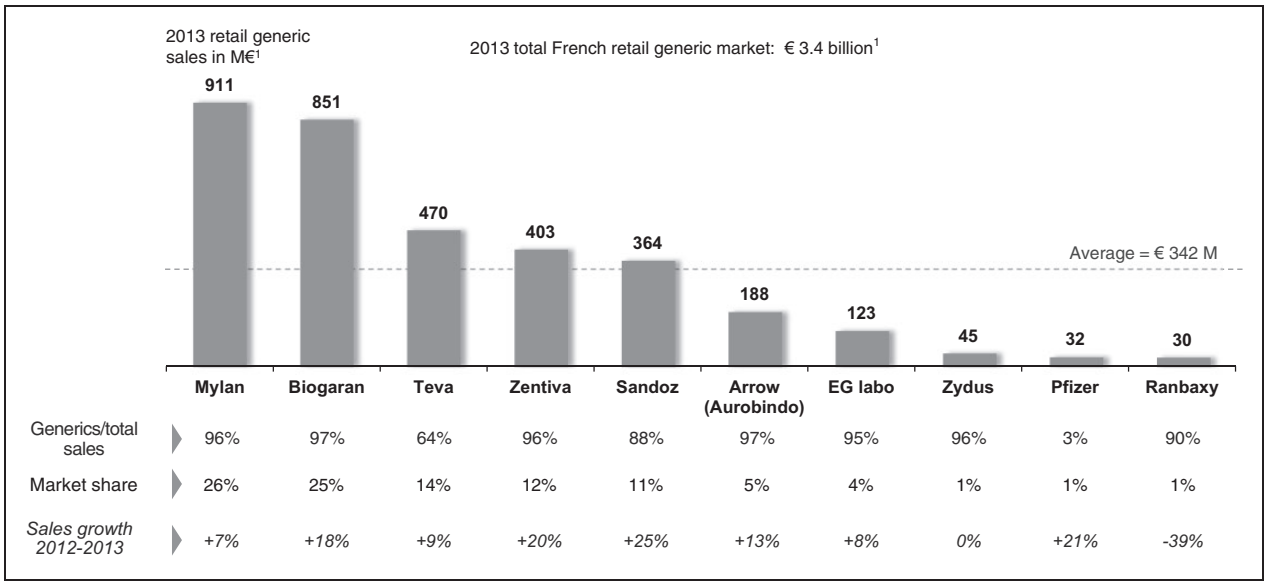

Figure 4. Top 10 companies by generic sales on the French retail market, in value (2013).
[1]Includes only sales of the ANSM (French National Security Agency of Medicines and Health Products) generic directory, at ex-factory prices.
Source: GERS, Smart Pharma Consulting analysis.

"cash advance vs. generics" rule to all territories in July 2012. Thus, patients refusing substitution by generic products have to pay for their drugs and then get reimbursed (as opposed to the "non cash advance system" usually applied in pharmacies).

Generic company's behaviour

The competitive intensity amongst generic manufacturers is very high in France. The market is very concentrated with the five largest companies representing 88% of the total retail generic market in value in 2013 (Figure 4). The challenge for generic players is to gain market share on a market where the respective positions of incumbents vary little across time. This situation explains why it is difficult, if not impossible, for newcomers to succeed from scratch. The performance analysis of generic companies operating in France shows that first market entrants have the biggest sales and the best profits. Over the past three years, only Mylan and Biogaran have managed to secure a relatively stable but modest operating profitability of 8% of their revenues. To make operating profits on the French retail generic market, companies should have generated sales above €500 million in 2013 (Figure 5).

To grow, generic companies must try to extend their base of clients and for each of them maximize their share of wallet. Most pharmacists list two generic manufacturers as usual direct suppliers, with the leading one accounting on average for 78% of total generic purchases in value. To be listed by retail pharmacists and then become the preferred suppliers, generic companies must better perform than their competitors on the four components of the Generic Preference Mix:

1. The breadth and quality of their portfolio;
2. Their commercial offer;
3. The quality of their service;
4. Their corporate reputation.

The Generic Preference Mix index (Figure 6) enables to evaluate the preference level of pharmacists for a given generic company, over time and compared to its competitors. The relative importance attached to the four components of the Generic Preference Mix (GPM) and the performance on each of them is determined, through pharmacists' interviews, by a market research company or sales representatives of the company. The identification and analysis of the reasons underlying the scores granted by pharmacists can enable generic companies to devise appropriate solutions to implement to strengthen their performance on those four components. A pilot study carried out in 2012 has shown that Mylan and Zentiva obtained the highest Generic Preference Mix index, just ahead of Teva, Sandoz and Biogaran whose index was slightly lower. The study confirmed the relative primary importance of commercial conditions offered and of the breadth and quality of their product portfolio. The quality of the services and the reputation of the company are less important but can make the difference. To gain market share, generic companies must,

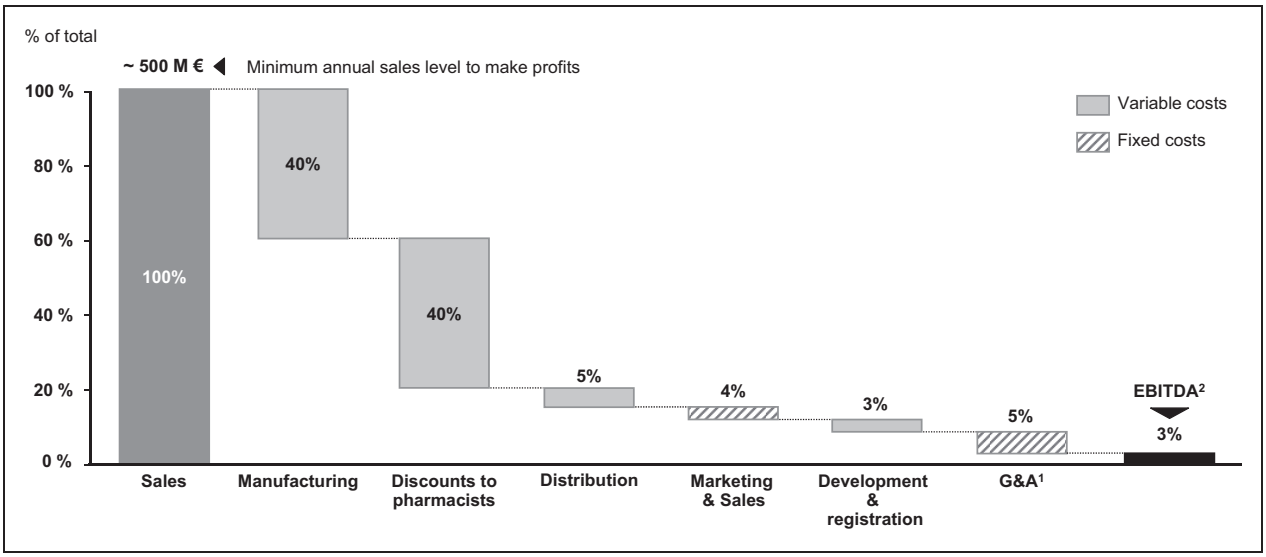

Figure 5. Estimated cost structure of generic companies operating in France in 2013.
[1]General & Administrative.
[2]Earnings before interests, taxes, depreciation and amortization.
Source: Smart Pharma Consulting analyses and estimates.

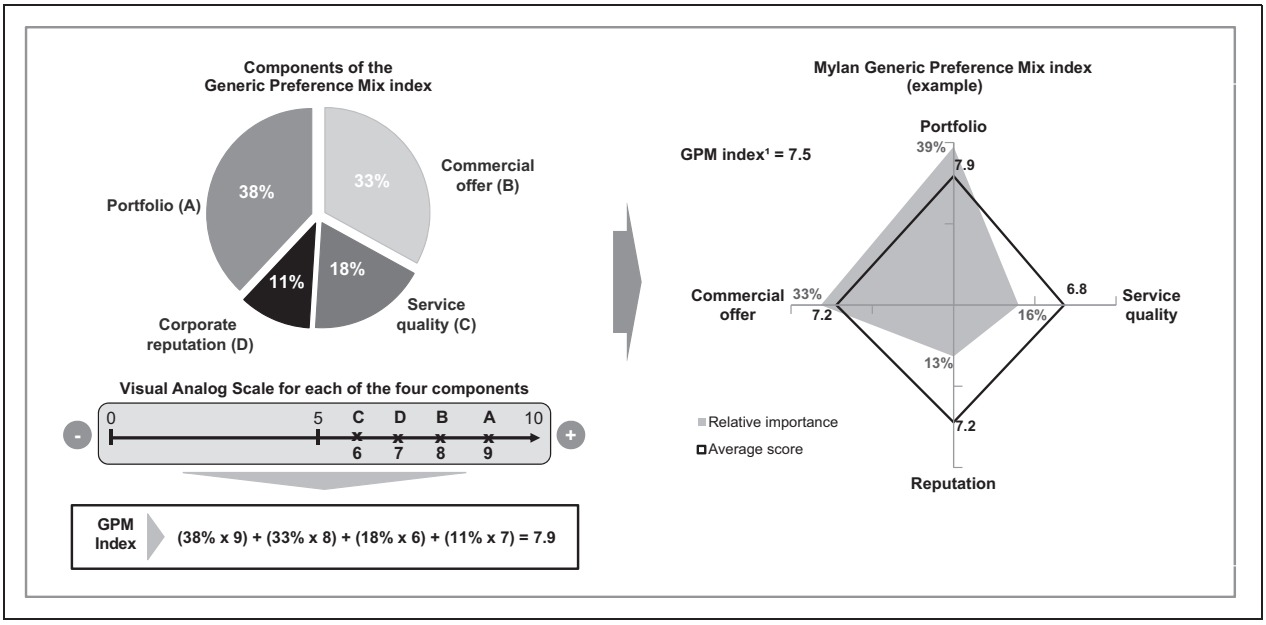

Figure 6. Generic Preference Mix index by pharmacists – Tool and application to Mylan.
[1]Average score on each component which is weighted according to its relative importance as stated by respondents.
[2]Interviewees are only made of pharmacists who have listed the respective generic company.
Source: Phone interviews with 31 pharmacists (February 2012) and analyses by Smart Pharma Consulting.

pharmacy by pharmacy, attempt to optimize their Generic Preference Mix index.

Price cuts

To contain the rise of healthcare costs, the French government has introduced a series of initiatives to boost the volume of generic products used and apply regular price cuts. At the moment of its market entry, the price of the generic product is set at 60% below the original brand' price and 18 months later, its price is further decreased by 7%.

In addition to these predetermined measures, the government may impose price cuts to generic

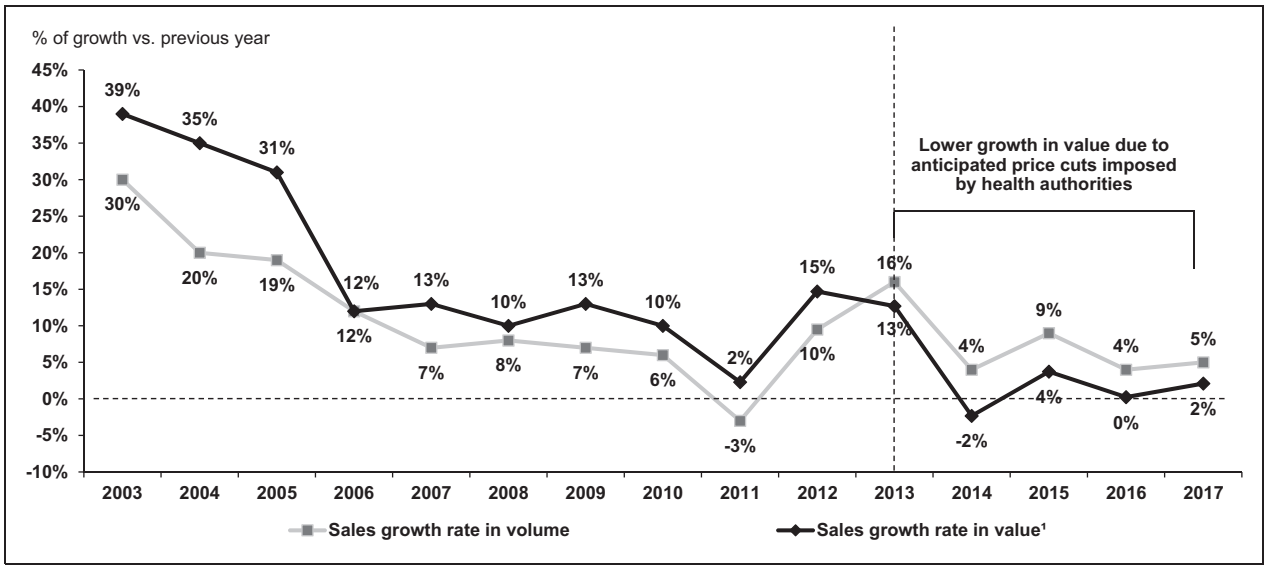

Figure 7. Generic sales growth on the French retail market (2003–2017)
[1]At ex-factory price.
Source: GERS, Smart Pharma Consulting forecasts.

products, on *ad hoc* basis. Thus, in March 2013, a price cut of 20–25% has been decided for the most sold generic products. Other targeted price reductions have been introduced in 2014 and are planned for 2015. The French government uses this means as an adjustment variable, amongst many others, to contain the deficit of the Sickness Funds.

The new regulation increasing the maximum legal discount granted by generic companies to retail pharmacists, from 17 to 40% of the ex-factory price, brings more transparency regarding the commercial practices of generic companies and thus a good excuse for health authorities to keep on pushing downward the price of generic products. In a price-controlled market such as in France, it is very tempting for health authorities to cut generic product' prices. It is an easy measure to implement and the results obtained are immediate and lasting.

2015–2017 perspectives

By the end of 2017, the French generic market should remain the sixth or seventh largest in the world, with sales estimated at € 3.6 billion versus € 3.4 billion in 2013, corresponding to a compound annual growth rate of 1% (Figure 7). Such a low growth can be explained by three major factors:

1. The number of high potential original brands which will lose their patent protection during the period will be relatively limited;
2. The government will keep on imposing regular and drastic price cuts;
3. The increase of discounts levels granted by generic manufacturers to retail pharmacists.

In terms of unit sold, the French generic market should grow by 5% p.a. over the 2013–2017 period, provided health authorities put more pressure at physicians' level so that they prescribe significantly more genericized brands, at the expense of patent-protected me-too products. In addition, the obligation for physicians to systematically prescribe by INN should progressively increase the average rate of substitution by 8–10 points, in the three coming years. The number of generic players should not change significantly, nor their competitive position. However, we anticipate an average deterioration of their respective operating profitability by two or three points for the leading companies and up to five or six points for the smaller ones.

Conclusions

For the past 20 years, to develop the generic market, French health authorities have tried to stimulate generic prescription by physicians, generic substitution by pharmacists and generic acceptance by patients. The results have been mixed so far, despite the numerous measures that have been introduced. This is the reason why, to compensate the limited volume of generic products in the total pharmaceutical market, compared to Germany or the UK, health authorities will need to apply drastic price pressure. They are aware of the low profitability of generic companies operating in France but consider that 40% or more discounts offered to retail pharmacists are not justified and that

they should reduce them to improve their profitability. The new regulation bringing more transparency on discount levels, retail pharmacies will not hesitate to delist generic companies that will not offer the best commercial conditions.

In such a context, generic companies appear to be at risk, being trapped between health authorities who will keep on decreasing the price of generic products and retail pharmacists who will not accept lower discounts. Can generic companies survive? Some of them may decide to give up, knowing that survivors in this difficult market will be the biggest players who will have the lowest manufacturing costs and the highest Generic Preference Mix index to secure the preference of the largest number of retail pharmacists.

References

1. Peny JM. *Pharma market insight & strategy*. Paris: Smart Pharma Consulting, 2013.
2. Peny JM. *The French healthcare system and pharmaceutical market*. Paris: Smart Pharma Consulting, 2014.
3. Peny JM. *The French generics market: strategic insights*. Paris: Smart Pharma Consulting, 2012.
4. Peny JM. Barriers to substitution. *Scrip Mag* 2005; 4: 19–23.

Author's biography

Jean-Michel Peny is CEO of Smart Pharma Consulting which provides strategy and management advice to pharmaceutical companies. He is Director of Smart Pharma Institute of Management and Senior Lecturer at the ESCP Europe and ESSEC business schools, and at the University of Pharmaceutical Sciences in Paris. He has a Doctorate in Pharmacy from the University of Nantes, and an MBA from the HEC business school, Paris. His research interests focus on issues surrounding competitive analysis and strategy formulation in the pharmaceutical industry.