Interview with Pascal Brière , President, Biogaran

03.03.2010

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Biogaran was an initiative from Servier in the mid 1990s before there was even a generic pharmaceutical market in France. Could you speak of your history and of the origins of Biogaran and the vision behind starting this company?

Biogaran is in line with my previous experience as I was a former creator of a generic injectable drug company, Qualimed, for the hospital sector which existed before the mid 1990's in France. It was a former part of the Hoechst-Roussel group which after several mergers is today Sanofi Aventis. It was very curious at the time because Hoechst-Roussel was the leading worldwide generics company because they owned Copley in the US, Cox in the UK and a few generic companies such as Qualimed in France but they decided it was not strategic.

After this experience I left to join Servier, whose intention was to start a generic company pushed by the Authorities considering there was no demand for generics nor offer on the market. Both an offer and a demand are necessary to have a market so, France being a highly regulated market, the regulators decided to create a generics market from scratch and effectively asked pharmaceutical originator companies to build the offer. This meant contacting the biggest companies in the industry and effectively telling them that if they made an offering for the market, then they may expect attractive conditions for the originator business. While this may seem typically French in nature, it motivated multinational companies, such as Servier, Aventis, Sanofi, Bayer, MSD and others, to begin developing generics divisions.

In this way, Biogaran was established in 1996 and officially launched in 1997. We started with a small portfolio and expanded as quickly as we could. At the very beginning we were targeting the physicians but there was no incentive for either them or the pharmacists to prescribe or dispense

generics. It was a full mess! Physicians were not keen to prescribe because they see no medical nor financial reasons for that, while pharmacists had no incentive at all to switch from branded offerings since they were loosing money on each generic pack.

These low sales made 1998 a very difficult year. The passing of the generic substitution right in 1999 led to an explosion in the marketplace with a reorientation toward the pharmacists. While this incentivisation of pharmacists was rational, the physicians were still reluctant to generics. None the less, the market grew until 2002 until reaching a ceiling due to physician reluctance. Naturally, the government decided to make a deal, giving one euro extra per consultation in exchange for prescribing generics. While this didn't lead to the widespread prescription of generics, it did manage to stop physician opposition to the generics. As the pharmacist was putting the foot on the accelerator, and the physician on the break, so when the physician stopped holding down the break, the market exploded once more.

Over time, the market slowed down again and as a regulated country, the government once again investigated why the market was slowing down. They decided it was time to motivate to the patient by obliging them to pay for the drug at the pharmacy and receive reimbursement after should they refuse the generic offering. Since in France you typically don't pay anything when you enter the pharmacy patients were enticed to take the generic medication to avoid paying upfront. This led to the rate of generics increasing to an average 80 % substitution.

Today, generic penetration quickly reaches 70 – 80% on major molecules, similar to the USA. In a country where the patient does not pay anything, we do think it is a real success. Nevertheless, there are always some patients that do not want to switch or physicians who do not want their patient to be switched. So it is impossible to go in excess of 80%. We do not have a problem reaching 70 -80 % very quickly with big molecules. Where we do have a problem is smaller and specialty molecules. Not in value, but volume. With specialty drugs, like anti-epilepsy products, pharmacists and physicians can be reluctant to substitution so for these we usually see a ceiling of 50% penetration. However, the government thought of a solution for this: if a product does not meet a substitution rate of 50% within the first 18 months then it receives reference pricing. The whole system is coherent between pharmacists, physicians, patients and prices and it is a true success. Remember the French market is the second European market by value.

In 2009, the government thought the market was slowing down again, so a new system has been put forward to incentivise physicians with individual contracts. If physician prescribes a product within the perimeter of competitive products (the "Répertoire" ; i.e. directory of generics), then they will be rewarded monetarily allowing them to earn up to 7,000 USD a year if they meet all their objectives.

As this market becomes more mature – which it has managed to do in a short period – how do you compete in an environment that is no longer one of growth?

Biogaran has been co-leading the market with Mylan since 2003. We started from scratch and figured there were three ways we could position the company: discount pricing, range of products and services to prescribers. Originally, we focused primarily on services to the pharmacists, and we have maintained this orientation through today while our product range is now amongst the hugest.

Discount pricing is the simplest way to compete, while the range of products is a question of time and network. However, we were late on the market because some companies, such as Ratiopharm, Merck Generics, and Sandoz, were already established in France from other mature markets. So we needed time to develop and decided to focus primarily on services. The first service was the packaging of our products, which is very customer and pharmacist friendly: everything that is useful to know about the medication is on the box. This approach was well received and everyone copied our packaging in time but overall we are still at the forefront in terms of appreciation of our services. Another example of our service orientation was a DVD regarding generics that we produced and delivered to pharmacies to give to patients. We make a lot of efforts to train pharmacists to be accustomed to substitution.

One of our real advantages is that we are French, family-owned company with a founder, Dr. Servier, who looks at the market with a long-term perspective. We are not focused on the quarterly report and we are able to invest for long periods while maintaining our strategic direction as well as key people. This is a major factor of success. Being French was a positive factor as well and we have the image of a strong and serious company dedicated to services. Today, we have one of the biggest ranges and many assets.

Due to these are the reason why we achieved our 23 % market share in 2009 putting us at number two in the market with the first being Mylan with more than 29% of the market. While we would be happy to have 1 or 2 points, we must recognize the market is not moving fast and has not for years.

Looking to the future, there are still big patent expirations on the horizon despite there being a gap between 2013 and 2014. While the future is bright, the main concern is the price, for instance, our average price is already low — 2.9 euro for a pack of 30. Generic prices derive from regulated originator prices that are not that high to begin with and since 2003, there has been continuous pressure to bring down prices. Our price setting is minus 55 % to the originator which is the biggest decrease in countries where price linkage applies.

This downward pressure is a problem for us because most of our production is in France and Europe with less that 5% of production from abroad like the US or India. The more they continue this pressure on the price, the more we will be obliged to delocalize production, which is not good

for employment in Europe or quality management. The concern we have is the tendering tendency being led by Holland and Germany which potentially painful for the whole industry because the model of the French generic industry is based on confidence in products and consistency of generic drug delivered.

The 5% that you produce outside of France or Europe, is that because you are unable to produce before patent expiration?

Yes this is true and in the future the more products will come off patent the more we will be obliged to produce outside of Europe, but there has been a transitory period within the EU accession for countries so we are able to go to Portugal, Spain, and Greece. However, in the near-term this door will close and we will be obliged to go somewhere else. This issue is a real problem and should be handled by the European commission because Europe has a very strong pharmaceutical industry and knowhow in this field: it would be a pity to this transferred outside of the EU.

It seems that even though you are Generics Company, you are looking to do some OTC's as well as look more international with your sales. Could you speak to the diversification of the model?

It's correct to say we are looking to the OTC business, which frankly speaking, is not very developed because the drugs are not reimbursed by social security. Nevertheless, we have made an alliance with Thea for eyedrops and we are looking into several other OTC products. This is a tough and different market when compared to the generic arena.

In generics, we have a single product: Biogaran. In the OTC business every product has its own rationale so it's a very different scenario. Our sales people have to take orders for 400 products, which leave them with very little time to do handle the OTC business, but we are trying.

In regard to international business, Servier holds 51 % of the shares of EGIS, a sister company, who is headquartered in Hungary and operates in many CIS and CEE countries. Together we cover the second European market, which is France, as well as the former eastern block, which is not bad in terms of overall reach. However, until now we have not invested in acquisitions or international expansion. There was a window four or five years ago in countries such as Brazil, Portugal, Italy or Spain to start from scratch. But momentum is the essence of the generic business and you have to be willing to invest a lot of money at the right time. Since we are a medium sized international group, we cannot diversify too much.

That does mean that Biogaran is very focused on the 2nd market in Europe, which is enormous. This is our competitive advantage because we can develop very specific products for the French market that big, worldwide companies may not develop because there are only one or two countries where the product is marketed. As a result Biogaran has its own development team that

focuses on Franco-Français products which represent significant turnover, but historically were not internationalized. This is due to the fact that French companies were not as active on the international level in the past which limited some products to the French market with significant turnovers.

Biosimilars is not a direction that everyone is taking, especially in France. Why is Biogaran deciding to go in this direction and what is the strategy for the future?

Biosimilars are described as the new El Dorado for the pharmaceutical industry. I am a bit less enthusiastic, but we are looking to that market, specifically through exploring an alliance with a specialized biotech company. The business model is different from generics as biosimilar products are very big, complex molecules which are not identical; it's not simple chemistry with molecules of 10 atoms but rather molecules that are 10 000 times larger. Moreover, the business model – as it's not substitution at the pharmacy level- is different. You have to detail the product to the physician, hospital, specialist, and opinion leaders among others. Therefore it is a "me-too" market that more resembles the originator business rather than a generic market. It demands detailing your product to the physicians and ensuring you have the opinion leaders on your side.

Biosimilars work very much like the biotech business, not the generic industry in that you have both people that develop and produce in addition to people that market. It is new knowhow we have to acquire. So to begin we will have to find one or several partners to supply product, for which we will try to make an alliance. I am sure that with the good reputation of Biogaran and our high quality of people and promotion, we will be able to attract someone willing to gain a significant part of the biosimilar business in France when it eventually exists as it's till some way off. We are on first generation product which are mostly replaced by the second generation. The target for this development is between 2013 and 2014, so we have time, but it's certainly an area of development.

As you have been part of the generics industry for quite a while, playing a role in Biogaran and GEMME, what do you think in the coming decade of generics will look like?

It's terribly difficult to say as this market is heavily dependent on regulation. For the 10 last years, the government put established a very coherent and successful policy. The new contract with physicians and ability to keep the model for several years should be able to ensure growth for many years. However, despite a substitution rate of 80% generics account for only for 12 % in value and 23% in volume which is still limited. This is due to the fact that when a product goes generic, physicians do not hear anymore about this molecule and prescriptions decrease.. France is the only country, probably in the world, where this occurs. In Germany once the first product in a therapeutic class is genericized, the volume of that product increases very much which is exactly the opposite case in France. What we look for with the Gemme in particular, is to bring the

prescription back to the repertoire, which is a competitive area. With this new contract with physicians we have a reservoir for growth in the 5 years to come.

What the market will look like in a decade is uncertain as there are currently a lot of big mergers in the industry. What we can see is that there are global players, local players and regional players, the most difficult of which to occupy is the regional position as they are not big enough to have the synergies of global actors and not small enough to be dedicated to a single market. There will be very big players like Teva and Sandoz but there will still be some local players like Biogaran, if the model does not change dramatically. While I cannot make any guarantees, I can say that France is a regulated country and I'm not so sure that we will drop regulation, especially in wake of the current crisis.

There will be big players in biosimilars such as Sandoz, who has a taken a good move towards being a leading player. They have an integrated scheme for development and production while starting very early to invest a lot of money in the business with low return yet which is normal as you have to invest to get money in the long-term. In competitive generics, where Biogaran is positioned, there are some uncertainties for sure if perhaps not in the short or medium term, but in the next 10 years the field may be different. Today, the generic market is a mosaic of local markets, which is completely different from the ethical business but it will globalize over the coming decade. In the ethical business you have a single product, indications, prescription and regulations using the same clinical studies that allow for business everywhere. In the generic business you have many different models across Europe and the world with very few markets resembling one another. Some markets are characterized by substitution, others by tenders, and still others by prescription or by patients.

What would be the one thing that you would alter here in France?

There are three different leverages, price is one that has been very much worked in the last three years going to an extremely low level while substitution is the other which is now up to 80 %. We must concentrate now on prescription within the competitive field (i.e. "Répertoire"). If we can expand the market from 23% to 50% of volumes then we have a bright future. There is a big reservoir of growth available in the "Répertoire"(i.e. the Directory of generics and their originators).

My wish is to maintain Biogaran as a leading company for the next five years and perhaps improve upon our lead as there are a lot of potential leaders but only a few actually on top.

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