

Interview with Philippe Baudier, Managing Director, S.M.B. Laboratories

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Mr Baudier, what inspired you when you joined the company back in 1978 and what are your main goals today?

Prior to joining SMB Laboratories, I worked in a publishing company. Consequently, I joined SMB Laboratories in 1978 as a result of identifying certain commercial opportunities, as is the case with many business ventures. Since the beginning, the main goal of the company was to focus on the development of galenic formulations in the field of oral drug delivery systems for both prescription and over-the-counter products.

Today, SMB laboratories is also specialized in the research and development of respiratory products and have developed technologies for dry powder inhaler (DPI) devices. We invest approximately 20% of our turnover into our R&D activities, which is a little over the industry average of 16%. In that regard, we are currently developing three orphan drugs in our pipeline which represent our main areas of investment. These orphan drugs are intended for the treatment of the HIV/AIDS virus side-effects, Cystic Fibrosis and for the treatment of lung infections and have all received both FDA and EMA approval as orphan drugs. In this context, we expect to be able to introduce the first file by 2016, followed by a second in 2017 and the third at a later stage. On the other hand, we currently have one product already available on the market and another that is set to gain marketing approval very soon. The first is Pravafenix[®], a fixed dose combination of Fenofibrate and Pravastatin and represents a new approach for the treatment of high-risk patients with mixed hyperlipidemia for which we have very recently received European marketing approval. In addition to this, we expect to obtain marketing approval for our original combination of Budesonide-Salmeterol by 2013 that is used in the treatment of chronic obstructive pulmonary disease (COPD) and asthma.

Having been in the pharmaceutical business for over 30 years, what would you say has been the single most important change in the business model of the industry?

I believe that the penetration of the generic drugs into the market has had a profound effect on the pharmaceutical market as a whole. Having said that however, I also believe that the generic drugs industry has now reached its climax, marking the end of the good times for them. In turn, I believe that the biotech industry is well underway to becoming the new growth segment of the pharmaceuticals industry, representing a wealth of opportunities for the both the industry and patients alike.

As an innovator with strong global ambitions, what are the competitive advantages of being a Belgian based pharmaceutical research company?

From my perspective, I believe that the stability of the Belgian market has served as a solid foundation on which we were able to develop SMB Laboratories over the years. Given the current economic environment and the government's budgetary constraints, the market has been somewhat flat over the past two or three years, as is the case in most if not all European countries. Nonetheless, prior to that, the pharmaceutical market was indeed experiencing a steady growth rate of about 5% each year for the past two decades. In addition to this, another crucial characteristic of the local pharmaceutical industry is the impressive qualifications and capabilities of Belgium's researchers, academic institutions and physicians.

On the other hand, how would you rate the various government incentive programs in Belgium designed to stimulate investment in the industry?

I would not go as far as to say that we are presented with too many incentive programs from the government. Nonetheless, there are a number of incentive programs that we participate in that certainly play a positive role in the development of the industry. For instance, the government has introduced a tax relief program that lowers the tax burden on the revenues generated from products whose patents were locally developed. Another important program, especially for growing small and medium enterprises, is represented by share-based incentives for optimising the remuneration of executives in Belgium. In short, this system limits the taxable amount of the stock options to a certain percentage (between 7.5% and 20%) of the fair market value of the underlying shares at the time of their offer. Broadly speaking, this helps to retain the best talents in the organization as it develops over time.

On a similar topic, I believe it is worth noting the relative ease in which one can engage in open discussion and dialogue with the relevant ministries and authorities. Admittedly, Belgium does have a vast array of ministers to contend with, however this is an important option to have, especially when dealing with regulatory or policy issues. By contrast, I believe this is much more difficult to achieve in larger countries such as France or Italy for example.

To what extent does SMB focus solely on R&D activities as opposed to commercial activities?

From the onset, we develop all of our products internally and do not have a marketing organization outside of the Benelux region. When we make the decision to market and distribute a certain product outside of this region, we proceed to seek out potential partners which have the capacity to properly carry out these activities and then award them with licencing agreements for their respective markets. The R&D and production activities however remain under our control and are carried out by SMB in our own facilities in the US and the EU. Of course, this operating model applies both in the US, as it does in the Europe.

In line with your ambition to become a worldwide player, what strategy are you employing in order to realize that goal?

We aim on achieving this goal simply by developing our core products. I believe this is the only way in which one can successfully develop their business in the pharmaceutical industry; to offer a differentiated product that presents a real advantage for healthcare payers and patients alike. This is highlighted by the government's refusal nowadays to reimburse products that do not demonstrate a clear value-added advantage. In fact, this has been a very important consideration to take into account for the past 5 years. More specifically, when conducting clinical trials on candidate drugs nowadays, it is no longer the case that they are benchmarked against a placebo. Instead upcoming drugs are now directly compared to the "gold standard" drug in their respective domains to determine whether or not they offer a superior therapy. Hence, only those drugs that can successfully demonstrate that they are better than the best will be eligible for reimbursement

approval.

What criteria do you place when selecting your international partners for your commercial activities?

In general, we prefer to work together with small local partners in our international markets rather than with large multinational organizations (MNCs). Although we have generated some interest from a number of MNCs and have a working relationship with the likes of Sanofi for instance, I find that MNCs tend to experience managerial or executive rotations intermittently every 3 or 4 years. Such high executive turnover rates present a risk for SMB because of the looming threat of dissolving established agreements and having to continuously build up new relationships. By contrast, this phenomenon is not as prevalent in smaller businesses and this allows us to build genuine and long lasting relationships with those partners.

Conversely, what in your opinion makes SMB Laboratories the partner of choice?

I believe it is a mixture of factors. Owing to our expertise in the galenic field, one is the fact that we offer unique proprietary products that are patented making us the only providers of such products. In this context, we have been able to successfully register approximately 30 patents so far. In addition to this, we are a company dedicated to the highest quality and safety standards with strong growth ambitions.

What are your most prominent growth markets & which will be the most challenging or complex countries to deal with in the future?

Considering that we are a European based organization, the EU is the important market for SMB. We export 60% of our production predominantly to European markets. On the other hand, as the world's largest pharmaceuticals market, the United States is our most profitable market while Japan is certainly the most complex as a result of their stringent regulatory environment. Moreover, Russia is also a special and unique market for SMB since any success there depends on the relationships built with the local partners and stakeholders. Furthermore, it is worth noting that we have recently expanded our geographical reach and have begun exporting to various markets worldwide including Russia, Ukraine, South Korea, The Philippines, Malaysia, Vietnam for instance. As a result of these efforts, we have been able to increase our sales turnover figures by 10% per annum for the past ten years.

Considering that innovation is at the core of your activities, how have you shaped SMB's structure and policies in order to promote an environment of creativity and innovation?

My philosophy on the subject matter first involves the identification of a given problem followed by determining the best possible solution. In this respect, we seek to establish solid relationships with various researchers and academic institutions, something that Belgium is fortunate enough to have good share of.

Interestingly, as you may have noticed, Belgium is fragmented into mainly the Flemish and French speaking communities. Although this may inherently present some challenges in the socio-political sphere, it also presents certain advantages. That is, this social fragmentation gives us access to two quite dissimilar perspectives and mentalities. More specifically, the French speaking community in Belgium are more inclined to take a Latin approach to things, while the Flemish tend to take an Anglo-Saxon approach. Therefore, since Belgium is a melting pot of the two, we have an on-going clash between the two mentalities and I believe that this presents Belgium with a very interesting characteristic and crucial opportunity.

Some have pointed out that, in reality, companies are not really taking advantage of the opportunities to partner with academic institutions. Do you agree with this view and how would you describe your partnering activities with academic institutions?

To some extent, yes I do agree. I believe that over the past ten years the academic community and industry have been intensifying their collaborative efforts. This runs in sharp contrast to the situation as it was over thirty years ago when I first started in this business. At that time, SMB had partnered with a certain professor from the University of Liege. However, this professor was stigmatized by his academic counterparts for choosing to work with the industry – which at that time was considered to be a dishonest act in Belgium. This was highly divergent from the trends prevalent in the US for instance where academics actively seek partnering activities with the industry. Nevertheless, times have fortunately changed and such industry-academic collaborations are now widely accepted in Belgium and Europe as a whole.

Looking ahead, where would you like to take the SMB operations over the next 3 years and what goals would you like to achieve?

With the introduction of our two new products, we intend to focus on their successful deployment and marketing over the next few years. Moreover, I believe that these products will allow SMB to double its sales revenues over the next five years. Consequently, I believe this growth momentum will be further accelerated with the introduction of our three orphan drugs that I mentioned earlier, marking a new era in the development of SMB Laboratories.

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