# Interview with Guillaume Bouchara, General Secretary, AGIPHARM – Association des Groupes Internationaux pour la Pharmacie de Recherche

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guillaume-bouchara-general-secretary-jpg.JPG

**3 pharmaceutical companies have not been in the French market but in your experience how do you feel they have integrated the differences in culture? Is this a finished topic in this industry?**

In France, many US companies are in reality French companies, meaning most general managers are French, and so are all their collaborators. In fact, I cannot remember any US subsidiaries in France led by an American citizen. This has been true for most multinational companies with the exception of some Japanese firms in the past.

Most of the GMs have an international background and experience on the global level but are typically in tune with European or French culture. In my opinion this is especially important in the pharmaceutical industry here for two reasons. This is a subject that is highly linked to social opinion with a lot of directly human implications so a manager has to be comfortable with the culture. Secondly, the ties between government and industry in terms of pricing and reimbursement are uniquely strong in France when compared to the US or UK which means there is a great need to understand the nuances of the system.

If you take Pfizer for example, Louis Couillard comes from Canada originally but he is very in touch with French culture and has spent time here prior to managing their French operations. Thus, there are some differences in culture for American companies here in France. However, they have some similar approaches in terms of development and try to defend pricing as a way to recognize

innovation. This stems from the way the National Institutes of Health are organized and how much funding goes to public-private research in order to be successful in developing innovations. It is a very strong cultural position that you can observe in the way American companies go about business here in France. They promote and defend their products with a similar spirit to both the government and paying parties. For 10 years now promoting and defending innovation has been my message and that of AGIPHARM as well.

Pricing is a good illustration because it is originally a simple scale: if a product costs €10 it is usually likely better than an €8 product. In France we have the Transparency Committee, a Health Technology Assessment (HTA) public commission program that uses the ASMR which is a benefit assessment scale to evaluate the improvement of medical innovations. France was one of the first countries to develop a system for comparative evaluation of drugs while the FDA has always evaluated the efficacy and the risks of the products. The market was in charge of defining the prices, but it is currently changing. Logistically, the social approach to covering as many people as possible requires arbitration between products in order to define a reasonable price and budget for public expenses. That approach is very important as it promotes genuine innovation and I am pleased to see that the US has recently announced plans for an HTA program.

**The easiest way to promote your products in the US is advertising. Of course, this is a huge difference from France where there is no exposure to advertising reimbursable prescription medications. Surprisingly, AGIPHARM does not lobby for advertising of ethical products while its members use this method in their home markets. Is this not a double standard?**

There are two perspectives here. Firstly, as I mentioned before AGIPHARM is not representative of a purely American spirit promoting an American system and its way of life in France. The goals of the group are to respect its environment which is shaped by the social policies as well as the state's role in healthcare. In Europe and France in particular, the public and state are not willing to see the promotion of ethical medicines on television even if the platform has been authorized for vaccines as well as over-the-counter (OTC) drugs.

The other perspective is that Europe is an old continent and it comes after the US in certain arenas. Moreover, the US experience with promotion has changed over the long-term and Europe has been following the results. The FDA was very supportive of an advertising initiative ten years ago because of the idea it would promote knowledge of the products and help developers compete in the market. American audiences were more comfortable in a culture of promotion so the environment was right at the time to hear these messages. When I arrived at AGIPHARM ten years ago, the position of the American companies was that they were not opposed to a similar system here. They tried to initiate the debate at the European level but the response by many was to keep a very high level of control of information and promotion in particular, also they pointed out the changing opinion in the US and the fact that the FDA itself realized certain aspects of the model

needed to be addressed.

American pragmatism has been very efficient in terms of promotion for many years because when it looks okay, they increase their promotional expenses and when it is felt as potentially non-efficient, they stop or at least decrease the level of promotion. This is very different from France where they see something might be good but they try to change every little aspect before moving forward. The French prefer to wait many years before giving a regulatory basis for therapeutic education for example.

AGIPHARM has done some very important work with authorities both in France and at the European level to promote patient education in the form of information. It is important to distinguish between promotion, information and patient education because they are three very different ways to inform patients of their options. The big issue has been overcoming the image that big pharmaceutical companies only want to use promotion as a way to increase volumes. It was not easy to explain that multinationals and the government could be partners to improve observation, compliance and implementation of treatments.

**You mentioned most of the US companies operating in France have become largely French companies themselves. What is the need then for an association such as AGIPHARM that groups them together?**

Originally, the group was more or less a club of GMs who acted like a think-tank for the industry. When I arrived I thought it was an interesting group as they commanded a lot of power with many innovative medicines so my initial question was how can we valorize the pipelines? Overtime it has become a mini trade association representing American companies within the LEEM. Thus we have worked to promote specific points that are central to our members' interests such as therapeutic education, innovation, HTA evaluation. By grouping together we have more leverage on authorities and public opinion.

If you look at it through a wider lens, in France the global pharmaceutical industry does not always have the best image and neither do the American companies, so when mixing the two together in the French market there was a clear need for solidarity. In the end it works to be more modest and promote the pipelines as well as ideas through the various vectors of communication and influence. We try to be clear on our messages and honest about our objectives and the value-added brought by the research of those companies.

**While the pharmaceutical industry does have a tainted image in many regions around the world they have always been very good to their employees. For years, everybody wanted to work for pharmaceutical companies because of their benefits and opportunities. Now that the market is slowing with a combination of cost reduction from the government, patent expiration, proliferation of generics and the shift to biotechnologies there seems to be the**

**first signs of discontent between employers and employees in the industry. How are your members affected by this decline and what position are they taking?**

I would not say the industry is declining but rather restructuring which began before the crisis. The biggest event in the lifespan of these companies is the expiration of their blockbuster patents which has been a model followed for nearly 20 years but soon everyone will be on the same playing field again. This moment is the end of the blockbuster model and in the future the mentality of IP may change to something like an open source approach but this is not the current paradigm. The great companies work with the paradigm that property is equivalent to economic return thus they have to defend it tooth and nail.

Secondly, the genomic and biotech companies appear to have a more individually oriented approach to treatments. This means following the fall of the blockbuster model there will likely be a more expensive but more suited medicine market that will change how the companies and the state work.

The subplot to this is that the markets are more globalized and changing in terms of perspectives and growth. Even in the US there is a willingness to cover more of the population with healthcare and change the model of individual insurance to a more volume market. France has a very durable model where the budgets may be tight but there is a stable market to other countries like the UK whose fluctuations challenge companies operating there. So while it is slightly contrary to growth ambitions, a stable environment at least offers visibility which is important to big pharmaceutical companies.

The main question lies in the future: if the industry moves towards very innovative, tailored products it will command high prices and the governments will have to figure out how to finance these treatments while rewarding innovation under constraints.

**There are two types of golden markets for the pharmaceutical industry, the US where the prices are so high there is direct reward to innovation and a French-style market where there is widespread coverage for a large population. While the French market provides stability for companies it has reached a plateau in sales. So how are pharmaceutical companies, especially those from the US, integrating this knowledge into their approach to the market? Is there worry about the future of the French market?**

There are worries about investing in France for specific reasons but there is no specific worry about the market and I would say there are three good reasons to be attracted to it. The market for reimbursable drugs is actually growing in the 2.5-4.5% range. Overall through the sectors when you mix US companies with other global players, some of which are declining due to older portfolios, you find that US companies are performing better than the market. However, the natural growth of the market is around 6-7% but cost containment measures from the government impair

these gains by up to sometimes 5%.

France is still appealing though for a number of reasons. First, penetration to the market is extremely fast here because when a physician has a new drug he is very happy to prescribe it as he or she has the information and knows that it is covered by healthcare. Secondly, this is historically a volume market (which is less true now) and physicians have always been quick to suggest drugs here. This is a very debated issue and some say the cost is too high especially in areas like anti-depression but when you look at the suicide rates in France compared to other countries one has to question the meaning of too expensive. It is important to be honest with the fact that sometimes people need the products and they do not have it while others have it and do not need it. This could change if France moves towards a pricing model such as what happened with antibiotics in a very short period. While we have to be careful with the volume approach it is important that France provides the patients with the opportunity to have the necessary treatment.

Thirdly, the prices for innovation are very attractive and AGIPHARM has worked hard in the past with CEPS to setup the ASMR price registration system where companies with innovative drugs can propose their own prices very fast (called “Dépôt de prix”). The committee takes the proposed price and volume and shortens the delay to market as a counterpart of payback discussions and various commitments.

**In the past year, what has been the most significant US investment in the French pharmaceutical market? Is France still an investment destination?**

To be honest, in the last ten years there has been a lot of production investment in developing markets rather than in France for traditional products. This is to be expected however, as costs are higher here but there has been investment from MSD and Lilly to extend the life of their existing plants and distribution centers. Additionally, both Genzyme and MSD have recently invested in research centers in France. These investments are led by the high level of education in specific technologies and innovative research in France.

There are also several specific fiscal benefits for foundations and research-oriented firms despite the complexities of the system and variations. The government is working very hard on expanding the fiscal advantages for companies engaged in innovative research for the healthcare market. Recently, the strategic committee (CSIS) organized by and presented by Nicolas Sarkozy, concluded that it is important to promote the industry and give it strategic importance in France. On the 26th of October, when the CSIS meeting was held the CEOs of Pfizer, Lilly and other US companies met with the Government representatives (3 ministries and President Sarkozy) for the announcement of new measures to promote the industry such as a new biotech fund.

Lastly, there is a large clinical trial capacity in France due to the mixed population of significant size and an established infrastructure. This is a critical point because it is changing with the rise of

countries like Poland who are beginning to be real challengers in Europe so if France does not adapt its laws and maintain an attractive environment it will likely lose out in this sector.

Guillaume BOUCHARA is also running Nextep, a consulting company specialized in healthcare issues which provides its clients in the healthcare sector (associations of patients, pharmaceutical laboratories, lobbying organizations) with high-level expertise in public affairs, regulatory affairs and economic intelligence, economic affairs and business development. http://www.nextep.fr

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