

Interview with Jean-Pierre Barrère, President, FPS & Facophar Santé

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World organization with roots in the beginning of the last century representing today SME suppliers to the health industries. Given the variety of its membership what are the current priorities of FPS and how does the organization stay relevant to its multiple industries?

Firstly I must point out that despite the fact we have been around for more than 100 years, the FPS of today cannot be compared to the one of yesterday. The global pharmaceutical industry, as well as the other health industries, has changed immensely over the past century and we have followed this with a constant process of refining and change. Today it is recognized that in spite of its roots, FPS represents a series of specialized subgroups designed to correspond to the needs of the health industries:

- ? The manufacturers of active ingredients or actives principles of natural origin,
- ? The contract manufacturing organizations & CMOs,
- ? The research and evaluation companies.

Could you outline the priorities and challenges of the active ingredients manufacturers the CMOs and research companies of FPS?

For the producers of active ingredients from natural origin, we are in the process to end their accurate involvement in the implementation of the new European REACH Regulation (Registration, Evaluation and Authorization of Chemicals) while taking in account the very complex nature of natural active ingredients. For example, a marigold extract can contain up to 200 different molecules, so as you can imagine, there is some difficulty when having to record this amount. It has required from us a highly specific qualitative and quantitative approach. As a result, only 10% of the natural active ingredients will have to be registered under the REACH Regulation and we have now to consider, for the 5 next years, a huge research program aiming to improve the safety knowledge about the remaining 90%.

The other main concern of producers of natural active ingredients, both today and tomorrow, is protection of biodiversity. These companies, which are already, and naturally, engaged in the process of sustainable development, work in a positive atmosphere with a strong emphasis on the natural environment.

However, we are concerned about some aspects of the Rio Convention aiming to the protection of Biodiversity and signed by almost 160 countries. Nobody can disagree with such a Convention and we fully subscribe to its principles. Nevertheless, we feel very anxious about the current negotiations

concerning the provisions of their implementation which looks turning in a way where obstacles to trade, innovation and development of new products can be introduced. Beside the risk of breach of the intellectual property rights, one of the major problems stands in insufficient definition of the scope of benefit sharing in the exploitation of biological resources and their derivatives. What is a derivative? The first extract manufactured after importation of a crude botanical or the pharmaceutical drug finally marketed after several other processes applied to the extract? There is also the planned implementation at national levels of the global principle of states sovereignty on their biological resources. This can, from one national regulation to the other create a lot of heterogeneousness and consequently of confusion and distortions which are the contrary of what the companies need. Moreover, The Raw Material Initiative proposed by the European Commission and the Doha round touch on a similar subject without clear coordination. This increases the risk of confusion in a field which is of crucial importance for the planet.

As you know, companies are not opposed to rules but they need clear, fair and universal rules to be able to conform to them in an efficient way. We tend to think that in this very important field like in others there is no efficient implementation of international rules without global governance equipped with a strong power of sanctions. The recent financial crisis made this very evident. The CMOs are confronted to another kind of concern.

They constitute a significant branch of the French health industries recognized for the high level of its technology and know how which enables them to guarantee full traceability and safety of the drugs they manufacture.

This sector is still expanding thanks to the generic market but it has to face the slowing down of the pharmaceutical market enhanced by the fact they are mainly working on mature products. They have also to resist the nascent competition of emerging countries. Moreover, as they have been missing, at least until now, and together with their clients, the turn towards biotechnologies they are trying to extend their potential of development through an offer of complementary services.

Nevertheless, in the long run, they will have to find a way of development for the core of their activity which is contract manufacturing.

On their side, the research and evaluation companies have to deal with the French law framing the protection of human volunteers in clinical studies. This Law, which is unique in Europe, is certainly very useful but for some studies which do not constitute any risk for the volunteers, essentially in the cosmetic field, its implementation can constitute an incentive to delocalize the studies. Thus, the challenge for these companies is to become more international.

In front of these very diverse issues, FPS stands at the sides of its members so as to support them and contribute to propose and find solutions at French, European and International levels.

As I often say, our Organization is not a very large one but it is very active and mobile on concrete issues.

What really attracts us about your Organization is the focus on SMEs. In the context of globalization, multinational giants and mergers SMEs are arguably in a difficult position. Germany is a great example of this. What is your opinion?

In a given country, the presence of big companies generally means the presence of a market, which in turn means that SMEs, which are small and mobile, can operate.

In Germany there is a very specific case. Since the last war, Germany has benefited, in addition to its technical and commercial ability, from extremely stable means of finance for its SMEs, giving it a

distinct advantage over France. The very stable financial backing from German banks and Landers means they have been able to innovate and expand abroad. As a result, German companies were able to settle subsidiaries or offices abroad much more than French companies. Only a few % of French SMEs have achieved this in comparison with almost 30% of German counterparts. And settlement on international markets, technical or commercial, is a key factor for the expansion of a company.

However, it would be unrealistic to ignore the recent changes: competition from emerging markets such as China, Brazil and India is now weakening Germany's competitiveness and affecting its advantage.

As you said, French SMEs are not known internationally compared to German ones. What do you think is missing and can French ones become more successful on an international level too?

One issue for French SMEs is that during long decades many of them have considered Strasbourg and Brest as the end of the world. Outside France, business did not seem to exist. France was the most important market first and foremost. The creation of the European space helped to go out of this and with globalization, things are changing fast. Many of our SMEs began or begin to look around the planet and try to make up for lost time.

We can refer to the example of CMOs, a sector which, as I said, works extremely well in France, is dynamic and from which many important groups have emerged but which also have to face the question of its future development and the competition of China and India. To expand abroad and to manufacture in foreign markets, and especially in and for the emerging markets of tomorrow, is one of the major keys to their future in my opinion. It has been proven that such an approach leads the most often to development, globally and even inside the country of origin.

In the pharmaceutical industry, it is essential for our SMEs to work closely with big Laboratories, and exchange knowledge and experience to facilitate this process.

Another problem for French SMEs is the dichotomy that reigned for a long time between the world of politics and the world of business which, it must be said, was not the case for Germany. Fortunately the today's French Government is closer to the concerns of the French industries and makes significant efforts to support them, including SMEs willing to export.

Take China for example, how easy do you think this is? How easy is it for French companies to be successful in China?

I can give you an example: 20 years ago, a French company decided to expand into China. Before doing so, they hired a Chinese native who was trained in France and then sent in China to study, understand and describe the market during 4 years even before even beginning. Now this company is well established in China. Ultimately it is impossible to approach business in China from a Western point of view as the way of thinking is very different to ours. Especially, time and understanding are very necessary. It is clearly a difficult task, particularly for SMEs but it is possible. And if we want to preserve dynamism and move on, expansion in this country is essential as well as in Brazil, India, Russia and, why not, other markets.

A white paper in September was released detailing 6 main drivers. As vice-president of FEFIS and president of Facophar-SantÃ©, which is most important of these for the SMEs you represent?

They are all important, but if we can maintain and develop innovation, if, for instance, we can come back faster on biotech, this will be profitable for everyone including our industries.

The other point is the support of important companies to facilitate the access of SMEs to settlement on new markets. If, beyond the declaration of intent, practical cooperation is developed, if, for example the major pharmaceutical companies concretely help their CMOs or active principles suppliers to go along with them on new markets through cooperative local settlements, our White paper will have a very positive effect.

In terms of biotech, do you believe France is behind, and if so, what is the future?

Everybody knows and recognizes that France is late in the field of biotech. However, all parties involved, from the government to industry, are now conscious that it is necessary to make up lost time. We have the ability to do it and, as we say in France, it is never too late to do well. So I am optimistic and I think that the French industries will come back on this scene during the coming years. It's a possibility that the measures taken to get out of the economic crisis could boost this process.

What are the things France doesn't wish to change quickly?

With a touch of humor, I would say that all individual French wishes many changes except for himself! More seriously, it is true that there are many corporative resistances to change. But this is probably valid in many other countries. In France the only problem is that the need for changes being huge everything comes now fast and in the same time. It creates a kind of shock.

I really believe France would like to change, or better, improve. Significant changes already occurred during the two last decades, especially with the globalization. Many other changes have been engaged for two years by our present Government and the results will appear progressively within the next years. New changes are still to come soon and France is moving ahead.

Obviously this implies also a drastic change in the spirits and in some aspect this will take time. We have, for instance to end with the concept according which work is considered as unnatural when, beyond the gained wages, it is a real way to construct individuals and make them proud of their life. We have to rebuild a system of references which will rule the social life during the 21st century when the previous ones have been destroyed following the events of May 1968.

We have also to put an end to the trend to "cold war" between the different components of the French society and relearn to work together for a shared benefit. In order to do so, the political world and the media will have to achieve their change and stop disseminating combative messages instead of unity. It will take a bit of time but we are on the way.

The only thing France does not wish to change is its social system even if it looks costly. This will be the challenge of the next years and decades: change the country, its economy, its society but keep the social protection which was so precious during the recent crisis.

What is your final message for our readers about the French pharmaceutical industry?

I would urge them to recognize the potential of our industry, see beyond the particular characteristics of our country and buy French or look to expand here for opportunity, plenty of which exists.

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