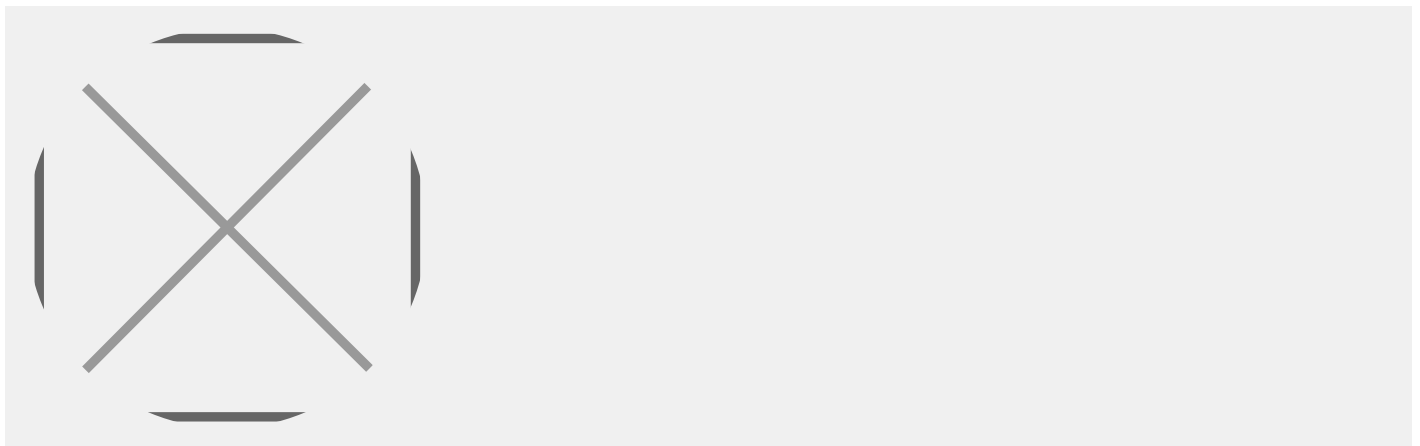


Interview with Christian Rodié, FEFIS - Fédération Française des Industries de Santé



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FEFIS represents 11 different associations across the industry with a very broad scope. How does the organization represent all of these different sectors?

FEFIS represents as much as possible activities involving the health field. For many years, the organization was a sleeping association but about five years ago Jean-Pierre Cassan, the former president of AstraZeneca France, realized the importance of such an organization and started to act. At the time there was significantly fewer members, among the first members were LEEM and Sicos but under Cassan, FEFIS reorganized under a new statute to admit more members. Today, we represent a larger scope of the health industry including distributor, optical, medical device as well as veterinary associations which represent over 900 companies and 2300 industrial facilities in France.

As an organization we may have an important effect on the government through lobbying, especially by working with the MEDEF to draw attention to the health industrial sector. It's very important for all of the health associations to work together as you have a larger impact with a combined voice. For example, if you have a factory with 60 people in a small town they have a lot more leverage with local authorities if they are part of our organization. This is why we are making a push to be present at the local level and ensure we are seen as an influential association. We think that combined, all of these activities are very important because in the end there is more export than import activity in this sector which means this industry supports France. Moreover, in the long run the health industry is growing so France can take advantage of this, provided the Chinese and Indian companies do not come and buy up all of our chemical plants and laboratories.

France has a good history of innovation which is evident through our research facilities and programs like Institut Pasteur. There is a tradition to investigate health problems and develop solutions. I cannot say whether this led to a good protection system or if the protection system led to this drive to research but in either way it has brought about a strong pharmaceutical industry and health sector. However, year by year we are losing our range of innovative talent which is a pity. Individually, France has a lot of quality researchers but the governing and financial system is restrictive to the point that it restricts the ability to work together. This means that a researcher will likely work for himself within a company and that the company will work for itself rather than for the country and so on up the chain. As a result, rather than being a leader we are going backwards and losing the drive to innovate.

Just last September, FEFIS and MEDEF released a joint white paper which identifies the principals of the organization and at the same time MEDEF announced the founding of the business committee MEDEF health. Can you speak to the importance of this group?

Laurence Parisot and MEDEF agree with us that the industrial activity of the healthcare sector is not a burden but rather an opportunity for employment and economic success in France. Therefore in order to improve the landscape for the industry, MEDEF decided to create this committee that can identify the key issues. At the same time, President Sarkozy has accepted to reconvene the Conseil Stratégique des Industries de Santé (CSIS) on the 26th of October which was originally created in 2004 by former President Chirac. FEFIS as well as the LEEM has been pushing for this meeting since the last one in early 2007 and in the beginning of 2009 we learned there would finally be another. This means that the French government is considering the health sector as one to protect and develop because it benefits the overall economy. If this attitude had transpired several years before, then maybe France would not be so late to develop the biotech arena. This is an unfortunate setback as 50% of new medicines will use biotechnologies and France's presence in the field is small compared with the UK, Germany, Japan and the US. However, France still has to be attractive to some people because French laboratories are being purchased by foreign companies which mean there is individually some energy left in the country but there is no chef d'orchestre.

With the expiration of many big patents approaching it looks as if there will be a shift in the industry to the biotechnology field. How is an organization like FEFIS prepared for the rise of biotechs as there appears to be no association representing this sector?

There is no particular group however. Sicos also represents biochemical companies but from our 70 members there are very few involved in this field. When we attempt to make a group around this sector nobody wants to participate, instead they prefer to stay within their own company and keep their secrets. Therefore I doubt FEFIS will make any particular group for biotechnology.

There is a clear lack of biotechnology in France and Madame Bachelot at the Ministry of Health will tell you how they are pushing the industry and the foundation of Lyon Biopole as well as the poles of competition. However, I still do not know how we can recover from the delayed start.

Laurence Parisot at the MEDEF has been pushing for more liberalized employment laws. How much do the labor laws have an impact on the investment environment for research?

What we need is for people to be confident of the future which is a challenge in France because the priorities are constantly changing. When you want to initiate a big sector like biotechnologies you need a long-term view which France does not currently have. Laurence Parisot is pushing for the time being and if others continue to push for years and years then there is a chance for success. If after two years people decide to shift focus then nothing will happen. Therefore we need persistent pressure from the government, MEDEF and companies to push biotechnologies into the future.

The rise of China and India is apparent in their production of APIs and growth up the value chain but there is still a lot of hype around these markets. What does France need to do to stay ahead of these rising pharmaceutical powers?

France has to join in with other European countries and push policy at the European level to obtain appropriate regulations in order to draw level with China in the future. While China does pose a threat at the time being it is also making mistakes. For instance, what would happen if somebody died in France from a tainted product produced in China? It already happened in the US but when you bring it up with AFSSAPS they point out that there were no cases here. If European authorities were to really investigate the entire production process in China and India they would likely run into complications. This means they would have to convene and come up with a solution while condemning the standards used for production.

As long as China and India do not play with the same rules as France then it will be quite difficult for France to maintain position. This is not to say there are not good companies in India or China but there are still problems in these markets. AFSSAPS needs to follow the role of the US and conduct compulsory audits on Chinese companies before importing. When a Chinese company wants to sell its product within China it has to go through certification that is comparable to cGMP but if they want to export they do not need to meet the same qualifications. Therefore the Italian, French and other European chemical companies will suffer as long as this double standard exists. Over time the costs to the Chinese companies will increase but by the time it reaches French companies they will be finished already.

There needs to be more transparency in the industry. Over five years ago I proposed adding the source country of a medicine's APIs on boxes in the pharmacy similar to how produce is labeled in a supermarket. It does not make sense that a consumer can know they have a Spanish orange or

Chilean cherry but have no indication where their drugs come from. Personally, I would pay more or be reimbursed less, for a drug using APIs sourced from Europe because I trust the source more and I prefer to support the European workforce. It should be my choice as I am the consumer.

One of the main issues in France is the perception that health is free because we do not directly pay with our carte vitale. Naturally you do not care about the details of something that is free which is why every French medicine cabinet is overflowing at home.

Don't the consumer's trust the labels of Sanofi-Aventis, Pfizer, MSD and the like?

For two to three years now the government has been pushing generic medications in the pharmacies so that today when people receive these prescriptions they think: why not? There is a problem of quality information and distributing it to the public. Generics have historically struggled in France because of the lower prices of innovative drugs compared to the rest of Europe. For instance 15 years ago I was selling an API to a French affiliate of a US lab as well as to his German subsidiary lab, which were making the same capsules. I always had a problem with the French subsidiary because their selling price to the public had to be very low: half of what the German company was selling at. Since generic offerings have to sell at a discount to original products there was no room for their producers to make a margin. Today the situation is much better and the originator prices are higher and in line with Europe. However, this means sometimes you will go to a pharmacist and ask for the Sanofi-Aventis brand and they will not have it.

The definition of generic has also changed overtime as it originally was the name for a medicine after a patent expired and would have the same composition as the innovative product. Now, the name applies to anything with the same equivalent APIs while for instance the pressure used for tableting can differ from tablet to tablet so it is no longer exactly the same, even if you accept the bioequivalence.

You have been in the chemical industry for quite some time. How would you grade the industry today against its global counterparts such as Italy and Germany?

Historically both the French and the Italians have been very active; the Italians because they were free not to respect patents and France because the chemical companies belonged to laboratories. This was due to the fact that prices for French medicines were tied directly to government decisions for reimbursement; once this was set your price was effectively fixed. In order to circumvent this issue, laboratories would create new medicines that were not far from the original in design. Each time a laboratory did this they were asking their chemical company to innovate their ingredients which resulted in higher activity. Moreover, laboratories wanted their own chemical companies because the ingredient prices were set at a market price and if a lab could make the raw material for less in house then they would gain higher margins.

As a result there were a lot of chemical companies and know-how residing in France so they began to produce for the external market. When I first joined the business in 1966, the company I was working for made only 1% of their turnover on exports. There was a lot of opportunity in the international market and when you participate on the global level you are in competition with others which demands a better product. These factors are what developed the French chemical industry to its current level.

Today, French chemical producers no longer belong to laboratories with the exception of in-house production at Sanofi-Aventis, Servier, and a few others. They are still competitive on the global level but the government is highly restrictive of the industry. The Ministry of Industry as well as Environment have created Directions Régionales de l'Industrie, de la Recherche et de l'Environnement (DRIRE) which is responsible for auditing production sites to see if they meet regulations. The way that they follow regulations is unfavorable to companies in that they come to check the books, examine the processes and issue fees without considering the business environment. If you examine a comparable organization in Germany the process is approached differently because people favor industry and chemistry. Moreover, because these rules are implemented by the officials in each region, the requirements are up to interpretation.

What is your final message about the French pharmaceutical industry to our readers of Pharmaceutical Executive?

There are many people in France trusting and hoping that fine chemical activity will at least remain or grow from its current level. We want to be seen as positive influences on the economy as well as safe for the environment.

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