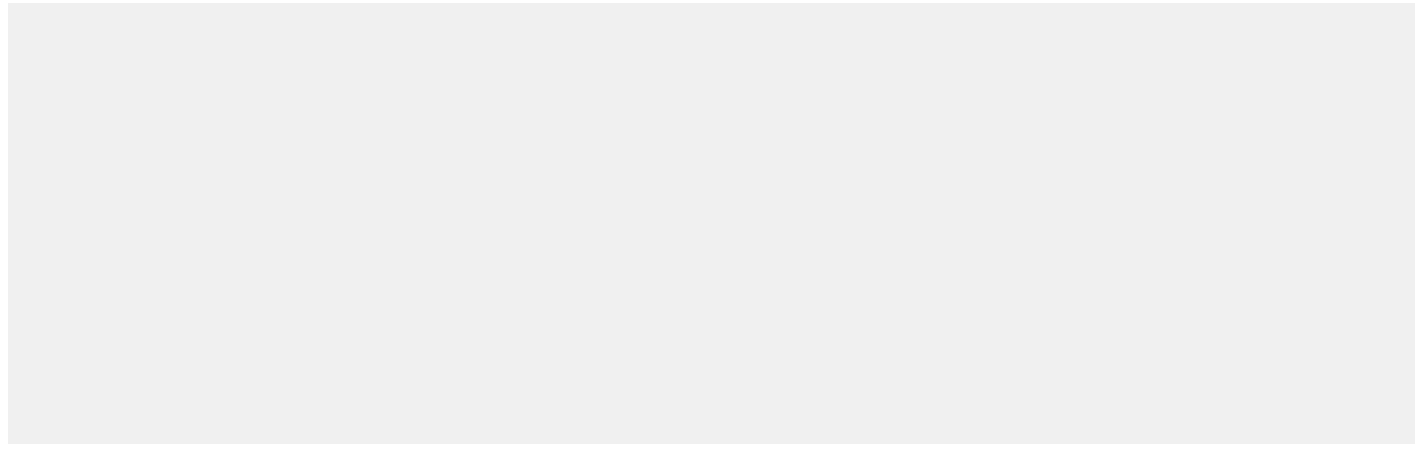


Interview with Ernesto Felicio, Executive Director of CAEme and Executive Vice President of FIFARMA, CAEMe



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Through your work as member of the Council of the IFPMA, as well as FIFARMA, and CAEMe, you must have a very developed and unique perspective on the characteristics of the Argentinean and International pharmaceutical markets. Can you explain the importance of Argentina within the Latin American framework?

One important thing to highlight when we talk about Argentina in the Latin American context is that local companies hold more than 50% of the national market. This is something that not all international companies keep in mind when working within a global or regional model or template. It is fine to think global, but unless you act local you run the risk of paying a high price here. Any Regional President at any headquarters of most MNC's will tell you that the Argentinean operation is management time consuming as there are other major markets. It's not easy for the local managers to transmit and communicate what's going on, without generating sometimes, uncertainties that are not more than the result of the regular way of doing business in Argentina. This market is unnecessarily complex and complicated. That's the rules of the game.

In the 70s, Argentina's main export in our Industry was people. Besides human talent, Argentina has a very well developed industry in terms of quality, and of course this also relates to the fact that several local companies did the proper homework. In fact, many multinational companies have

contracts with local manufacturers who are internationally certified to export to markets with high quality standards. In spite of that, more than two-thirds of the exports of finished pharmaceutical products belong to companies that are members of CAEMe. We have a lot of inter-company trade. This, among other reasons may have to do with the fact that CAEMe is the oldest trade association in Latin America: we're 85 years old.

Due to its recognized quality and efficiency of our medical doctors, Argentina is one of the leading R&D markets in Latin America. We are very proud of what we call "the industry without chimneys" that invest in R&D in Argentina more than \$ 150 million, almost on an annual basis. This is equivalent to the amount required to build several manufacturing facilities. It is important to highlight that this annual investment, implies hiring highly qualified hand labor as well as making an effective and clear transfer of technology. This transfer of technology will be the base for the future generations of Argentinean Investigators. In this figure we are not taking into account the CRO's operating in Argentina that would claim a similar amount of investment in our country. Just think for a moment, that for each 1.0 percentage point invested in the clinical trials performed in Argentina, there is approximately 1.5 point per cent increase in the hiring of highly qualified labor.

Argentina is a market that requires a seasoned executive in the position of General Manager. Sometimes, companies are not willing to invest those human resources in this market, especially after the traumatic devaluation of our local currency to the American Dollar at the end of 2001. In many cases they lost competitive advantage against not only the well established local companies, but also their multinational colleagues with whom they also compete.

A lot of local Argentinean pharma companies fought against Intellectual Property regulation for a long time before it was finally implemented in 2000. As you not only represent both multinationals and local players, but also have experience with a local pharmaceutical group, how do you feel towards the implementation of these regulations?

Like in many wars, problems start due to a lack of communication. Don't forget that institutions does not exist but through their people. In this case we should add other ingredients to the lack of communication, like too much ambition from one side and too much arrogance from the other. But this is history now. Hopefully we can learn from it. Let's look forward. It is worth to say that after many years of inactivity, in 2005 the INPI has started to work again, and grant patents.

We were very happy to see the changes that took place at INPI four years ago. Over 1000 patents have already been granted, including process and compounds. As mentioned, after a huge initial push, we saw INPI significantly reduce their output. They explained that they were focused at the

beginning on moving forward those applications that had already been pre-reviewed, and now they are starting to review new applications, which is taking more time. They have done a very good job between 2005 and 2007, and I know they are looking at options to increase productivity. It's not easy, as since they became better respected and more relied-upon, they are on the lookout for more IP-trained lawyers to work with.

While we had some concerns over the last year and a half, because the productivity was not comparable to previous levels they are trying to do their best to catch up with the significant backlog they still have. We remain confident they will reverse the current trend. No doubt they have a significant challenge ahead. If they fail, the image of the country will suffer.

ANMAT has a very good international reputation . It was created with the coaching of the FDA, and it was ANMAT who helped to create ANVISA in Brazil later on. Again, the time it takes to register a product in Argentina is very short: if the product was already approved in a market with high quality standards, it will receive immediate approval in Argentina. It can take about six months. Few countries can show that.

Another issue that is very important to the multinationals is that of pricing. Could you comment on the pricing situation in Argentina for our readers, and what it means for the companies you represent?

It means the same for any company in any business. In countries that have not a very strong currency and have the threat of inflation, the net results of mixing inflation, devaluation and price will make the difference of those who die and those who remain alive. As a consequence, there are no doubts that in a country like Argentina, prices are critical. When the country started to face the threat of inflation, the government started to do something that they had not done since 1991, which was to intervene in pricing. The Secretary of Commerce took the leap, and started to give directions to the industry about how much to increase prices and when. After years of proven responsibility, the Industry deserve the right of going back to the self control model.

Your government recently launched investment opportunities in the biotech sector. Argentina has been at the forefront of applying biotech to agribusiness, but how do you see these opportunities will reflect on the healthcare sector in Argentina?

I think it's going to be the next move, absolutely. There will be a lot of competition, not only from multinationals but from local companies too. By no means every local company, as we have 300 companies registered in Argentina. However, there are several local companies that are working in biotech. The ANMAT is working in a regulation for the approval of biological products. Taking into

consideration the well earned international reputation of ANMAT, we feel confident that the final outcome will be a regulation « second to none.

Things are getting more global, and in addition of having most of the R&D-based companies, we also have other companies that don't necessarily perform R&D, but share our values. This include all of the argentinean companies that are members of our association and we are very proud of it. Specially, because all our 47 company members, are the only ones, out of more than 300 that suscribed a Code of Ethics for Marketing Practices.

The creation of the Ministry of Science and Technology was an excellent step, and we are very happy that the Government appointed to lead it, somebody who knows what he is talking about. It was not a political appointment, but a technical professional appointment, and there are high expectations from the R&D community.

How do you think the framework to put this innovative economy into place is coming together in Argentina?

We have to hope that the government will walk the talk. For the first time, we have a Ministry of Science, Technology and Productive Innovation, and this is not only a very good sign, but a very encouraging one.

What makes Argentina such a good place for this investment to come to?

Its human resources and the committment of the government to stimulate investments. Since everything related to intellectual property on pharmaceutical R&D is relatively new in Argentina, the acid test has not taken place yet. We remain confident that the laws will be properly enforced when and if necessary. Will keep an eye on that.

The Executive should not underestimate that Argentina is the country with the largest amount of single inventors regardless of the size of the population than anywhere else in Latin America. There are many small firms and small inventors applying for patents or trying to do so, being the only limit their economic resources. We still do not understand the reasons while Argentina did not suscribed the Patent Cooperation Treaty (PCT) that will allow, basically small inventors, to take advantage of its benefits.

From what we've been reading, the government is aware of the potential of the industry; now it's waiting for the different actors to come together. As you said, you work alongside CILFA and COOPERALA, but how much do you work with ANMAT, INPI and the government in order to join all the pieces together?

With a few exceptions, we work together and collaborate as a team. There are obviously some specific interests that are not necessarily the same, but they are real exceptions.

Usually, the associations representing local companies and multinationals fight a little with each other because of their interests.

The quality of the problems and the impact of those problems is the same, no matter what your association. So when you talk about intellectual property, you might hear noise from some corners, but CILFA has some companies that apply for patents outside of Argentina, so it will be in their own interests to protect intellectual property. Only a responsible government can take care of this. We hope that the government of Argentina will make decisions on sensitive issues such as intellectual property by taking into consideration what is best for the whole country, and not just a group of companies. This has to do with education, maturity and a healthy defense of the real national interest.

The rankings for the top pharma companies in Argentina show Roemmers, Bagó, Ivax, and Gador all ahead of Sanofi-Aventis, Bayer, and Pfizer. How is CAEMe helping these companies to reach the top spots on the list? Is it possible?

There is a limit in what a non-for profit organization can do on commercial matters. Nevertheless, our association, together with the the sister associations, negotiate agreements for drug supplies with the different provinces and HMO's . In addition to that, we deal with government related issues like taxes, health regulations, Customs, Mercosur, etc. that are common issues for all of our company members. In addition to that, we can say that when you are a big company, a high percentage of growth is more difficult to achieve than when you are a smaller company. While organic growth is smooth and healthy, the main « fast growth » of multinational companies comes from mergers and acquisitions, not always as healthy as the organic growth, I have no doubts that the trend of mergers and acquisitions will continue, and we will see more of that in the future. Still, our industry is very fragmented worldwide. When you compare it, for instance, to the automobile industry, 90% of the top players can be seated in this table.

Is there a final message that you would like to send to the local and international community about CAEMe's activities?

Yes, a couple: We will keep working to stimulate and support R&D activities in Argentina: it's excellent for the country; it brings an effective transfer of technology, and training of people, it allows patients to have access to a last generation of products. Also, it brings training to future opinion-makers. At the beginning, only professors and heads of universities were hired to do R&D.

The explosion of R&D in the middle of the 1990s was such that a lot of young people, excellent professionals, started working in this field too, and that is important for the local community to understand.

Another comment, nothing new, is that normally, whenever major problems arise, those problems are not always solved within the same fiscal year. So, It is important not just in Argentina, but in any developing country, for companies to have a long-term view. I have seen companies repeating the same mistakes they made several years ago. If they can find a way to develop a corporate memory, can make a difference.

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