

CAEMe - Ernesto Felicio, Executive President - Argentina



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Tags: [association](#), [regulation](#), [pricing](#), [MNCs](#), [innovation](#), [support](#)

On behalf of the chamber of industry that represents research-based pharma and biopharma companies in Argentina, Ernesto Felicio discusses the current challenges facing the industry, and the chambers current agenda for change.

To what extent has the environment for multinationals, or their role in the Argentinian pharmaceutical industry, significantly changed over the last five years? Have the “rules of the games” changed?

Over the past five years the situation has changed for all the economy, and that has had an impact on all activities, including the pharmaceutical industry. The economy as a whole is slowing down, costs (due to the evolution of the currency exchange rate and inflation) have increased and the prices have not accompanied this evolution.

Nevertheless, we haven't see major changes in the overall market share held by our company members. What we saw in the past years was an increase in joint initiatives between local and international companies.

What have been the priorities of CAEMe?

We deal with a variety of issues.

The participation of biotechnological products is increasing worldwide. We believe that the regulatory framework for these products has to take into account their special characteristics, and be in line with international standards. We have been accompanying the process locally and offering technical information to ANMAT in this regard. If Argentina is going to export products manufactured here, we need regulations that meet the international requirements.

We have also been, and are still, working to promote our Code of Ethics which deals with good pharmaceutical practices and interactions with healthcare professionals. CAEMe associates subscribed to a Code which was the first of its kind for pharmaceutical industry in Argentina and there is none which can be compared in terms of scope and depth.

Another area of concern has been export of services, through an increase of clinical trials that accounts for more than 400 million dollars over the past twelve months.

Also, CAEMe has just obtained an ISO 9001:2008 certification, for its quality management systems. We are the first chamber in our industry to get such certification.

We are very pleased with this achievement, which comes when we are about to celebrate our 90th anniversary in 2015.

One big challenge for some of your members is the weak intellectual property protections. What remains to accomplish in Argentina in this matter?

Intellectual property is a tool to foster innovation worldwide. In fact we see many local companies developing products and filing for patents in many countries. Locally, however, we see a setback, which we believe will affect not just companies but the overall R&D scenario. In May 2012, the ministries of Industry and Health and the INPI issued a joint resolution that introduced a set of criteria for pharmaceutical patent applications, and has in effect created a significant barrier preventing many innovators from receiving legal recognition of the Intellectual Property, as these criteria apply to most pharmaceutical applications. This is bound to affect future investments in the country.

It contradicts the government's decision to support and foster scientific and technological development, which will also affect local companies, universities and research centers and future collaboration with other government and international research organizations.

Despite the challenging macroeconomic environment, we are seeing many investments from the MNCs both in manufacturing sites and research activities (Pfizer, AstraZeneca, Sanofi, for example). Could you share with us the biggest achievements and

investments of CAEMe members?

The continuous expansion in the clinical trial activities as mentioned before plus the sustainable exports as a result of the intercompany trade that, depending on the moment of measurement, account for 40 to 60 percent of the annual exports of finished pharmaceutical products.

There have also been some joint ventures between MNCs and domestic firms, which have resulted in significant investments. For example, a vaccine production facility, which will be jointly owned by a domestic and foreign firm, is currently under development.

What potential do you see for your members to conduct clinical trials in Argentina?

The fact that more physicians have been trained in this activity and the recognition of the high quality of the Argentine medical community are the main drivers. Also the local regulation is very good and in line with international standards when it comes to controls and patient safety. When you see that Argentina today represents less than one percent of the worldwide share, you can easily envision that there is still a lot of room to grow.

What trends do you see in the pharma industry for the future?

A consistently significant growth in the biological field, as a result of trend of personalized medicine.

The Argentinian markets cyclical and unpredictability makes a general manager's ability to act and adapt quickly an essential key to success. Local companies have the advantage in terms of making faster decisions in changing conditions as they have specialized knowledge of the market, so for foreign companies to be successful they need managers who have an in-depth understanding of the local environment that are able to make significant decisions deftly and quickly, which limits the field of suitable candidates to those managers with extensive experience in this market.

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