UNC Hemoderivados – Catalina Massa, Executive Director – Argentina

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The executive director of Latin America's largest plasma fractionation plant, a publicly-funded laboratory within the 400 year old National University of Cordoba, discusses the organization's social responsibility as a provider and leader for plasma derived therapies in the region, and their exciting pipeline of innovative biotech products.

How does Hemoderivados's role as a regional leader affect the organization's social mission?

Being responsible for the supply of medicines to patients in multiple countries with separate healthcare systems is much more complex and significant responsibility than dealing with only one county's system and patient population. We do our best to provide a stable and positive response to our partners in Chile, Uruguay and Ecuador, and treat their medical facilities the same way as we treat Argentinian facilities.

Do you think that this model of South Cone mutual cooperation has the potential to work in other areas of healthcare?

I was recently invited to present our model at a medical symposium in the United States, and the attendees were very impressed with the success and quality of our “public industry” here in Argentina. Moreover, many people were surprised to learn that we were working with other countries and helping our region as a whole to reach self-sufficiency for plasma products.

So yes, I think it is quite clear that there is significant potential for mutually beneficial regional cooperation on other healthcare issues. One example, that we are already taking steps to develop, is the need for organ preservation liquids across the region, as there are no other facilities producing these products in the region at the moment. Once we develop enough capacity to meet Argentina’s needs, our next objective will be to meet the demand for the region, while cooperating with their own health authorities.

Furthermore, we have a social responsibility to do our best to work with the other countries in our region because the quality of healthcare varies greatly from country to country; in some areas within the South Cone region, health authorities are not adequately treating some immunodeficiencies or hemophilia due to a lack of plasma products. As a society with the capability of helping to improve and develop the quality of healthcare in these countries, and with the benefit of being more prosperous in general, I see it as our moral duty to contribute as we are able.

What have been UNC Hemoderivados's biggest achievements in the last five years?

We are in the process of signing a new plasma exchange agreement with Paraguay that should be finalized by the end of the year, which will be the fourth such agreement, as we already exchange plasma for plasma products with Chile, Uruguay and Ecuador. Furthermore, we have obtained marketing authorization for a new plasma product, prothrombin complex concentrate, and have registered an immunoglobulin product for the treatment of Hepatitis B.

As you have seen, we have expanded our facilities by 5000 square meters: we have built a new Injectable Drug Plant, a new plant for final formulation plasma products, a new plant to produce water for injectable drugs and we have expanded our plasma fractionation facilities.

In addition we received two subsidies from the Ministry of Science, to develop Recombinant Factor IX products and drugs for the treatment of tuberculosis. Both projects will be done in collaboration with CONICET.

What was the motivation behind moving in the generics direction? How would you describe the "social role" of Hemoderivados?

The social role of Hemoderivados has two somewhat separate aspects, one is to produce expensive medicines at a more affordable price, the other is to produce medications that are not currently being produced by anyone in our country, or in the region. One of our ultimate goals is to help the south cone region of Latin America reach self-sufficiency for plasma and blood products.

In Argentina, many injectable products are quite expensive, much more expensive than the price that we are able to produce them at. We have always been an institution that the federal and provincial ministries of health will contact with requests to produce certain medicines for the public system, and we always have accepted such requests that we can reasonably meet. As time has moved on, the list of primary care products we produce has grown, and now we are producing some orphan drugs that were currently being imported at very high prices. Now, we are producing Edetate Calcium, to treat lead poisoning, which is not produced in any other laboratories in the South Cone region, Chloride Hypertonic Solution (7 percent) for cystic fibrosis which is not a popular drug to produce due to the low profit margins, and we are developing Hematin for Porphyria, which is currently only produced at one other laboratory in the world. Another area that we are working is organ preservation fluids, at the request of the ministry of health since 100 percent of these fluids were being imported previously.

How comprehensive is UNC Hemoderivados's portfolio of plasma products at the moment? What are some of the treatments you would like to add to it in the future?

We currently have some plasma products in development that we hope to register in the future. Our Plasma Factor IX is currently undergoing stability studies, and our Fibrinogen concentrate and Fibrin glue are products currently in the development stage. A subcutaneous immunoglobulin has also recently been submitted to ANMAT for registration. There are many other treatments and areas that we would like to develop in the future, and we are constantly reviewing proposals and requests to find the opportunities that are most attractive in terms of efficiency and social impact.

UNC Hemoderivados is one branch of the National University of Cordoba. What role does the rest of the university play in your research process?

As a 400-year-old education institution, the university has an impact on everything we do, and an impact on most things that happen in Cordoba. The main impact is that because we work in proximity to academics, and are still academics in many regards as we are technically employed by the university, our mindset and culture is more rigorously scientific in nature and not dominated by commercial concerns. More tangibly, we work closely with different departments of the university when developing many of our products, and benefit from the academic staff's expertise.

Of course the other side of the equation is that the university tries to use us as a resource for furthering their research in many cases. Everyday I get requests from researchers wanting to do different projects with us, and unfortunately we're only able to accept a fraction of the proposals brought before us.

When our colleagues met with you in 2009, you were organizing a technology transfer with Cuba that fell through. What were the repercussions of this failure, and what solution did you find in the end?

The proposed transfer would have involved us giving them part of our method to obtain immunoglobulins in return for a plasmapheresis technique that would have improved our ability to obtain plasma. For us, it was fairly critical that we develop a plasmapheresis method as we were severely constrained by the quantity of plasma that we were able to obtain from blood transfusions. When they rejected our proposal, we started to look for other ways that we could develop a plasmapheresis process and program, which in the end we did largely by ourselves with some support. Two years ago, we finished development of the necessary technology and began the operation of a plasmapheresis program at the blood bank here at the National University of Cordoba.

In 2009, your fractionation capacity was roughly 150,000kg per year, and you were actually fractionating nearly 100,000kg. How much have these numbers increased in the last five years, and how significant is it at the regional level?

Our current capacity is 250,000 kg per year, and by the end of the year we will have fractionated about 140,000 kg. Next year, taking into account the plasma coming from Paraguay as a result of the exchange agreement that we are currently finalizing, our output will increase materially.

At present, roughly 35,000 kg of our plasma supply comes from outside of Argentina, and we are their primary source of plasma products. In the few cases when our shipments have been delayed, we start receiving phone calls from the foreign health authorities immediately as they do not have the budget to replace the volume we supply by buying from the private market.

What would you like Hemoderivados to achieve over the coming five years?

I'd like us to continue to develop our role as the institution of reference for plasma products in Latin America, and continue to increase our output to help our region reach self-sufficiency of plasma products. All of our other objectives for our plasma division are in support of this mission; continuing to update and improve our technology and processes and to maintain the quality of our products and continue to meet international standards. Furthermore, I would of course like to see us launch as many of the products we currently have in development as possible, especially our recombinant factor IX. To commercialize some of these products, we will likely create a new semi-autonomous organization that will specialize in producing raw materials for the manufacturing of recombinant products, although this project will likely extend beyond the five year horizon.

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