

# Interview: Eduardo Arce Parellada - General Manager, Sanofi Pasteur Mexico

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*Eduardo Arce Parellada, General Manager at Sanofi Pasteur Mexico until March 2017, explains the positive impact that*

*the vaccine against Dengue could generate for the national health system and showcases the positioning of Sanofi Pasteur as the partner of choice for the government in vaccinology, based on its local R&D and manufacturing capabilities.*

**In December 2015, Mexico approved Sanofi Pasteur's dengue vaccine, marking the first time a dengue vaccine has been licensed for use in a country, and therefore a major milestone in the history of vaccinology. How has this experience been for you as General Manager for Sanofi Pasteur in Mexico?**

The end-to-end development of the vaccine against Dengue® in Mexico has been a milestone for Sanofi Pasteur and I am proud to have actively participated in it. Dengue is one of the most important health burdens globally and it is continuously growing its footprint because half of the global population is living in endemic areas. Just to give a real example, there were 10 states in Mexico with Dengue cases a decade ago and such disease can be currently found in 30 out of the 32 national states.

The discovery of this vaccine has taken more than 20 years of development in our R&D centers. Indeed, Mexico participated in the development of the vaccine from phase I to phase III and it is worth mentioning that, on December 9<sup>th</sup> 2015, Mexico was the first country in the world to have the Dengue vaccine registered. It is the first time that Sanofi Pasteur has implemented phase I trials outside the US, Canada or Europe.

The rationale behind the decision of developing such vaccine in a country like Mexico is that Dengue is an infectious disease with strong impact in low or middle income countries; rather than already high developed nations such as France and Spain. Such strategic decision has changed the pharmaceutical industry paradigm of developing new medicines in rich nations before launching them in emerging countries.

### **Could you expand on the impact that such an innovative vaccine has had on Mexico?**

It is the first time that the Mexican population and the rest of the citizens from those countries where the vaccine against Dengue is already registered can really prevent the disease. Indeed, the vaccine can prevent two out of three cases of Dengue and prevents 80 percent of the hospitalizations as well as 93 percent of the severe cases.

It is obvious that such immunization enhances the quality of life of the global population but, if you look at it from the economic standpoint, this vaccine can create huge savings to the public and private institutions as a consequence of reducing the cost of the treatment.

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Referring to Mexico, the vaccine against Dengue plays a critical role because the national public health infrastructure is highly saturated. Such vaccine, thanks to its aforementioned reduction of hospitalization cases, would help the Mexican government treating more patients that are suffering from other diseases such as oncology and diabetes.

**The treatment is now approved in more than 14 countries, and in Mexico it has recently entered the private hospitals. Dr. Narro Robles told us that his first mission was to consolidate Mexico's public health successes, particularly in terms of vaccination. As partner of the government, why are you optimistic that major vaccination programs will soon happen in the country, both in the public and private institutions?**

It is an interesting fact that Mexico is a country with one of the best and more complete vaccination programs globally. Therefore, it means that vaccinology plays an important role within the Mexican healthcare plan. I would like to reinforce that Sanofi Pasteur is not positioned only as a vaccine

manufacturer but also as a public health partner to ensure the successful implementation of the Mexican vaccination programs. Sanofi Pasteur is perceived as the expert in the field.

In this sense, and considering the strong benefits that the vaccine against Dengue could generate to the entire healthcare system, we will do as much as we can to ensure that the vaccine is finally well introduced in the public vaccination program. To achieve this goal, the vaccine has to pass through a well-defined process. Therefore, even though the vaccine against Dengue is approved by Cofepris and that it already counts with the recommendation of CONAVA (National Vaccination Council of Mexico) since June 2016, the vaccine must be introduced in the national basic health formulary to finally be submitted to the national price commission approval. That will be the last stage to define, jointly with the government, the exact national expenditure to launch the vaccine against Dengue<sup>®</sup> in the public health institutions such as IMSS and ISSSTE; it is just a matter of time.

**In Mexico, Sanofi Pasteur has concentrated the largest R&D platform for vaccines in Latin America to develop products intended to satisfy local needs. The company is now leveraging its success to launch a Zika vaccine project. Could you expand on the role such R&D center has played in Mexico and in the region?**

Our R&D activities carried out in Mexico create strong benefits for the country. Sanofi Pasteur develops locally several clinical research initiatives. In this sense, we have built up a strong infrastructure of clinical research centers located in Mexico to continuously investigate in finding new ways to address the national and regional health burdens as we did with Dengue and as we are currently doing with Zika.

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In parallel to our R&D partnerships, we also have a strong manufacturing collaboration with the public health institutions. Indeed, we signed an agreement with the government in 2010 to serve the national flu demand, which is up to 34 million of dosages of flu genes manufactured annually. However, we have extra production capabilities in Mexico to produce up to 90 million flu gene dosages to face any pandemic risk that Mexico could suffer.

It is worth mentioning that Sanofi Pasteur has five manufacturing plants: two in France, one in the US, one in Canada and one in Mexico. In fact, we are the only company in the world with a vaccination manufacturing facility to serve Latin America.

**Cofepris' recognition as a Functional Regulatory Agency for vaccines by the World Health Organization (WHO) is crucial in your ambition to transform Sanofi Pasteur Mexico into a production platform for Latin America and you already started to develop your manufacturing capacity with the plan to double the current capacity by building an additional manufacturing plant. How has such recognition impacted your exports?**

The whole industry recognizes the job done and the results obtained by Cofepris during the last years. Cofepris has put the Mexican healthcare regulation in the spotlight of Latin America. Such factor has been highly important to attract investments from the international and national healthcare business community. Referring to Sanofi Pasteur, such recognition is one of the reason we decided to establish Mexico as the regional manufacturing hub.

**What are the main objectives that you would like to achieve in the upcoming two years?**

First, one of the main topics on the agenda is to continue enlarging our manufacturing capabilities in Mexico through our strong partnership with the government; in this sense, our strategy is to be able to manufacture not only flu genes but also other type of vaccines. Secondly, the definitive introduction of the vaccine against Dengue both in public and private institutions is one of the main goals of the Mexican subsidiary. Finally, to maintain our positioning as the partner of choice in public health and to ensure that Sanofi Pasteur Mexico attracts the best projects and health initiatives to address the current and future national and regional health burdens.

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