Interview: Jean-Pierre Baylet – Country Head South Asia, Sanofi Pasteur, India

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Jean-Pierre Baylet, country head for India and cluster head for South Asia at Sanofi Pasteur, provides insights into the progress and room for improvement that lie ahead for India's immunization program, while highlighting Sanofi's unrivalled commitment to protecting the Indian population from vaccine- preventable diseases like polio and flu as well as his objectives and expectations regarding other critical diseases such as cholera, IPV, and dengue.

India's Universal Immunization Program (U.I.P.) is one of the most comprehensive in the world when it comes to the number of vaccines used, the number of beneficiaries and immunization session organized, as well as with regards to its geographical spread and the diversity of areas covered. Leveraging on your experience honed in various Latin American countries, what is your assessment of India's UIP?

It is true Latin America stands as a particularly well advanced region in terms of routine immunization, while several Latin American countries have implemented some of the world's broadest National Immunization Programs (NIP). Working in Colombia, in Peru or Ecuador provided me with a great overview of the kind of vaccines policy that Countries in south Asia should aim at implementing.

In this regard, the efforts of the government of India over the past few years are absolutely praiseworthy. As per today, 11 vaccines are included in India's UIP, which means that the country

still holds rooms for improvements vis-à-vis some Latin American NIPs where up to 14 vaccines are typically included.

My view on this is that the government should aim at accelerating the inclusions of critical vaccines, while taking into account the specificities of the country's epidemiological profile. For example, there is still no routine immunization against flu in India while the country went through several outbreaks over the past 8 years. As we speak, government is discussing the opportunity to integrate HPV vaccines into the UIP, which would emerge as a great step forward *[cervical cancer being the second leading cause of cancer deaths among women in India – Ed].* Nevertheless, this vaccine – which is typically administrated to preteens, teens, and adolescents – still faces social and cultural resistance in India.

In parallel to the inclusion of new vaccines, another area of focus should be the improvement of vaccination coverage of the population for vaccines that are already available through the UIP. As you know, a large coverage of the population is required for mass vaccination to be effective; however, the immunization rate for inactivated polio vaccines in India still hovers around 50 percent of the population, which is way too low to fulfill the government's objective to reach polio eradication by 2022.

How do you explain such a low coverage rate for vaccines that are freely available through India's UIP?

India being the world's seventh largest geography in the world, reaching out to the population in rural areas is no easy task, especially given the inherent challenges posed by vaccines in terms of cold chain management. Currently, the government of India moreover holds 30.000 vaccination centers scattered across the country – and this is not enough to cater to the country's demand while guarantying an utmost quality of storage. In this context, additional investments are required to further densifying and develop the country's distribution and storage network.

In the meantime, education and awareness also emerge as two pillars that must be tirelessly strengthened. This aspect notably entails convincing parents that they must bring their kids to vaccination centers and ensure that the latter are up to date with routine immunization. In this regard, healthcare providers play a crucial role in conveying to the parents how important it is to get kids vaccinated.

Twenty years after autism was falsely linked to vaccines, mandatory vaccination is increasingly contested in some parts of the world, including in Europe. How accepted is vaccination among the civil society in India?

Generally speaking, vaccination is well received among the Indian population, and especially among the physician community. This aspect is particularly important in India, as doctors enjoy a great authority and patients and parents tend to follow physicians' recommendations.

Like anywhere else in the world, we nonetheless do find reluctant people and parents, but this is clearly not a mass problem in India. Once science and data have proven that a given vaccine can prevent a targeted disease, the government and doctors alike typically take the right decision and integrate this vaccine in their guidelines.

[Featured_in]

India being a federal republic comprising 29 states, at which level of action does Sanofi Pasteur concentrate its efforts when it comes to engaging with the government?

In India, operating exclusively at the Union level is not sufficient. While the central government is responsible for designing and updating the country's UIP and routine immunization programs, the states are entitled with their implementation. The latter also have their own vaccination campaigns with regards to locally needed vaccines – such as Japanese encephalitis vaccines in some states – as well as vaccines that have not yet included in the country's UIP – such as flu and cholera vaccines.

Although this fragmentation creates opportunities to bring to some states' population vaccines that are not yet mandatory across the entire country, it also creates disparities and challenges with regards to the enforcement of the country's healthcare vision. Let me give you a concrete example: over the past years, India has experienced several flu outbreaks, and a particularly significant one occurred in 2015, with over 30.000 cases of flu reported within the first three months of the year. Nevertheless, only a handful of states actually implemented vaccination programs, while the total number of people duly vaccinated per state was not higher than several hundreds of thousands of people – in states that sometimes gather together more than 100 million inhabitants…

As per Sanofi Pasteur, we therefore truly operate at both levels and across the entire country. At the state level, we work closely with Chief Ministers and states' Ministers of Health, and we notably strive to provide these stakeholders with highly needed data regarding this state's epidemiological profiles and the cost effectiveness of potential immunization programs. Some diseases like meningitis are highly underreported in India, because the country's surveillance system is not robust enough. In this regard, Sanofi Pasteur performs or co-performs studies in hospitals across the country to more accurately assess the impact of the disease among the population, so the

government and physicians can take better decisions.

What is the importance and attractiveness of India within the global strategy of Sanofi Pasteur?

India’s vaccines market has been increasing at an eye-catching pace over the past five years, with annual growth rates comprised between 10 and 15 percent. We moreover forecast that the Indian market will continue growing at a similar pace moving forward.

India’s USD600 million vaccines market is almost equally split between the public market – characterized by huge volumes and very affordable prices – and its private counterpart, where parents are looking for high quality, high efficiency vaccines for the one million Indian babies followed by pediatricians every year. These parents are also looking for more convenient vaccination options, such as six-in-one vaccines. Overall, there are 26 million newborns every year in India, with around one million of them part of the private market.

Looking forward, I see growth opportunities for Sanofi Pasteur in both the public and private markets. In the public sector, the government is currently discussing the introduction of five new vaccines: rotavirus, novo conjugates for measles, rubella, and varicella as well as diphtheria & tetanus (DT) and HPV vaccines, while all of them are already approved in India and available through the Vaccine-Alliance Gavi. These five crucial vaccines are part of the government’s target for 2020, and the latter is also working on new introductions after this date, which will bring opportunities to companies like Sanofi Pasteur.

In the private market, we see that the purchasing power of the population is rapidly increasing and Indian families look at accessing more sophisticated health services. Another aspect that is worth mentioning is that pediatricians are truly looking at the best vaccines available, while they clearly follow the recommendations of international medical agencies. In the meantime, we use digital tools such as webcasts to raise awareness among critical health issues and vaccines within India’s huge pediatrician community, and we regularly invite international KOLs to share their expertise on our digital platforms. To give you a concrete example, we recently held a very successful webinar on meningitis, which remains a true health issue in some areas of the country.

You have heading the Indian affiliate since July 2015 – what would you highlight as Sanofi Pasteur’s main achievement under your tenure?

Sanofi Pasteur played a key role in controlling the aforementioned 2015 flu outbreak by leveraging our organization’s reactiveness and flexibility, and we swiftly brought huge quantities of vaccines

to both the government and practitioners. Overall, more than two million Indian patients in 2015 alone were protected against flu thanks to our vaccines.

Sanofi Pasteur also introduced inactivated polio vaccines in India in 2016 and therefore established itself as the key partner of the government in fulfilling this crucial milestone. As a matter of fact, over 50 percent of all Indian newborns are protected against polio thanks to Sanofi Pasteur's vaccines.

We are also more committed than ever to promoting vaccination against cholera, a disease that is affecting almost all parts of India. Although Indian's immunization program in this field has gained momentum over the past five years, the latter has not yet reached a truly satisfactory speed and scope.

From a personal standpoint, I am also proud that we have been able to outperform the market growth, and Sanofi Pasteur has been growing over 20 percent a year since 2016.

However, from a prevention and healthcare perspective, we are only scratching the surface of what could be done in India, and life-changing vaccines should be more swiftly accessible to Indian patients. Although Sanofi Pasteur's dengue vaccine emerged as the exception to the rule, the traditional approach is to develop and register products in the developed markets first, before launching them in emerging countries. In this regard, we need to ensure Indian patients do not wait for three to five years before receiving vaccines already approved in the West. To reach this objective, we must work hand-in-hand with government and regulatory authorities to foster a greater recognition of US and EU market approvals.

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Talking of Sanofi's vaccine against dengue Dengvaxia®, we understand that the company may seek US approval while it is currently under review by the EMA. What is this status of this vaccine in India, and what has been the impact of the Philippines controversy in your dialogue with government and regulatory stakeholders in India?

Dengue is a major public health issue in India. Data from the Ministry of Health show that around 100.000 new cases a year are reported, but we believe that these numbers largely underrepresent the reality. From July to November, dengue is affecting all layers of the Indian population regardless of the area, age, or social background of the people.

Furthermore, various independent studies show that a significant percentage of the population in India has already been exposed to dengue before the age of 18 and is therefore seropositive. As a

matter of fact, when we conducted a phase II clinical trial in India for Dengvaxia®, we realized that around 70 percent of the people enrolled were seropositive.

We have been closely working with the government of India on rendering this vaccine available to the population for several years already. We received a first positive opinion for the approval of the vaccine around 18 months ago; nevertheless, the Ministry of Health has since then put the dossier on hold. We have transparently communicated to the government the results of the NS1 study disclosed in November 2017 *[an analysis of long-term Dengvaxia® data found differences in vaccine performance based on prior dengue infection, which has led Sanofi Pasteur to ask regulators to update product label to reflect new information – Ed],* and the Indian government is still reviewing our dossier. Simultaneously, we have been informed that the Government is currently carrying out a detailed epidemiological study on dengue seroprevalence in the country.

There is no doubt that dengue is a public health issue in India, for which there is no cure or treatment today. For people with past dengue infection who are the majority of people living in an endemic country such as India, the results of our new analysis confirm that the dengue vaccine provides persistent protective benefit against dengue fever, including hospitalizations and severe illness due to dengue. We believe that our vaccine can make a difference in public health. Ongoing long-term safety follow up of these large-scale clinical studies show significantly fewer hospitalizations due to dengue in the vaccinated study population 9 years and older vs. placebo for up to 6 years.

Again, dengue emerges as tremendous public health issue in India, and Sanofi Pasteur's vaccine can truly have a huge impact on the country's healthcare ecosystem. Moving forward, we will continue working hand-in-hand with the government to protect and save lives, be it with regards to dengue and to all other vaccine preventable diseases.

You are one of the few expatriates heading a multinational pharmaceutical company in India. How has been your experience so far?

First and foremost, India is a country that teaches you humility. In all aspects, the Indian ecosystem is evolving at a very fast pace, which – at times – generates unpredictability. As an executive, one must anticipate these changes and continuously nurture a strong communication flow at both internal and external levels.

Second, Indians are extremely positive and tend to see the glass half full rather than half empty. In this context, it has been an amazing experience to work alongside my Indian colleagues, and the latter are always ready to make great things happen. Besides being a fun environment to work in,

my time in India has drastically changed the way I see life.

In the same way, Indians happen to be extremely resourceful and creative people, as illustrated by the colloquial Hindi word *jugaad,* which refers to the capacity to find innovative and creative fix to issues. This is another thing that you learn when working in India: there is always a solution to any problem!

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