

David Loew - Executive Vice President, Sanofi Pasteur



Vaccination is the most effective public health intervention in medicine after clean water.

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In this exclusive interview

, David Loew, executive vice president of Sanofi Pasteur, discusses the future of vaccines in France and the rest of the world, their strategic role in reducing public healthcare expenditure and the revolutionary force of machine learning that promises to disrupt the vaccines space.

Olivier Brandicourt, CEO of Sanofi, seems to be placing the vaccines business right at the heart of Sanofi Group's strategic growth plans. What makes this business so relevant today?

Vaccination is the most effective public health intervention in medicine after clean water. At a time when governments are increasingly concerned about public budgets, it is necessary to focus on prophylaxis. Achieving higher vaccination rates and creating latest generation vaccines can have a massive impact on enabling the society to stay healthy, without needing to spend additional resources on cures. Personally, I find it an extremely fascinating business, as it is a mix between pharma and public health, involving frequent interactions with Ministries of Health, Ministries of Finance and global organizations such as the WHO and UN agencies such as UNICEF.

Only a handful of multinational companies are present in the vaccines segment. What is the positioning of Sanofi Pasteur?

There are four large players in vaccination. GSK is probably the one with the broadest offering, while Sanofi Pasteur and MSD deploy a more targeted approach. For example, we are focused on pediatric vaccines, epidemic vaccines, traveller vaccines, and flu vaccines, where we possess a 40 percent market share in all the large Western markets. MSD, meanwhile, is specialized in other segments, like Rotavirus, Measles and HPV. Finally, you have Pfizer, which has more of a trimmed-down portfolio, but with some mega blockbuster vaccines, such as Prevenar.

A tendency towards specialization is one of the main trends underway within pharma at the moment. Does it also reflect the strategy of Sanofi Pasteur?

Specialization is a need, rather than a specific strategy. The hurdle in vaccines development is high due to the extraordinary levels of safety and efficacy required. At the end of the day, we are vaccinating healthy people so we cannot be placing their safety at risk. Moreover, it is a capital-intensive industry with high barriers to entry, as margins are not as high as in other fields (for example, oncology) and it takes years and a EUR 500 million investment to build a plant. Given these elements, accurate demand forecasts are critical to plan production, as the underutilization of capacity immediately destroys profitability. The fact that each plant might be specialized in a single antigen adds a layer of complexity connected to the inflexibility of production. However, given the widespread practice of tenders, where we are not sure if we win, is one of the reasons why so many stock-outs happen in this industry.

Tender processes based solely on lowest price have been defined as a threat to the sustainability of vaccine manufacturing to meet steadily growing demand. How can this sort of market failure be remedied?

Payers have been focusing on keeping the costs down through tendering, which might lead to public expenditure savings in the short term. However, it creates a significant problem for vaccine availability in the long run. Producers do not know in advance if they will win and, thus, if they will be able to produce large quantities: the uncertainty related to capacity utilization is high. Some governments, like the US and Germany, have understood this and abolished the tendering system, creating an economic environment where the industry can thrive and yet the prices are reasonable, a combination beneficial both for the country and the industry. France never had tendering but this system is still prevalent in Italy, Spain and most emerging markets. It would be unrealistic to advocate its complete abolishment around the world, but factors other than prices

should be taken into account. We are transparent about this and even presented this argument to UNICEF: they need to think harder about creating the right economic environment for vaccines producers.

Sanofi Pasteur announced in April that it will double its vaccine output by 2023 by building a state-of-the-art manufacturing plant in Toronto to the tune of EUR 350 million. Why was Canada selected as the destination for this big-ticket industrial investment?

Canada is just one of the countries in which we are currently investing. Historically, Sanofi Pasteur has four major plants: a large site in Canada, Swiftwater in the US, Marcy and Val de Reuil here in France. As some plants were coming to the end of their term, we had the need to replace them. In Canada we had specific know-how related to booster vaccines, so we decided to leverage it and build more capacity to face an increase in demand. Similarly, in Val de Reuil we built more capacity for the production of flu vaccines, considering the prospective increase in vaccinations in this field.

What are the main drivers of the increase in demand you are forecasting in flu vaccinations?

Many governments have understood the cost-effectiveness of flu vaccinations, this is why the demand will increase in the future. So far, flu has been underestimated by the population and regarded as a mere inconvenience. In France, in the last season, it led to thirteen thousand deaths, which ranks as substantially more than death from car accidents, and I find this ethically really difficult to accept. The decision to get vaccinated depends on some key factors, like personal beliefs and logistical convenience. Countries like the US and UK spend a huge effort promoting vaccination and making vaccinations really easy; in the US for example, you simply have to walk to the nearest CVS pharmacy and get a flu shot, which has helped the country to attain 65 percent vaccination rates. Our Minister of Health, Agnes Buzyn, is keen to learn the lessons from other countries and has now authorized French pharmacists to vaccinate which is a very positive step forward.

Two in every five French people believe that vaccines are unsafe and, as you mentioned, personal beliefs are still the main factor affecting vaccination rates. What

are the reasons behind this attitude?

French people are particularly sceptical. Maybe it is because of the buzz in the press in the 80s-90s, where some theories connected autism to vaccinations. Later, these theories proved to be scientifically wrong, but still, a lot of people continued to believe in them. Recent developments, however, are encouraging. When Trump questioned the need for vaccinations in the US, autism patient associations and key opinion leaders reacted in their favour, hence sending an important signal to the whole world. In France, Minister Buzyn has been very assertive and introduced scientific reasoning into the dialogue, backing the government's preventative healthcare strategy with hard scientific data. Again these are very important actions showing a positive impact.

What is the role of Sanofi Pasteur in working with the government and change the wrong image of unsafety related to vaccines?

Our role and responsibility is to provide scientific data and hard facts. We are making larger and larger trials on a global scale to make sure that our data is stable. So far all the results confirm the efficacy and safety of vaccinations. For example, with flu vaccines, we have not just fewer flu cases, but importantly also far fewer hospitalizations, fewer cases of pneumonia and fewer cardiac deaths. The benefits accrued are truly impressive.

Sanofi Pasteur registered a robust 8.3 percent growth in 2017. What will be your main growth drivers in the future?

I am very optimistic about our future growth, which is connected to two main factors. The first is the effort of the government in the creation of a more friendly environment to invest in this field. The second is an observed appetite for innovation, as new vaccine generations exhibit fewer side effects. This feature is extremely important in paediatrics: the new pertussis vaccine is far better tolerated by babies in terms of the side effect profile. They do not get cranky and fevery like in the old days, allowing the parents to bring them more easily to the paediatrician.

Similarly, we have launched a special edition of flu vaccines for patients over-65s, containing four times more antigen, hence leading to fewer cases of pneumonia, hospitalization and cardiovascular events. In this context, the acquisition of Protein Sciences has been a strategic advancement due to their development of a recombinant flu vaccine beneficial for high-risk senior patients with pre-existing conditions such as diabetes and cardiovascular conditions. The product was launched this

season in the US and obtained a huge success, reaching sales of USD 100 million.

Clearly, the appetite for innovation leads to a need for higher production capacity. Hence, we are investing significantly in new plants: I am proud to confirm that, in France alone, we are going to increase the investment by a full 50 percent.

How would you describe Sanofi Pasteur's approach to partnering?

Certainly, vaccines are a tighter space than pharma, so it is necessary to carefully look for partners. We have established very successful partnerships with several biotechs. For example, we collaborate with Medimmune for the co-development of monoclonal antibodies against Respiratory Syncytial Virus (RSV), which works like a vaccine: it is administered to the baby after birth and protects it for six-seven months. We also did license deals in early stages, such as the deal signed with TranslateBio on messenger RNA, as well as the one done with SK for cell-based flu vaccines, which, together with recombinant vaccines, constitute new avenues for development. Furthermore, we collaborate with universities, as they develop innovative vaccines at early stages.

What today constitutes the top five markets globally for Sanofi Pasteur?

The first one is obviously the US, the second is Europe and then emerging markets like Mexico. Japan is somewhat smaller, as similarly to China, there are regulatory barriers and such nations opened up to parallel development just ten years ago. If they start changing the regulation, Japan could also become very big.

As for China, we want to deliver and introduce greater innovation. The country used to be slow in embracing innovation, as it required registrations in the US or EU before even starting to develop a product locally. Recently, parallel development has been allowed in pharma, signalling an important effort to accelerate innovation. In vaccines, the situation is less advanced, but the momentum is right and I think the country has the potential to become our second largest market within a decade. Chinese people should get fast access to innovative vaccines, like everyone else around the world.

Where would you like to take Sanofi Pasteur in the next five years?

In the R&D sphere, we plan to commercialize around the world the modern products that we have launched in the US. In the shorter term, we will introduce the new meningitis vaccine and, hopefully, the Respiratory Syncytial Virus (RSV) vaccines for babies, one of the existing big gaps in the vaccination calendar. Longer term, we have an attractive pipeline of new vaccines. We are for example working on broadly protective flu vaccines, that would ensure protection for several seasons. On the industrial affairs side, we want to ensure access to people around the world through a capacity increase. Last but not least, we are aiming at a real transformation in terms of machine learning, a disruptive force in our industry.

To what extent the developments in machine learning constitute a revolutionary force in the vaccine field and how will it affect patients?

Machine learning will allow us to digest much larger data samples and come up with new findings above any human capability. For example, by looking at big data sets in terms of circulating strains, we can now predict what flu strains will be circulating in the next seasons.

In operational terms, this means being able to start production earlier, well before March, when the WHO guides us on which strains to focus and which vaccines will need to be in the pharmacies by July. We are also running a trial with flu blocks including 800.000 patients in collaboration with Kaiser Permanente, a HMO organization in California, allowing us to generate huge data sets at a lower cost based on anonymized patient records. As a company, we need to accelerate this ongoing digital transformation and become a driving force in this field.

This revolution clearly involves the payers but also a societal shift, as it implies the creation of digital patient records and tracking data about the whole population. In Germany, for example, a significantly lower number of flu deaths is recorded; this phenomenon, however, is not related to an actual lower number but rather to the inability to see the correlation between a death and a flu episode that the patient had weeks before, simply because the data does not exist. Conversely, in other systems, it is possible to identify a correlation between a cardiac arrest and a precedent flu episode, which might have triggered inflammation. Big data and machine learning are a win-win-win situation: they help governments save money, they allow patients to get more targeted and faster treatments, and they enable the industry to analyze more scientific data and innovate in the optimum directions.

What does it mean to be a French company today?

It is about leveraging the legacy that we have, coming from Louis Pasteur. It entails curiosity and creative mindset oriented towards discovery, which I find very strong here in France. This is coherent with our mission, to envision a world where no one dies from a vaccine-preventable disease. Creativity and passion, this is the essence of our company operating in the vaccines space.

What final message would you like to send to our audience?

Make sure you get your vaccinations because you are protecting not only yourself but also your children, your parents and friends and people that you meet. It is a public mission to protect your environment.

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