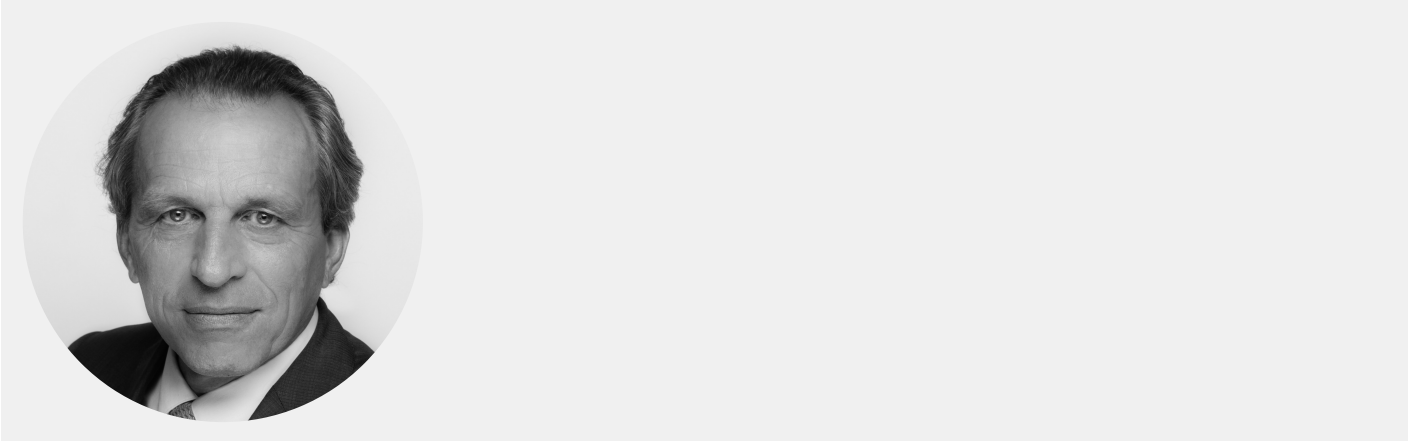
Interview: Philippe Barrois – CEO, Novartis, France



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The CEO of Novartis France reveals how the construction of a new French headquarters demonstrates a commitment to develop operations in the country, how the Huningue Biotechnology Centre is the group's flagship biotech facility, and why having become the country's number one pharmaceutical company, the goal is not only to cement such a leadership position, but use it to help shape a new pharma and healthcare environment.

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In June 2015, Novartis announced an investment of EUR 800 million (USD 880 million) in France over the next three years, to be invested in clinical research, in industrial rehabilitation and a new headquarters. What is behind such a significant investment?

First of all, these announcements demonstrate the importance of France's position within the group. The substantial role that France plays in our global operations can be seen in the diversity of our projects in the country. We have a long-term commitment to maintaining and further developing our operations in France. The construction of a new French headquarters – which will be finalized by 2019 – is a major undertaking and a part of our group strategy for the coming years. The vision is to have all three Divisions, Novartis Pharma, Alcon, and Sandoz, housed at the same location, to enhance cross divisional synergies especially in back offices functions. This will be a significant undertaking that represents an investment of over EUR 300 million (USD 330 million).

France’s Huningue location where we have a modern biotech facility in charge of worldwide production for five biologics, is very convenient for us, with its shared border with Switzerland, and in particular, its proximity to Basel. The recent trend in biologics, evident in the increasing number of new molecules being developed, means that this unit remains a very important component of our global operations.

Your Huningue Biotechnology Center, is considered as a pioneering biotech facility in France. What is the rationale behind this reputation?

The Huningue Biotechnology Center is our flagship biotech facility. We have another biologic facility under Sandoz in Austria and we are planning to build a third one in Singapore. It is not easy to find the right site, as we need the right expertise and environment. Thus, our decision to place our flagship biotech facility in France is very significant, and we are investing in it because it has – and will continue to be – a critical component of our operations. We are undertaking a major rehabilitation project of land in the industrial area in Huningue.

The quality our Huningue facility is extremely high. We have around 420 employees there and they are all at the top of their fields. The output has been excellent on all metrics, notably in terms of quality and timeliness. The facility has an excellent reputation, which is critical for the production of active substances, as we do not have many backup facilities. A failure in one plant would cause a major issue in our entire production line. The production of biologics is by nature also a very sensitive issue, and we are very cautious to eliminate any potential deviations from quality. As a result, it is important to have the solid foundation of an experienced team with a strong track record, and we are committed to further improving it.

You have said that with the oncology research center in France, Novartis is among the three most active laboratories in the country for clinical research. What has been Novartis’ experience in terms of conducting clinical research in France?

Out of our EUR 800 million (USD 880 million) investment over the next 3 years, EUR 100 million (USD 110 million) will be invested in clinical research every year, with half of that dedicated specifically to oncology. France represents a significant proportion of our global clinical research operations. We conduct a lot of phase I trials, particularly in oncology which is a testament to the excellence of the French research environment. In addition to the excellent quality of French researchers and academics, the financial incentives available for clinical research – especially the *crédit d’impôt recherche* (tax credits) were another factor in our decision to conduct clinical research here and to locate one of our Global hubs for clinical development in the field of oncology

in France .

The perennial challenge is the speed at which we are able to initiate clinical trials in France. This is where we are working closely with the authorities in order to try and find a new process that could accelerate the administrative timelines and thus increase the competitiveness of our French operations.

Progress has been made, most notably with the creation of the Standard Contract, which greatly simplifies the process for organizing clinical trials. There are still related issues that need to be ironed out, for instance, with the system of financing. With this new Contract, the financing of the clinical trials is transferred to the hospitals and not to the research unit itself, which creates a potential incentive issue for researchers, because they may not receive the financial support needed.. Another question is how to make these contracts mandatory for private institutions, not just public ones.

Another major administrative challenge relates to the protection of data privacy. The *Commission Nationale de l'Informatique et des Libertés CNIL* (the national data protection authority for France), currently lacks a framework for priority setting, which delays the advancement of clinical research, because there is no order of priority that puts clinical research before aspects such as database collection. Improvements on this would certainly facilitate our mission which is to find solutions to get the right treatment to the right patient at the right time as quickly as possible.

There is a growing worry about the decline of French competitiveness within the global pharmaceutical industry. Christian Lajoux, President of Fefis, told us that out of the 13 new molecules recently developed in Europe, not one was manufactured in France, a troubling omen for the future. What is Novartis' position on this?

The problem is not just present in France. Worldwide, there is an excess of production capacity, which is now being manifested in the sale and sometimes closure of many plants. But there are also new plants being built, and they reflect the development of new technology plants. It is true that in France, the construction of newer production units has not been happening at the same pace as the rate of innovation. There are two main reasons. Firstly, the growth is predominantly in emerging markets, in Asia and Latin America for instance, and hence most of the new plants are being built there. I would argue, however, that France remains a good choice for high-tech plants, due to the quality and overall competency of the work force, particularly in terms of technical skills.

Secondly, and more worryingly, the financial attractiveness of building in France is currently lacking. Industries willing to invest in production facilities in France should be seen as partners for

economic development. Particularly for the pharmaceutical industry, this fact needs to be taken into consideration when the authorities decide on the pharmaceutical market regulation. It is difficult to ask our industry to operate in a negative market growth mandated by the political agenda and at the same time, increase our employment and build factories in France.

There is currently a lot of debate as to the sustainability of the French healthcare system. What is Novartis' perspective on this issue?

I understand that the authorities' task of balancing the healthcare budget is not an easy one, and a sustainable healthcare budget is absolutely essential for all stakeholders. But the current dependency on industry as the main source of savings can only work in the short run. Such a strategy has numerous implications that will adversely affect the system in the long-run, in terms of investment, research, innovation and overall economic growth. The current *Loi de Financement de la Sécurité Sociale* bill (Health Care Budget Bill) proposed by the Health Minister Marisol Touraine, is asking the pharma industry to bear 50 percent of the budgeted savings, as has been the case in the past two years. Given that drug costs only represent about 15 to 17 percent of overall healthcare expenditures, there is a discrepancy between our contribution to healthcare expenditures and healthcare savings.

As a pharmaceutical company, our main challenge in France is adapting to and navigating within the regulatory environment, not just in terms of concrete administrative issues, but the overall mentality of the regulatory authorities.

A comprehensive review of the healthcare system should take into account not just drug costs but also inefficiencies within the system. For instance, statistics show that the share of hospital costs within the healthcare system is ten percent in France over Germany. We have a bloated hospital system at a time when we should be moving away from the old hospital model of care, with the expansion of outpatient care, the increased incidence of chronic disease and improved, personalized patient care pathways. The political will to address effectively this issue has been lacking thus far but reform is necessary. The system is evolving and we are in continuous dialogue with the authorities, but more needs to be done.

We are aiming at :

- making sure that the patient has access to the best medicine with optimized management pathways,
- meeting the needs to build a more efficient healthcare system based on outcomes

- and ensuring that pharmaceutical companies keep financing the R&D that will translate into the medicines of tomorrow.

Novartis has been competing with Sanofi to be the number one pharmaceutical player in France for a number of year, a feat Novartis achieved in 2015. What explains this success?

Despite the aforementioned challenges with regard to operating in France, the country remains an important part of our operations and we are very pleased that our hard work and commitment have been rewarded. France's strengths should not be underestimated. Its universal healthcare system and the strong and competent healthcare institutions make France an extremely attractive pharmaceutical market. Other important positive qualities are the degree of innovation available in France and the access the pharmaceutical industry has to the French patient population.

In addition, the French work ethic is very admirable. There is a running joke that the French take too many vacations, but from my three decades of working in various Novartis operations worldwide, I am very impressed by the dedication I see in my French employees, who take their work very seriously.

Our achievement of being ranked number one company in the French pharmaceutical industry should be attributed to the successful implementation of our strategy, encapsulated in the phrase 'winning for patients in a responsible way'. The six pillars are: to bring innovation to market, to ensure market access to innovation, to continually invest in a long-term pipeline, to remain a credible private partner in healthcare, to optimize resource allocation and to develop the talents and adaptability of our employees.

Having achieved the goal of being the top pharma company in France, what is next for Novartis?

In the short-term, we have five product launches in the next year alone with a significant breakthrough in the field of cardiac insufficiency. More broadly, now that Novartis has reached number one in France, we want to not only stay at the top, but use our position and influence to help shape a new pharma and healthcare environment in France. We would like to develop an industry that is more focused on efficiency, outcomes and patient welfare.

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