Thierry Hulot â?? President Biopharma, Merck France

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Thierry Hulot, president biopharma of Merck France, explains how France has become more open to diversity, while still needing significant reforms in the healthcare sector to remain competitive. He also shares insights into his career and the learnings from the Levothyrox case.

You have been with Merck for over 25 years. Could you give us an overview of your career and explain the reasons that led you to return to Lyon and France after a decade in Switzerland?

After obtaining my pharmacy degree and after working for a few years for the French company SynthÃ©labo, I joined Merck in 1995 as a scientist in the R&D department field. In this position, I collaborated closely with our marketing department, which encouraged me to do an MBA at University of Ashridge in the UK to improve the cooperation between research and marketing within the company and engage in a dialogue. Subsequently, I was appointed as a manager for a product in a phase 2 clinical trial. This would turn out as my first leadership experience, as my task was to assemble a highly intercultural team, and as a French citizen, I was leading an international project of a German company in the US. I was later given the opportunity to move to Switzerland, where I had the privilege of working on the integration of Serono within Merck. Given the very different corporate cultures of both entities, the integration was a challenging but utterly interesting task. It was a unique experience as it involved a cultural shift towards a more diverse company. After 15 years in R&D, I decided to take on a new challenge as the chief of staff of the head of pharma, which, back then, was Stefan Oschmann, who is today our global CEO. The position was completely new to me and it gave me the chance to see how the board and senior leadership teams work.

Together with Stefan we convinced the board within six months to take on biosimilars, as we saw it as an opportunity for Merck I was then placed in charge of starting a biosimilar business from scratch and later was appointed as head of manufacturing, due to my experience in leadership and governance. As our pipeline grew stronger, we divested from the biosimilar field and sold it to Fresenius; a fact which I am hugely proud of. My journey continued four years later when I was offered to become the president of Merck Biopharma in France. The plan was to launch new products in the country and for that, a fresh vision was needed, so I accepted. Today Merck in France has 3300 employees, with 300 open positions a year for recruitment to refill and sustain growth. 60% of Merckâ??s French revenues come from exports. We have 11 facilities spread across the French territory â?? both production and R&D â?? while we maintain our headquarters here in Lyon. Overall, we are a very important branch of the Merck group and we have a positive impact on the French economy, with significant investments in this country.

How has the life sciences business evolved between the last time you were here 15 years ago and today?

Before I left France, I was mainly active in the R&D sector, without paying too much attention to the marketing side in the country. Therefore, it is hard for me to compare. What I have seen, however, is that France has become more open to diversity and international players. This can be seen at the governmental level. When President Macron invited global leaders to stop by in Versailles before the World Economic Forum in Davos, his and Prime Minister Edouard Phillipeâ??s speeches were delivered in English. Everyone was shocked by this, as it never happened before. I really do think it is a good example and illustrative of the changes afoot.

What are your thoughts on this new approach on health care and life sciences announced by the Macron Government during the 8th edition of the CSIS (Conseil stratÃ©gique des industries de santÃ© â?? Strategic council of the health industry) in July 2018? Some of your

peers are already talking about a major discrepancy between the announcements and the reality on the groundâ?¦

We usually do experience a delay in the political wish and the execution by the French administration and it is no different in this instance. There will be always constraints, as you cannot change mentalities, culture and behaviour by decree. The president has undoubtedly engaged in remodelling this system and he sees the need for radical reforms. The same goes for his cabinet and his advisors, as they have started to address our needs through the CSIS. They are open to a dialogue with all stakeholders involved, which also has not been the case in the past. There is now empathy towards our industry and the willingness to discuss and change things, so this is a big step forward.

When going into detail, it is clear that we need a reform of the market access regulations. The criteria to assess the medical benefit of our products (namely the SMR and the ASMR,), as well as the financing rules for major hospital drugs (liste en sus), need to be revised in depth. They are no longer a guarantee of a fair evaluation of the product efficacy and overall added value for the country and the system. They are outdated. They very often represent a hindrance to patient access to innovation. We need to assure that French patients get access to innovation. The Minister has announced a reform of those criteria: one of the objectives is to ensure that products with a European Market Authorization addressing very critical diseases (cancer, orphan, very debilitating chronic diseases such as MSâ?¦) are accessible to prescribers and that they are able to choose which product goes to which patients.

We have a very recent example that is unfortunately not isolated: one of our product, which has been approved and is reimbursed in 28 other European countries, has just been denied access in France. With Multiple Sclerosis for instance, you are better off being a German citizen, because the last three innovative products that were brought to France for market access were denied access! Physicians cannot prescribe them for their patients. It is a pity but a reality: in many cases, France does not give patients access to all available innovations as well as the other countries do. The promise of the CSIS is to change the evaluation criteria and to allow that to change, come 2020. Letâ??s hope that the civil servants who will be working with our trade association on the reform will be able to share our common objectives.

Clinical trials are another issue that has been addressed by the CSIS. We have all the technical requirements to conduct clinical trials in France, but it is very difficult to actually set them up, as it takes between 12 and 18 months to get the agreements with ethics committees. Moreover, there is also the question of why doing clinical trials in France, when there is no market access for these products. We cannot forget that we are faced with international competition, so why would companies invest in a country where they will not be able to sell their product?

Overall, I appreciate the openness and the willingness to change of the new government, but it must align the administration and embrace the change to make sure our health care system opens up to innovation for the patients. Additionally, there seems to be an issue with experts being used by the administration in France. The government has made the honourable call to make sure experts in evaluation bodies are not involved with the industry; however, this wish is very naive. We need experts with recent research and innovation experience: most of the time this means you have to work with the industry, amongst the many public / private partnerships that the government is encouraging, or within trials and development that are led by the industry. This is an area where France has not changed yet. We need to find ways to get the best experts to advise our authorities. There are other ways to counterbalance industry influence, for example by using a panel of experts or call in international opinion leaders.

In 2017, there was a public row over a new formula for Levothyrox in which patients felt negative side-effects despite the ANSM and Merck confirming that the new product was virtually unchanged from the old one. What has been the impact on Merck Franceâ??s business to navigating the challenge and what lessons have been learnt?

The learnings of this case have been well described by the commission put in place by Minister of Health Agnes Buzyn. It is mainly focused on the question of how patient information is managed in the social media era. There is a need to reply to rumours on social media within minutes, while a public authority needs weeks or even months to react. While there have been many proposals made in the report on how to deal with this better on a social media level, I will even go a step further. As patients and their families are becoming more involved in the decision-making process and true actors of their medical and care pathways, we cannot give all the responsibility of educating the population on diseases to general practitioners, which mostly only see the patient for 20 minutes or less. Hence, I strongly advocate establishing stronger patient associations in France, as they currently are not structured and not supported enough. Today, the law on the promotion of pharmaceutical products prohibits a pharmaceutical company from communicating directly to the public on its prescribed and reimbursed products because any such communication is automatically qualified as a promotional activity. In this context, we also do have to differentiate between promotion and information, since it is the manufacturer that knows its drug best and can explain the effects. There still exists suspicion amongst the general population about the pharma industry so we need to re-establish credibility. This is the big challenge in the age of social media and misinformation.

What are you three key priorities leading Merck in France in the upcoming few years?

My first key point is to unleash market access to innovation in France, which is essential for the entire industry. Secondly, access to health care professionals is changing as there are more restrictions and rules. The priority here is to figure out how to adapt our business model to this change and still give them the necessary information they need. My third priority is employee education to ensure a constant learning and development journey to be able to continue to provide innovative high-quality products to the patients, as we have done for three and a half centuries. Merck is indeed celebrating this year, 350 years of continued innovation.

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