Jean Monin â?? General Manager, Amgen France

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Jean Monin, general manager of Amgen France, discusses the challenges of bringing products to market in France and what is needed to better promote biosimilars. He also talks about his main achievements since joining the company six years ago.

Amgen has been present in France since 1990. How would you describe the companyâ??s legacy in France to date?

We have been active in France for nearly 30 years and are proud to have been one of the first biotech companies to enter the local market. Our legacy can clearly be seen in the fields of haematology and oncology since we stand out as the first company that provided a product for supportive care within oncology. These products carry the advantage of allowing treatments by chemotherapy without the usual side effects, reducing the mortality rate and hence improving the efficiency and acceptability of chemotherapies. While we are active in other domains like rheumatology, cardiovascular and inflammation, the fields of haematology and oncology currently make up the lionâ??s share â?? some 80 percent â?? of our revenues. Our legacy product brands are AranespÂ® and NeulastaÂ®, which constitute some two-thirds of our turnover. We simultaneously possess other products in areas outside of supportive care, which also play some part in driving growth too.

What would you describe as the biggest achievements you have accomplished since assuming the reins of Amgenâ??s French affiliate in 2012?

Our biggest achievement has undoubtedly been the successful launch of seven products. We have managed to strengthen our product launch capability significantly in France, especially because the negotiations with the authorities on market access were somewhat stuck when I was nominated to lead the affiliate and this bottleneck needed to be unblocked. Securing access for cutting-edge therapies remains the foremost challenge for innovative drug developers in France. For instance, it took us nearly 1,000 days to get our product KyprolisÂ® for the treatment of multiple myeloma, a type of blood cancer, on the market last summer. These delays are clearly unacceptable from a patient perspective so there remains much work still to do.

What causes these delays of market entry in France?

There are two reasons. The first one is linked to the way products are assessed, which is very old-fashioned and simply not fit for purpose in the current context of advancements in medicinal science. Treatment pathways are undergoing a profound change in the light of new styles of therapies and the regulatory frameworks need to catch up. The second reason is connected to an increasing importance of price matters when assessing the product, rather than the anticipated value. This means that when your product is considered too expensive they will not let it pass.

As you may know, the revenues of the entire French pharma industry are about the same as they were a decade ago. Our argument, which has also been a hot topic at this yearâ??s Strategic Council of the Health Care Industry (CSIS), is that we require growth since the French industry is slowly losing attractivity on a global scale. When we country managers appeal to our global management boards for investment, we are competing with the heads of the affiliates in other power markets. It is essential for us to have some positive news to report otherwise the investment flows will go elsewhere.

In my opinion, there is a strong difference between the CSIS outputs and the implementation of these measures. For us innovators, there are three main points of interest: Firstly, the finance regulation mechanisms, which need to go back to growth; Secondly, access to innovation through early access mechanisms such as the Temporary Usage Authorization (ATU); and thirdly, the criteria used to assess the comparative merits of different drugs.

While the CSIS has promised a minimum of 0.5 percent growth, this will not be reached next year when you read the small print of the policies being drawn up. The ATU mechanism is, of course, welcome but we are calling for considerably greater simplification and streamlining of the regulatory process. When it comes to drug assessment procedures there are some obvious illogicalities. Having a channel whereby a company can appeal the decisions of the committee makes very little sense if you are prevented from adding any new data and are appealing to the very same adjudicators who have denied authorization for your product, in the vast majority of instances, a foregone conclusion. We are calling for the authorities to inject much greater transparency and predictability into all these processes.

Are you therefore disappointed with this yearâ??s CSIS then?

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It is still very early days. Expectations were sky high at the CSIS because of the explicitly pro-business orientation of the Macron government. We really detect willingness on the part of our political leaders to take on board the concerns of the business community and to effect meaningful change. At the pinnacle of power, there appears to be a real momentum underway. However, when it comes to the implementation of the grand promises of the CSIS the Social Security Financing Bill (PLFFS) currently under evaluation in the parliament is a real letdown. Nothing has really changed yet. At the CSIS, it was promised that market access timeframes would be condensed to bring them back to being more in line with the EU average of 180 days, but we have seen no steps yet being taken to make good on this promise. In short, though the right noises were made during the CSIS, the follow-up and translation of its output into tangible actions has been hugely disappointing.

How do you explain this inconsistency?

We sense there is a strong disconnect between the political leaders and bureaucracy, which may well be blocking and diluting these measures. Obviously, we appreciate that it is difficult for the government to enact a quick fix, but there is a need to capitalize upon the current window of opportunity and not to lose the confidence and trust of the business community.

What winning strategies are you pursuing to bring new products to market?

We have significant projects with institutes, hospitals, doctors and patients in order to shape the market with the target of communicating the value of our products. Through Amgen Ventures we also are placing financial investments of around EUR 10 million (USD 11.34 million) in France to subsidize smaller companies in what we consider to be important areas of interest such as biology and digital health. Each organization receives financial support of up to half a million euros as well as expert advice and guidance from Amgen.

As an American company, we believe it is essential to invest into the French ecosystem and this is also part of a three-pillar strategy we have: One pillar is to play our part in fostering the right kind of enabling ecosystem where innovation can flourish. The second pillar is about supporting education around medical science. While we have forged longstanding partnerships with organizations such as the Institut Pasteur, we also look to work together with universities and the Ministry of Higher Education to enable doctors to also work in the industry rather than only at hospitals. The third pillar revolves around investing in digital health and critical future technologies such as artificial intelligence (AI). We seek to pivot away from the current â??break and fixâ?• model of medicine towards a posture of â??predict and preventâ?•. This model is considerably less costly for society. Through AI, we can predict the risk of experiencing cardiovascular events, for instance, increasing the precision of these forecasts from 50 percent to 75 percent.

Amgen has been at the forefront of pioneering biosimilars and you have recently launched your new product KanjintiÂ®. Can you tell us about how Amgen is progressing in this field?

Amgen has decided to develop a range of ten biosimilars. We are one of the best companies out there for the production of biological ingredients and with this knowledge, we will produce our biosimilars to the same high standards in our production facilities like all our other biology-based products. Through the introduction of biosimilars, we can deliver significant savings to the authorities that will generate headroom for new innovation by freeing up capital. The goal is however not to turn Amgen into a biosimilar company. The biosimilars are fueling our R&D since they afford leeway to the social security budget because they are cheaper.

How attractive is the French biosimilars space? Just how ready and prepared is the country to receive these types of therapies?

This is a hugely important market for us, but we still need to educate doctors, patients and authorities on biosimilars. As you might recall, generics penetration took a long time to gain traction in France because of deeply ingrained consumer and prescriber preferences. Not enough had been done to educate French practitioners and patients around the value that generics deliver and that is why the segment endured troubled beginnings and, as an industry we need to learn these lessons of the past so a to avoid similar pitfalls with biosimilars.

Even today, generics in France are noticeably more expensive than in many other Western European markets though this is mainly down to the business model of French pharmacies that are dependent on these margins. For biosimilars, it is not only about the price, but also about conveying the value of this product. If you do not support educating people around the importance of biosimilars for the health care system, these products will fail to take off. Obviously, for patients, it is more convenient to go with the product they already know, so companies like Amgen need to be proactive in changing hearts and minds. The good news is that, right now in France, biosimilars are registering ever-greater acceptance. The first biosimilars enjoyed around 10 percent market penetration and the second generation is now up to 20 percent, so we are witnessing a quick adoption rate.

What is driving this rapid adoption?

Generally, there are two different ways to speed up adoption, namely the hospital approach and the retail approach. For the hospital approach, the decision is centrally driven and there are incentives in place meaning that the penetration is very high. While there has been some resistance by doctors to prescribe biosimilars earlier on, it is becoming more common now. Financial incentives at hospital level are widespread but we will also need to transpose these incentives to the retail level as well. Frankly, pharmacies havenâ??t been receiving much information on biosimilars yet, so this is something that clearly needs to be rectified.

To this effect, Amgen has assembled field teams tasked with informing doctors and pharmacists about the true benefits of biosimilars. We are also going the extra mile when it comes to shaping the narrative around this style of therapy. During our clinical trials, we have been studying the effects of switching a patientsâ?? treatment pathway from the originator biologic to the biosimilar to ascertain whether there are any possible consequences for the patient. This is not something required by the regulators, but it is a step that we, as a company, considered important so as to gain a comprehensive understanding of the dynamics of these medications.

A few words to conclude?

Personally, I am very proud to work in this company, which brings groundbreaking science to the patients. We have been launching three products in the last two months and were able to hire 80 new employees this year, so I really do feel we have a very positive momentum underway. Amgen has the role of granting the patients new solutions and you can see throughout our pipeline that the patient is really our focus. We still have a start-up spirit with low hierarchies and this adds a lot of value to the outputs that we are delivering.

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