Soren Giese – General Manager, Amgen Italy

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In a wide-ranging and candid conversation, Amgen Italy General Manager Soren Giese outlines the strategy he put in place to restructure Amgen's operations in the Italian market, the company's third largest in Europe and sixth largest globally. Giese also touches on ensuring the affiliate's product launch readiness, consistently increasing Italy's level of participation in Amgen's global clinical trials, and why Amgen's biosimilars represent a "triple win" for patients and doctors, healthcare systems, and for the company itself.

What advantages does coming into a market like Italy as a foreign country manager bring compared to having a local in place, as is the case in most established EU markets?

Perhaps I am able to look at things in a slightly different way than local colleagues who have worked in this market for many years and may have become accustomed to a certain status quo. Having worked in several different markets, both in a regional capacity as well as running various affiliates in a variety of different circumstances, I have a unique blend of experiences that allow me to come to a market like Italy, even though it is an established market, have a fresh view on things, shape the organisation to be more efficient, and potentially realise unrealised opportunities and make the market even more successful than it has been before.

Were you given a particular mandate upon taking this role?

When I arrived in Italy, we put together a three-to-four-year business plan with some ambitious goals around opportunities for further investment and further growth in the short- to medium-term, taking advantage of new launches and completed negotiations with the Italian Medicines Agency (AIFA). Since then, we have entirely restructured operations, drawing on my wealth of global experience to move to a leaner and more efficient model focused on cross-functional collaboration.

More established markets with more resources and bigger teams can become more siloed than emerging markets where teams are smaller, employees need to wear many hats, and things can be done more quickly and cheaply. Different markets have different circumstances, challenges, and opportunities, but teams will always win when they work together and collaborate. That is a learning that, when implemented, can catapult a business forward in any situation.

What struck you most about the Italian healthcare sector and its market dynamics when you first arrived in the country?

In general, Italy is a developed market with a very efficient healthcare system that provides holistic care to its citizens, with a well-established product reimbursement process. As a player in that process, we know exactly what is required of us, and the process works quite well. My one critique would be that this process takes a very long time; after approval from the European Medicines Agency (EMA), it takes about a year and a half to get reimbursement at the national level. That means that for a year and a half, patients are waiting to get their medicines while the same medicines are already available in other European markets.

Nevertheless, the process is quite flexible, which is a huge advantage in terms of access and reimbursement. It allows for a continuous dialogue between the company and the payer which can also be enriched with the contribution of scientific experts who ensure that the various committees exactly understand where the treatment fits in. That is a significant advantage over a more rigid system.

Italy stands as one of Amgen’s most important global markets; just how crucial is the country to the company, and how deep is your footprint in Italy across different

business operations?

Italy is Amgen's third-largest market in Europe after Germany and France and the sixth-largest worldwide. It is therefore a very strategic market for Amgen, not just in terms of its commercial potential but also around the interaction that we have with the scientific community here. Given the quality of medical research that is going on in Italy, we can interact with Italian thought leaders at a very high level. Consistently increasing Italy's level of participation in Amgen's global clinical trials was another of our key priorities; something we have been able to achieve with a 14 percent increase in global trial participation in 2021 compared to 2020. Even though 2020 was a particular year due to COVID, this is still a significant increase and puts Italy in Amgen's global Top 10 countries for enrolment in investigational and observational trials.

Another significant milestone is that over the last two years, for the first time, we have conducted Phase I clinical trials here in Italy. While Phase III trials come with their own challenges, Phase I is really the frontier of medical research and therefore highly complex. We should be very proud of this as it showcases exactly the role we want to play within Italy's healthcare ecosystem and what Italy as a market can give back to Amgen.

How strong was the commercial performance of Amgen Italy in 2021?

Amgen Italy had a very good year in 2021 and our affiliate led all other large European markets in year-over-year growth. That is due to a variety of factors. The main one, in my opinion, is that from the get-go in Italy we were able to focus on getting back out there and reconnect with the scientific community. This was obviously challenging in a year in which we were still emerging from the pandemic and when access to doctors and hospitals was still restricted, but we were able to strengthen our face-to-face interactions as well as our engagement capabilities through digital, virtual and remote channels. In fact, in Q4 2021 we had even more interactions than prior to the pandemic, showing that our customers are more engaged than ever and appreciate our willingness to engage in continuous dialogue.

We did not have a launch last year, meaning that this strong performance was due to organic growth. Amgen in Italy has been successfully shifting its focus from some mature treatments to a variety of growth products that are still in the early stages of their lifecycle and we are heavily investing to ensure that the benefit that these products bring to society is maximised. One of our products for hypercholesterolemia has grown quite nicely over the last couple of years, which clearly speaks to a substantial unmet need for patients.

Amgen is the only large global biotech that has not been acquired by a competitor, colleagues are often keen to play up the company's continuing 'biotech spirit'. How relevant is this spirit for you in Italy?

Amgen does have a biotech and entrepreneurial spirit, which I can certainly feel having worked in other pharma companies before. This spirit comes from our people – it is they who make the difference – and we attract a certain type of individual: results-oriented self-starters who want to make a difference to patients' lives. Our people are not content to fly under the radar and collect their paycheque, but instead want to get involved, roll up their sleeves and get their hands dirty so to speak. With these people on board, an entrepreneurial spirit within the company is natural.

For seven years in a row we have been awarded with 'Best Place to Work' certification and focus on issues that matter to our staff; issues like diversity, inclusion, and belonging. I see my staff as a family; together, engaged, motivated and driven by our mission to help patients overcome very serious diseases. This is what drives our culture.

With a full pipeline and recent approvals from the EMA and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan for LUMYKRAS™ (sotorasib), how ready is Amgen Italy for more product launches in 2022 and how would you characterise the Italian market access scenario overall?

The good news is that patients in Italy will not have to wait for LUMYKRAS to be reimbursed by the payer to access the product. We have committed to a special early access program for anyone in Italy who needs the product between now and when it becomes reimbursed; a substantial commitment, but the right thing to do for a product that could be the difference between life or death for non-small cell lung cancer patients. Patients should not have to wait because of AIFA's slow reimbursement process. Even prior to EMA approval, close to 300 patients in Italy have already used the product in Italy through clinical trials and other early access programs.

Over the next couple of weeks, we will be submitting a reimbursement dossier to AIFA. There is typically a two-step procedure, first with a scientific evaluation of the benefit of the product from a clinical perspective, where it fits in therapy, and how it should be used. Following that is a pricing discussion. This is in essence a good process that allows for dialogue between the company and the payer and avoids bureaucratic decisions that fail to take into consideration the patient who will

be receiving that product. Unfortunately, it is a long process of a year and a half, but we will provide the product to those who need it ahead of full reimbursement approval expected in Q2 2023.

The Italian government was intending at some point to revolutionize the way in which payers look at pricing by asking for a sort of full transparency; how far has this proposal gone?

We very often negotiate confidential discounts with AIFA; that's just the way the industry operates in Italy and many other markets. Confidential should mean confidential, meaning that when we offer a price to the government under certain conditions, we expect that the government honours those conditions. That goes both ways; if a discount is negotiated as confidential, it should be kept as such. This makes a difference in terms of reference pricing with other countries around Europe and elsewhere and without the other side's commitment to keeping these prices confidential, it would be very difficult for us to manage.

In Italy, the government instituted a payback system many years ago that has been at the centre of many discussions and legal disputes. How well is this process working today?

Paybacks are a big topic but the signals we are receiving from the government are positive. The problem with the payback is that it applies only to innovative products in the hospital channel. Over the last 10 years or more, not a single euro has been paid back in the retail channel. This creates somewhat of a penalty on innovation and de-incentivises companies from bringing innovative products to market here. We believe that this should be discussed. Thankfully, over the last two years, there has been some re-modulation of the system and this year the government has increased its spending on hospital products, as well as for the Innovation Fund.

In general, a more open dialogue between all stakeholders is needed. This could ultimately reform the system to remove the penalty on innovative products. Amgen is happy to play its part in this; we have effectively resolved all outstanding payments for all years prior, including 2020, as a sign of goodwill and of our willingness to engage in this open dialogue.

Other interviewees have commented that while Italy has several good fundamentals as a clinical trial hub, there is perhaps too many bureaucratic layers preventing the country from being truly globally competitive in the field. What is your take?

There are a few levels of bureaucracy that should be removed. Conducting a clinical trial is a very complex project; it involves patients and there ought to be a level of due diligence. However, that should not mean that the process should be buried under layers of bureaucracy; as a matter of fact, we should remove them. I would call on the Italian government to do whatever is possible to make it easier and more efficient to do clinical trials in Italy, simply because it is an investment that companies are willing and able to make. It is also an investment that brings know-how to Italy in terms of new treatments, diagnoses, and healthcare technology that would otherwise come years later after those technologies ultimately make it to market.

The investment that companies make in clinical trials is substantial; in Italy alone, we spend close to USD 20 million on clinical trials and we are just a mid-sized company here. If the trial process was made more efficient, it would make Italy more competitive internationally.

It must, however, be noted that the quality of thought leadership and medical research in Italy is very high. For example, for one of our medicines, BLINCYTO® (Blinatumomab) in acute lymphoblastic leukaemia, Italy has been probably *the* market that has shaped how this product is used and how that disease is being treated. The work that some of the centres in Italy have done has not only resulted in several scientific publications in very highly regarded journals, such as the *New England Journal of Medicine*, but also in the submission of a reimbursement dossier to AIFA on changing the ways we treat these patients and expanding the use of the product. It is a best-in-class example of what Italy as a market and scientific powerhouse can bring to companies in our industry.

Globally, Amgen is increasingly prioritising partnerships and collaborations around open innovation; to what extent is Italy a part of this strategy?

It is probably still too early for Italy to be a core part of this strategy, but some positive first steps have already been taken towards it. The issue of intellectual property (IP) adds complexity as this is the lifeblood of our industry and no innovation happens without somebody being able to claim that property and commercialise the end result. Certain hurdles exist, but that does not mean that we cannot pursue innovation via more traditional channels, such as investigator sponsored trials or real-world evidence (RWE) generation.

This RWE is very interesting to clinicians as it happens outside of clinical trials in day-to-day operations in the hospital, considering factors like compliance and side effects. I am happy to see these insights being made available to the scientific community.

Europe has been at the forefront of biosimilar adoption globally and Amgen has a burgeoning footprint in the field. How does Amgen Italy's biosimilars portfolio dovetail with your innovative medicines?

We have successfully launched three biosimilars in Italy. When AMGEVITA® was launched in Italy, it was the number one biosimilar to Humira® (adalimumab) for some time. The same goes for the bevacizumab biosimilar we launched about two years ago, where we are still number one.

Our biosimilars provide a triple win. The first win is for patients and doctors; if a doctor prescribes an Amgen biosimilar and the patient takes it, both know that the biosimilar is manufactured to the same quality standards as any other Amgen product. If for example, a patient has rheumatoid arthritis, previously took Humira®, and is now being switched to a biosimilar, they will want to make sure that the biosimilar works and that it is as close to the originator as possible.

Biosimilars are also a win for the healthcare system because they allow to realise savings and reinvest those savings into new, innovative treatments. That is what the circle of innovation is all about. A new innovative medicine is launched and provides benefit and the company now has, due to patent laws, the right to realise a return on the investment. However, once the patent expires, the healthcare system needs to reallocate those funds to new medicines.

The final win is for Amgen. It is a great way for us to become partners to the healthcare system, not just providing new innovative medicines but also providing a platform of products that allow healthcare systems to realise savings and make the economics work.

My one small criticism of Italy in terms of biosimilars is the winner-takes-all tender-driven market, which ultimately means that the lifespan of a biosimilar is very short. This creates a risk of patients simply being cycled in and out of biosimilars that constantly get switched. There needs to be a safeguarding mechanism built in to provide some continuity; once the patient is on the first biosimilar, it should be very carefully evaluated whether that patient should be switched to the second, third or fourth biosimilar just because of availability or the winner of a tender. There is a benefit both to the patient as well as to the healthcare system of maintaining therapeutic continuity, which we are lobbying for. The big saving has already been realised by switching to a

biosimilar but moving from one biosimilar to another creates only a marginal saving for the healthcare system while adding a huge risk for individual patients.

What would be your final message to PharmaBoardroom's global audience on Italy and on Amgen?

Italy is a beautiful country, full of great people, fantastic food, superb cities, and a rich culture; it is a pleasure to be here. The country has a very developed and holistically integrated healthcare system that provides reasonable access to both innovative medicines as well as overall care. The government is rethinking the payback system to better incentivise innovation and we are seeing increased openness to dialogue with the industry to solve this and other problems.

On Amgen, we are an exciting company. We have a great portfolio of innovative products that address serious unmet medical need. Even more impressive is our pipeline of blockbuster candidates with the potential to be either first or best in class. Finally, our biosimilar portfolio makes us truly diversified and a unique partner to any healthcare system.

It is a great time to work in this industry; I wouldn't want to work in any other. No other industry can impact people's lives in the way that biotech or pharma does. We always remember that there is a patient taking or receiving our medicines, which is why we come into work every day.

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