Interview: Eric Baclet – President & General Manager Italy, Central Eastern Europe and Southern Eastern Europe, Eli Lilly Italy



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The General Manager for Eli Lilly Italy, discusses how the company's continuous commitment to Italy has benefited the organization, the promise the country holds if certain barriers can be overcome, and how Lilly's rich pipeline is set to boost growth in new areas over the next few years.

We interviewed you during your time in China in 2013. Italy is of course a very different market to China, where the opportunities seem endless. Many might say Italy holds less obvious promise, how would you characterize Italy's potential for Lilly?

Eli Lilly has a long history in Italy, we established ourselves here in 1959, and have remained committed to the country ever since, with a constant improvement of investment in our manufacturing site. Today we are approximately 1,100 employees, more than 550 of which engaged in the manufacturing site.

Looking at the pharmaceutical market, it is one which historically has been very strong, especially in manufacturing, where the quality of the people has consistently given it an advantage. Today, it is a very attractive market through its size and the potential for innovation that this brings, and it still has a strong manufacturing side where much of its production is exported. As an example, we are the only insulin producer in Italy, and 97% of our production at Eli Lilly Italy is exported to more

than fifty countries worldwide. Just our production site here provides the group with 40% of its total insulin requirements.

In terms of our commitment, which reflects our view of the country’s potential, once you have a manufacturing presence this naturally establishes firm roots in the country. These investments act to seal our commitment to Italy, and they also establish a trust between our company and the different stakeholders we interact with. The fact that we have never wavered in this commitment, and have been constant in our belief in Italy in both good and bad times, has reinforced this trust. That has proven crucial to us, because in the pharmaceutical business, trust is certainly the most important factor to consider when building a strong relationship with the different partners and governmental constituencies we deal with.

After your second year at Eli Lilly Italy, how would you rate the performance of the company in 2015, and how are you positioned to grow in the market over the course of 2016?

As a company, Lilly has been going through significant patent expirations over the last few years, four of which were blockbusters accounting for a large portion of our revenue. Faced with such a patent cliff, the first thing you look at is your pipeline. Today, we can say that we are very successful in consistently hitting new milestones in the development of our treatments, whether in oncology, diabetes or biomedicine. Linking this to Italy, as an affiliate we are following the cycle of the global company, meaning that we are also going through these patent expiries. This year we are losing Cymbalta for example, but at the same time we are launching a very promising diabetes portfolio. In the last three years we have launched Tradjenta and Jardiance, which are both oral antidiabetics, together with our partner, Boehringer Ingelheim. We are also going to be launching Trulicity in the very near future. These are high-potential, best in class molecules, with extremely positive clinical trial feedback offering very significant improvements over existing treatments. In the diabetes area we are also launching Abasaglar, the first biosimilar of Lantus. Two of these products, Trulicity and Abasaglar, are being manufactured in Italy, a feat made possible by the more than four hundred million dollars invested in the site over the last ten years. This means that both from a global, and an Italian perspective, we are going to be in a position to provide a full range of treatments to diabetic patients, from oral treatment to insulin, and customized to what is best for each patient. No other company in the market today is able to match this portfolio, and we are eager to combine this with a full range of peripheral services to our patients as well. Our aim therefore is to become the number one company for diabetes in the countries in which we operate. Currently Novo Nordisk is top for diabetes globally, but with the portfolio we have we believe that

we will catch up to them by 2020, and Italy is a good example of a country in which we believe that we can be very strong in this area.

On the oncology side we are launching Cyramza for gastric cancer, and Necitumumab, a monoclonal antibody for lung cancer which has been approved at the European level. This means that we will also have several oncological drugs targeting lung- and breast cancer, and soft tissue sarcoma as well. In other words, we have a huge portfolio in oncology either already on the way, or under late-stage clinical development.

Finally, in the bio-medicines unit we have two molecules submitted or close to being submitted. One of these, Baricitinib, targets rheumatoid arthritis and the other, Ixekizumab, targets moderate to severe psoriasis. These molecules too are best in class, with stellar clinical trial feedback. To conclude, we are going through significant patent expiries, however we have a very strong pipeline which, by 2017, will allow us to be back in a position of growth.

As you mentioned, one example of the innovation Eli Lilly puts at the core of its mission is its newly developed insulin pen using Dulaglutide, being manufactured in the company's Italian plant. What are the advantages you see to maintaining and in fact, heavily investing in, a biotechnology plant in Italy?

When making these decisions, and this is the same for any global pharmaceutical company, the most important element is the attractiveness of the country as a whole from an investment perspective. Here there are strategic and financial considerations to be made. Looking at Italy, there is a history of high-quality manufacturing here which tells us that we can rely on the quality of any manufacturing output coming from the country, that the qualifications of our employees are solid, and that the 'Made in Italy' brand carries a significant global weight behind it.

Today, the manufacturing site here is state-of-the-art when it comes to biotechnology and automation. It should also be noted that historically, this was a manufacturing site specialized in antibiotics, which, although there are many constraints, is not a particularly difficult area from a manufacturing perspective. When the company moved away from antibiotics we had to decide whether to close, sell, or transform the site. We decided to transform it, changing an antibiotic manufacturing site into a biotech manufacturing plant and retraining our employees accordingly. We made this commitment to Italy, because of the trust we have in the country and in our people here, and because we believe this is a very promising market in the long-term.

The Sesto Fiorentino production site was the result of a strategy of the national economy, which has seen working together the three key subjects of social, regional and national levels:

institutions, companies, and civil society. In this way, opportunities were seized that otherwise would have been diverted to other countries.

A number of factors made Italy in general and the Sesto Fiorentino site in particular especially attractive for us: (1) A highly trained and specialized workforce; (2) A political environment that, despite its complexity, in the last five years has been able to give a continuity of strategic vision for the pharmaceutical sector; (3) An attractive domestic market due to its size. Italy is the second largest country in terms of production capacity at the European level, therefore it is an important market in which to be present, work and compete; and (4) The institutions which include the value of economic, social, and scientific innovation to society..

So investment is a matter of looking at whether we have sufficient trust in the country, whether there is enough visibility on our investments, whether we have enough intellectual property protection here and finally what the pricing and reimbursement conditions are.

We have heard many different views on the current pricing and reimbursement system, but some have said that when companies offer truly innovative drugs, it is still possible to get a fair price. Do you agree?

First, the reimbursement process, even for innovative drugs, is still too long. When innovation produces results, and patients are waiting for a cure to save their lives or to release them from suffering, and you have a treatment that is best in class and which can help them, having to wait between one and two years to deliver this to them is unacceptable.

From a pricing perspective, Italy still sits quite low, which poses a challenge to pharmaceutical companies such as ours. This is a problem that needs to be solved by AIFA in order to keep Italy competitive. We are now at a pivotal stage where the authorities could make Italy a top country for investment in pharmaceuticals. This will depend on pricing and especially the current claw-back system, on the regulatory aspects surrounding clinical development, on manufacturing audits and validation, and on research. If Italy wants to be a top destination, then the authorities will need to make it an easier place to operate in for the entire value-chain of the pharmaceutical industry. This is not yet the case today, unfortunately progress is currently too slow and too fragmented on many fronts, however the opportunity is certainly there to create a solid ecosystem supporting companies’ operations in the country.

In Italy’s regionalized system, building partnerships with the different regions will certainly be crucial. Beyond the central government, how does Lilly engage its regional stakeholders and the authorities especially?

It is indeed crucial for us to be engaged with our stakeholders, both in the government and the communities, at regional level. As a result, we actively pursue good relationships with Italy's regions, but of course our emphasis here lies in Tuscany, as that is the region in which we are based. We are here as the success story for Tuscany. We are proud of this, and in order to build on this success we need to maintain good relationships with the constituencies involved whether they are the regional government, the city, or other institutions active in Tuscany.

As General Manager, where would you like to see Eli Lilly Italy evolve to over the next few years?

Clearly in the next five years, we will be resuming significant growth as a company by virtue of our portfolio. Our vision therefore, is to unite caring for patients with the discovery of new treatments. Naturally for an innovative company, discovery is key. Today however, patient care has also become crucial, and that requires that every part of the organization thinks about the customer first. It is only by putting the customer first in every element that we will become first in the mind of the customer. It will be up to us, as an organization, to translate our valuable portfolio into becoming the preferred company for our customers. That is the challenge for Lilly Italy, it is the challenge for our global company, and the transformation we are going through will allow us to do just that.

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