

Interview: Alexander Zehnder - President & Managing Director (Italy and Malta), Sanofi



19.04.2016

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Alexander Zehnder discusses Sanofi's sizable contribution to the Italian economy, manufacturing in Italy, and the country's labyrinthine drug approval processes.

What have been your main areas of focus and priorities since your appointment as head of Sanofi's Italy and Malta operations in October 2014?

Sanofi is in the midst of a transition from a traditional pharmaceutical company to more of a specialty and biotech outfit. If you analyze today's pipeline, you will discover that almost 80 percent of the products are now biotech drugs. This requires radically different capabilities and a fresh approach and mindset, so my focus has been very much about guiding the local operations through this decisive period of transformation.

My other key priority at the macro level relates to increasing awareness about our presence within and contribution to the Italian market and economy. We actually have quite a large footprint in Italy with an in-country workforce of more than 2700 personnel, of which 1300 are engaged on the commercial side and 1400 on the industrial side. Nevertheless, the scope of our activity is not necessarily widely known or appreciated as much as I think it should be.

We contribute some 850 million euros every year to Italy's GDP and pay 350 million euros in taxes and yet the notion and perception remains that the value of non-Italian companies is not as high as that of indigenous enterprise.

In terms of job creation, we are also quite impactful. Beyond the 2700 workers that we employ directly, the number rises to over 6000 jobs when you take into consideration our immediate supply chain and our support industries.

Being a big player on the local scene that invests so heavily, it is also very important that we play a proactive role in shaping the agenda. A further aspiration of mine is therefore to switch our stance from being reactive to seizing the initiative.

Your footprint is one of the most eye-catching features of Sanofi's engagement with the Italian market. Not only are you ranked second place in turnover, but you also maintain six manufacturing sites that are highly embedded in the local ecosystem. Just how strategically relevant is Italy to Sanofi's global and regional activities?

Italy is Sanofi's third most strategic market after France and Germany. In terms of sales, in 2014 we had income of around 1.6 billion euros. We have the second biggest consumer health business after France and also a significant business in established products with 700 million euros in sales. On the manufacturing side we maintain 6 sites; although we are in the process of selling the facility in Garessio which is one of the older chemical plants and no longer aligns neatly with recent shifts in our product portfolio.

Global CEO Olivier Brandicourt has been speaking out publicly about adopting a three-way turnaround strategy focused on: [1] capital investments in biologics, [2] competitiveness, and [3] evolution of the manufacturing network. How is this trickling down and impacting the Italian operations?

What I can say is that Sanofi is in a process of transformation and simplification. Also in Italy, there are now 5 global business units grouping different therapeutic areas so as to maximize synergies. Support functions – such as finance and HR – are transversal to each unit but with dedicated business partners. This will simplify the organization, while speeding up decisional processes, with a balance between local flexibility and overall consistency and uniformity of approach.

Sanofi has traditionally chosen to be a very diversified company; our portfolio encompasses consumer health, vaccines, specialty care and a wide-sweeping established product business. The idea is that we want to be within the top three for every field that we participate in. If you are

diversified to the extent that each segment is small within the corresponding sector, then you are not so competitive anymore.

As far as Italy is concerned, we need to be more focused on our strengths to meaningfully outcompete more specialized companies who focus on a single therapeutic area. Vertical, leaner, streamlined structures and clarity of focus are ways to achieve this and sustain our future growth.

How would you describe Sanofi's Italian manufacturing capabilities?

Our in-country manufacturing generates approximately 350 million euros worth of turnover and around 90 percent of what our 6 sites produce is exported worldwide, making us an important part of the overall Sanofi global manufacturing network. All of the facilities are FDA approved and possess the requisite certification from the regulators of other markets that Sanofi exports to, such as those of Japan and China. Each site is dedicated to different manufacturing processes – whether API, liquids, chemicals, solids or injectables – and all are fully fitted with state-of-the-art, latest generation technology. Indeed every year we invest between 40 and 50 million euros on process and efficiency updates and in kitting them out for the production of new drug categories and formulations.

We've witnessed some companies such as Takeda going down the route of delocalization and moving their production lines out of the country, yet Sanofi remains staunchly committed to manufacturing in Italy. Why? What exactly makes Italy an attractive and competitive destination for pharmaceutical production?

There is a historical legacy that needs to be factored in when analyzing the makeup of Sanofi's Italian manufacturing base. Sanofi was built on the back of multiple mergers and acquisitions over the years and that is how we came to have six distinct factories spread across the country. Probably, if we had been starting out afresh we would have structured it differently. Our local manufacturing base is, however, consistent with the corporate spirit within the company. There is a very strong manufacturing culture deeply ingrained within the culture of Sanofi as can be demonstrated by the fact that the company currently has 110 industrial sites worldwide.

Italy as a country also enjoys a very strong manufacturing heritage whether in the mechanical, chemical or automotive industries. Moreover, the country definitely possesses specialized human capital capabilities. Having said that, pharmaceutical manufacturing is an increasingly competitive business and alternative destinations in countries where labor costs are lower do pose a real challenge. Italy-based producers shouldn't hope to compete on costs alone, but need to differentiate themselves on quality while simultaneously operating with efficient, lean structures. It

will also be important to scale the value chain in terms of complexity while perhaps outsourcing some basic production processes such as API manufacturing.

The “made in Italy” brand may look in good shape right now, but this is based on years of solid investment. Right now the market is decisively shifting over to biologics and that is an area where Italy seems to be left behind, due also to challenges and limits posed by R&D capacity and investments in the country. The existing portfolio of companies should ensure Italian manufacturing remains resilient over the next decade, but after that the industry risks losing its shine. Blockbusters’ patents are expiring. The shift to biologics needs to be made now.

Sanofi enjoys a very exciting project pipeline, but how do you go about navigating the complexities of the Italian drug approval process and ensuring your products are brought to market when there are in fact 21 distinctive regional healthcare systems to deal with?

The main challenges are the extraordinarily elongated product approval timeframes. Generally it takes 12 months to secure approvals at the national level after the European “green light”; then from three months up to two years to go through the regional authorities. This is a challenge to companies and a problem for patients because they face having to wait longer compared to other European countries to have access to medicines that could probably make the difference in their fight against the disease or in their quality of life. We do our best to raise the awareness of the authorities on such aspects of the actual approval framework.

Beside this, I believe that Italian pharmaceutical companies should make a change in their commercial approach, very much focused on the relationship between sales representatives and physicians. The future is going to be about deploying much smaller, specialized, and medically prepared sales forces, while enlarging the internal expertise in market access and governmental affairs. Within Sanofi we are already well underway reconfiguring our teams to reflect emerging realities. In the past couple of years we’ve more than doubled our market access and government affairs departments by bringing in capabilities. We’ve also been strengthening our medical department as the types of products we are projecting onto the market have risen in complexity.

I believe we need to be much more extrovert as a company and actually partner with the authorities and different stakeholders to forge joint solutions to problems like the overall unsustainability of Italy’s healthcare model. We’ve perceived a great deal of progress since the advent of the Renzi administration. There’s more stability and certainty of rules in general, and in our sector. In the past, we were more frequently confronted with price cuts and budget changes

that required prompt adaptation. The remaining hurdle today is dealing with the 21 regional governments which have decisional power also in terms of healthcare policy and procedures. It is quite complicated having to deal with multiple government levels – European, national and regional. This is an area where simplification would result in a real benefit to the whole country system and, above all, to citizens.

Can you please elaborate upon Sanofi's own contribution to fostering sustainability and pioneering new models of healthcare?

We have rolled out a number of projects that seek to push the boundaries and rethink the way that healthcare is provided. One of the approaches we have been promoting in the diabetes segment is the idea of 360 degree integrated care involving harnessing synergies between our consumer, generics and established products portfolios and delivering a holistic and joined-up treatment plan to the patient, involving all HCPs.

At the same time we are mobilizing different forms of technology to empower patients and enable them to better manage their health needs. Examples would be: Mystar Connect – the software we support that directly connects diabetes patients with their physician, helping them share the patient's electronic medical record and glycaemia self-monitoring, to better manage the disease; and the reshaping of our B2B and B2C portals that aim to harness digital communications to enhance the relationship two of our most important external stakeholders, patients and pharmacists. At a global level, we could mention, among others, the collaboration with Google Life Sciences to develop digital technologies and devices that can improve the monitoring and management of diabetes patients' glucose levels.

In recent times, Sanofi in Italy has resolved to start shaping the healthcare landscape and setting the agenda with a view to improving the livelihoods of patients and fostering smarter ways of delivering healthcare. Our governmental affairs department is working hard to partner with national and local Institutions. We already appreciate the current cooperation with the government on a level that is quite remarkable for a non-Italian company and we wish to build upon this for the future.

Our intention is not to compete with the public healthcare structures, but to fill in the gaps and give the support of our expertise where possible. Right now, pharmaceutical expenditure only accounts for 15 percent of public health spending; so we are keen to help policymakers and practitioners alike in rethinking the system, with a view to identifying areas for optimization. Innovation can go beyond the pill itself and be applied to processes, techniques and delivery mechanisms. That way,

savings can be generated and resources can be channeled towards bringing in latest generation therapies.

Tell us about your involvement in clinical trials in Italy.

In Italy, there is a clinical studies unit (CSU), which actually provides coordination for the Adriatic cluster covering some 11 countries. We have actually been increasing the number of trials conducted in Italy significantly. Last year we invested nearly eight million euros in 70 studies involving 34 different molecules and 2300 patients. The quality of Italian researchers and capabilities embedded within the research centers are excellent and their work is a fundamental part of the drug development process. We are keen to do more in this arena - especially for phase I and II type studies.

What is your vision for developing Sanofi's Italian operations?

Around 42 million people in Italy consume Sanofi products and therapies. We are already one of the first pharmaceutical companies in the world and strive to be the first in Italy as well. Within Italy we have a long and successful heritage dating back over a century. Our vision now is to actively collaborate with all the stakeholders involved in the healthcare sector and with Farmindustria, the Italian Association of Pharmaceutical Companies - to reshape the Italian healthcare system for generations to come.

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