Interview: Manlio Florenzano – Country Head and Managing Director, Sandoz Italy

17.03.2016

Tags: Pharma, Pharmaceuticals, Italy, Sandoz, Novartis, Generics, Manlio Florenzano, Healthcare, Strategy, Interview, Insight, Exclusive, Executive, Free, Italian, Europe

Manlio Florenzano discusses Sandoz's engagement in Italy and the role of generics firms in contributing to a more affordable and sustainable Italian healthcare system.

Can you please start by introducing Sandoz's historic engagement with the Italian market?

Sandoz began marketing in Italy back in 2000. My own background, meanwhile, was as general manager at Hexal, first directing the spinoff of the company from a joint venture with Angelini and then overseeing the merger of Hexal into Sandoz in 2005. Initially Sandoz started out with very low market penetration, but was able to take advantage of the mid-to-late 2000s, which in Italy represented the period of the big patent expiries and the moment when many of the generics companies scrambled to gain a slice of market share. The name of the game back then was all about the substitution of classic products with the cheaper generic-ized versions.

As the pace of patent expiry dropped off, almost all of the generics companies were compelled to look elsewhere to prop up their revenues. Sandoz's own pathway was to pioneer the advent of biosimilars and indeed we look set to secure a future windfall over the coming years when the patents of biological products reach the end of their lifespans. Today we are proud to be global leader in biosimilars both globally and in the local marketplace.

Compared to the other generics players in the Italian market, we currently rank as number 3 with only Teva and Mylan ahead of us. What is perhaps even more interesting is how we fare on the IMS rankings for the overall local pharma market. This year, we are in 19th place up from 25th a year ago, which seems to be indicative of a broader trend in which all the generics companies have been scaling the league tables supported by double-digit growth that is outpacing the broader pharmaceuticals market.

In Italy Sandoz has also a plant in Rovereto, with 164 associates, with an export budget of 113 million USD in 2015. It is a plant dedicated to to the production of API (Acid Clavulanic, Acid Mycophenolate and Tiamulina). As part of our long-term strategy we continue to upgrade and modernize our facilities: in 2015-2016 alone, 5 million euros were invested in technological innovation to ensure the highest standards of quality.

That said, the performance of generics in penetrating the Italian market is still noticeably lower than in many equivalent mature Western European economies. Why is this?

That’s absolutely true, even if the expenditure of off-patent medicines increased in value from 0.7% in 2001 to over 10% in 2015 Most of the market share is still owned by the originators and the substitution-logic that works well in many European markets has clearly been less effective in Italy. There are a number of explanations for this. Firstly, the legislation tends to treat former originators and generics in very much the same way. When a patent expires, we negotiate the price with AIFA and then innovative companies tend to drop their prices accordingly to the point where the substitution logic loses its relevance. If a customer is only going to spend a couple of euros for an originator then the incentive to substitute is considerably lowered. It’s therefore quite easy to get sucked into a race to the bottom on pricing. Secondly, a large part of the market is still driven by prescriptions and the pharmacists are obliged by law to offer the customer the choice of either an originator or generic. Thirdly, there are certain cultural dynamics at play as well with Italian patients displaying a high level of brand consciousness. The result of this confluence of factors is that we only tend to see between 10 to 15 percent of originator drugs being substituted in our favor.

Despite lower levels of market penetration, the size and potential of the Italian market is such that everyone continues to invest in a big way. The untapped potential out there is clear to all. Almost everyone is busy trying to create mechanisms to grab prescriptions from the originators especially in instances where drugs are medically as opposed to pharmacy driven. Many firms are investing in large medical field forces to that effect. The returns that are being made are also decent for many

actors. Sandoz's Italian office is actually the 7th best performing affiliate across the company's worldwide operations.

What sort of alternative business strategies is Sandoz deploying so as to be able to maintain such a performance?

We are constantly on the look out for new areas that can be generic-ized. Remaining ahead of the curve for the biosimilars segment is one priority and an area that we will surely continue to invest in. Our recent purchase of the rights for the development and commercialization of infliximabin from Pfizer is a case in point. We analyze the biosimilars market to be an especially powerful opportunity because the general expenditure on biologics is huge.

Another strategy that has been fairly successful has been our willingness to go down the path of what we call 'medical specialties', which is essentially promoting off-patent drugs to certain clusters of physicians. We started doing this around 5 years ago and some of our competitors subsequently started emulating us. Now we are looking into expanding out and covering additional therapeutic areas. Our attachment to Novartis is one of our stronger points.

How else is Sandoz differentiating itself from its competitors?

Sandoz is the global number one player in biosimilars, generic injectables, ophthalmics, dermatology, and anti-infectives, and a top player in respiratory.

Sandoz now has six molecules in Phase III clinical trials/filing prep – more than any other company in the industry – and we continue to make progress on all of them

Sandoz's strategy is to extract maximal potential from our existing assets in the Group. We focus in on our list of 400 or so products, selecting some, rebranding them and then going to specific categories of physicians: those dealing with pain management, gynecology and respiratory illness. One of the benefits of being part of the greater Novartis group is we can take ownership of some of their off-patent drugs. Belonging to Novartis Group also affords us greater credibility with the medical and patient communities than if we were a lone generics outfit. Our hope is that some of these products bequeathed by Novartis can help deliver us the critical mass that we are seeking in terms of market penetration and share.

What role can generics firms play in rendering Italian healthcare more sustainable?

We firmly believe that generics have a considerable role to play in making healthcare more affordable and thus in turn more sustainable. For this very reason Sandoz has been making an

effort to collaborate with the national and local authorities in terms of both raising awareness and informing policymaking. The synergy with Novartis is useful because we can present joint solutions to the two main issues: latest generation innovative products to address patient needs, and generics and biosimilars to address the issue of overstretched public budgets.

We will have to do much more to educate the authorities and medical community as to the cost savings that our products can deliver. It’s amazing how some of the poorer regions still resist instruments that could significantly reduce their expenditures while simultaneously freeing up money for re-investment in real innovation. One area where we can assist is in delivering correct information and in supporting policy makers in the creation of legal frameworks that will encourage cost-efficiency and an uptake of generics. If we can achieve this, then the real beneficiaries will be the patients through increased access to medicine.

How do you foresee Sandoz’s Italian operations evolving over the next 4 to 5 years?

My wish is that we will be more integrated into the Novartis system proper and will have been able to conquer a greater market share through a 360-degree proposal for Italian healthcare that encompasses both innovation and genericization. We will be a unique player on the market and a strong partner to the authorities and medical community alike in ushering in a new era of enlightened healthcare.

Click here to read more articles and interviews from Italy, and to download the latest free pharma report on the country.

See more interviews