

Interview: Francesco Scopesi - VP & General Manager, Shire Italy



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Shire Italy's Francesco Scopesi discusses innovative medicine, rare diseases, growth drivers, global strategy, and the new trend of home care.

Shire is today one of the leading biotechs delivering innovative medicines to patients with rare diseases and other specialty conditions. Could you please start by describing the company's engagement with the Italian market and the main milestones attained since your appointment as general manager in 2007?

Shire has been present on the Italian market since 2000 and the company has been strengthening its footprint ever since. Prior to my appointment as General Manager, I was actually the Area Manager of TKT, which is one of a number of specialty companies that Shire acquired. 2014 was an especially important year for the company because that was the moment when we relocated from Genoa and Florence, consolidating our in-country operations and directing everything from new flagship offices in Milan. This is when we transitioned beyond merely a 'start-up' structure to possessing full capabilities on the ground such as in-house legal and market access units.

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During my stewardship of the Italian operations, we have enjoyed a fair degree of success with a variety of new products being launched on the market and a compound annual growth rate (CAGR)

of 9 percent. Our intent is not to let up, but to continue to push the boundaries and seek out new growth opportunities, building upon the momentum that we have generated to date.

Shire's portfolio today spans a wide range of therapeutic areas including lysosomal storage disorders, hereditary angioedema, endocrinology, hematology, nephrology, and gastroenterology. Which areas in that portfolio do you see as the biggest growth drivers?

We possess particular expertise and a formidable track record in developing therapies for treating lysosomal storage disorders such as Gaucher and Fabry disease and also in the area of hereditary angioedema, so these will continue to be major growth drivers of our business. We also maintain a business unit dedicated to specialty diseases in endocrinology and nephrology.

Shire's global strategy, however, as we position ourselves as the world's leading biotech company focused on rare diseases, is to move away from a portfolio aligned to specific therapeutic areas and instead to target any condition with rare disease characteristics where patient needs remain unmet. This is the approach that will guide our future portfolio development.

Shire has expanded globally through a series of strategic acquisitions. In January, the company made its most significant purchase yet, with the USD 32 billion acquisition of Baxalta, a leading company in hematology with a strong presence also in immunology and oncology, creating the largest global biotech company focused solely on rare diseases. How have these developments been trickling down to the local level?

The announcement of the Baxalta acquisition is an important milestone for Shire. Naturally we are all excited about it. Our global CEO, Dr. Flemming Ornskov, has set an ambitious target of driving up revenue to more than USD 20 billion by 2020 and the integration of Baxalta will ensure we realize this objective.

Shire is the sort of company that is always ready to seize the moment and has a long history of making high-profile acquisitions. Our versatility and willingness to be bold is very much part of our corporate ethos and is something that all of our workforce buy into. We are one of the more fast changing and dynamic companies out there, in a positive sense and that's something that can take a little bit of getting accustomed to as a new employee, but it's also something that you grow to love. Being part of a company like ours is energizing – you never have a flat day.

The Baxalta combination will trickle down to the local country level in time and there will, no doubt, be organizational changes to implement. My responsibility, however, is to ensure that we maintain

a cohesive strategy at country level where our energies and focus remain firmly channeled towards carrying out our core functions and fulfilling (and even surpassing our targets). In short, we won't be taking our eyes off the ball or allowing any sort of mission drift. We need to remain responsive to patient needs and that remains our focus.

Globally you have a workforce of 5,000 spread out across 40 odd countries. Just how strategically important are the Italian operations relative to what the company is doing elsewhere?

Italy is one of the top five European economies for pharmaceuticals representing around 15-percent of sales. In spite of some of the lowest prices in the entire region, the health system is actually highly advanced. There are also laws in place enabling access to a product prior to official approval status under the 326 and 648 regulations, which mean that you can respond to unmet needs earlier than you might think, just so long as the product and patients satisfy certain conditions. This means that, when there is a pronounced medical need that is recognized, the Italian system is capable of delivering. There are thus some very appealing characteristics that the medical community very much appreciates.

Shire is highly committed to Italy. The authorities, for their part, constitute a reliable partner that is sensitive to the issue of rare diseases. Obviously cost-control is a priority for state actors, but we are always able to identify points of convergence and they do prove receptive in understanding the benefits we can deliver to patients.

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There is a finite amount of state money available for healthcare expenditure and yet reimbursement is being sought for a large number of costly innovative therapies. How can innovation-driven pharma firms work with the authorities to come up with a more sustainable system? To what extent is Shire contributing to this endeavor in its promotion of concepts such as 'home care', 'patient autonomy' and 'preventative healthcare and screening'?

There needs to be much greater appreciation and wider understanding of the savings that governments generate directly thanks to our therapies. When you start factoring in the social costs of chronic disease and the need for patients and family members caring for them to take considerable time off work because of the shortcomings of existing treatment delivery mechanisms, then you start to understand the value additions that our own optimized therapies can bring.

Shire is proud to have been one of the pioneers of home care in 2008 when we started delivering, through a certified third party home care provider, enzyme replacement therapies in patients' own homes rather than requiring them to travel many kilometers to a specialist hospital every couple of weeks and spending hours there while getting the infusion. This is about creating smarter models of public health. Not only is this less disruptive to patients' lives, but it also frees up scarce resources and spaces in overburdened public hospitals. It thus represents a win-win-win scenario for patients, practitioners and the state coffers.

Over time we have scaled up the program to include Gaucher disease and Hunter syndrome patients and even introduced a 'follow-me' aspect so that patients travelling abroad in certain other European countries, such as Germany and Spain, can receive their infusions abroad from a third party. As you imagine, these sorts of initiatives transform lives and greatly enhance patient satisfaction.

From my perspective, a new era of patient services is already underway that will prove much more sustainable when handling chronic cases.

Do you consider 'home care' to be a model that can be replicated and emulated across the healthcare spectrum or is it specifically appropriate to the rare disease segment that Shire operates in?

I see all sorts of possibilities for new models of dealing with chronic disease in general. After the success of our own 'home care' initiatives we have been busy defining new types of service that leverage leaps in communications technology and respond to day-to-day issues that patients and physicians encounter. First of all, we listen to them intently and collect inputs on how we can better serve them. Then we come up with practical solutions that can be fine tweaked at the pilot phase before being adopted in a more standardized manner.

One service that we have been rolling out deals with psychological assistance for those afflicted with debilitating chronic diseases and is essentially a hotline where the patient and caregivers can get immediate advice. Another is a tailored counseling program that starts off with a hospital visit and is followed up by eight subsequent phone or Skype calls thus ensuring continuity of care.

Then there are other electronic-health services that provide tools for physicians so that they do not lose track of their patients. To qualify for a particular type of hereditary angioedema therapy, patients must have experienced at least four attacks a month over a three month period and yet it has been very difficult for practitioners to keep records of rate of incidence and that in turn has

resulted in sub-optimal treatment plans. Having a fully integrated program of home visits and follow up communications remotely means a much clearer situational picture can be established which can then inform the treatment plans.

From my perspective, a new era of patient services is already underway that will prove much more sustainable when handling chronic cases. Sometimes we experience hurdles such as the fact that a few of the Italian regions don't permit home visits as they fear it could be used as a pretext to push prescription, but this sort of resistance to change is completely natural and will subside with time. Ultimately, with ageing populations, and a rise in certain types of chronic disease, existing healthcare models are unsustainable over the long run and a new, smarter *modus operandi* has to be identified for the future. Shire is proud to be playing its part at the forefront of this process.

Shire has also been very keen to promote increased emphasis on diagnostics. How is this essential to both sustainability and patient welfare?

In the rare disease field, proper diagnosis is especially important. There have been many instances in the past where diseases such as Fabry and Gaucher have not been correctly diagnosed leaving patients abandoned without treatment for many years or in situations where treatment has been administered for the wrong disease. This is both highly detrimental to the patients' health and incredibly wasteful for the healthcare system. Back in 2003, it was typical for a delay of 20 years before patients would be correctly diagnosed with a storage disorder because there were only 10 centers in the country that had any experience in dealing with such conditions. One of our first tasks was therefore to raise awareness across the clinical community and to co-opt the physicians so that they were fully aware of the signs to look out for. Research in Germany, for instance, demonstrates that 2-3 percent of strokes in people younger than 55 is an indicator of Fabry disease, yet until recently many clinicians were largely unaware of that fact.

In that sense, Shire's field representatives are much more than a sales force but rather a partner and consultant to clinicians in delivering and raising awareness. It's a much more noble way of promoting a product. We have promoted several initiatives to make the importance of the diagnosis recognized and gradually state actors are becoming more conscious of the economic savings to be derived from early screening.

As General Manager for a company, with a well-stocked pipeline of new drugs and strong revenue growth, what are your strategic ambitions and vision for developing Shire's Italian business over the next 4-5 years?

With such a robust pipeline we are already seeing the fruits of our efforts. We must commend aspects of the Italian healthcare system on this as well, as it allows patients with rare diseases who have no therapeutic alternatives to have access to new medicines that become available. My focus is decisively on the growth of the company and bringing the best technologies out there to market to ease disease burdens. I am committed to making inroads in addressing the struggle against rare disease, and to quote our own corporate motto, to 'enable people with life-altering conditions to lead better lives.'

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