Jan Kirsten, Managing Director & President – Merck Italia



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Merck Italia's Managing Director & President, Jan Kirsten explains the importance of the Italian affiliate within the global organisation, Merck's aim to strengthen its position in oncology and the challenges of fertility in a country with one of the lowest birthrates in the world.



You went from leading the global fertility franchise in Germany to managing Merck Italy. How did that shift come about?

At Merck, we have a very strong focus on "people development" and for this reason we have the opportunity to change from global and local roles just to make sure we foster the understanding of

the needs both on global and local levels (e.g., not losing the context and insights from the market). In my last global role as global head of the fertility franchise, I had the benefit of seeing the uniqueness of different countries.

This comes with a lot of travel and exchange with all the different countries, so I was not really based in Germany, as the role required closeness to the people in the country and dialogues with the local stakeholders, e.g., customers.

For me, it was time to go back to a local role. I thought a lot about what could be the best place for me and in the end, I applied for the job in Italy because I really appreciate culture, which reflects a strong sense of creativity and passion that you cannot find so easily somewhere else. These are great components to create and drive businesses, and to grow businesses here.

Although you were familiar with the Italian market in your previous role, experiencing it first hand in a more operational role is quite different. What were your first impressions?

I have to say, I did not see my previous position as a typical global role, as we were working very closely with the countries, including Italy, on many cross-country-projects. But of course, there are differences that I would like to point out. I think one of the biggest differences is that as a country GM you have to deal with topics which are not directly business-related, like taking care and maintaining the building. You have to make sure everything is safe and comfortable for your employees also from an infrastructure perspective. Hence, the spectrum of liabilities goes far beyond just business. This I found very interesting, because it allows you to be much closer to your people and this is what I love about my job. The other big difference is that in a local role, you can drive ideas faster; you are very close to stakeholders' needs and you can interact with them on a daily basis. That is what I really like and why I wanted this change.

In large European markets, including Italy, most Country Managers are chosen locally. What was the reasoning behind bringing in a foreigner?

I think the trend is more and more to bring foreigners into such roles, also in Italy. Many other pharma companies have also appointed foreigners in the last three years. One of the reasons behind this is to facilitate new ideas from the outside and through this change the way of working, introducing new approaches and perspectives, about leadership, strategy, driving business and

developing people. I think it can be a win-win opportunity for the person coming to the new country, and for the local teams as it is a cross-fertilisation for both sides and allows them to emerge with many new elements and ideas by mixing different visions and cultures.

What is the importance of Italy for Merck?

Italy has been a key country for a long time: it is the place where Serono was founded more than 100 years ago, where all our fertility drugs were discovered and developed. Merck had a small presence in Italy, but with the acquisition of Serono, Italy became one of our top 10 countries worldwide. In addition, Italy is an impressive place where we have a strong presence in R&D and manufacturing.

Here, we have two strong sites for R&D. The Ivrea one has very strong research capabilities especially in the genetics space, like next generation sequencing (NGS), and it is, worldwide, the only pre-clinical centre in Merck Healthcare.

Our second R&D site is close to Rome, in Guidonia, and combines unique analytic and formulation development capabilities. Guidonia is the only place in the world where Merck does stability testing for all our healthcare products.

And in Bari we have our production plant whose products reach as many as 150 countries. With an average export value over the past five years of EUR 1 billion, this site is the leading exporter for Bari and its province. Furthermore, it is amongst the three biggest production plants in Merck Healthcare.

To confirm the importance of the Merck Italy organization for the group, we made several huge investments in the last years: in total, more than EUR 200 million since 2016. In the Guidonia plant alone, over EUR 50 million have been invested in the last 7 years.

Italy is an excellent place for R&D, because the scientific level is very high, and the government fosters R&D and manufacturing collaboration and investments.

Merck’s commitment in Italy is of great value for the country: we are talking about a company that every year contributes to the Italian GDP, between direct, indirect and induced impact, with about EUR 400 million. Furthermore, Merck directly employs 1,210 people in Italy, plus a further 2,854 who are supported indirectly in the economic chains activated, for a total of 4,064 jobs.

With such a large footprint, it seems the Italian affiliate is an important one for Merck. How would you define your objectives here?

Italy has always been a strong affiliate, but nowadays we are launching more and more new products and have been expanding our R&D and manufacturing footprint. For example, in the neurology space Italy is one of Merck's key countries with the recent launch of Cladribine tablets, an oral treatment for highly-active relapsing-remitting multiple sclerosis. For oncology, we have just launched avelumab as a monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC). In this indication avelumab showed great impact, by extending significantly, for more than 8 months, overall survival.

All these new launches require the organisation to become more agile and faster. Compared to many other companies, our portfolio is a mixture of mature products and highly innovative new launch products. We need to find the right balance between getting faster on the launches and ensuring stability for our mature products. Therefore, one of the mandates is to make the organisation ready for the agility required in this new launch environment and make sure we evolve the Italian organisation as part of the global organisation. The second mandate is to further foster the strong talent we have in Italy and to help it also grow in our global organisation where we need such talent in this very fast and very ambitious environment.

Does Merck already have a reputation in the fields of oncology and immuno-oncology? What expectations do you have for this area of your portfolio?

In neurology, where we launched cladribine three years ago, we were market leaders with our previous drug already. This new oral treatment for multiple sclerosis is a fantastic therapy for patients, because it not only helps to stabilize the disease, but also gives patients their quality of life back. With a maximum duration of treatment of only 20 days carried out over a two-year period, patients can keep the disease under control for four years. This is something which has changed the patient's perspective on the disease, which is quite severe and very disturbing. In this area, I would say we are fostering and strengthening our leadership position. In oncology, our research began in the mid-80s, and about 18 years ago we introduced our first biotech therapy in oncology: the monoclonal antibody cetuximab, in metastatic colorectal cancer. After almost 40 years, since the beginning of this great story of science and innovation, our relentless commitment does not stop, and we want to continue to leverage on our scientific knowledge to advance the standard of care in selected areas of the oncology space. With the launches of avelumab in merkel

cell carcinoma, and, more recently, in urothelial cancer, hence, I would say we are broadening and strengthening our position.

With respect to agility on new product launches, each country's system has its particularities and Italy specifically is segmented into different regions. What are your thoughts on the Italian healthcare system's specificities?

Compared to other countries in Europe, but also outside of Europe, the system is complex. Often it is easier to launch somewhere else because in Italy, you start to get the regulatory approval and reimbursement on a national level, but then you must ensure access in 20 regions separately, which are acting as small dedicated healthcare systems. If you do not have an agile team that has thought through the whole plan before, you can lose months. In the interest of Italian patients, where there is an urgent unmet need, we try to create early access programs. This can give the patients access to therapies which are still in the reimbursement process, free of charge. That is a great example of agility applied to the most important aspect of our mandate: helping patients.

Would you say that regionalisation creates health inequalities between the different regions?

I think this has been an important challenge in Italy for a long time. The regional system is creating "disparity", but I think we are all very committed to overcoming this imbalance: institutions, pharma companies and other healthcare providers. I think that it is our mission where we have to work together, and I am convinced that Italy has a great opportunity ahead. If we start to foster collaboration between institutions on a national and regional level, together with industry and academia, I think we can move even faster and overcome these challenges. If we overcome these challenges, Italy will become one of the best places for patients and healthcare providers in Europe. But collaboration is key to creating this agile environment.

Has the relationship between industry and the government improved since the pandemic?

After one year here, I am impressed by a government that acknowledges and sees the challenges they have in the healthcare structure and system; the dialogue has been getting better week by

week. I want to point out especially the efforts of the Ministry of Economic Development, which is taking big steps towards providing financing opportunities for companies wanting to co-invest in R&D, but also starting a dialogue with them. They have just announced the “Enea Tech e Biomedical” foundation, a vehicle to work with pharma companies and other industries to co-invest in R&D in Italy, and also to take on concerns about healthcare challenges, from a structural perspective: a foundation which is financed and initiated by the ministry, but independent.

What about scientific collaborations with academic institutions?

Yes, we spend a lot of time of discussing those opportunities. I am in very close contact with different institutions in Italy to think through new opportunities to drive the dialogue between institutions and pharma companies. I think the idea of creating collaboration between the two is extremely important. In Italy this is especially important. With our strong scientific base we have great opportunities to bring global projects to Italy and drive R&D investments, which is one of my aims here. There are many forms of collaboration that we consider at Merck Italy, e.g. broadening our manufacturing site with governmental support, which for example means more labour for Italians in the region and increased capacity for us. Therefore, we see this from many perspectives and think of Italy not just as a country where we sell our drugs; we invest in the country ourselves, because we have a strong commitment based on the more than 100 years that we have been present here.

It sounds like there are some excellent initiatives underway, but if you were to look at areas where there is room for improvement in Italy, what would those be?

If I can pick an area, it would be the complexity of access to medicine because we cannot do R&D in one country and then distribute our drugs somewhere else; it must go hand in hand. I think there is still a lot of complexity relating to access to patient in Italy, but I do not want to say that the Italian government or institutions have to get better in this. I think this goes back to my point about dialogue and collaboration. It is now time for both parties, together with academia, to think through new ways of working together early on to improve speed of access. The only way to make this better is for everybody to put this on the table to start to think how we can create a real win-win situation, because in the end, only one party must win: the patients.

Over the past few years there has been more understanding of the connection between clinical trials and market access and innovation. Can you tell us about Merck's clinical trials in Italy?

Over the last five years we have had a double-digit number of clinical trials: the country has participated in 49 clinical trials, most of which are still ongoing. If we go back to the period between 2015 and 2019, which was really intense for the whole group in terms of research, these figures are nearly double: we had more than 90 clinical trials running in Italy. For our new products to come in neurology, Italy is the largest country for clinical trials in Europe. Also, for oncology it is one of the biggest places for Merck in Europe.

Is there anything else you would like to share with PharmaBoardroom's readers?

There are two things I would like to add. When we talked about infrastructure here in Italy, and we talked about Merck Italy's presence, if you consider this from a different perspective and those two aspects together, we have the full pharma and life science value chain from the early start of research to the manufacturing and selling of drugs. This full healthcare value chain has another dimension, it allows us to understand our stakeholders' needs extremely well, because we have been there for each step of the journey. We are very proud of this at Merck because we are the only company in Italy with this strength.

This brings me to my last point. We talked about our very innovative oncology and neurology products, but we also have two more relevant areas. One is our cardiometabolic care and thyroid business, which is a very traditional Merck business and has been present for a long time here. But we also have the fertility business here where we are market leaders worldwide, including in Italy. This is interesting because Italy was the birthplace of our products for the whole business more than 60 years ago. It is also important if you consider that Italy is the country that struggles most with births in Europe. It is far below European averages, with the over-age component being extreme as well. A very important root cause of this is infertility, the true disease of infertility, which comes from the environment, pollution, etc., but also a big part of it is that couples who want to conceive get too old and natural conception is not working. And we need to start to discuss those challenges and respective solutions more intensely in Italy. The importance of our future generations and the socio-economic value of births have to be understood by everybody. Given our deep roots and our role in fertility, we feel responsible for fostering a virtuous and fruitful dialogue between health professionals, institutions, and industry in order to help more and more people fulfil their dream of parenthood and fight demographic decline.

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