Giovanni Sala, General Manager – Medac Pharma Italy



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25.04.2022

Tags: Italy, Europe, Medac, Haematology, Onco-urology, Neurosurgery, Generics

Medac Pharma Italy's Giovanni Sala describes the Italian affiliate's unique portfolio of haematology, onco-urology, and neurosurgery products, as well as generics, and outlines the challenges of the Italian market.

2022 represents your 10th anniversary as GM of Medac Pharma Italy, and the 10th anniversary of the Italian affiliate. Can you outline what has been achieved in that time and where Medac Pharma Italy stands today?

We started exactly 10 years ago, but in a slightly different way from any other Medac subsidiary; Medac Pharma Italy in fact didn’t have in its portfolio the biggest Medac product, methotrexate in prefilled syringes and injectors. This product had been licensed out to another Italian company, years before our set-up and it was decided it would have made little sense to take it back.

We therefore started with a smaller product franchise, primarily in urology, before adding some generic products and over the years launching even more products, both those coming from headquarters as well as locally in-licensed products. Without the global star product in our portfolio, Medac Italy was given the autonomy to beef up its franchise locally. Today, our product portfolio is focused on three main therapeutic areas: haematology, onco-urology, and neurosurgery, where we promote our branded products. We also have a large basket of pure generic tender products.

What is the revenue split between Medac's branded products and its generics, and do you position the company as a generics player?

Today, two thirds of our revenues, as well as 90 percent of our growth, comes from our branded products. This is quite a recent change to our business model: historically we started as a generic company distributing hospital products. As a consequence we are associated with Egualia, the generic pharma companies association, which has always represented in a very valuable way our interests.

This recent adjustment to our business model has to do with the fact that also Medac globally is not exactly a generics company. Medac can be considered more as a specialty pharmaceutical company with a generic portfolio. To stay competitive in the generic arena we would need to register many more products every year considering the ever shorter lifecycle of these products. The strategic decision also at a global level was to put more emphasis on Medac's branded products and projects. Over the past three or four years we have invested heavily in our brands and results have been very positive.

In addition to its unique portfolio and strategy, does the Italian affiliate have any greater resonance for Medac globally?

Given this unusual path, we have always been asked to be more proactive and aggressive in terms of acquiring new products, which we have managed to do quite successfully over the years. The fact is that these local deals are usually limited to generic products and the chances of being considered for more global product transactions are minimal. That is why here in Italy we have developed a dual strategy: on one side in-licence local generic products; while on the other side we tried to push proactively the global organization to increase our business development activities to acquire mid-, late-stage development products. We tried to use our risk-taking culture to influence the central company culture to become a more proactive player in the business development arena. In parallel, we have always championed the importance of speed to market and cost competitiveness to compete in the generic arena.

How significant an impact did the COVID-19 pandemic have on your business?

As all the other companies the big challenge we had to face was the fact that hospitals were closed and there was no possibility to visit doctors or pharmacists. Almost all promotional activities had come to a complete halt so in spring 2020 we put our reps on temporary leave, helped by some subsidies from the Italian government. However, in the second half of 2020, things started to improve and we were able to leverage the new remote promotional tools that had been designed and implemented during the first wave. It was surprising just how quickly new ways of promoting products and talking to doctors were established.

Some of our product revenues were, of course, hit due to the lower number of therapies and surgeries being carried out. We saw slowdown particularly in some of our generic products used for more traditional types of chemotherapy. However, despite these factors, our business continued to grow, as it has done every year. For example, despite nine months of our 2021-2022 fiscal year being in 2021, we managed to grow our revenues by 50 percent year on year.

With respect to remote communication, what changes have you witnessed in terms of how your teams work and interact in Italy?

While we adapted during the worst of the pandemic, we have largely reverted to the face-to-face system now. Both our teams and doctors prefer it. The heritage of the pandemic is that now we know how to do remote calls, and we can use this new system if necessary.

However, where we see a lot of change is in the organization of our promotional events: scientific focus groups and seminars. Today there are greater possibilities to organise meetings with more participants in a remote way. The remote model has allowed us to do more and the number of promotional events that we have organised has increased significantly, because they are simpler and cheaper. Now that the worst of the pandemic is over, the new challenge is to go back to hosting bigger events face to face, as requested by doctors. This year, we will have hybrid scenarios where we hold some remote events, but others will be live.

What is your take on the market access scenario in Italy today, and how have you seen it evolving over the past ten years?

Italy is still a difficult market with on average slower market access than in other European countries. Although the situation for generic products has improved somewhat, compared to much of the rest of Europe our access timelines are still longer.

Things need to change in terms of governance. All our products are for the hospital sector, so we negotiate the reimbursement of the product with AIFA and, for generic products, this is quite easy because there is a clear system to define the reimbursement price. However, in the first few tenders following product launch the price will drop dramatically providing immediately huge savings for the health care system.

The problem we currently face in the generics hospital pharmaceutical world is the payback system. Today there is a global budget assigned for pharmaceutical expenditure within the healthcare budget, one part for retail products and another for hospital products. The hospital budget is always underestimated and every year the expenditure is exceeded, while in the retail channel, seems to be adequate, if not oversized. The fact that the budget is exceeded in the hospital segment, then makes it so the companies must pay back part of this extra expenditure on a market share basis.

What makes this type of governance non-sustainable for generic products is that the more you sell, the more savings you give to the healthcare system, but at the same time you grow your market share and as a consequence you will have a higher payback. On the first day that a product is genericised, the price will plummet, meaning that if the system is spending EUR 100 million, then the following year it will be spending five million, but the five million will still be taxed with this payback system.

Along with other generic companies, we continue to put pressure to amend this system which in our opinion can limit competition and our ability to provide further savings for the system. After all, the big over- expenditures in hospitals come from very high-priced innovative products while generics make it possible to save money to reinvest in those products. Asking the generic products to contribute to the payback system in my opinion is illogical.

Is there any openness on the part of the authorities to recognise this fact and change the system?

So far, despite all the declarations we keep hearing, we have witnessed no real changes to the system. The only recent change we've seen is that this year there is an increase of the hospital expenditure budget. To have a significant impact this should have been coupled with the possibility to use the savings made in the retail channel expenditure – where typically the yearly budget is oversized.

On the branded products side, the challenge we face is that historically and culturally, prices in Italy have always been lower than in other European markets. This has caused some problems because for international companies, Italy always tends to be the last or among the last markets in Europe in which to launch a product due to wanting to first negotiate prices in the higher-priced markets. This low-price environment causes delays in getting new products on the market. The other challenge in the market access of innovative products is that once a price has successfully been centrally negotiated, the product then must be listed in all the regional formularies, a task which is quite time and resource consuming.

How challenging is it continue to convince headquarters to invest in Italy, given this market context?

The good news is that Italy is still a big market; the fact that 60 million people live in Italy counter these lower margins. Italy also boasts a universal healthcare system where nearly all pharmaceutical products are reimbursed.

Nevertheless, to convince our headquarters to keep investing we must be efficient, have a very lean organisation and provide around the same level of profitability as other markets. This means being very tight on cost control and making sure that every penny spent is well spent.

What have you most enjoyed about working at Medac over the last decade?

Let me say that what I really enjoyed most at Medac during these years is the level of trust I always got from our headquarters. I really can say that I was empowered to manage our business here in a very independent and autonomous way. While we of course have to submit yearly strategic plans and budgets, in terms of where to spend the money, how to decide our local strategy, and how to buy and license local products, we have always been free to do what was good for the business. I must say that our headquarters places a great deal of faith in the judgement of affiliate heads like myself.

We have gone through difficult periods, especially at the beginning, because we set up the Italian organisation with the idea that we would have gained back the methotrexate product after two or three years. Because of this, we established an organisation that was probably not completely fit to our needs leading to a restructuring that we completed a couple of years ago. However, throughout the

years headquarters was understanding of the situation and always supported us in our efforts. This collaborative spirit is definitely what I really enjoyed most at Medac.

Is there a final message you want to share with our audience?

Italy is still a good place to do business in pharma! Registrations might be slow and prices low, but Italy remains a market which, if you do things with passion and empower people, gives back a lot. Medac’s reputation in the urology, haematology and neurology arenas is very strong, which is rewarding and a testament to what can be achieved by a team of just 25 people.

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