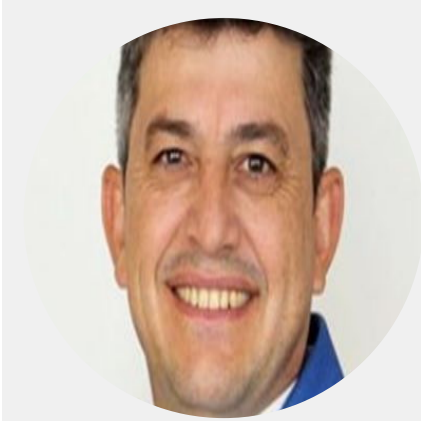


Schalk Opperman - General Manager, Merck Romania



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Schalk Opperman, general manager of Merck Romania explains the key factors behind successful product launches in what is an unpredictable market. He shares his insights on Merck's impressive growth in Romania and navigating the intricacies of the country's pricing policy. In addition, he discloses advice for newcomers and reveals the opportunities that Romania offers.

What were the highlights of 2019 for Merck in Romania?

2019 was a good year for Merck despite not having launched two new molecules that were planned to be launched during the year: Bavencio® for metastatic Merkel cell carcinoma, and Mavenclad® for Multiple Sclerosis. In the meantime, we have launched Bavencio® in January, but Mavenclad® still has not reached Romanian patients.

Merck's fertility business had a very successful year. The increased awareness about infertility in the country was highlighted by the announcement of Bucharest's mayor, Gabriela Fiera, of extending a fertility treatment program which reinforced the national one. Merck has a large market share in the fertility segment, and implicitly it has played a role in the birth of more than 1,500 babies in 2019.

In neurology, our established brand Rebif® performed well but the absence of Mavenclad® was unfortunate for patients. The only silver-lining with delayed launches is that established brands perform better for longer. The slow bureaucracy is detrimental to patients' health and treatment

options and quite frustrating for companies, from a planning point of view.

Our oncology business also had a good year, one of the best years in the history of this affiliate. Presently, there is a good Oncology program in Romania. The National program is relatively well funded and managed and most importantly patients usually have access to the necessary drugs.

Merck's General Medicine business suffered from a disruption in their production process caused by the EU serialization guideline. This not only impacted Romania but the European supply chain of medicines, affecting countries in the CEE region more significantly. The slowed distribution with the increased demand in Europe created shortages for Romanian patients.

What is preventing companies from entering the market and competing against established brands?

Prices in Romania are governed by International Reference Pricing (IRP), and originator products are required to sell at the cheapest price of the 12 reference countries. In addition to being the cheapest in Europe, there is also the compulsory clawback tax that needs to be paid, ranging between 23 – 26 percent in 2019. Generics who want to enter the market must compete at a 35 percent discounted price to the originator, whilst still paying on top of that the required clawback tax. However, within a year, the originator product must drop to the same price level as the generic or leave the Romanian market, which often happens.

This pricing policy ultimately inhibits new competitors from entering the market, or forces existing products out of it, which is detrimental to patients. A free pricing option should be considered to encourage more entrants coming to Romania and allow normal market forces to drive the prices down.

What made you move from South Africa and how was your transition into Romania?

Historically Merck sold its products through agents in Romania. Initially, Merck started only as a Life Science entity in 2007. In 2010 the decision was taken to reintegrate our neurology and fertility businesses under the Merck Romania umbrella. In 2013 oncology followed suit, strengthening the Healthcare side of Merck Romania.

My major task when coming from Merck South Africa in June 2016, was to integrate the general medicine business into Merck Romania's portfolio— which includes thyroid, diabetes and

cardiovascular products. These medicines were present for 25 years before taken back. Since then we showed significant growth and are currently assisting approximately 500,000 patients with their health needs every month.

My integration in Romania was quite easy, people are very friendly and welcoming and soon my family and I were well established. All in all, the transition was seamless.

How has the regulatory environment and market dynamics evolved since your arrival in Romania?

The environment changes continuously on a monthly or quarterly basis, this sharpens your scenario planning skills significantly. As an example, when I joined in June 2016 a law was to be enacted that would have cut prices significantly and put the presence of Merck in the Romanian market at risk: to this day this law has not come into action in the form initially proposed.

Another example is that my market access team regularly must adjust and recalculate pricing submissions as either deadlines or legislations continuously change.

The average lifespan of a Minister of Health in Romania is approximately one year, which makes continuity and predictability regarding the national health strategy difficult, adding to the unpredictable environment. This is frustrating for companies as we cannot implement long-term road maps. Currently, a new Minister has been appointed in November, but the government will change again with the upcoming elections or before, which might change again their stance on health policies.

What makes a successful product launch in Romania amid these uncertainties?

Speed is paramount for a successful launch. Due to the unpredictable nature of the HTA approval process, it is difficult to impossible to accurately predict when a product will be approved and ready for launch. The only benefit of the delays is that in the meantime, you have learned from other countries how patients and markets respond to a product launched there much earlier.

Mavenclad®, our Multiple Sclerosis product, has a unique posology as patients take a maximum of 20 tablets for two weeks in year one and again in year two and then no tablets in year three and four, with the same efficacy as other treatments that need to be taken daily. As it has been introduced in many other markets, we know how to introduce it successfully in Romania once it will

be finally approved.

What are some of the challenges that companies like Merck face when launching a new product?

The main challenge is managing market expectations and properly allocating resources. As there is no predictability with approval deadlines, it is imperative to balance your marketing efforts against local hurdles. The market needs to be prepared for launch but not tired about hearing about the product and waiting too long for it. On average, the waiting period is approximately two and half years for a drug to be accepted by the National Agency for Medicine and Medical Devices (ANMDMR) after it has passed through the European Medicine Association (EMA).

Mavenclad® crystallizes the challenges companies are facing in the market as it was approved by EMA in Oct 2017. Mavenclad® was submitted for approval in Nov 2018 in Romania and still has no reimbursement decision in Feb 2020.

Merck bought back the cardiology and metabolic disease portfolio from a local distributor, what impact did it have on the business?

This decision had a very positive impact on the business for Merck Romania, it has been a major growth driver over the past 3 years since taking it back. Historically, when managed by an agent, it represented a small portion of Merck's business, and today general medicine and endocrinology (GM&E) constitute 40 percent of the affiliate's business.

In the affiliate, we have a strong performing team which delivers double-digit growth. The number of Merck employees have increased significantly since the repatriation of GM&E, we also moved to bigger offices in 2017, and all these factors translate into a positive employee culture.

This has also given our employees a boost in confidence as it was inducive to vertical mobility in the organization. Development is a focus area and presently, we have six Romanian employees that have regional and even global responsibilities within Merck. This fact and the growing performance of the affiliate illustrates the availability of opportunities and the high professionalism of Romanians. Conceptually, this has widened the perception of the employees' role and has shown them that they can achieve great things.

How different is Merck today than it was four years ago?

One of the differences is that English is widely used in meetings, this has to do with me as GM not being able to converse in Romanian very effectively. It was a challenge at first, but the employees rose to the occasion and the company even offered language training to help. The people loved it, were extremely receptive and they realized that this is beneficial if they want to take the next step in their careers.

Historically the country is very hierarchical, but we have worked hard to break down that structure and mentality in the affiliate. Additionally, business unit managers were given the autonomy to run their teams and budgets independently. Managers are asked to take ownership of their responsibilities and are entrusted to lead. The environment has become more open and communicative. There is an exchange of different ideas and opinions, which leads to the best solutions being implemented.

As General Manager, my passion is to develop people and one of my roles is to create space for employees to grow and have new experiences, which hopefully influences their beliefs and ultimately has a positive effect on their habits and professional development.

If you were to move to another country, what advice would you give to your successor?

My advice would be to integrate yourself completely into the team—not only professionally—and to leave space for the team to perform and grow. Reinforce trust within the organisation as the people are competent and have proven their worth through their efforts.

It will be difficult for me to leave one day as a lot of effort has been put into building strong relationships and creating this environment and culture. Additionally, I would advise having regular conversations over a cup of coffee with every single person in the organisation. This is a great way to understand your people as well as what is happening in the market. It is also a great way to communicate your vision as well as expectations to the team.

What can we wish you for 2020?

I wish that the industry and the country will have increased predictability and stability. The expectation is that the upcoming elections will happen in October-November 2020 and that there will then be a stable government in place for the next four years.

For my team, I wish the same: stability. We have a strong performing team that should stay in place and keep growing. We have increased collaboration a lot across the various departments, and I am excited to see where this will lead us.

What would you like to say to organisations that are considering Romania as an investment destination?

Romania offers an amazing opportunity to impact the lives of patients, despite the challenges. Those who are willing to take the risk have a chance to address plenty of unmet needs. As the country is still developing, it presents an opportunity for growth. In Romania, catered products and real service will be rewarded with positive feedback as brand loyalty is very high.

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