Rogier Janssens – General Manager Biopharma, Merck KGaA, Darmstadt, Germany in China



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Rogier Janssens, GM of the Biopharma business of Merck KGaA, Darmstadt, Germany in China, shares the highlights of his first 16 months at the affiliate; the impact of the regulatory changes on the Biopharma business of Merck KGaA, Darmstadt, Germany in China; the significance of the affiliate's commercial growth as well as Nantong manufacturing site, the second-largest in the global pharmaceutical manufacturing network of Merck KGaA, Darmstadt, Germany; and the firm commitment of Merck KGaA, Darmstadt, Germany to China as a country.

Rogier, you joined Merck KGaA, Darmstadt, Germany's Biopharma business in China in July 2017, in the midst of a period of extraordinary change within the Chinese healthcare landscape. How did you begin the process of grasping the fundamentals of a complex and changing market like China?

I must say, I am still learning about the market every day! First and foremost, however, it is not unusual within this sector for general managers to be transferred to a new country with very little advance notice. I came to the end of my term at Merck KGaA, Darmstadt, Germany in Russia and then China was there waiting for me!

Nevertheless, this is not the first move for me. China is the sixth country I have lived and worked in. Of course, China is very different from the previous countries I have been in Denmark,

Switzerland, the US, Belgium and even Russia. However, this is how I like to look at it: yes, the regulatory system is different here – as it is everywhere. The financial system is different – as it is everywhere. The portfolio of Merck KGaA, Darmstadt, Germany here is very different as well.

As GM, you need to get past these basic points of differences in the initial onboarding to quickly grasp the characteristics of the market where you are now based. There is a process of meeting with the local leadership teams and getting to know the business. Around six weeks after my arrival, together with the leadership team here, I went to HQ to present our operational plan for the following year.

I am deeply convinced that as an industry we face a lot of challenges and opportunities and therefore I seized the opportunity to join the MNC association here, RDPAC, when they were just in the process of electing a new Executive Committee. It was very opportune timing for me as I only just qualified to participate in the elections based on the time of my appointment as GM China and was elected onto the Executive Committee. This has helped me a lot in terms of interacting with and learning from industry peers and leaders.

From a practical viewpoint, I also had to get used to the fact that the China operations are split fairly evenly between Beijing and Shanghai. Out of Merck KGaA, Darmstadt, Germany's three business segments, only the Fertility BU is based in Beijing, and the other two, Oncology and General Medicines and Endocrinology Business, are based in Shanghai. While Russia was similar to China in being a large country, much of the business is concentrated around Moscow.

Finally, I also want to commend the team I am working with here, who are all very experienced and are instrumental to the work that Merck KGaA, Darmstadt, Germany is doing here.

Were there any key takeaways from your time as GM with Merck KGaA, Darmstadt, Germany Biopharma Russia that you have brought to China?

What is most striking is that both are countries with huge unmet medical needs. In particular, 'access to medicines' has different meanings in emerging markets and in developed markets. In most developed markets, once a drug is approved for the market, it usually means that most patients have access to it and – usually – the drug is paid for. In countries like China and Russia, even if the drug is approved and there is formal access, patients would still need to pay for them until they are put on the national reimbursement list, which many cannot afford to do. There is a difference between formal and real access.

Everyone is speaking a lot about the recent healthcare reforms in China, which are very positive, but we have to bear in mind that these reforms do not always translate immediately into patient access to medicines.

Merck KGaA, Darmstadt, Germany has a long history in China and just this year alone has made significant investments into the country across its three business segments. Can you outline the strategic significance of China for the company?

The first reason is obvious and well-established: China is a big market, there are huge unmet medical needs, and many people are unaware of their health conditions. These unmet medical needs are not necessarily the same as those we see in other countries because they include really basic, essential medical needs. For instance, we are a strong player in diabetes here, and we see a huge need for the most basic medications.

The other strategic reason is the particular development of the environment here. We believe that the kind of innovation we will see in the Chinese market will not necessarily be in terms of the next molecule or mechanism of action, but in terms of the market approach and commercial models, such as through the use of e-commerce, digitalization and so on. As a simple example, due to the severe shortage of primary care doctors in the Chinese healthcare system, we will probably see a digital solution to training primary care physicians in the mid- to long-term, and probably much faster than we can even imagine, coming from more developed markets. This is what makes China such an important market: the pace of technological development, implementation and scale-up. We are keen to share these lessons and models with our global colleagues.

Last but definitely not least, the revenues here are already very significant – and they continue to grow. It is certainly encouraging that the regulatory system here has changed to allow innovations to start coming through more quickly, though the pace is still not in line with developed markets. In China, we were the fastest growing multinational pharma company in 2016 and, we expect to see the contribution of the Healthcare China affiliate to global continue to grow for the next few years.

You mention that your portfolio here is quite different from other markets for Merck KGaA, Darmstadt, Germany, and 80 percent of your revenues come from essential medicines. With China now speeding up the launch of innovative products and looking to implement cost-cutting measures on off-patent products, how will this impact on

Merck KGaA, Darmstadt, Germany's commercial business?

This is a question that all companies in China face. We have not seen the impact of the price cuts yet. What is most important is that we are now able to bring our innovations to the Chinese market because the environment has opened up. This is very positive. Today it is now possible for an innovative product approved in the US or the EU to be launched in the same year in China! Just one year ago, that would have been completely impossible. The average time lag was six to seven years. That said, this is only scratching the surface of China's potential because we still need to see improvements on the reimbursement front.

For Merck KGaA, Darmstadt, Germany, this year we had our product for colorectal cancer, ERBITUX®, listed on the National Reimbursement Drug List (NRDL), which is a very positive step. Based on the data available, patient uptake increases very significantly once a product is listed on NDRL. For instance, 36 new molecules were added to the NDRL in 2017, which tripled or even quadrupled the number of patients treated by each drug.

Of course, this listing also came with a price cut, which goes beyond the discount negotiated by the government because companies, including Merck KGaA, Darmstadt, Germany, are also making additional investments in patient support programs for these new molecules. Adding all these investments together means that the effective discount is very significant.

However, the end result is that we can reach many more patients with our innovative treatments, which we are very proud of. To take ERBITUX® as a single example, it is a targeted treatment and not all colorectal cancer patients qualify, but for those that do, it can extend their lives by more than 27 weeks compared to all existing treatments or no treatment. Imagine what it means for a patient and their family to have that extra 27 weekends. That is the importance of the work we are doing.

On the topic of new innovative business models, you have mentioned the development of digitalization in China, and Merck KGaA, Darmstadt, Germany has signed a partnership with Alibaba Health Partnership this year. How is Merck KGaA, Darmstadt, Germany investing in this area in China?

In terms of the Alibaba Health Partnership, what we are doing first and foremost is learning from each other. Our dialogues are highly strategic. But we are first starting small and on very technical, niche projects. For instance, we are working with Alibaba on barcodes to help patients do 'track

and trace' and identify counterfeit drugs. We also support them in disease awareness efforts because they have access to so many mobile users.

We are certainly very proud of our collaboration with Alibaba but our efforts go far beyond that. When it comes to digitalization, we believe that it will be Big Tech companies like Google, Amazon, Alibaba, Baidu and Tencent that will drive this change. Even if the pharma industry as a whole pooled our resources to develop our IT capabilities, we will not be able to achieve the scale that these players have. All of these players have different strengths. Alibaba is an e-commerce company, for instance – the joke is that they know the shoe sizes of 650 million people! Tencent's business model is very different. But the commonality between all of them is that they see healthcare as an anchor point for their future development. That is why there are so many opportunities for interesting and fruitful collaborations between us and them here in China because the pace of these digitalization efforts here is staggering.

The government has implemented a series of favourable policies to encourage innovation and promote access to high-quality therapies. However, it still needs to match the pace of industry development! Right now, if I want to order an Americano from Starbucks, it can be delivered in 10 minutes. People are now asking if they have a regular prescription for something like a beta-blocker or an ACE-inhibitor, why can they not receive it directly at their house? This is already technically possible in terms of the logistics but the policy framework is still in the making.

Globally, there is sometimes a perception that China cannot be at the forefront of innovation. This is also particularly relevant to the pharmaceutical industry. How do you feel about this being on the ground here in China?

The reality is that our industry has been historically centred around North America and Western Europe. It has a lot to do with how innovations have developed and how our revenue models have been built, which are mostly centred around launching innovations and re-investing the profits to develop new innovations. But today, when we can expect new biopharma innovations to reach the Chinese market in the same year as the North American and European markets, I think the revenue model will change drastically.

It is true that there is still a perception that China lacks truly innovative products – and with all due respect, the reality is that we have not seen genuine pharmaceutical innovations from China. There have been many 'me too' or 'me better' drugs but in terms of a first-in-class, totally new mechanism of action, we have not seen that yet. I think the idea that China cannot produce

innovations is slowly changing. But the world will not be convinced until we see the first truly innovative product from China.

Everyone is talking about what is needed for that to happen. China does not lack money now. The speed and pace of development are also incredible. For instance, there are around 25 PD-X products undergoing clinical trials in China right now! But that also demonstrates the issue: the resources are not being invested in the right way. They are too focused on the same areas, areas where foreign companies already dominate. If Chinese companies would diversify their investments and efforts, I think they would see a lot more results.

The Biopharma business of Merck KGaA, Darmstadt, Germany also has a significant manufacturing presence here. How does this complement your commercial business here?

It is very important to us to have a local manufacturing footprint. What is very significant is that our Nantong manufacturing facility produces pharma products for the essential needs of millions of Chinese patients, not highly advanced, targeted therapies for a small handful. Our facility serves huge numbers in relatively basic, essential needs, particularly in terms of non-communicable diseases (NCDs) like thyroid disease, cardiovascular conditions and diabetes.

We actually have a very important target to reach 40 million Chinese patients by 2025. We are currently at 15 million, so we hope to double that in the next seven years.

We have already invested a total of EUR 170 million (USD 193 million) in the Nantong facility, and we are currently in phase II of the construction, which will add distribution capabilities as well. When phase II is completed, that facility will be able to produce 10 billion tablets a year, making it the second-largest tablet factory in our global network.

A critical element of having our own manufacturing facility here is to ensure that our products for the Chinese market meet our global quality standards. We need to be able to manufacture the same quality and consistency of products for the Chinese market as for our international markets – and at local prices. This is even more important given that the Chinese government is starting to implement new policies relating to pricing and the quality and consistency of generics. What we expect is that the Chinese government will look for suppliers with the most competitive prices – but taking into account the quality of the products.

Let me illustrate using our GLUCOPHAGE® product as an example, which contains the active ingredient metformin. There are currently over 100 producers of metformin in the Chinese market but many, if not most of them are not quality producers. When the government starts to compare prices, they will only choose from the handful of manufacturers with quality products. This is also another factor we took into consideration when we were deciding between having our own manufacturing presence or going down the CMO or local in-licensing route. As we say: in China for China!

Is there a strong affinity between Merck KGaA, Darmstadt, Germany and China?

That may certainly be the case but at the end of the day, it comes down to the present commitment of the company into this geography. At the highest level, Merck KGaA, Darmstadt, Germany is extremely committed to this region. As you know, Merck KGaA, Darmstadt, Germany is still majority-owned by the original founding family, and they are not only highly committed to new drug discovery and development but also to this geography. We actually had the family board visit us earlier this year.

There is a strong awareness within Merck KGaA, Darmstadt, Germany that there are great scientists in China, great science happening in China, and that the speed of technological advancement and innovation is very fast here. I heard a very interesting statistic at a recent conference: 350,000 Chinese students are now studying in the US and 80 percent of them will return to China. China will become a powerhouse of science and innovation – and already is, in some areas. It is just a matter of time. This is why Merck KGaA, Darmstadt, Germany has based the presidents of some global R&D teams in our R&D hub here. At the Group level, we have also just opened an Innovation Hub in Guangzhou and we will open another one in Shanghai.

This is also why Merck KGaA, Darmstadt, Germany is increasing our footprint here, not only in terms of manufacturing or sales and marketing. We are very interested in China’s innovation culture and future.

To begin wrapping up then, what are your strategic priorities for the remainder of your term at Biopharma China of Merck KGaA, Darmstadt, Germany?

Merck KGaA, Darmstadt, Germany’s unique value proposition – which differentiates us from other companies – is that we are able to cover the life cycle. We are able to create life with our fertility

treatments, we have the ability to improve lives with our products for oncology and NCDs, and we are also able to prolong lives.

In 2017, Merck KGaA, Darmstadt, Germany made our strategic planning for the following eight years, from 2017-2025. Our 2025 horizon is quite clear for China: we want to transform the lives of 40 million patients, of which a good part will be from off-patent products for NCDs, but at the same time, we are looking to launch major innovations in the Chinese market. For instance, just a few months ago, in partnership with Xi'an Janssen, we launched INVOKANA®, an innovative product in diabetes, which is extremely meaningful in this marketplace because of the significant unmet medical needs in diabetes.

Globally, Merck KGaA, Darmstadt, Germany's focus is in immuno-oncology, oncology and immunology. As mentioned, ERBITUX® being placed on the NDRL for colorectal cancer is a milestone for us. ERBITUX® also has global approvals for a number of other indications, notably head and neck cancer, which has a high prevalence in China, so we hope to get it approved for new indications in China soon too. Another product is BAVENCIO®, approved in the US and Europe for Merkel cell carcinoma (MCC) and urothelial carcinoma. We are looking to launch this product in the next couple of years too. Even earlier on in our pipeline, we have included China in a few of our development programs, which is extremely important for eventual access to the Chinese market.

Finally, if I can sum it up: firstly, we want to build a patient-centric platform in the ways we engage with patients and the public. Secondly, through our work with Alibaba and other digital platforms, we want to develop innovative business models and forge new and interesting partnerships with stakeholders here. Finally, with our Nantong and global manufacturing and supply network in China, we want to be a fully-fledged local player that is strongly embedded in the local ecosystem.

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