

Novartis Malaysia â?? Michaela Dinboeck, President & Managing Director



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â??Clinical trials are an area where we want to build capabilities, both internally and externallyâ?• says Novartis Malaysiaâ??s president and managing director. Novartis, with 22 ongoing trials, is one of the leaders in Malaysia and clearly understands the benefits as the government is promoting trials through the healthcare NKEA.

Could you start by introducing Novartis in Malaysia and how the company has been performing?

Last year the organization was already in a transition phase, as the company went from a broad organizational structure to a more focused and specialized disease area structure. One of my key duties as the head of the organization was to continue implementing the new processes and guidelines into this new organizational structure. By doing so, Novartis has achieved great results as today we are ranked fifth in the Malaysian market.

Novartis is organized in various divisions and one of our key divisions is Sandoz, currently number one international generic provider in Malaysia. Our generics are of the highest quality and part of our philosophy is to maintain the highest standards in all divisions. We understand there is a time for innovation and development of new innovative drugs, but at the same time we also see that there is a crucial need for governments to use high quality generics which are much more affordable. This is why we want to be well diversified and flexible to answer different needs. Through our expertise and long track record excellence, we work to ensure efficiency of our products and patient safety.

In Malaysia, various diseases such as diabetes, hypertension, cancer and respiratory diseases represent a growing burden for the Ministry of Health and Malaysian population. However, they also bring opportunities from a company perspective, even more so because our portfolio is well aligned to tackle these diseases. Linked to these four main disease areas, we are also present in ophthalmology as blindness is many times a consequence of diabetes complications. Finally kidney

disease and transplantation can be a result of diabetes and Novartis has many solutions to treat them effectively.

At the moment, Novartis's share between the public and private sector follows the industry's average. This entails that the public sector represents 40 percent in value and 60 percent in volume, whereas the private sector is 60 percent in value and 40 percent in volume. Having the opportunity to be present on both sides also enabled us to perform well in Malaysia and to give access to our medicines to the broad population.

Among the efforts that have been implemented by the government recently, especially with the healthcare NKEA program, how is Novartis performing on the clinical trial side?

The government has done a great job at raising the profile of Malaysia as a destination for good clinical trials. Since Novartis is an innovation driven company and we hold one of the richest pipelines in the industry covering a wide range of diseases, it has been mutually beneficial to perform clinical trials locally. Clinical trials are an area where we want to build capabilities both internally and externally. Therefore we have run training workshops with over a hundred scientists and experts on how to establish strong scientific hypotheses or write applications. All of these workshops have the aim to reinforce the local capabilities which then allows us to run good clinical trials.

We are currently running 22 clinical trials in Malaysia with 900 patients involved and we are developing various feasibility studies to bring in more trials. Malaysia therefore represents an important trial site for the group. English is well spoken and the government supports the industry and intervenes if we are facing issues. This is not the case in many countries. Finally, Malaysia has an increasing number of institutions capable of running high quality studies, which is fundamental for us.

The trials we conduct are part of global multicenter studies, which means they fulfill the highest criteria and standards in terms of data, processes, safety and results. We are conducting trials locally in heart failure, oncology and ophthalmology.

Could you take us through the industry's market access challenges, and the necessary steps needed before getting your products registered on the "blue book"?

The regulatory process in Malaysia is relatively straightforward; with a timeline of 12 to 15 months for non-high risk disease areas or six to nine months with fast track regulatory approval for high demand and crucial medicines targeting the most important diseases. Once this regulatory approval is fulfilled, it is possible to launch our products on the private market. The public sector requires getting listing in the blue book. From an industry perspective it is an advantage to be able to directly launch products on the private sector, while getting listed for the public sector.

To access the blue book you need to go through many different steps. The first step is that you need to have a base of doctors who would be willing and interested to use your product. Once they find this product to be of value, there are a series of administrative processes. Once these are fulfilled, you get listed in the blue book. Listing in the blue book is not a guarantee for funds. Registration is a straight forward process, whereas government reimbursement for broad patient access to certain drugs still requires multiple steps and effort. So far, we have blue book listings in diabetes, hypertension, ophthalmology, neurology and oncology.

What do you see as the main challenges faced by Novartis in Malaysia?

Managing the uncertainty around the implementation of the “One Care” program as well as the GST (Goods and Services Taxes) represent a challenge. Both will demand very different strategies and so far it is impossible to know what will be the best way to address these two issues.

Around the world and locally Novartis is a flagship company and two years ago, Novartis began a Memorandum of Understanding MOU with the Ministry of Health. Could you tell us about your special collaboration with the government?

Our collaboration with the government would have taken place with or without a MoU. But because we identified various areas where the government was focusing, such as clinical trials, capability building and access to medicine which we were doing as well, we decided it would be mutually beneficial to work hand in hand on these matters to take them to the next level. In this sense, the MoU was very positive.

Building the right team is one of the key success factors for any pharma CEO anywhere in the world. In an emerging market, finding human capital may be even more challenging. What are your observations of the situation in Malaysia?

Our biggest challenge is retention of talent as there is virtually no unemployment. Therefore we see that many companies are competing for the right talent, making retention even more challenging.

Novartis has implemented various human resources programs beyond the usual talent mapping and development planning to help develop new capabilities and to keep associates motivated. One of the most interesting ones is our program called “Be Healthy”. Be Healthy is a health and well-being initiative that encourages our associates to live healthier lives. As part of a global initiative, Novartis participates in a corporate challenge, where every affiliate and participant competes on who is walking the most number of steps. Many of our employees have decided for instance to use the stairway instead of the elevator, and have moved from the average 10,000 steps per day to as high as 29,000 steps a day.

How will the company keep growing in the next three to five years?

Given the focus on generics in the local environment and financing burden of the government, our generic division will remain a very strong asset for Novartis. In the pharmaceutical division, oncology will be one of our best assets. Hypertension, diabetes, ophthalmology and respiratory will also grow given the rapid expansion of these diseases in Malaysia. Further growth for us will come from our rich pipeline which will bring innovation in heart failure, dermatology area and new compounds in rheumatology. This means that our entire portfolio has excellent prospects for the future. We are expecting for the coming two years, five new molecules to receive approval. Our continuous innovation globally and locally will be a key growth driver.

Given that similar size countries (population) around the world like Taiwan or Spain are 3 to 10 times bigger in terms of value, Malaysia therefore has exponential potential to be unleashed.

Do you believe that this double digit growth is sustainable on a long term basis?

Absolutely. We see that the current population’s income is growing but hasn’t reached a very high level yet. This means there is still room for growth. More expenditure per capita will of course generate more revenues for our entire industry. The government currently spends around 4.8 percent of GDP on healthcare, whereas the most developed markets spend double. This also means there is room for growth.

Malaysia is rich in natural resources and tourism. These will enable the country to continue growing. The government is still attracting new investors and given the good incentives available, many more will come.

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