

Interview with Urs Flueckiger, President, Roche South Korea

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You are one of the foreign multinational directors with most time in the Korean pharmaceutical industry, since 2003. What is your assessment of the direction the market has taken in these last 5 years?

Like in many other parts of the world, the Korean pharmaceutical market has become much more regulated in recent years. On the registration and approval side, though there are some areas of concern, overall there is a good working relationship with the Korean FDA when compared to the situation in other countries. On the other hand, South Korea has become particularly strict in terms of the pricing and reimbursement process since 2003.

At that time, a new policy was put in place aiming to significantly reduce drug prices and introduce a positive list system. This is not something bad per se, but unfortunately certain aspects of the implementation like the product selection and evaluation criteria have not been very transparent. The government has not been proactive in terms of developing a dialogue with the industry in order to find joint solutions, so we have had to be in a reactive mode.

The problem with this is that it is very difficult for a company to carry out the whole process leading up to the launching of a new product without having certainty regarding the price that will apply. And this is the situation today in Korea, particularly over the last 18 months in which products are getting stuck in the approval process, not because of the KFDA, but due to pricing and

reimbursement issues. The decision-making process has become even more complex since companies are now required not only to get HIRA approval, but also NHIC whose focus is very much on simply slashing prices.

This situation is already having a direct impact on Roche's activity in South Korea. A product like Avastin, which is #2 in its field globally, is not being reimbursed in South Korea. Moreover, it took over two years of discussions with the government in order to finally be able to launch Herceptin, a breast cancer drug, while in other countries the process lasted only a few weeks. We understand the government's need to control spending, but it is going too far in proposing prices far below international standards.

Another big issue now for both local and multinational companies is related to transparency and compliancy in business practices. How serious do you consider this problem to be in S. Korea, and what do you make of the industry's reaction?

Multinational companies like Roche always have their own global codes of conduct, and in addition there is an ethics code elaborated by KRPIA that we all adhere to. In theory the local companies have similar initiatives, but many of them still have a long way to go in terms of compliance. Their practices are also made possible by a system which ensures generic products high prices and margins, which are in fact in large part responsible for driving up the health insurance deficit. Unfortunately, instead of focusing on bringing down the price of generics closer to international standards, the government is going after innovative products in the hope that generics will then follow.

What is the relative importance of South Korea within Roche, considering it is one of the largest emerging markets and located in the strategic Asia-Pacific region?

South Korea is one of the 7 countries in Roche's emerging markets group, but compared to others like China and Russia the growth is much slower. Although South Korea is by market size the 13th or 14th largest in the world, generics make up a disproportional part of it. The country's fantastic story of economic development over just one generation has not been matched in terms of the healthcare industry. Korean companies have invested little in R&D, historically focusing on manufacturing and selling OTC and generic products, which has been very profitable for them. The local industry has also relied heavily on in-licensing agreements since the 1980s, but in many cases that pipeline is drying up. Western multinational companies are doing less licensing and more co-promotion or co-marketing activities with Korean companies. Indeed, this is a market where many foreign players still do not feel comfortable going at it alone, but this applies to Korea

in general. In the pharmaceutical sector, on average multinational companies have 70-80% market share around the world, but in Korea it is still much lower.

In this context, how would you rate Roche's commercial performance on the Korean market?

Roche in South Korea has been growing at above-average rates in recent years, though not at spectacular rates like China. We are bringing our innovative and very niche products to the market, particularly our oncology portfolio which is a core part of our business. Prescriptions of our products could grow even further if there were a better reimbursement system. Indeed, though in theory there is a universal healthcare system, it does not cover the self-employed which make up an important part of the population. The out-of-pocket payments are very high in some cases, and therefore certain patients cannot afford it.

It is often said that Asia is the new hot spot for clinical trials by the leading global multinational companies. How does South Korea fit into this broad picture?

Things started improving when the system was opened up in 2002 to allow clinical trials in South Korea. In terms of cost there is no real advantage, but there are many other aspects that make this an attractive place for clinical trials: top medical centers, skilled and highly motivated doctors, and patient potential. People are very willing to join clinical trials and it is possible to recruit them very quickly, which is crucial for pharmaceutical companies. Moreover, in Korea there are many patients with cancer, particularly gastric cancer, which makes it a very important location for Roche's oncology clinical trials.

Having said that, the government needs to realize that in order for foreign companies to have incentives to continue investing in new clinical trials in South Korea we should also be able to sell our products at a fair price. If this whole pricing and reimbursement situation does not improve for the research-based companies, eventually the dynamism seen in recent years in this area will diminish. There is a major risk of a 'sucking effect' in terms of clinical trials towards China, as is already happening in other types of investments, even though quality standards are still superior in Korea

Many companies are also looking at South Korea for its biotech potential. How active is Roche in this regard?

South Korea's science and technology are definitely on the map for Roche. In the region, Japan has been a first step thanks to its solid base, and subsequently the company has been looking into opportunities in Korea and China. Though there is no fixed position dedicated to this in South

Korea, there are regular visits from the Japanese and Chinese offices to Korean universities and start-ups. For the moment, we see potential particularly in terms of delivering technologies.

What are your main ambitions for Roche in South Korea in the coming years?

For a long time, Roche worked as a joint-venture, and it was only in 2000 that we became independent. In South Korea, we used to have manufacturing facilities, but like in the case of many other foreign companies they have been sold or closed down over the last several years, as this is not a very competitive base for this activity. In terms of new drug discovery R&D, this is not happening in South Korea either since it is carried out in just a few locations in the world.

On the other hand, Roche is currently very active in clinical developments here in South Korea. There are more than 60 clinical trials running in different indications such as oncology, virology and metabolism. This is a tremendous leap from just a few years ago when there were maybe only 5 clinical trials in the country. But right now everyone is very cautious and waiting to see what is going to happen with the pricing and reimbursement situation. There have been high hopes following the election of a more pro-business president, Lee Myung-bak, but the pharmaceutical industry has seen little improvement thus far. We are hoping to see more positive signals that healthcare is a top priority for this administration, in order to continue investing in South Korea's potential.

What is the most motivating aspect of your experience as the head of Roche in South Korea?

South Korea is very different from my previous assignment in the Philippines, which is a primary care market, without insurance and therefore it was difficult to sell our oncology products there. Here most people are a part of the healthcare system, so they have access to our great portfolio of products which we can bring to the market. Korean doctors are very enthusiastic and embracing them, and for us this is very fulfilling to witness.

What is your final message to the readers of Pharmaceutical Executive?

In South Korea, like in the rest of the world, Roche is focused on targeted medicines. This is something that Koreans highly appreciate, as they are particularly interested in being treated with specific products. This is however a difficult market and you need to have a lot of endurance, but it is very interesting as well. We hope to see better results and positive signals from the government in order to continue moving forward Roche in South Korea.

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