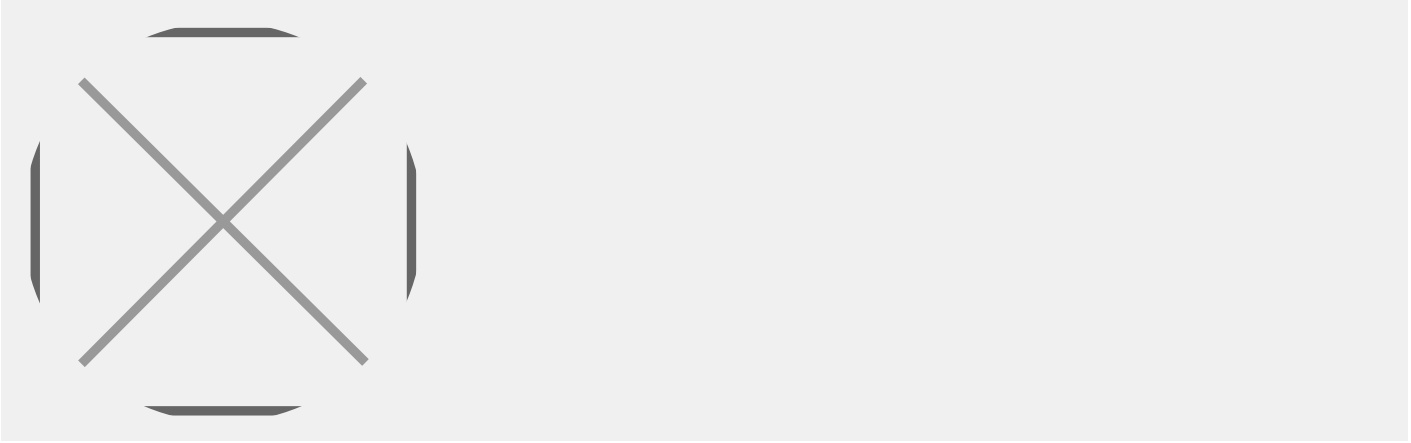
Interview: Thomas Willemsen, Vice President and General Manager, GSK Taiwan



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In Taiwan, GSK recently signed Memorandum of Understanding with the National Research Program of Biopharmaceuticals (NRPB), building on research partnerships in Taiwan that include a 2007 agreement with National Taiwan University Hospital (NTU)—the first agreement of its kind—a later MoU with Taipei Veterans General Hospital, and a major 2012 collaboration with Chang Gung Memorial Hospital that established the CGMH-GSK Clinical Research & Development Center. In this interview, Thomas Willemsen, Vice President and General Manager of GSK Taiwan explains how his company is trying to keep its foot in the door of Taiwan, and build on its existing commitment to the country.

After investing over USD 33 million in research in Taiwan, what can you tell us about your research strategy in the country? Why did GSK choose Taiwan for these investments?

Investing in R&D in Taiwan is part of our long-term commitment to this market. We believe that this commitment needs to be tangible and based on confidence that ultimately the data that we generate will support our scientific arguments why our vaccines and pharmaceutical innovations are really adding value to the Taiwan healthcare environment. This long-term promise also creates

a partnership with key Taiwan stakeholders based on trust and mutual respect. This is a very important part of how we define our purpose as a player in this market. We don't want to just be viewed as a marketing and sales organization that aims to increase market share, but rather enter a long-term partnership with Taiwan's hospitals, doctors and government stakeholders to improve the healthcare environment in Taiwan. Over the years this strategy has helped us build trust, which is essential for us to be able to operate successfully in Taiwan. Taiwan remains one of the best R&D locations in the Asia Pacific region, despite its relatively small market size. R&D in Taiwan is fast, relatively inexpensive compared to markets like China, and most of all, reliable. As well as a good research platform, Taiwan is also the perfect epidemiological environment for proof of concept or early phase trials for products destined for the Chinese market.

Can you give us an example of how you have generated a tangible outcome for GSK or the industry through this "building trust" agenda?

This is an excellent question. An example of a time when we have been able to change the environment in a fundamental way, as a result of the trust that we have created, happened a few years ago. In the past, the process of getting access in Taiwan was a three-step process: regulatory approval, reimbursement, and listing in the hospital. Each step took around one to two years, which is rather slow. One of the biggest issues was that the procedure was consecutive: companies needed the regulatory approval in hand before they could begin applying for reimbursement.

At a dinner with the head of the TFDA, Prof KangJaw-Jou, the Vice President of the BNHI, Dr Lee Chun-Hua, and Dr. Lin Fang-Yue, the superintendent of the VGH and Taiwan's former minister of health, we discussed how to speed up this process to enhance patient access to new drugs, and this eventually led to an improvement in the system. We realized that there was a point in the regulatory approval process where the government decided to approve the product and issued an approval letter to the company, but some administrative steps such as the final content of the insert sheet and the packaging of the product would still be pending before a company would receive the final license needed to apply for reimbursement. The time from the approval letter to final license issuance can take 2-3 months or in some cases 6-12 months (if in addition a manufacturing site needs to be validated)

We realized that if companies could start applying for reimbursement once they had received the approval letter, they could save an average of 3-6 months in the process of getting their products into hospitals. After two years of lobbying, which involved the ECCT, IRPMA, personal contacts, and the UK minister for trade and investment, we have now achieved this step. As a result of this, Taiwan is now one of the fastest countries in the region for getting a new product on the

reimbursement list.

What is so remarkable about this story is that the idea was born at this dinner with the key stakeholders. Had I not build up trust with them over many years, they would have not invited me to join and share my views with them.

The Second Generation National Health Insurance Act came into force in Taiwan on January 1st 2013. How does the marketplace look as a result of that act?

In a way, the act makes the market more predictable, which is positive. The industry is still waiting for the final insights as to how it will be implemented, as some of the key decisions have not been taken yet by the BNHI.

The key topics here are ‘DET (Drug Expenditure Target)’, the newly established ‘PBRS (Pharmaceutical Benefit and Reimbursement Scheme)’ and ‘Article 46.’

The Drug Expenditure Target is a virtual budget given to the entire Pharmaceutical Industry based on a growth rate that is decided by the National Health Insurance Committee. Should the following year’s actual industry drug cost exceed this budget, then a price cut should be applied. According to the latest communication by the BNHI they will use the tool of PVS (price volume survey) to identify by how much they can adjust prices of pharmaceutical products based on their market transaction prices. They will however apply a ratio to these price cuts that depends on the size of the excess over DET. A simple example looks like this: A PVS for the entire industry would result in a cut of USD 33.4 million. The excess over the last years DET was half this. The ratio is 50% between the two numbers. Now the PVS-based price adjustments will be multiplied with that ratio, so if according to PVS your product should have been reduced by 10% it now will be only 5%. My expectation is that indeed this first “DET capped” PVS will result in a significantly smaller price cut for all. In addition this cut will only be applied in January 2014, which gives us a few months delay to the PVS we would have expected in late 2013. However, one of the more manageable aspects of PVS was that it only related to your products, and the price cut was based on the discounts that you had been giving to the hospitals, which made working out by how much your prices would drop biannually fairly predictable. With DET, the cuts will depend on the annual growth rate for which we have no long term guidance and the DET based cuts will be applied annually instead of bi-annually as the current PVS. My overall prediction is that it will boil down to roughly the same impact over time.

Now we come to Article 46. One of the problems with PVS, according to the BNHI, is that new products and innovations do not receive high discounts. 5-10 years ago, you could launch a new

biological drug in Taiwan, and it would only receive a low single digital digit discount, because there is a high medical need and no competition.

The PVS could only cut based on discounts, so if there is not a big discount, it is very difficult to cut. On top of that, this system relies on the presence of generics to bring down prices, as the originator drug is put in a basket with the generics when looking for discounts, and generics receive a much higher discount than originator products. The problem for the BNHI was that with many innovative products, there are no generic equivalents. Taiwan is only just beginning to consider biosimilars, but even so, there are very few generic oncology drugs on the market today, for example.

The BNHI wants to solve this problem by having a price cut that immediately affects products that are going off patent. This is what Article 46 is about, which says that when your patent expires, your price needs to go down immediately, to a certain level. It’s not clear how this will actually be effected, the relevant regulation has not been finalized and announced yet. There are many options on the table, from a universal price cut to a comparison to reference markets, but no one knows what the bottom level will be. This creates a lot of uncertainty in the market, which will impact foreign companies to further reduce cost rather than increase much needed investment in Taiwan’s emerging biotech sector.

Lastly the PBRS is a newly established committee that reviews and approves all new drugs for reimbursement. So far the addition of the new committee to the already exiting review process under the BNHI has significantly slowed down the rate of approvals. We estimate that in 2013 the number of new drugs approved in Taiwan will be 50% to 70% less than last year. This will have a significant impact on the quality of care in the mid-term. One way to improve the situation would be to increase the frequency of the meetings of the PBRS to monthly meetings as used to be the case for the Drug Benefit Committee that used to review reimbursement applications in the past.

What can the BNHI do to make the situation better for innovators?

There is currently an incentive in place for conducting R&D trials of a new drug locally: if a company has a certain number of patients enrolled and it is a certain percentage of the overall population then the company can get around 10% markup on its new product. However, to my knowledge, up to now, no company has been able to get this markup.This is an incentive that looks great on paper, but the implementation effectiveness remains to be seen.

Taiwan’s BNHI needs a long term strategy in preparing the market to reward for innovation. Not just for the multinational players, but also for the local companies. To give an example: the last

PVS price cut, executed in December 2011, affected the international companies a lot more than the local companies, as it was decided to increase the price for some of the local generic brands if they would reach certain quality standards, or to increase if they were below a certain absolute price threshold. There is pressure on these companies because low medicines prices make it difficult to increase quality with their margins. But the challenge with this is that using quality as a price indicator is not right, because quality is a basic requirement. Take other developed markets as an example: No government gives price incentives for achieving quality standards that are enforced by law. And in Taiwan, from 2014 all manufacturers need to meet PICS/GMP standard for their factories, so it will become mandatory. What would be more meaningful and could stimulate the Taiwan manufacturers to become more internationally competitive is to give an incentive for being accredited by FDA or EMA. This incentive however should not be a higher price, but rather a tax incentive or another stimulus. Taiwan has already the highest prices for Generics in percentage comparison to originators. While in EU and US Generics usually enter the market with 50-60% or originators, Taiwan sees prices of 90% to 100% of originators. With such high prices for Generics it may not be surprising that Taiwan has so many local manufacturers of Generics. I am very supportive of a healthy Generics market, since it is necessary for the Payer to manage their budgets and to create savings to be able to reimburse innovative and patented drugs. I however do not agree that quality should be a price differentiator, quality should be “a given” to ensure that all patients can enjoy save and efficient medicine regardless where and how they are treated.

The bottom line for multinationals in Taiwan is that they have more than 70% market share, and originators have 90% market share of that 70%. Is there so much to be pessimistic about?

Indeed the multinationals and originators command still the lion share of the market. Why is that the case? In my point of view there are a few reasons for this:

First: Taiwan has a very slow access, which is due to lengthy regulatory, reimbursement and hospital listing process. The listing in hospitals may take some time, as Medical Centers now require for every new drug an existing drug to be de-listed.

Second: Many doctors, especially in Medical Centers are not convinced that local Generics meet the quality of their international originator competitors. As mentioned above there are yet only few Taiwan manufacturers that are accredited by FDA or EMA and hence Medical Centers such as NTUH tend to list few Generics.

Third: Only few international Generic players have established their presence in Taiwan. This may be due to the small size of the market or due to the rapid price deterioration that follows the PVS adjustment of Generics that have to give significant discounts to enter Hospitals.

I believe for the Generics market to really take off you need to have a very different environment. You would have to have a separation of dispensing and prescription, a strict rule on discounting (for example a limit to a single digit administration fee like in Japan) and then a robust pharmacies network with pharmacists being able to substitute. For substitution to be implemented you would also need strictly enforced quality standards that are the same as in developed markets of EU and USA. When all of this happens, a more sustainable Generics market will emerge and then the ratios will change.

How has your business been over the last three years, since we met you last?

Last year was a very difficult year for everyone. As I mentioned most international pharmaceutical companies declined last year; the whole industry went down by roughly 2%, which is the first negative growth in the last 10 years in Taiwan. If we look at the last three years however I am quite pleased with our average growth rates which compare competitively to our peers especially when we analyze our performance in the markets where we compete.

How does Taiwan rate on the following measures of market attractiveness: predictability, sustainability, transparency and market growth?

Taiwan has an aging population, incredible infrastructure, and a single payer that has access to data on patient usage that is unique in the world, which is an absolute goldmine for epidemiological data. Taiwan has however also the unique feature of offering some of lowest prices for new drugs in the world and it regularly adjusts these down. In addition the hospitals finance themselves via discounts that we need to give to be listed there. In order to break the negative cycle of price adjustments Taiwan needs to move from a per-profit to a transaction-price-based purchase for pharmaceuticals. As in other markets, it should be regulated and not negotiated based on discounts given. The other thing that is still a problem in Taiwan is separation of prescription and dispensing. The major hospitals are all dispensing. This is a conflict of interest: the hospital has an influence on how the doctor prescribes and it is not in the best interest of the patient to consider only the financial benefit of a drug for the hospital.

I also believe that in Taiwan, the patient needs to be participating more in healthcare. What I mean by that is that we need to have a robust OTC market. In western countries, a lot of simple remedies, from cough syrups to headache pills, are all non-prescription and non-reimbursed. Many

of these drugs are still reimbursed in Taiwan, meaning that if I have a cold, I go to the doctor, and get a free prescription. These remedies however could be self-paid as they are not costly and that would reduce the burden on the system and allow more serious diseases to be treated with reimbursed drugs. Fundamentally this would be more fair and closer to the concept of a health insurance. In addition a healthy self medication market would also increase the patient's choice for more international brands. I myself struggle to find international brands for some pediatric medicines for my daughter here as the OTC market is dominated by reimbursed local generic brands. On the other hand the fact that even drugs such as antacids or cough and cold remedies are reimbursed leads to over-prescription which is not good for the patient. I think if Taiwan would adopt the EU experience of establishing a more mature OTC market, not only it would generate huge budget savings by de-listing these products from the reimbursement list it also would reduce unnecessary poly-pharmacy and reduce the waste of drug prescriptions.

After all this, what position is GSK in the market? In 2010 you were 6th, and you were quite bullish about the need to be in the top five. Have you reached this target?

Actually the question for me is where would we be had we not made significant changes in the last 4 years. We are still number 6 in the market and becoming a top 5 or top 3 player is still our goal, however we also encountered a number of challenges that affected our growth momentum. I would say in terms of what we were actually able to influence we have done a fantastic job and when I look at our volume growth and how our brands performed, that were not affected by global developments beyond our control, we have accelerated our growth significantly over the last 4 years.

So you implemented what you wanted to, but it hasn't brought you to the position where you want to be?

We have launched more new products in the last 2 years than any other top ten pharmaceutical company, and on a global level, GSK now has the most productive pipeline in the industry. Without setting up new structures for Market Access, Key Account Management and External Affairs we would not have been able to achieve so many access opportunities. Without investing heavily in internal capability build up in Launch Excellence and Team collaboration our launch track record would not be so successful.

So are we going to be number three in 2015? No. Number five – maybe. It depends on how the latest market interventions of the 2nd Generation NHI law turn out.

Ultimately, GSK is in a very good position, because unlike other companies, we do not have big blockbusters. This may seem counterintuitive, but we are playing in many areas, which means the company is not so much the target of the major market corrections that are taking place right now. Another reason for our current market position is the fact that GSK actually does not play a big role in the markets that are driving the growth in Taiwan, i.e. CV, Diabetes and Oncology. On the other hand we are leading in markets such as Respiratory, HIV and CNS that are smaller by comparison. I therefore tend to look rather at the markets where we participate and measure if we can beat the competition there. This is a better marker of excellence and I am proud to say that in all of our core markets we either lead the market or grow faster than the average.

If you had a piece of advice for another expat manager that is parachuted into Taipei and face this market, what would you tell him?

Despite all the challenges of the pharmaceutical environment in Taiwan, this is still a very positive environment. There is a dynamic in the market that welcomes high tech. Despite the obvious tendency to favor local companies, which happens in every market, there is that sense of open-mindedness due to the fact that Taiwan is a small island, and Taiwanese people are incredibly friendly and genuine in their interest in what comes from outside of Taiwan.

So as a GM of a pharma company in Taiwan, be open and listen respectfully to what you hear from the key players in the market; don’t make vast and western-minded judgments too quickly. The problems of the market are the problems of every emerging mature market, and Taiwan is always going to be at that tipping point: on the one hand it is a mature market, with slow growth rates. On the other hand, it is a sophisticated market, with a dynamic that is more comparable to an emerging market, and that has played out in how we engage with customers, how the customers engage with patients, and the frequency and quality of care, which are features of emerging markets. That is why it is an excellent market to be in: not an easy one, but a rewarding one for those who are patient and resilient.

Last but not least focus on your people and spend sufficient time to build up a team that is truly connected and aligned. My experience is that with good alignment and healthy level of trust, you can move mountains and in addition also enjoy working with your team. Bringing the right people together and earning their trust may take time so you need to be a little patient.

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