Interview: Freddie Höglund – CEO, European Chamber of Commerce Taiwan (ECCT); Mike Exton – Co-chair, ECCT Pharmaceutical Committee, Managing Director & Country President, Novartis Taiwan



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21.03.2017

Tags: Taiwan, ECCT, European Chamber, Chamber of Commerce, Investment, Pharma, Biotech

Freddie Höglund, CEO of the European Chamber of Commerce Taiwan (ECCT), and Mike Exton, Managing Director of Novartis Taiwan and Co-Chair of the Pharmaceutical Committee of the ECCT, document the main issues at stake for the international pharmaceutical companies implanted in Taiwan, while providing us with a broader overview of the main innovation-oriented opportunities currently being discussed with Taiwan's new government.

Taiwan's new government took position in May 2016 and established the pharmaceutical and biopharmaceutical sectors as one of the key pillars of the country's new economic model, focused on innovation-driven industries. As the co-chair of the pharmaceutical committee of the ECCT, what are the main priorities on top of your agenda?

Mike Exton ME: We are currently focusing our efforts on two main topics.

The first one relates to the ambition of President Tsai and Taiwan's new government to foster the development of the country's new economic model, in which the biotech industry is set to play a critical role. Looking at the contribution of international, innovation-driven companies to this

endeavor, we are already leveraging Taiwan's world-class scientific and clinical capacities by closely partnering with local academic and research institutions such as Academia Sinica as well as with the country's top medical centers. The international industry implanted in Taiwan is also increasingly reaching out to some of the most prominent R&D-driven, local biotech companies, and we look at identifying early-phase projects and more advanced products which European companies could co-develop and/or jointly bring onto the international stage.

Without any doubt, international pharmaceutical companies can greatly enhance Taiwan's innovative eco-system through a variety of different partnerships and collaborations that go beyond our companies' own products. Nevertheless, our industry's game changing commitment to Taiwan is also subject to some crucial conditions, which stand as the second main issue that we are discussing with the country's public and regulatory stakeholders.

These conditions essentially encompass two main aspects: first, a heightened protection of intellectual property; and, second, the strengthening of satisfactory access to innovative medicines, mostly by displaying greater speed and transparency throughout NHIA's reimbursement process. In this regard, Taiwan still lags behind the vast majority of OECD countries.

Do you feel that bolstering R&D-driven investments of international companies stands as a clear priority of the new government?

ME: Although is still too early to truly gauge the government's ambitions in this regard, I feel that it does not stand as one of its foremost priorities at the moment.

[Featured_in]

New drug development is undeniably a particularly risky and investment intensive activity, while nurturing the rise of a competitive, R&D-driven biopharmaceutical sector comes at an even higher cost – without any guarantee of success. As a result, I do not believe it is the government's role to fully support the financial development of Taiwan's biotech sector by itself, and it should rather concentrate its efforts on further improving the country's fundamental capacities in the scientific, clinical and medical fields.

By focusing its efforts on improving Taiwan's core scientific and medical capacities, the government could then let the private sector, including both local and international venture capital firms and pharmaceutical MNCs, bring the investment and R&D partnerships needed to take Taiwan's biotech industry to the next step. At the end of day, the annual R&D budget of a global company alone will always be more substantial than what Taiwan's government could reasonably

afford to invest in the development of the local biotech industry.

You mentioned Taiwan's bottlenecks to innovation access. How do you explain such a difficult context in a country that is widely considered to have one of the best healthcare systems in the region?

ME: Total healthcare spending in Taiwan only amounts to 6.6 percent of GDP, which is particularly low, even by Asian standards. Official statistics show that the number of people aged 65 and older is growing faster than in most Asian countries, making up around 13 percent of the total population of 23 million in 2016. By some estimates, thirty percent of the Taiwanese population will be 65 or older by 2025, which explains the current government's heightened focus on long-term care.

To tackle the challenges posed by the country's rapidly aging population, Taiwan's NHI needs to become ever more efficient, which has traditionally been one of the main strengths of the overall health system here. Nevertheless, an aging population also implies a higher demand for complex, more expensive, comprehensive treatments. If the government wants to perpetuate Taiwan's tremendous successes in providing its population with universal health coverage, it is then left with only two choices: either increasing NHI funding through the implementation of new taxes or increasing co-payments. Nevertheless, it is absolutely clear that continuously squeezing the margins of healthcare providers and pharmaceutical companies does not stand as a sustainable solution.

Freddie Höglund (FH): Taiwan's reimbursement prices for innovative drugs are probably among the lowest in the world, but successive governments have always perceived this worrying fact as a proud evidence of NHI's efficiency.

Approval rates of the NHI remain particularly high as it is considered cheap and efficient by the public. Nevertheless, most patients do not know that some of the most innovative, life-changing treatments may not be available in Taiwan because of the government's pricing policy.

Talking about access to innovation, what is your assessment of TFDA's improvements in terms of market approval timelines?

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ME: Although TFDA has indisputably improved its overall processes over the last year, it still lacks flexibility. For example, the majority of our clinical trials include Asian patients – but it is not always the case. TFDA will then systematically reject any new drug submission that does not include Asian patients in its clinical trials. Nevertheless, for more than 90 percent of the diseases, genetic

differences do not translate into different clinical trials. For these diseases, a more flexible approach could allow for the market approval process to be triggered while running parallel studies in the meantime.

Looking specifically at the drug reimbursement process, which remains the main barrier to innovation access in Taiwan, what are the main areas for improvements that you identify?

ME: Looking at the NHIA's reimbursement approach, the industry's main issue relates to the lack of transparency of the overall process. According to data collected by the Pharmaceutical Committee of the European Chamber of Commerce, it takes on average 417 days for drugs to be approved for reimbursement, while NHIA's drug approval rate as of June 2016 reached just 50 percent, with only 50 percent of the approved cases having been approved for reimbursement. Beside the extraordinary length of the overall process and the poor approval rate, companies also struggle to follow the advancement of their reimbursement applications, while the rationales behind NHIA's pricing decisions are cost-, rather than value-focused.

NHIA's reimbursement process is composed of two main parts: the first one is very clinical and data-orientated, which means companies can easily predict its outcomes – as long as it holds strong clinical evidence backing your submission. The second part of the reimbursement process is far less transparent, as it is handled by a committee chaired by hospital directors who seem to be essentially concerned by the impact that these new treatments will have on their hospitals' budget. Furthermore, a unanimous vote is required for a product to be granted a reimbursement price, which means a single member of this committee holds the power to deprive 99.9 percent of Taiwan's population from accessing a new treatment.

Without any doubt, innovative pharmaceutical companies need to acknowledge that the NHIA does not hold unlimited financial resources. In this regard, our focus should be on showcasing the value that our treatments can bring to Taiwanese patients and Taiwan's health system in general. Nevertheless, the current reimbursement process does not really allow us to prove the heightened cost-effectiveness generated by our treatments, as the committee's criteria seem to be essentially centered on these treatments' costs – in absolute terms. In this regard, Taiwan needs to urgently follow the path of other advanced countries, which have already favored a much more rigorous evaluation of the health economics of new, innovative medicines, notably by reducing palliative care expenditures and dependence on the hospital sector.

Nevertheless, I am confident that the industry and the government will continue to work together to provide Taiwanese patients with better health outcomes. In this regard, we have to praise the openness of the new government to jointly discussing the changes we need to implement.

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Moving from a pharma-centered perspective to the bigger picture, President Tsai recently said that she wanted to turn Taiwan into an Asian Tiger again and renew its role as a pioneer. Freddie Höglund, as CEO of the ECCT, to what extent do you see this ambition translating into a new era of opportunity for European companies?

FH: It is difficult to answer this question because the new government only stepped in eight months ago. After a full year in office, we will be better positioned to assess the first reforms it has already implemented.

Nevertheless, in some specific areas we have seen major changes within the first six months of the new government’s tenure. The government has for example set up very ambitious targets to revitalize and revamp the energy sector, including the objective that – by 2025 – there will be no more nuclear power generation in Taiwan. At the moment, nuclear power makes up around 16 percent of the country’s electricity generation, while the share of electricity production coming from renewable energy sources is around the two percent mark. Nevertheless, the government’s objective is to ensure renewable energies make up 20 percent of Taiwan’s electricity generation by 2025.

This aggressive and ambitious target entails great opportunities for European companies, which indisputably stand as some of the most advanced in the world when it comes to renewable energy and energy efficiency. Beside these great opportunities lying ahead, we however identify structural challenges that need to be overcome. For example, Taipower, the state-owned electric company, still holds a complete monopoly on electricity generation. Although private companies can be involved in electricity production, Taipower remains the only buyer in the market. A major update of the Energy Act is currently under assessment by the Legislative Yuan which aims to ensure that – within the next two years – producers of renewable-based electricity in Taiwan could be authorized to directly sell its production to a third party. We will of course carefully look at the details of this upcoming legislative update, but it truly stands as one of the first important reforms triggered by the current government.

The 2016 World Bank report ranked Taiwan the 11th most business-friendly country in the world and the 5th in the APAC region. What should be the priorities of the Minister of Economic Affairs to build a more attractive eco-system and ensure international companies further increase their investments to the country?

FH: Overall, Taiwan's position is good, while – compared to some neighboring countries – it is a fairly open society.

The main challenge that European companies and the ECCT face relate to the adoption of international standards. Taiwan is an export-driven economy, which requires that Taiwanese products always comply with the regulatory standards of their export markets. On the other hand, for imports, Taiwan has a tendency to set its own standards while most test certificates issued in Europe are unfortunately not recognized in Taiwan. This unfortunate situation leaves foreign companies with no choice but to conduct double testing of their products, which also generates increased delays and costs. The overall export process becomes costly and inconvenient, which at the end of the day negatively impacts Taiwanese customers.

The Minister of Economic Affairs also mentioned its ambition to ease the hiring of international talent to bolster the development of both local and foreign companies implanted in the country. What is your assessment of the current situation?

FH: Taiwan's current labor situation is marked by a dual shortage of both skilled and unskilled labor, which affects both international and local companies.

Regarding skilled labor, talented Taiwanese are easily tempted to move abroad, as other countries in the region often offer higher wages. China, for example, offers lucrative opportunities for Taiwan-born managers to supervise Taiwanese investments there. In South Korea, middle and senior managers are paid approximately twice the income they would receive in Taiwan.

Skilled workers' wages in Taiwan have been stagnant for over a decade, which may seem like an advantage from a cost perspective but this isn't good for the long-term economic development of Taiwan. Taiwanese labor is highly qualified and skilled but low paid, which renders overseas opportunities very appealing. Add to this the regional disparities in terms of personal income taxation. As a comparison, in Hong Kong, where salaries are generally higher than in Taiwan, especially in the financial services industry, the maximum rate for personal income tax is 15 percent compared to 45 percent in Taiwan.

Taiwan's Minister of Economic Affairs told us that he wanted to further diversify investment sources and reduce Taiwan's dependence on Chinese investments while reconnecting to Europe and the US. What would you highlight as interesting signs in the development of trade relationships?

FH: In terms of diversification, the Taiwanese government recently announced its 'New Southbound Policy' to enhance cooperation and exchanges between Taiwan and countries in Southeast Asia, and Australasia. It is still too early to predict the impact of this policy, but it highlights the government's ambition to diversify investment.

In October 2015, EU Trade Commissioner, Cecilia Malmström, publicly announced in the EU trade policy paper "Trade For All" that the EU would explore a bilateral investment agreement (BIA) between the EU and Taiwan. This is the first time that Taiwan has been mentioned in an EU trade policy paper, and it followed the announcement made in November 2013 that China and EU would launch negotiations of a comprehensive EU-China Investment Agreement.

In the past, we have seen that negotiations between China and a given country could open the door for negotiations of a similar agreement with Taiwan. For example, FTAs signed between China and Singapore and China and New Zealand were followed by similar FTAs signed between these countries and Taiwan.

In the US, President Trump has made it clear from day 1 that the TPP would no longer be part of the US trade strategy. There is a lot of uncertainty regarding what will happen to the TPP, but joining this multilateral trade agreement was a priority of the Taiwanese government. As the TPP may now not get off the ground, at least not in its current form, it could create a necessity for Taiwan to focus more on Europe, entailing in turn greater opportunities for Europe and European companies operating in Taiwan.

As CEO of the ECCT, what would be your final message to our international readers?

FH: I should end with highlighting the quality of the business environment that Taiwan has to offer. Taiwan is a fully-fledged democracy where the rule of law is respected, making it a more predictable business environment than most other Asian countries. As an example, in October 2016, draft regulations related to investments, trade and IPR saw the review period extended from 14 to 60 days, which now provides the industry with a greater opportunity to provide feedback on draft resolutions. This stands as a major breakthrough that we have been advocating for several years. Overall, the Taiwanese are indisputably reliable and friendly business partners, and we at the ECCT enjoy good access to the government. As an example, the ECCT organizes around 300

meetings and events a year, many of them with high-level government officials as our guests.

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Secondly, Taiwan has a highly skilled and educated workforce. International companies can benefit from a level of public infrastructure equivalent to the most advanced countries in the world. Geographically, the country is remarkably well positioned, as most Asian countries are reachable within a four-hour flight range, making Taiwan particularly strategic for logistics and transportation. Taiwan’s population and its government are also becoming increasingly environmentally aware and developing green initiatives is clearly a priority of the current government. This ambition will also contribute to making Taiwan an ever-more livable country, especially in comparison to China, where pollution peaks continue to make headlines.

Finally, Taiwan is a country where both public and private stakeholders work together to solve issues hindering economic growth. Our annual Position Papers provide a comprehensive review of the issues at hand, and we see that on average around 20 percent of our issues are resolved each year. Interestingly, the absolute number of issues has remained stable in recent years while in China for example, the number of issues is increasing. Undoubtedly, the business environment in Taiwan is particularly positive and the country stands as a favorable place to do business.

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