Interview: Wu Tsung-Tsong â?? Minister Without Portfolio of the Executive Yuan, Republic of China (Taiwan)

â??Fostering the development of the pharmaceutical and biotech industries holds a central importance within President Tsaiâ??s strategic vision to build Taiwanâ??s new economic model.â?•

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Wu Tsung-Tsong, Minister Without Portfolio of the Republic of China (Taiwan) supervises and coordinates Taiwanâ??s Biomedical Industry Innovation Program. In this exclusive interview, he documents his main priorities and the governmentâ??s unrivalled commitment to further enhancing the attractiveness of Taiwanâ??s biotech ecosystem and bolstering a win-win relationship between Taiwan, the countryâ??s innovative companies, and the leading multinationals in the sector.

As Executive Yuanâ??s Minister without Portfolio, could you provide an insight into your main responsibilities regarding the development of Taiwanâ??s pharmaceutical, biotech, and biomedical sectors?

Fostering the development of the pharmaceutical and biotech industries holds a central importance within President Tsaiâ??s strategic vision to build Taiwanâ??s new economic model. Highlighting the governmentâ??s ambitions and commitment to this fundamental objective, the pharmaceutical and biotech industries were included in Taiwanâ??s â??5+2 Industrial Innovation Program,â?• which aims to prioritize resource allocation to five innovation-centered industries that are set to nurture the long-term growth of our countryâ??s economy.

To coordinate such an ambitious effort and ensure it delivers tangible outcomes, the â??Biomedical Industry Innovation Programâ?• was set up by the Executive Yuan, the executive branch of the Republic of China (Taiwan), as a cross-ministry collaboration between the Ministry of Science and

Technology, the Ministry of Economic Affairs, the Ministry of Health and Welfare, the National Development Council, the Ministry of Education, the Financial Supervisory Commission, and Academia Sinica *[Taiwanâ??s national academy, e.d.].*

As Minister Without Portfolio, I was entrusted with the strategic mission of handling the overall planning, supervision, and the inter-ministerial coordination of the â??Biomedical Industry Innovation Programâ?• within the Executive Yuan and in line with the strategic objectives of President Tsai for this sector.

What are the strategic priorities of this â??Biomedical Industry Innovation Programâ?• which you are heading on behalf of the Executive Yuan?

Overall, this Programâ??s objectives are perfectly aligned with President Tsaiâ??s grand vision for the development of the biotech sector, as it aims to strengthen our innovation-centered ecosystem to the benefits of both local and international companies, build stronger bridges between our domestic industry and the world, and position Taiwan as a major hub for biomedical and biotech R&D in Asia Pacific.

As part of this strategic program, we have identified four main areas on which we will concentrate our efforts.

Firstly, we want to accelerate the development of a comprehensive innovation ecosystem to sharpen the global competitiveness of our local companies. This approach encompasses six critical fields: capital, talent, industry specialization, intellectual property, regulation, and resources, which we have identified as the most important in our objective to nurture the long-term development of our biotech and biomedical industries.

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Secondly, we want to accelerate the integration of our different innovation clusters and bolster the improvement of this industryâ??s value chain. This objective notably targets our countryâ??s world-class bio clusters in Nangang [*in the Taipei area, mostly focused on new drug development, e.d.],* and HsinChu *[commonly referred to as Taiwanâ??s Silicon Valley, e.d*.] and in Central and Southern Taiwan, which form our countryâ??s â??biotech corridorâ?•. As HsinChu already stands as the heart of Taiwanâ??s ICT industry, the further development of this biotech and biomedical cluster could foster an extremely promising interplay between these two pioneering industries, and cross-sector investments, research projects, and other partnerships could truly propel the development of Taiwanâ??s â??bio-ICTâ?• sector. In the grand scheme of things, this integration approach follows the global convergence trend happening between the pharmaceutical and medtech sectors, while Taiwan already stands out as a global frontrunner in the precision medicine field for oncology treatments, for example.

The third pillar of the Biomedical Industry Innovation Program relates to our ambition to attract more international talents and companies to undertake innovation-oriented projects in Taiwan. In this objective, our countryâ??s world-class medical and clinical capabilities as well as our vibrant stock and capital markets undeniably emerge as critical and appealing assets. Nevertheless, attracting international investments is a global competition and we need to continuously sharpen our competitive advantages, which means further harmonizing our regulations, better positioning our countryâ??s offering vis-Ã -vis international healthcare demand, and generating new market opportunities for international companies.

Finally, we want to further promote Taiwanâ??s centers of excellence and niche sectors, which notably includes the aforementioned development of precision medicines, but also the establishment

of world-class specialty clinics and specialized healthcare services. In this regard, we launched our Global Clinics Program in Hsinschu, where we try to leverage the large presence of world-class KOLs in this area to develop a healthcare offering that will appeal to international patients and physicians, in partnership with National Taiwan University *[one of the best universities in the country, e.d.].* Our overarching strategy in this field is also to build Taiwanâ??s reputation as a world leader in some specific areas and become the partner of choice of international companies for their global R&D projects. The latter can already leverage Taiwanâ??s utmost capacity in drug discovery, the data accumulated by the National Health Insurance (NHI), our excellent environment for clinical studies, as well as the international recognition of Taiwan FDA to use the results of clinical studies conducted in Taiwan for the registration of their products in the US or in the EU.

What are some of the reforms that the government is currently working on?

We are currently working on a series of major regulatory updates. Due to the inherent specificities of the pharmaceutical and medical devices fields, regulations governing medical devices and pharmaceuticals will be separated within the Pharmaceutical Affairs Law. Furthermore, President Tsai announced on January 18, 2017 that Article 3 of the Biotech and New Pharmaceutical Development Act will be amended to offer greater tax incentives for biotech and biomedical companies involved in R&D activities.

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We also want to provide pharmaceutical and biotech companies with greater access to the local market. The first aspect relates to the speed to market for new drugs approval. In this regard, the draft of the Regulations Governing the Establishment of the National Center for Drug Evaluation is now under review at the Legislative Yuan. This new organization will work hand-in-hand with the Taiwan FDA and handle all approval reviews nationwide, taking over the responsibilities of the non-governmental and non-profit Center for Drug Evaluation and several other entities that currently deal with the evaluation of medical devices and drugs, highlighting the governmentâ??s ambition to significantly streamline and shorten market access process. On the other hand, we are also working with the NHIA to see how we could increase reimbursement prices and ensure that the reward-to-innovation ratio remains aligned with international standards.

In the meantime, we want to accelerate the translation of Taiwanâ??s medical and research leadership into the development of marketable innovations. Currently, one of the most pressing issues at hand is encouraging researchers from academia to found their own businesses. In Taiwan, many excellent research works are produced by professors affiliated to public universities, whose status prevents them from founding or chairing private companies â?? even on a part-time basis. Such limitations clearly hinder the commercialization of innovative technologies and absolutely need to be relaxed.

On the other hand, we noticed that most researchers still lack experience in the commercialization process, whether related to the planning of intellectual property, the pre-clinical planning and execution, fundraising, or registering a new company. The government has decided to establish a commercialization center for drugs and medical devices, which will gather industry experts to guide new entrepreneurs through the commercialization process.

Taiwanâ??s vision for the development of the biotech sector has historically been focused on fostering the set-up of emerging companies. As the local industry has been gaining in maturity, how do you plan to help local companies reach the next step in their development path?

One of our main strategies at the moment is to tremendously facilitate mergers and strategic alliances among small and medium enterprises in the country, and also to promote mergers with international companies.

As a result, the government is currently revising the Business Merger and Acquisition Act, while we have significantly reduced the review process for inward investments. At the end of July 2016, the Executive Yuan also decided to set up a public-private fund worth NTD100 billion (around USD3.15 billion) to support M&A activities. In the API segment for example, out of more than 100 PIC/S GMP pharmaceutical manufacturers, most of them are still too small to be truly competitive on the global stage. Our approach is then to encourage local and international consolation to help these companies gain the critical size they need to fully leverage their unique expertise.

Nevertheless, our overarching strategy is to make regulations more aligned with the needs of the development of the industry â?? embracing an approach that goes beyond direct financial support. In this regard, we recently decided to follow the example of the US and established the promotion of the local industry as one of the key missions of the Ministry of Health and Welfare, in addition to their historical responsibilities for the evaluation of product safety and efficacy.

Some pharmaceutical manufacturers have highlighted to us that emerging biotech companies have been receiving huge financial support from the government, while so far, these companies have brought little value to the countryâ??s economy. In the meantime, these historical manufacturers stressed their contribution in terms of investment, taxes and export efforts, which â?? according to them â?? do not receive enough government support. How does the government position itself on this subject?

Although our biotech industry has been gaining momentum and companies like Taigen, PBF, and PharmaEngine have already managed to bring innovative products into international markets, it is true that the contribution of these emerging companies to the overall output of the industry is still extremely low. In the meantime, we see that the export of pharmaceutical products has been steadily increasing year after year, mostly driven by our countryâ??s capacity in the API and generics fields.

Nevertheless, we are confident that our biotech industry holds a bright future, as 225 drugs developed by Taiwanese companies are currently undergoing clinical trials, including more than 115 products that received an IND approval from the US FDA. As the innovation momentum is gaining in intensity, new drugs and biological products may contribute to an increasing share of the growth rate of the overall industry.

In this regard, our objective is to nurture a collaborative approach between emerging biotech companies and historical manufacturers, be it through contract manufacturing partnerships, joint investments or joint ventures. The overall expertise and capabilities of these manufacturing companies are absolutely world-class, and a great share of them already hold GMP, US FDA, EU EMA, or Japan CPMDA approved facilities â?? even for the manufacturing of complex products such as injectables. After the full implementation of the PIC/S GMP in 2015, we now want to help these manufacturers to further upgrade and develop their capabilities, in order to ensure they can become the manufacturing partner of choice of our biotech companies but also bolster their regional and international expansion.

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What would be your final message to our international readers?

The commitment of Taiwanâ??s government toward the development of the pharmaceutical, biotech, and biomedical industries is probably unrivalled in the world. In the upcoming years, we will continue to invest and provide local and international biotech companies with the support they need to consolidate Taiwanâ??s positioning at the forefront of this industry, while continuously connecting our companies to the global market and incentivizing leading multinationals to invest in Taiwan. Our countryâ??s attractiveness in terms of medical, clinical, and research capacities and the strength of our capital market are already remarkable â?? but we will restlessly work to further bring them to the next level.

The market capitalization of Taiwanâ??s healthcare-related industry amounted to around NTD 200 billion [around USD 6.5 billion] in 2016. Our ambition is to see this value increasing to around NTD 500 billion [over USD 16 billion] over the next decade, which stands as a very conservative objective. If we continue to sharpen the attractiveness of our biotech ecosystem and adapt the governmentâ??s support to the evolving needs of our pioneering companies, reaching a capitalization of NTD 1000 billion [around USD 32 billon] clearly stands as an objective within our reach.

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