Interview: Samuel Wang – Honorary President, Taiwan Generic Pharmaceutical Association (TGPA)



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Samuel Wang, Honorary President of the Taiwan Generics Pharmaceutical Association (TGPA) and President of the local distributor Weal-Chance Trading, provides insights into the recent international achievements of TGPA and the main strengths of Taiwan's generics industry on the global stage, while he explains how bolstering the country's historical strengths in new formulations and drug delivery systems could also help Taiwan to eventually fulfill its ambitions in terms of new drug development.

TGPA notably holds the ambition to promote and foster the development of Taiwan's generics industry on the international stage. How have you been progressing in this regard over the past years?

In 2015, TGPA proudly joined the International Generic and Biosimilar Medicines Association (IGBA), which stands as a major milestone in our association's history. TGPA is now part of a powerful cross-border organization that is committed to promoting generic and biosimilar medicines at the global level, alongside members of other prestigious international generics associations, such as the Canadian Generic Pharmaceutical Association (CGPA), Medicines for Europe, the Generic Pharmaceutical Association (from the US) or the Japan Generic Medicines Association (JGA).

Beside crucial promotion activities we are jointly conducting through IGBA, this association also operates as a crucial network of international expertise significantly bolstering knowledge transfer

among its different members. As part of IGBA, TGPA can now more easily foster a strategic dialogue with the aforementioned associations and – above all – access to the most updated information and market trends in a variety of different strategic fields, from international regulatory affairs to marketing strategy, which will ultimately benefit to our members and Taiwan's pharmaceutical eco-system as a whole.

When it comes to compete on the global market, what are the main strengths and remaining rooms for improvements that you identify for Taiwan's generics industry?

Taiwan undoubtedly holds a very experienced generics industry that has already reached international standards. For example, Taiwan and the TFDA *(Taiwan's regulatory agency, e.d.)* joined in 2013 the Pharmaceutical Inspection Co-operation Scheme (PICS), which contributed to tremendously reduce inspection cost and allowed our members to save more than a year in their go-to-market process. TGPA's members also boast eye-catching strengths in the most innovative part of our industry's value chain, displaying world-class capacities in new drug delivery systems and developing new formulations, combinations, and also biosimilars. This high added value expertise in particular has already been drawing a strong and increasing interest from our international partners.

From an international standpoint, Taiwan's generics industry nevertheless still holds very interesting rooms for improvement, especially when it comes to our current export performance. Regarding our aforementioned capacity in new formulations, we could for example better leverage their international attractiveness by further developing our export network and more largely sell our formulations to other countries, following the successful strategy implemented by countries like India, Korea or Portugal.

Given we already hold the research and manufacturing capacity to compete on the global stage, promoting Taiwan's generics industry and its unique offering to the world has clearly become the primary objective of TGPA. In this regard, TGPA holds excellent relationships with its Asian counterparts, such as the Malaysian Organization of Pharmaceutical Industries (MOPI) for example, which allows our members to more swiftly penetrate new target markets or further intensify their activities in the region.

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Taiwan indeed joined the PICS system in 2013. What could stand as an interesting next step for the local industry, in its endeavor to be evermore aligned with the best international standards?

In our industry's export-oriented vision, regulation harmonization undoubtedly emerges as a crucial aspect of our growth strategy. Taiwan's industry indeed has historically been extremely focused on ensuring it is perfectly aligned with the highest international standards and regulatory requirements developed by the most advanced countries in the world. Nevertheless, we know we cannot afford to rest on our laurels, and we tirelessly look at ways to raise the bar and remain at the forefront of the global industry.

In this continuous improvement approach, an interesting next step for our eco-system could be to further upgrade our API capacity to the DMF (Drug Master File) standards, which are sometimes required by the US FDA to supply bulk materials to the United States.

Taiwan's Administrative Yuan recently passed a draft amendment to the Pharmaceutical Affairs Act to introduce a patent linkage system, which will impact the relationship between the market approval process of generic drugs and the patent status of the originator product. What is TGPA's position regarding the implementation of this important regulatory reform?

The establishment of a patent linkage system has been high in the agenda of Taiwan's regulatory authorities for the last two years. We now expect that this reform will probably be implemented before the end of 2016 or in 2017 the latest.

For the last two years, TGPA and its members have been meticulously assessing the impact of this regulatory reform. We ultimately came to the conclusion that the implementation of a patent linkage system would move Taiwan's ecosystem to the right direction, and that it will display acceptable outcomes to TGPA's members. As part of this strategic thinking, we indeed consider that this patent linkage system can stand as a formidable occasion to further upgrade our industry, because only the competent manufacturers can survive and the weak will be eliminated from the market.

As a new government recently took over, what are your strategic priorities as Honorary President of TGPA?

TGPA undoubtedly operates as the bridge between most of the members of Taiwan's generics industry and the government. Although President Tsai's economic program is particularly focused on boosting the development of Taiwan's biotech industry, which is mainly involved in new chemical entities (NCEs), generics remain very important to the eyes of the new government and the National Health Insurance Administration (NHIA). From an economic standpoint, developing high-quality generics also has historically been the focus of Taiwan's pharmaceutical industry for

many decades, while most of the largest pharmaceutical manufacturers of the country are members of TGPA.

Nevertheless, we need to clearly highlight that supporting our generics industry will also positively impact the maturation pace of Taiwan's NCE expertise. At the end of the day, if we truly want to bolster Taiwan's capacity in new drug development, we should not underestimate the importance to strengthen Taiwan's competences in new formulations, combinations, and new delivery systems in the meantime.

If it is true these three areas of expertise can serve as a powerful catalyst to propel Taiwan's new drug development ambitions, this technological asset also needs to be nurtured and supported. So far, the new government has been particularly receptive to the strategic importance of this matter, and – according to the numerous meetings we already held with key members of President Tsai's government and administration – I am particularly confident we will receive more support to develop our industry's capacity with regards to new formulations and new drug delivery systems.

Our country's pharmaceutical eco-system hasn't yet managed to bring to the market a first NCE entirely developed in Taiwan. Nevertheless, I am convinced that by proceeding step by step, and strengthening intermediary capabilities such as the three crucial ones I just mentioned, our country can reach this goal within the next decade.

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Looking at the domestic market, in 2016, generics already make up 70 percent of the volume of drugs sold in Taiwan, but less than 30 percent of the total value. How do you see Taiwan's generics market evolving in the upcoming years?

As you know, Taiwan's National Health Insurance system covers more than 99 percent of our population. I think that one of the main issues that our health system face relates to the pricing policy that overprotect innovators' prices despite the market entry of generics alternatives.

In Korea, the local patent linkage system clearly stipulates that the price of any patented drug will be reduced by 30 percent as soon as generics are available on the market. Furthermore, innovator's price in Korea will also be automatically decrease to the level of price of its generics alternatives exactly one year after the latter have entered the Korean market.

In Taiwan, NHIA's system offers a fifteen-year price protection to patent originator. This unfair and unsatisfactory regulation mainly explains why generics only make up 25 percent of the value of the market whereas they already account for more than 70 percent of Taiwan's market volume, while it

also prevents our healthcare system to make substantial savings, especially in the context of Taiwan’s rapidly aging population.

We are currently discussing this strategic aspect with both Taiwan’s Ministry of Health and Ministry of Economic Affairs. As President of TGPA, I have been firmly advocating for changing this pricing system over the two terms of my mandate at the head of TGPA, and it will undoubtedly remain one of the foremost priorities of our organization for the upcoming years.

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