Carol Cheng – Chief Operating Officer, TRPMA, Taiwan

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Carol Cheng, chief operating officer of the

Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA), gives an update on the current condition of Taiwan's biopharma environment and speaks about the country's innovative capacity as an industry leader not only in the region but globally.

What have been the key developments of Taiwan's biopharmaceutical industry over the past three years?

The Biotech and New Pharmaceutical Development Act helps support the industry by allowing new drug companies certified by the government to list for IPO on the Taiwan Stock Exchange and Taipei Exchange before having any products on the market. This helps companies to fundraise for their R&D while also benefiting from special tax advantages. As of today, there are over 120 biotechnology companies listed on Taiwan's stock exchange with a total market value reaching USD 23.4 billion in 2018. Being publicly listed, companies must report on their activities including fundraising, clinical trial results, and R&D progress. This has turned biotechnology into a very transparent and reliable industry, helping investors to feel secure in entering the sector.

Additionally, the clinical trial environment of Taiwan has also advanced. Our member companies have continued expanding their clinical trials overseas. In total, there are 295 Taiwan new drug projects entered in clinical trials worldwide. They have extended their footprint into markets like

the US, Canada, South Africa, Europe, and Australia. Since 2016, four small-molecule drugs and two biologics have been approved in the global market. For example, PharmaEngine's ONIVYDE®, a pancreatic cancer drug, has been launched in 38 markets total. Furthermore, one biosimilar and two 505b(2) products have also been launched globally.

What are the most pressing issues being faced by the TRPMA and its members today?

The gap that still exists in our industry is market capital. It takes a long time to bring products to market, up to ten years even, mainly due to lack of financial support. Taiwanese investors and venture capitalists lack the patience and innovative focus necessary to support this high-risk high return industry. Therefore, some companies look internationally for fundraising, but it is still not enough. More support is needed from the government and private capital market. The lack of capital is a hindrance to the R&D initiatives of the industry.

Secondly, in certain areas like pre-clinical evaluation and early Chemistry, Manufacturing, and Controls (CMC) strategies, we are trying to build up a stronger talent pool. Compared to earlier years, we understand better where the mechanical gap is, so we try and recruit international R&D experts to make our strategies more focused and precise.

In emerging technologies such as stem cell and regenerative medicine, Taiwan is trying to put legislation in place and catch up with the newest trend. The TRPMA is working collectively with start-ups in this area to make the environment friendlier and more predictable by collectively collaborating with the government and academia. The TRPMA formed a regenerative medicine committee comprised of 19 regenerative medicine companies.

How have the initiatives coming from the Biomedical Industry Innovation Program worked in addressing the problem areas that you spoke to us about?

So far, the initiative to have the most profound impact has been the Biotech and New Pharmaceutical Development Act. The Ministry of Science and Technology is trying to combine the biopharma industry with ICT, but from the industry perspective, it may have a quickened impact on medical devices but on new drug may need more efforts bringing in digitalization.

This all comes back to resource allocation. From the industry point of view, the private sector can be a capital engine while the government focuses especially on the regulatory environment. The

government needs to create a better ecosystem for biotech integration. There is a lot of resource allocation upstream, but whether or not they will reach the market reality is uncertain. Innovation should be primarily industry driven. If a company has a comprehensive business model for a given product it should be left in the hands of the private sector. The government's role should be to allocate resources rather than to lead the direction.

Have there been any recent developments in collaborations between Taiwan's local industry and big MNCs? What are Taiwan's strengths in comparison to regional competitors?

TRPMA members are still seen as small and medium-sized enterprises, so most of their partners in the region are also as small and medium-sized enterprises. International collaboration is increasing but not much with MNC big pharma, but more regional players and marketing companies.

In terms of pharma, unique competitive advantages are typically product specific. For product and economic development strategies, Taiwan has a special capability here. As well as in leveraging management teams as resource integrators. We have a strong feasibility for international collaborations and clinical trials strategy. Looking at our companies, even our 20 or so companies have international clinical trial activities.

When it comes to data integrity and the quality of process management, Taiwan is one of the most reliable in the area. Many organizations have very innovative development platforms, but if they are not producing results then their capabilities cannot be proven.

As a market, is Taiwan able to bring brand new innovation to the industry or is the country's role to develop incremental innovation?

The whole value chain of the biopharma industry is based on new drugs. The most profitable activity is the sales and marketing of innovative drugs. In earlier stages, people think of Taiwan as an incubator and they want to identify good projects in pre-clinical and accelerate them up to proof-of-concept in phase I and II. However, now people see the high investment return of sales marketing like the TaiMed and PharmaEngine story. The best strategy is to have part of the global market in-hand and gain approval. I do not believe that people will give up on the long haul.

During the process you need international partnership otherwise there is little support for late-stage trials. Furthermore, many biotech companies lack the sales and marketing muscle power necessary to distribute products on their own. But still, they will not let go of their product.

This is all key in the transitional strategy because biotechs do not have the experience or enough capital to market on their own. So they license out to build capital as a survival strategy, but this is changing as industry players are thinking more about maximizing profit strategy. Even if companies do not have new products to be approved, they apply for 505b2 to test the market and build up their distribution channels. This lets companies build expertise in niche areas. Taiwan is no longer focused on being positioned as an incubator with mainly licensing strategies.

How is the TRPMA's Regenerative Medicine Committee helping Taiwan to catch up with global trends?

The RM (Regenerative Medicine) Committee's mission is to build up a nation-wide ecosystem, which better integrates government and industry's resources and knowledge to expedite R&D and clinical trial approval as well as business development. So far, 19 Taiwanese RM start-ups have joined the committee. The first task is to promote the passage of "Regenerative Medicinal Products Management Act" by the Legislative Yuan in order to establish a conditional approval mechanism for RM products.

TRPMA is also working on a feasibility assessment study on a National Cell Therapy Monitory System for quality management and patient protection involved in RM treatment. We believe it is a crucial component for the RM industry development in Taiwan.

Of course, TRPMA continues strengthening the communication between the industry with the regulatory bodies with a view to seeing more successful clinical trials of the launch of new RM products developed in Taiwan.

In 2017, the TRPMA launched BioIPSeeds, a groundbreaking blockchain platform for data sharing. To what extent has the platform succeed in building collaborations between Taiwan's biopharma sector and the international business ecosystem?

Many big pharma companies are still not progressive enough to embrace blockchain technology. The industry is not as transparent as we had hoped they would be. It is challenging to establish

many international collaborations, so we are still focusing on collecting local Taiwanese cases. However, BioIPSeeds is well received in Taiwan and in the region, we often have Japanese companies that utilize the platform to look up cases.

After BioIPSeeds we also developed a digitalized personal health records system which was adopted in the Taipei Medical University Hospital so that patients can have their digital records which they can share with doctors.

What is your vision for Taiwan's biopharmaceutical sector within the next five years?

We hope we can achieve the country's 5+2 Innovative Industry Plan's goal of launching 20 new drugs worldwide and reaching USD 30 billion in sales revenue. At the pace we are going, I feel confident that this objective is achievable. The biotechnology industry is a high-risk area that requires a strong capital market and sound infrastructure. Building up biotech requires a strong commitment from the country. Taiwan has a talented pool of professionals and good delivery systems which help to support the development of the industry.

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