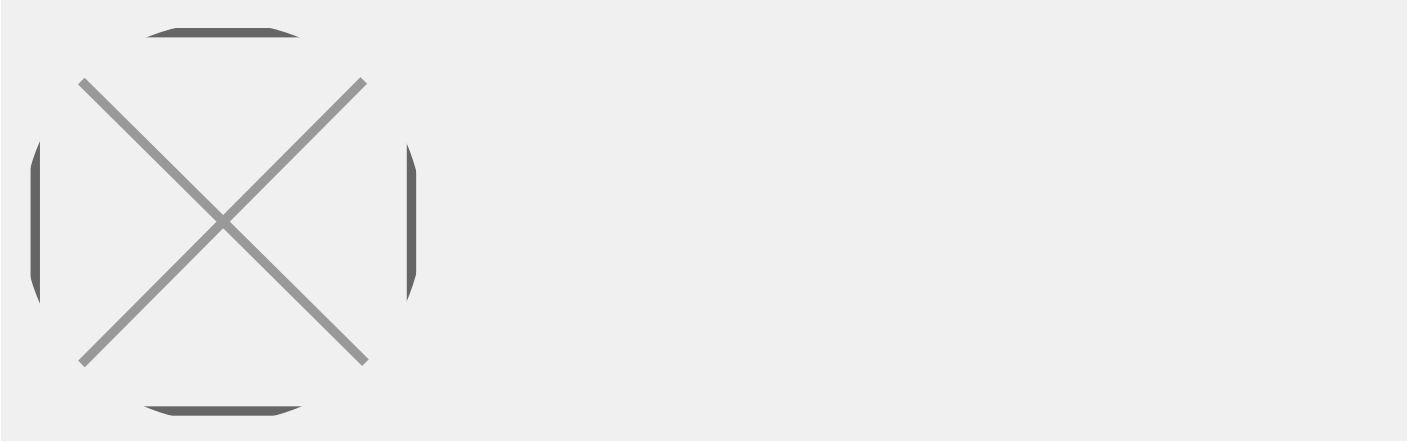
Interview: Dr. Leah Lo, President, Pharmaceutical Industry Technology and Development Center (PITDC), Taiwan



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The president of Pharmaceutical Industry Technology and Development Center (PITDC) considers the company's need to remain an international competitor and how to achieve it, the gap in new drug development in Taiwan, and PITDC's mission to bring the country's domestic companies to the international level.

What are your thoughts on the current strengths of the Taiwanese pharmaceutical ecosystem? Do you think there are pieces missing? Does it qualify as mature?

Taiwan has a very strong API industry. Although it is small, it provides specialty chemicals and high quality APIs for global needs. We are also one of the leading providers of excipients in the world.

In pharmaceutical formulation, we have almost 160 players operating today, and thanks to a government policy of proliferating PIC/S GMP, we now have more than 50 companies qualified for PIC/S GMP. There are also companies qualified by other health authority, such as US, Japan, Europe and Southeast Asia.

The reimbursement policy of the national health insurance program makes the domestic market particularly constraint. With price revisions coming every two years, this has certainly fueled the need to go global. In addition to Western markets and Japan, with ECFA, Taiwanese companies

have an excellent chance to capitalize on the Mainland China market. But we need to be aware that we must constantly improve our science and technology in order to compete internationally, even if today we look strong.

One area where the ecosystem is not strong enough yet is new drug development, but gradually we are seeing the results that are booming. One of the reasons we think that drug development in Taiwan is not so strong is because that the basic research is not well connected to the drug development stages. Most of the universities around the country mainly focus on basic research, but do not often evaluate whether or not it can be made into medicines. Although we have locally developed drugs undergoing clinical studies, there is room for improvement and growth in this area. The government is taking steps to improve this situation, but there is still a gap.

Do you think Taiwan can become internationally competitive in drug development and NCE?

In drug development, Taiwan does have some unique strengths because we have been working in this area for a long time. For example, our regulators are always keeping high standard on regulatory issues. This is our strength. I see a bright future for drug development in Taiwan. With NCE, I also see some locally developed projects going on, with around 13-20 small molecules or protein drugs currently on their way to clinical trials. We can gradually see the progress. There is light at the end of the tunnel, and this is encouraging for people in this ecosystem.

Where is Taiwan positioned in the global value chain? Taiwan wants to be present across the entire value chain, from drug discovery onwards. Is that too much to do for such a small country?

Taiwan looks at the pharmaceutical sector in a different way: we have a very wide spectrum in this area. It must be admitted that there are finite resources and talents in the country, despite the high level of education in the population. However, the humanity of this island people works very hard to stand out from an education standpoint and this gives both the country and the sector dynamism and diversity. This is the power making Taiwan different. We have many people involved in the drug development of small molecules, so gradually some of the results will come out. Although we are new for protein drugs, there are more and more people involved in the development of this area. I hope in the next ten years, some good projects will be completed that will encourage the rest of the sector. Although we have spent money in some areas that have not ultimately borne fruit, I would say that this is part of the learning curve.

International collaboration is one of the areas in which PITDC is focused. Multinational companies use the Taiwanese market for clinical trials, and do marketing and sales here, but they are not making connections with the local industry. Is this a missing component here?

I have a different opinion to yours on the extent of international collaboration in Taiwan. When I came back to this country, my job was in international collaboration at DCB, and later on I worked for NHRI, where we do have some international cooperation. For international collaboration to be successful, you need to be prepared to show something and share resources, and back then, Taiwan was rich and with many resources, and therefore in a good position internationally. Many foreign biotech companies came to Taiwan to collaborate with local companies.

Today, there are still some activities going on, but the resources are in short supply. However, companies are coming here to conduct their Phase III trials. We also put efforts in building up experiences in early-phase studies. The NHRI has devoted a lot of effort in this area, especially in clinical cancer research.

Taiwan used to have many big pharma companies establishing their manufacturing facilities here. We also have tried in the past to encourage big pharma companies to establish R&D centers here. But it has proven difficult for them to find funding to establish here, when mainland China is so tempting. However, the reality of operating R&D centers in China is that IP concerns make companies hesitant to develop important projects there. Six years ago, GSK was evaluating to set up their R&D center in Taiwan. Their goal was very clear that they would like to work with government. And for some other reasons, later on, it went to Singapore. Although companies are not establishing their R&D centers here, we can see more industrial-focused collaboration going on. PITDC is involved in this area by helping the domestic companies to cooperate with international distributors and pharma companies. Gradually, we are seeing some results from this.

To what extent has ECFA changed the Taiwan market dynamics?

ECFA will have a major effect on Taiwan market in the future. We are trying to harmonize certain regulations, and we have seen positive results. Although governments tend to harmonize regulations that are in their best interests, this should be true of any government: to put its own citizens and industries first. Taiwan and China, including high level governments and industries, are really having some conversation to work together in this area. We agree that Taiwan can be the gateway to China. With Chinese advantage, we can expect faster and cheaper R&D pyramid for botanic drugs or other products. The strength for mainland China is their large manufacturing

capacity. But this is also their weak part because they have to meet the most updated regulatory requirement. But for Taiwan, it is because we have to struggle for our lives, so we have devoted so much in R&D and have kept updated to meet the global standard. For the ECFA, we can see the good part is to bring together the global standard and R&D from Taiwan with the big market resources and large manufacturing capacity from China.

The PITDC is a part of the Ministry of Economic Affairs. Do you think that the pharmaceutical industry is already supporting the economy, or is that still coming?

I would say that we work hard to give people a better quality of life. For the economic side, the domestic market is very limited for local companies, partly because we have so many players competing for a pie of 26 million people. In order for the industry to have a significant economic impact, it needs to internationalize. When the government allocates its resources, it prioritizes ICT, because the sector offers huge capital returns compared to pharmaceuticals. But we contribute more in quality of life for the local population.

Do you think the government is betting on this industry for the future?

Yes of course. We have passed regulations to help and encourage biotech companies and individuals involved in drug discovery through tax holidays and subsidies. The policy is in place, such as “Taiwan Biotechnology Take-off Diamond Action Plan”, and the resources have been allocated.

What can you communicate to the international community about how the pharmaceutical industry is going to evolve in Taiwan?

We will work with global companies towards the market side in the future by building international collaborations that will help our companies to outgrow our small domestic market. We hope to bring more Taiwanese pharmaceutical products across the globe. We hope that in the meantime ECFA will continue to go smoothly. Today, we already have companies that have established strong links across the straits. With more harmonized regulations and mature products, people can see the advantage of working together across straits. We can work together to bring quality life to both sides of people.

What does the future look like for PITDC?

Technology-wise, we are looking for international collaboration with pharmaceutical companies. PITDC is an R&D arm to both local companies and foreign companies. Our strength is we are non-profit organization, and we have qualified people. We can also be partners, helping with

development, registration, and quality, for both pharmaceuticals and medical devices. We work very closely with domestic companies and will try our best to channel them to international companies and help them to strengthen their cooperation. Although we are not big in size, it is our mission to help the domestic industry to bring their products to the globe to make a better life.

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