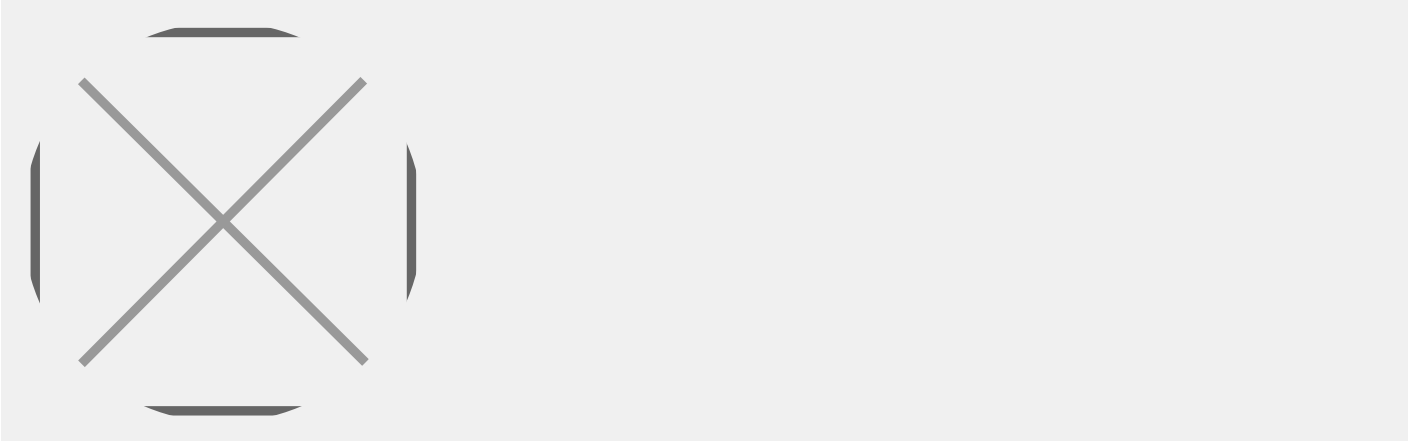
Interview: Jaw-Jou Kang, former Director General, Taiwan Food & Drug Administration (TFDA)



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Jaw-Jou Kang, former Director General of Taiwan Food & Drug Administration (TFDA) discusses the key successes the company has had since 2010, where it is looking to in the future and how a relationship with China would be mutually beneficial for both countries.

Since Taiwan Food & Drug Administration's founding in 2010, what have been the main achievements of the agency over these three years, and what have been the key lessons that you have learned about the role you need to play in the industry?

In the area related to drugs and healthcare, the agency's biggest achievement has been becoming a PIC/S member, which has been a major step in the development of our local pharmaceutical industry. As a result of becoming a PIC/S member, we have worked a lot to improve the quality of the drugs being manufactured in Taiwan. We have the aim of becoming the number one producer of generics in the world, when measured in terms of quality. This focus on quality has already yielded results, with a boost in the export of both generic drugs and APIs over the last two years. This is reflected in the growing stock price of Taiwan's leading pharmaceutical companies, which runs against the trend seen in the country's other major industrial sectors. We have also seen a record number of biotech companies being founded during this period, as investors gain confidence in the success of the Taiwanese pharmaceutical industry. We are also looking at playing a major role in the biosimilars segment in the years to come, and today we are putting in place the regulations in order to usher in this new age in the country.

In order to improve the quality of pharmaceuticals being produced in Taiwan, we have made a lot of changes to the drug review process, making it more transparent, setting up fast-track routes for the review of new drugs, and opening new avenues such as for botanical drugs. We have now shown our ability to run an independent review process for new drugs, and as a result, more and more international companies are coming to Taiwan to conduct their clinical trials.

We have heard a lot about the work the TFDA is doing with its counterpart in China, the CFDA, and we understand that when ECFA came into the market, it ushered in a new era of partnership and cooperation between Taiwan and China, as the two countries move towards harmonization of regulations and clinical trials. Can you tell us about the projects you are doing with the CFDA, and the goal of this collaboration?

We started working on this with the CFDA almost three years ago, but unfortunately, since this time, the organization has changed its head, as a reaction to food safety issues in China. Now, the head of the organization is a food safety expert. There will be major reforms to drug regulation in the country, which makes any kind of continuous planning difficult for us. However, we are engaged in meetings, and have set up a platform for communication that will remain continuous, even if there is new leadership, which will enable us to have fast, fluent communication between agencies.

We have also set up some test projects, including cooperation on clinical trials. We have agreed to set up a consortium to link the clinical trial centers in both China and Taiwan, so in the future, when applying for the NDA, the clinical trials in both countries can be linked together.

In addition, the CDE of CFDA and the CDE in Taiwan have signed a confidential agreement and will start exchanging the review experience and training of reviewers. We hope in the near future, we can set up a more close relationship in the review process, such as co-review or joint review in IND and NDA, under the guideline of ICH and GCP.

How far away are you from full mutual recognition of clinical trial results?

We have set up an agreement, which means that in principle, clinical trials are conducted with the same protocol, approved by both the CFDA and the TFDA, after GCP inspections, and the data will be mutually recognized. However, we still have some final details to agree upon, such as how many clinical trial centers are recognized in China, and how many in Taiwan. We are still working on this number, because we still have some small differences, but this has still been a major breakthrough. We expect that by August, the new leadership at the CFDA will be settled and we will be ready to move forward. In Taiwan, we are already ready: we have people ready to go to China to do the

inspections, and so after all these mutual inspections, we can properly begin our cooperation.

As well as this, both agencies have submitted several possibilities for working together on co-development projects. We are currently choosing from over a dozen cases, but both sides agreed that we would choose some special ones to start with. We now have a test trial case that has a prior NDA on both sides of the strait. We will learn through this cooperation, and in the future maybe we will conduct a joint review. We actually have the potential in the future to work on joint reviews not just with China, but other Asian countries, working towards a similar framework to that of EMA in Europe.

In China and Taiwan you are going through these processes for the first time. We have heard that Taiwan is very willing to harmonize standards with the west, but China is a little resistant to this. Is this a challenge you have come across?

It is true that China can sometimes be hesitant to adopt western standards, but at the same time, they recognize the importance of harmonization. However, for China the issue is not as pressing as it is for a small country like Taiwan, simply because of the size of the domestic Chinese market and the opportunity it presents. There is also an element of rhetoric involved: although policy wise, China seems very against close relationships with the west, in reality, the people in key positions seem to be in favor of it.

How important is the role of a regulator like the TFDA in creating globally competitive companies?

We are definitely part of the ecosystem, but it would not be fair to say that creating these companies is our responsibility alone. We do see the challenges in the market, and take steps to help companies address them. Right now, we believe the biggest obstacle in the way of the Taiwanese pharmaceutical industry becoming more globally competitive is the number of players in the market: if the major players were able to acquire smaller companies in the market, they would be able to scale up their operations. However, most companies in the market today are family-run, and extremely resistant to acquisition. I believe that this is a cultural problem more than anything else. However, there are a lot of new biotech companies starting up that are ignoring these traditions of family ownership, and this is where much of the investment is going today in the sector.

What are your thoughts on the future? What are the main programs that you are working on right now as the TFDA?

The most important program that we are currently working on is improving drug quality, because our major duty is still to the patient. I believe that in the future, with ECFA, Taiwan will become increasingly attractive for the big pharma companies. They could use Taiwan as a research center, doing early phase clinical trials here, and then moving later stage trials to China. However, the message from China is that any kind of agreements between us and them should be focused on the benefit for the two countries, not on the opportunities for multinationals, but I believe that in the end, we all have the same shared goals: what is good for us is also good for them.

How important internationally is the TFDA name nowadays? Do people respect the institution?

I believe so, and the PIC/S certification has certainly helped: today, countries like the US and Japan view the Taiwanese market with a lot more respect than they used to. We have had very positive feedback from international companies coming to inspect our facilities. Getting PIC/S certification was a huge responsibility for the TFDA as an agency, and we are working hard across the board to ensure compliance and maintain this new level of recognition.

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