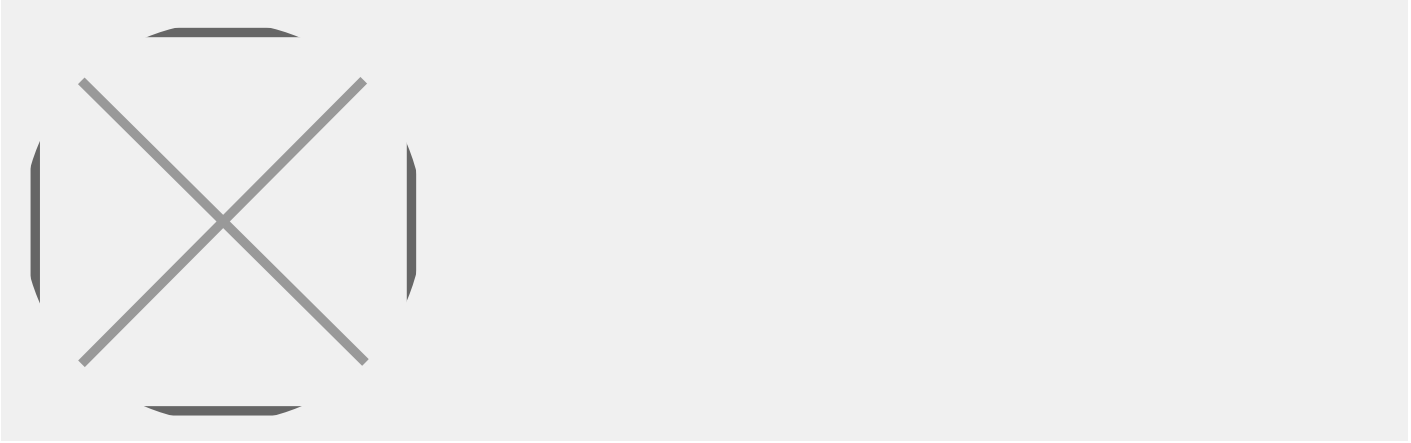
Interview with Jaw-Jou Kang, Director General, Taiwan Food & Drug Administration



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In January 2010, the Taiwan FDA was newly created from four existing agencies. What was the vision behind the creation of this new organisation? What did the government want to achieve in its creation?

Although all the administration work done today by the TFDA was already being done by the four pre-existing agencies, there were gaps between these different offices. Unification into a single Food and Drug Administration had been discussed within the Department of Health for over ten years, using the US FDA as a template. The main purpose of the reorganisation was to help these units to cooperate better, and to expand some of the work that has come about more recently, for example in the field of medical devices.

The main factor driving the change was a concern over food safety. By creating the TFDA we can try to foster a better relationship between administration and field inspection. Before we had the problem that the administration of the Bureau of Food Safety wanted to inspect every kind of food, but the inspection units were limited by analysis capacity and also manpower and budget. There was always conflict between the policy making unit and execution unit: this is why we wanted to combine them, so that policy making is more uniform. The similar situation also exist in pharmaceutical affairs.

Our government has put a lot of effort into drug development for the past few years, but there has not been approved a global innovative product as a result of these efforts. Since last year, the government realised that medical devices might be a key future industry for Taiwan. Taiwan has a

very good ICT industry, and this can provide a lot of help in the development of medical devices. Secondly, Taiwan is very good at transforming innovative ideas into prototypes. ITRI is currently working on many new innovations from all over the world. With this kind of cooperation, we hope that Taiwan can become a key medical device-manufacturing site in the world.

There are many factors that give a lot of potential to this idea. Taiwan is very strong at promoting and growing medium sized enterprises. This is very suitable for medical device development. North Asia is the fastest developing pharmaceutical market in the world, and will soon be comparable to the US and the EU. A lot of big pharma companies have difficulties entering the Chinese market because of regulations and conservative attitudes to business. The Taiwanese and Chinese governments have enjoyed a very good relationship since President Ma was elected in 2008. This year will see the signing of a treaty between China and Taiwan regarding the healthcare industry and regulations, and cooperation on clinical trials and new drug development. We are hoping that China will accept Taiwan's proposal for this type of collaboration, and this way that a lot of multinational pharmaceutical companies can use Taiwan as a bridge to enter the Chinese market.

Everything in the Taiwanese pharmaceutical market seems to be coming together, whether by chance or by good planning. How do you feel about the potential of the pharmaceutical industry to grow and develop in the years to come given the government's attitude to it, and what role will you play in helping to develop the industry?

Although no new drugs have yet been developed in Taiwan we see a lot of potential new drugs currently under development here. The TFDA is preparing itself for reviewing a brand new drug for the first time. We have ten more years experience from the previous institutions, and we have reviewed many new drugs, but these drugs have always been previously approved elsewhere, either in the US or Europe. However, we have built up the capacity for reviewing new drugs.

We are expecting at least three or four new drugs will come out in the next couple of years. We are expecting new medical devices coming out soon as well. In the export of medical devices to the United States, Taiwan ranks third.

Pharmaceutical companies look to the TFDA for speed and quality. How can Taiwan work with other countries in order to speed up these processes through harmonization?

As you might know, Taiwan has a unique political situation that means it cannot join a lot of international organisations, which makes it very difficult to communicate with other countries. The way that the TFDA has approached this problem is through bilateral cooperation: in April 2010 we signed a memorandum of understanding with the TGA in Australia for example. We also have exchanged letters with US, Switzerland and EU for information exchange of medical devices. Further to Exchange of Letter, we established Technical Cooperation Program with 12 Europe notified bodies to share GMP inspection report as acceptable evidence for submitting Quality

System Documentation applications to TFDA. This will speed up the process of foreign countries exporting their medical devices to Taiwan.

We hope that we can also do this for our international factory inspections, which costs a lot of manpower and travelling expenses if we have to go to each country to do inspections. So we are hoping that to sign agreements with the EU, and in this way exempt them from inspection, so we applied to join the PICS GMP association. We just submitted our application last month and are in the process of a review. If we can join PICS, then we can then consider adopt the factory inspection reports of PICS members in the future.

Another way that we are looking to speed up our processes is through a fast-track system. Most of the TFDA's reviewing processes for new drugs have been approved by the EU and the US FDA. We have set up an abbreviated, fast-track review system, which means that if a drug is approved by the US FDA and the EU, then we will go into this fast-track reviewing process, vastly reducing the time and the dossier that companies have to submit.

Also, in the future, if a company is developing a new drug and include Taiwan in its Phase I or II trial, then we can further speed up this the process by removing the need for a bridging study, which means these new drugs can enter the Taiwanese market earlier.

Mr. Huang of the TPMA said to us that a lot of his members are now also working towards making their facilities PICS standard. How do you assess the national industry and how are you helping to push it along as well?

Our second generation of national health insurance policy aims to bring all drugs up to the same levels of quality and the same price. Last year, the BNHI announced incentives, giving better prices if you have a PICS standard facility and a DMF for your drug. Because of these kinds of incentives, the whole pharmaceutical community is trying to meet the criteria. Our experience when we moved from GMP to cGMP leads us to believe that the number of local companies will reduce as a result of the increased quality requirements. An estimation by a local manufacturer said that there will be less than 100 local manufacturers in the years to come. We hope that the company mergence makes the number of manufacturers will eventually reduce to even fewer, and with this kind of capacity they can be competitive with the multinational pharmaceutical companies and go to international markets to compete.

At the time the TFDA was created, the Centre for Drug Evaluation (CDE) wasn't included in the grouping. What role do the two institutions play together?

We were hoping that both would be grouped together, but it turned out very difficult as the salary in the government agency is too low to hire qualified reviewers, especially medical doctors. When the creation of the TFDA was first proposed, I suggested that the reviewers of the CDE move into the

TFDA office and work in the same building to create a review unit , and this has been very successful.

With more than ten years of training we have the capability to review most cases. However, for these ten years, we relied a lot on our Advisory Committee (AC), because the reviewing capability in the CDE and before at the Department of Health was not as good as it is today. So the CDE did the reviews, and this decision was passed to the Department of Health who then consulted the Advisory Committee. This became a triangular situation and this made the industry very confused: they didn't know which agency was actually taking the final decisions.

Today we have the reviewing team from the CDE and also the people from the TFDA working together, they have all the knowledge and capability to do the reviewing. By using the reviewing model of the US FDA, there are only a few cases like brand new drugs and complex ethical issues that need the help of the Advisory Committee. It is now very clear that the AC is just an advisory committee, not the body taking the decisions. The industry welcomed this change, which makes the whole situation very transparent and simple.

What are your personal goals for the next few years? What would you like to achieve at the TFDA?

My main focus will be food safety issues, as that is our first priority. We are now very experienced in pharmaceutical affairs, so all that is needed are some slight changes: hiring more reviewers and eventually achieving a structure that is very similar to the Japanese model. Japan's PMDA do all the reviewing work, factory inspections and ADR reporting. Right now Taiwan does not have this kind of legal status for this kind of institution, but we are hoping that we will pass the necessary legislation in the near future. Assigning this legal status to the assigned agency is the only way that we can hire more hi-tech personnel and more MDs to do clinical reviews, and the only way we can have some breakthrough.

I think we are in a very good situation right now and I was hoping that we could have some achievements with bilateral agreements. Some countries are very sensitive to signing MoUs with Taiwan. We will do what we can to achieve some kind of mutual recognition with these countries at an industrial level. The first priority will be the EU, the US FDA, Korea, Japan and China. We are hoping we can achieve this in the next few years.

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