Tatsuya Kondo – Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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Dr. Tatsuya Kondo is chief executive of Japan's regulatory authority, the Pharmaceuticals and Medical Devices Agency (PMDA). Since taking the role in 2008, Dr. Kondo, a qualified neurosurgeon with wide-ranging experience in R&D activities, has been responsible for all the operations of PMDA, including relief for adverse health effects of drugs, drug and medical device reviews, and post-marketing safety measures. In this interview, Dr. Kondo discusses the importance of trust and transparency in his organization's operations, Japan's world-leading speed of drug approvals, and how PMDA positions itself in terms of regenerative medicine.

Standing at the midway point of the Agency's 2014-2019 strategic plan, how has it been proceeding in terms of execution?

The most important item, these past five years, has been winning the trust of the public, the industry and academia alike. This is something we have been steadfastly working towards for over a decade. To do that, we have needed to clarify our mission statement and overarching principles so as to ensure that everyone understands that our decisions are always made based on regulatory science. Secondly, we have made it our business to promote international harmonization, bearing in mind that pharmaceuticals and medical devices need to have a global reach.

What exactly do you mean by the term “regulatory science”?

“Regulatory science” has a vague definition in Japan as well as globally. The concept was first coined, back in 1987, by Dr. Mitsuru Uchiyama as the discipline that reconciles the fruits of science and technology with harmonious relations between people and society. The central tenet is to make accurate predictions, assessments, and judgments, based on real evidence. However, people’s perception of what “regulatory science” actually means tends to differ.

Two aspects are especially important here: “science for evaluation” and “science for regulatory engineering.” In terms of “science for evaluation,” for any pharmaceuticals or medical devices there are pros and cons. Therefore, you need to establish a holistic view by evaluating the product’s different aspects or dimensions. For “science for regulatory engineering,” if you identify any technology that may be useful for the future, you need to promote it at the same time as controlling it through regulation.

The PMDA represents the primary location for conducting this type of science. To advance this methodology it is necessary to engage in continued dialogue with the scientific community. There needs to be a mechanism which will enable reviewers at the organization to apply the latest, cutting-edge science to their practice. For that, we are undertaking two tasks. The first is to establish a “science board” where scientists from mainly academic societies can gather and engage in dialogue both between each other and with our staff. The second is to bring scientists who have made discoveries into the fold through having them work directly for the PMDA. The idea is to harmoniously blend regulatory science with academic science.

There is a lot of pressure both from pharma companies to be the first on the market and from patient groups to secure access to the latest treatments as soon as possible. How do go about practically managing this issue of speed?

My background is as a doctor, in hospitals, making new discoveries. My original aim when joining the PMDA was to make the regulatory authority understand what we doctors had been doing. On the other hand, I wanted those who invent and discover to know what this organization is supposed to think and do. Different objectives have to be aligned. Speed has to be balanced against safety and quality. The way to achieve this is through serious collaboration between industry, academia and policymakers. The science board has been established so as to develop and advance this sort of mutual understanding.

However, the people engaging with PMDA are not strictly academics, but representatives of the pharmaceutical industry, who may feel that increased regulatory strictness is causing costs of medicines to rise. Are they justified to claim this?

They are, of course, correct, but regulatory science can also help eliminate wastefulness. It all comes down to formulating rationally sound regulatory frameworks and then enforcing them consistently and properly.

PMDA enjoys the fastest approval timeframes in the world in 2015. Was this a deliberate target? And how was it attained?

Firstly, we grew the overall size of our staff and ensured they were well supported by academia, industry and government. Secondly, through the mechanism of the regulatory science consultation from the early stages of development, we managed to raise the caliber of expertise and knowledge. These two factors naturally translated into efficient approval timeframes.

Regulatory work becomes more challenging as the science of drug development itself becomes increasingly complex. Do you have a sufficient talent pool in Japan to cope with these new challenges? Is the language barrier ever a bottleneck?

Sourcing, attracting and retaining talent is always challenging and can doubtlessly be improved upon. As part of an older generation, my English is not perfect, but for the past ten years, I have encouraged younger people in our organization to routinely use English in their work. In an internationalized world, people need to use and speak English to stay on top of global trends. Most of the PMDA staff use and speak good English now. However, I do not want our employees to forget Japanese as that is our main operating language.

Obviously, your mandate as a regulator does not directly cover the issue of drug pricing. Nevertheless your actions can have an impact on the cost of drug development. Is this an issue that ever concerns the PMDA?

Of course we are concerned about price. It is not strictly part of our mandate; however, we have started an initiative called “Medical Information Database Network (MID-NET),” which, so far, has gathered the electronic medical records of about four million patients from around 23 hospitals and clinics in Japan. With this volume of records, we can start to investigate how prescribed medicines are being deployed and the resultant side effects on patients. The primary purpose of this is, of course, to increase safety. However, we can also leverage the data for other purposes such as post-marketing surveillance (PMS) and ensure it is captured when drafting policy. The ultimate aim is being able to predict the relationship between the efficacy and pricing of a drug. Therefore, perhaps in the future, the regulator will prove the efficacy of the drug rather than the company, which can shift the costs in that relationship.

A unique program in Japan is the ‘Strategy of Sakigake,’ which promotes ‘made in Japan’ innovation through a fast track of approvals. Does this initiative apply only to Japanese companies or to all companies innovating in Japan?

We support all innovation in Japan, especially if new pharmaceuticals and medical products are discovered in Japan, regardless of whether they are produced by Japanese or international companies. We strongly support international harmonization. The Sakigake designation system identifies innovative products at the early stages of development, and prioritizes the approval process. Through utilizing this system, I believe that innovative medical products are rapidly made available to the people of Japan and the rest of the world.

What results do you expect in the short and medium-term?

Promotion of the Agency itself is the main priority. We must increase understanding and awareness of what PMDA is and what we do.

Japan has attained a global leadership position in regenerative medicine. Can you explain your approach in this challenging field?

Tissue or cellular regenerative medicine products involve a lot of risks and can be considered quite dangerous. My research experience in cell culture taught me that many of the materials used are non-human and therefore dangerous when applied, as they are, directly to humans. In short, there

is a history of contamination. The most challenging issue is how to prohibit and regulate the contamination. This issue is gradually being overcome thanks to the efforts of scientists to decease the risks of contamination.

In terms of thinking about how we could approve these products, the Ministry of Health, Labor and Welfare (MHLW) amended the Pharmaceuticals and Medical Devices Act and also established a measure for conditional approval because it would take too long for companies to go through to the very end of the clinical trial stage. The relief system for suffers in Japan is another important point. If something disadvantageous for the patient occurs, such as side effects, there is a system in place to give relief. This applies to regenerative medicine products and helps manage risk. Patients who are sufferers of drug-induced effects or harm are also supportive of this widening of the application of the relief system.

In your experience today as a regulator, what do you believe are the most important public health problems in society today? And what is your message to our global audience?

We needed to develop and keep a mechanism or system which will facilitate trust in our day-to-day operations. Transparency and ethicality are absolutely crucial. It is also important to resolve any potential conflicts of interest. Innovation cannot be accelerated unless academia, industry and regulators work together hand in hand, with patients right at the center of everything that we do.

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