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International pharmaceutical companies [should] not only look at Japan as a single country, but also as the gateway to Asia

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In conversation at DIA Europe 2024 in Brussels, Shinobu Uzu of Japan's regulatory agency, PMDA, laid out the organisation's new five-year plan, how PMDA is hoping to incentivise more biopharmaceutical R&D in the country, and why Japan is "the gateway to Asia" in regulatory terms.

Yesterday's PMDA townhall started with the idea of mythbusting Japanese pharma regulation. What are the main misunderstandings that are you trying to correct?

The main misunderstanding is that Japan is mysterious, unknowable, and something of a black box. This may lead to international actors not considering Japan for investment and ultimately fewer innovative products making it to Japanese patients.

To correct this, we are proactive engaging internationally with other national regulators, international bodies, and individual companies – both big and small – to disseminate information about the transparent and efficient regulatory processes that exist in Japan. We are also publishing much more information in English in the hope of opening up the black box!

We should also remind international stakeholders of the history and expertise that PMDA holds. Our organization was one of the three founding members of the International Council for Regulatory Harmonisation (ICH), along with the EMA and FDA, and currently stands as the leading regulatory body in Asia. PMDA has contributed to regulatory harmonisation in Asia through both disseminating ICH guidelines as well as engaging in human resource development with other Asian regulators. We

are also an active member of several other international frameworks, including International Coalition of Medicines Regulatory Authorities (ICMRA) and Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), and continue to nurture deep collaboration with the EMA and FDA.

PMDA has a new Five-Year Plan up to 2029; can you outline its scope and aims?

There are three main aims. The first is enhancing the quality of PMDA's work through regulatory science. This covers everything from the consultation/review process to safety follow-ups, as well as the establishment of an emergency response system to deal with situations like pandemics. Secondly, we are engaging in more strategic international activities to inform and encourage overseas companies to develop new products in Japan. Finally, we are strengthening our governance and personnel.

Overall, the mission is to promote innovation and ensure rapid and stable access to innovative products. Against a backdrop of supply chain globalization, the emergence of new technologies, limited human resources, and the necessity of preparing for future pandemics, international collaboration will be crucial to achieving this mission.

PMDA will contribute to global health through international collaboration in terms of regulatory harmonisation, information sharing, and capacity building for developing countries. We are already a key player in the region through PMDA bilateral reliance schemes on the basis of good relations with Asian regulators that seek economic integration, and will develop further in the coming years, including through our new international office in Bangkok, Thailand. We have also moved to establish another international office in Washington DC, US.

Why were these two locations chosen for PMDA's international offices?

The rationale behind the DC office is fairly self-explanatory. The first is that we can make further collaboration with US FDA. The other is that the US is the global hub of innovative drug development and home to the most important bioventures. By having a PMDA office there, we will be able to engage with these companies earlier in the drug development process, explain our regulation to them, and ensure a smoother market access process if they eventually want to enter the Japanese market

The Asia office in Bangkok is all about strengthening our already-strong collaborations with ASEAN regulators. Since ASEAN is aiming for economic integration, through this office, we hope to support the promotion of regulatory harmonization among ASEAN countries directly, as well as drive the development of a regional clinical research network from regulator's viewpoints. Potential investors should be aware that ASEAN represents a population of 650 million and a GDP of USD 300 billion and is exhibiting steady growth. Taken together with Japan (population of 130 million and GDP of 540 billion) it is possible to access a substantial portion of the Asian market. PMDA can truly act as a "gateway to Asia" and create significant market opportunities.

A significant amount of global innovation is happening at small, US-based companies without the scale to consider Japan in their R&D programmes. Why is this an issue for Japan, and what is PMDA's plan to engage more with these companies?

Although small bioventures only account for 14 percent of global pharma sales today, these companies represent 80 percent of the global pipeline – meaning that they are assuming an increasingly important role internationally. However, very few of these bioventures are based in Japan. Additionally, while Japanese companies have a ten percent market share for synthetic chemical products, this drops to just three percent for new modalities such as biologics. All of this means that – unless action is taken to encourage drug development in Japan – our country and patients risk losing out on innovative new drugs.

Naturally, small US-based companies' first target is the US market, meaning that they initially pursue FDA approval. We would like these bioventures to instead consider global development including Japan as an attractive market in which to conduct multiregional clinical trials (MRCTs) and eventually enter.

To this end, we are engaging with companies earlier to show them how flexible and friendly PMDA is, and ultimately ensure that Japan is not losing out on innovation. Our regulatory processes boast a high level of predictability, there are a variety of consultations are available, and we offer a 90 percent discount on Regulatory Science consultation fees for academia and venture companies. Additionally, PMDA offers specific support for those companies with orphan drug designations, Japan has great expert doctors with years of experience in conducting clinical trials, and our country acts as a reference point for much of Asia. There is also a misunderstanding that Japanese Phase I studies are mandatory prior to MRCTs. This is not always the case, so we have issued new principles to clarify in which situations these studies are necessary

Do you feel that Japanese firms, with the support of PMDA, can also develop more biologic drugs in the future?

As a regulatory authority, PMDA does not have the remit to encourage the development of biologics in Japan, but there is clear support from the Japanese government for biopharmaceutical R&D and production.

Japan's problem is that our companies in general are late to the party with biologics. There are, however, some notable successes. Daiichi Sankyo, for its part, has developed some unique antibody drug conjugate (ADC) technology. Moreover, the blockbuster anti-cancer medication Opdivo was discovered by Nobel Prize Winner Tasuku Honjo before being developed by Ono Pharmaceutical in collaboration with BMS. In that sense, we are seeing the trend moving in the right direction.

Do you have a final message for our international audience?

PMDA is a founding member of ICH and the leading regulatory agency in Asia. We would like international pharmaceutical companies to not only look at Japan as a single country, but also as the "gateway to Asia" more broadly. We are open, flexible, and encourage any stakeholders with questions to approach us. By doing this, they can learn more about our work and find good solutions for introducing more innovative products to Japan and beyond.

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