

Closing Remarks from Vice President Naito

Thank you very much to all participants who joined this 7th APAC in Tokyo, firstly I would like to express my appreciation to all the lecturers and Head Director Mr. Kondo for their passionate and exciting presentations, thank you very much.

Greg Perry from the IFPMA started out by talking about trust, and that was a very good opening remark I believe, because after seven years of interactions among the members here, namely industry, regulators and academia, we have come to know each other well to foster these relationships of trust between us. Particularly, I am grateful to hear that the number of participants from regulatory agencies this time is the largest in the history of APAC. And this time I especially would like to say thank you to Dr. Cuong from Vietnam, Dr. Salmah from Malaysia, Dr. Wanchai from Thailand and Dr. Somani from India, as participation from the very top of the regulators is greatly appreciated by the organizers. Also I should point out this is the first time for Dr. Song from the industry association PhIRDA of China to participate in this group meeting, and we greatly appreciate it, thank you very much for joining.

This trust is derived from the fact that finally we know, among three constituencies of APAC, we share a common goal, “delivering effective and safer drugs to whoever needs them in our region in a timely manner”. Across the day the discussions on regulatory practices such as GMP and regulatory management of templates, post marketing evaluation, those were quite professional discussions, we were amazed by how intensively this was discussed by regulators, and that makes us again respect regulators for the great extent in which they think about quality and safety of drugs.

One thing from the RA session which was particularly interesting is early approval of drugs. We discussed many aspects of that. If I may extend my own feelings on conditional early approval, in these last five years or so, we are getting more human biological evidence in our hands at a much earlier stage using iPS cells or biomarkers, various genomic information, which enables us to present this data to regulators much sooner than before. This is quite an important challenge, because I believe we should not fail in our common understanding of early approval systems in Asian regions as we must not allow anything that may again cause some drug lag or regulatory lag. So human biology, combined with real world data and ICT, as well as other keywords like registry or surrogate end points, those are ideas and philosophies which will give us a lot of room to think about how we create an

Asian system for early approval.

We talked about ecosystems and I would like to reiterate the ideas of Dr. Nares on network effects, which are a key part of these ecosystems. Listening to those discussions I came to believe actually what we discussed for all seven years, we are trying to create an Asian ecosystem for pharmaceutical regulatory and discovery development, and of course the major players of the ecosystem are the patients, and what we need to create, as Dr. Nares touched on, is a unique platform for this Asian ecosystem. In the Asia region we are faced with diseases such as Neglected Tropical Diseases, malaria, TB, HIV, and if regulators, industry and academia can establish a system to find new remedies for these diseases with very quick review and early approval, if we can successfully establish such a platform, it will attract a lot of contributions from various parts of the world, and that is one of the network effects we can think about. And there are a lot of other network effects which we can dream about or imagine if we are able to successfully establish a unique platform through the collaboration of all three constituencies gathering here today.

Once again, thank you very much for your participation today, and I look forward to seeing you again at next year's event.