

8th APAC Opening Remarks: 4/9 (Tue.) 08:30-08:40

Mr. Nakayama welcomed nearly 400 participants from 14 economies, 90 from overseas, and 70 from national regulatory authorities including high ranking officers.

He showed his sincere appreciation to all who kindly agreed to join APAC and mentioned that APAC's mission can only be accomplished with the close cooperation of various stakeholders such as National Regulatory Authorities, Academia and Industry.

He appreciated the continued efforts of ATIM-TF, RA-EWG and DA-EWG and showed his expectations for new topics at the 8th APAC such as Stability Data Requirement for Post-Approval Changes, Reliance Pathway for Approval of Innovative Medicines in APAC and Revitalization of Drug Discovery using Natural Products by Open Innovation in Asia. In addition to that, Mr. Nakayama also appreciated other two initiatives, namely Value-Based Healthcare and a new integrated report named "Pharmaceutical Market and Regulatory Environment in Asia."

Mr. Nakayama referred to JPMA's "Policy Recommendation 2019". He emphasized necessity to consider methods and systems to assess multifaceted values of drugs from both objective and expert perspectives. He also mentioned, with regards to the reform of the healthcare and social security system, about three points as JPMA's basic stance; balancing "promotion of innovation" and "maintaining Universal Health Coverage", realizing both "reducing the national burden" and "improving the quality of healthcare", and "extending the healthy life expectancy and improving the future nation's quality of life."

Mr. Nakayama said that he believed it meaningful to share with the APAC participants joining from Asia the recognition about the ongoing environmental change of society and the economy in Japan, and deepen mutual understandings about how we should address the issues, because it's just a matter of time that all the countries and economies would face the same challenge. He expressed his wish that he would be more than happy if all the participants could bring back valuable takeaways through today's program especially from the VBH session.

Mr. Nakayama concluded his remarks by saying, "I would also like to have

stakeholders' understanding and continued support to APAC's activities toward the realization of our common goal "To expedite the launch of innovative medicines for the peoples in Asia."