Opening Remarks by
Mr. KIYA Masahiko, Ambassador of Japan to ASEAN

ASEAN-Japan Medical Devices Regulatory Symposium
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Prof. Dante Saksono Harbuwono, Vice Minister of Health,
Prof. Dr. Hamdi Muluk, M.Si. Vice Rector of UI for Research and Innovation,
Ms. ENDO Ayumi, Office Director of Asia Training Center and International Cooperation (OAIC), PMDA,
Distinguished guests, ladies and gentlemen,
Good morning.

(Introduction)

I would like to express my sincere gratitude for giving me the opportunity to make remarks at ASEAN-Japan Medical Devices Regulatory Symposium today.

I am pleased that so many people have gathered here in Jakarta for this symposium, both on-site and online.

I would first like to express my deep appreciation to all those who contributed to organizing this symposium, from the Ministry of Health of the Republic of Indonesia, the University of Indonesia, and Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

(Objective of the symposium)

Medical devices are essential for diagnosis, prevention and treatment of diseases in every country. To enhance patients' benefit, the prompt introduction of innovative and safe medical devices to medical and healthcare practice is highly significant. They include Software as Medical Devices (SaMD), AI and IoT.

This symposium, along with the two-day seminar to be held starting tomorrow, will provide a platform for regulatory authorities to share knowledge and experiences regarding medical device regulations and to promote capacity building. In addition, it also aims to deepen understanding towards the harmonization of regulations. These efforts contribute to ensuring fair access to safe, effective, and innovative medical devices in the ASEAN region.

(ASEAN-Japan cooperation in this field)

In the Implementation Plan of the Joint Vision Statement adopted at the Commemorative Summit for the 50th Year of ASEAN-Japan Friendship and Cooperation in 2023, ASEAN and Japan expressed their commitment to promoting cooperation on the expansion of access to quality health services, pharmaceuticals and medical devices for non-communicable diseases, including training in regulating pharmaceuticals and medical devices through platforms such as the PMDA-ATC (Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs).

This symposium, along with the seminar, is another concrete manifestation of our commitment.

Furthermore, following the ASEAN-Japan Risk Management Plan Symposium held in 2022 and 2023, Japan is supporting this Phase 2 project through Japan-ASEAN Integration Fund (JAIF), in collaboration with Japan International Cooperation Agency (JICA), reflecting our long-term commitment to the health sector.

(Role of PMDA)

At the center of these efforts is Japan's PMDA, which has strengthened its engagement in the ASEAN region, including the opening of its Bangkok office in July last year. PMDA is key to Japan's support for the health sector in ASEAN. The Mission of Japan to ASEAN strongly supports PMDA's efforts and will continue to do so for further development of the health sector in ASEAN.

(Conclusion)

I sincerely hope that today's symposium, along with the two-day seminar starting tomorrow, will be a great opportunity for each and every one of you, not only to strengthen ASEAN in this important field of medical device regulation, but also to deepen ties and friendship between ASEAN and Japan.

Thank you very much for your attention.

(End)