



Speakers in charge at PV Workshop for Balai POM

Badan POM provincial offices (Balai POM) play important roles in overseeing the safety of drugs circulating as a pharmacovigilance (PV) center in their jurisdiction. In 2020, as many as 22 Balai POM have carried out these functions and the number was targeted to increase to 28 by 2021, so that all Balai POM could be functioned as PV centers by 2022. Based on the development of Balai POM, the webinar for Balai POM was organized on 6th-7th July 2020 to increase their understanding and competence on drug safety control and PV functions.

Dra. I Gusti Ayu Adhi Aryapatni, Apt also shared her experience when visiting Ministry of Health, Labour and Welfare (MHLW), pharmaceutical companies, local governments, and hospitals in case of JICA's country-study program in Japan. The awareness and responsibility of the pharmaceutical industry through the marketing business in Japan is well recognized, as evidenced by product recall data that has more voluntary recall than mandatory recall. ADR reporting in Japan by healthcare professionals was not optimal as in Indonesia, however, pharmacists in each hospital ward really helped to increase ADR reporting. Several important findings were obtained from their visits, including increased supervision through strengthening regulations and coordination with related stakeholders. She recommended that Badan POM immediately has a reference in implementing Good Pharmacovigilance Practice and Risk Management Plan, for both Badan POM and pharmaceutical companies as the owner of products, and that awareness of drug safety/PV needed to be improved by increasing the competence of Balai POM /Loka officers, pharmaceutical industry, healthcare professionals, and the public.

This event had 165 participants, with following 6 speakers through zoom meeting. It was started with Dra. Rita Endang, Apt., M.Kes and Dra. Tri Asti Isnariani, Apt, M.Pharm by showing PV system in Indonesia; continued by Mr. Yohishiko Sano, JICA expert, giving presentation regarding Japan's PV system and local government's inspection to pharmaceutical companies; dr. Jarir At Thobari, PV expert, from Universitas Indonesia explaining about basic PV, adverse event and adverse drug reaction, and causality assessment; dr. Febria Rehinatha from PT AstraZeneca Indonesia briefing the implementation of PV in pharmaceutical industry including PV quality system and preparing summary of PV system, spontaneous report and signal management, development of PSUR/PBRER and post authorization safety study.

This webinar informed that Balai Pom, Pharmaceutical Industry, Healthcare Professionals, and the public need to increase their awareness of pharmacovigilance activities. Particularly, Balai Pom need to boost up their skill and knowledge. The quality of reporting, compliance of PV system implementation must be regularly identified and monitored. JICA project appreciates it, if this webinar successfully contributes to strengthening PV function in Balai POM further



All participants: Photo Session after Workshop