

Pharmacovigilance (PV) is one of Indonesian FDA programs that oversee and supervise post-market drug safety. In the midst of the pandemic, JICA continued to support the role and function of drug surveillance system in Indonesia and conducted an online PV inspection guideline workshop to strengthen the PV system in Indonesia in collaboration with Indonesian FDA. More than 70 participants from BPOM and UPT BPOM officers from Jakarta, Bandung, Serang, Semarang, Surabaya, Yogyakarta, Padang, Medan, Palembang, Bogor, Tangerang, Kediri and Surakarta contributed in this workshop. This activity is expected to improve Indonesian FDA officer capabilities and competency in terms of PV inspection through discussion and information sharing on Japan's cases.

This workshop was initially opened by Dra. Mayagustina Andarini, Head of Deputy for, Narcotics, Psychotropic, Precursors, and Addictive Substances Control of Badan POM. She emphasized the importance of PV inspector to bring awareness of more qualified PV management to pharmaceutical industry. Mr. Yoshihiko Sano, Chief Officer of JICA-BPOM Project gave presentations about how PV systems were implemented in Japan and how PV inspection was conducted by Osaka local government. In terms of PV inspection, according to his presentation, Osaka local government conducts two types of inspections: renewal inspections (every 5 years) and midway inspection (while the company still has a permit). >>

He also showed an example of a note of findings from an Osaka local government inspection. For example, if any producers or distributors were late in reporting adverse drug reactions, Osaka local government will direct them.

Four PV inspectors were invited to give an overview of the PV inspection to the participants. Dra. Tri Asti Isnariani, and Dra. Ega Febrina, explained about PV regulation and inspection for Pharmaceutical Industries in Indonesia; Ms Megrina Dian Agustin presented summary of PV system (SPS); and Dra. Fachdiana Fidia, illustrated the tools for PV inspection in detail. Furthermore, working group discussion was conducted for simulation of PV inspection and make an interim report. Each group divided by 3 different topics which are: Organization, Personalia, and Training; PV Report Handling Procedure and Implementation; Documentation, Data Management, PV Audit, and PV Agreement. The result were presented to another participants.

During the Q&A session and group discussion, all participants showed their enthusiasm for the whole sessions by participating actively. One of the participant stated at the end of the activity that the workshop was both interesting and informative. Participants were able to interact with each other through reciprocal case study sessions, despite the fact that the session was fully online. JICA Project hopes that PV inspectors in central/provinces will continue this activity to deepen their understanding on PV inspection by way of online or offline.

