To promote patient-public engagement in Japan

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1. PMDA

Patient voice is necessary to develop and provide innovative products to patients. Patients are involved in drug development and risk management in EU and US for long time. In EU, patients are already important key player in regulatory affairs. Patients are involved in scientific committees of the European Medicines Agency (EMA) which is regulatory agency in EU, and make comments from the view point of patients to drug development, review for regulatory approval, regulatory actions for risk management and so on. Hospitals of EU have patients panel to make advice to informed consent/study design for clinical trials. In some panels, the members are children and they make comments to as experts.

How about in Japan? Drug developments are proceeded by industries, academia and regulators. Patients are not involved although they are one of important stakeholders to promote patient access. To involve patients and citizens to drug development, some actions are recently taken by stakeholders. For example, the Pharmaceuticals and Medical Devices Agency (PMDA) established Patient Centricity Working Group to promote patient and citizens engagement to drug development in May 2019. The group is planning to publish a guidance by 2021. It started experience sharing with foreign regulatory agencies and communication with patient groups. Patients groups expect such tidal current. Understanding of real meaning of patient-public involvement and method to promote it are key in Japan.