S13-6 Regulatory perspective to use pharmacogenomics/biomarker in drug safety

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Application of pharmacogenomics (PGx) and biomarker (BM) has the potential impacts to improve drug development efficiencies and proper usages of drugs in clinical practices. To translate PGx/BM into clinical practices, however, multidisciplinary challenges such as cost and time in drug development, processes of (genomic) BM qualification, PGx/BM test availabilities and reimbursements, and educations on PGx still remain in clinical, pharmaceutical and regulatory settings.

In April 2009, Pharmaceuticals and Medical Devices Agency (PMDA) started the scientific consultation on PGx/BM qualification which is focusing on general strategy for using PGx/BM in drug development. PMDA has also been taking actions toward international harmonization (e.g., ICH, J-VXDS) to promote PGx/BM application in drug evaluation. These approaches in PMDA will contribute to create a foundation for regulatory implementation of PGx/BM in drug evaluation, including drug safety.