PMS System in Japan

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Before new medicines are approved or cleared for the marketing, clinical studies of these medicines are usually implemented over a limited period and on limited number of subjects of restricted population. Once approved and marketed, however, these new medicines can be prescribed to various patients who were mostly exlcuded from the preapproval studies, and in the clinical situations which were not tested before. The Post-Marketing Surveillance(PMS) is to ensure evaluations of medicine's efficacy and safety claimed in the pre-approval clinical studies, and to gather clinically relevant information that was hard to obtain before approval. Unlike most western countries where spontaneous reporting of Adverse Drug Reactions(ADR) is popular, Japan is unique in that they require pharmaceutical industries to perform the PMS for all new medicines on a legal basis after approval. The authors summarized and presented the PMS system in Japan, which include the Standard for Good Post-Marketing Surveillance Practice(GPMSP), basic concept of PMS investigations, types and contents of information to be collected, types of purposes of PMS investigations, and introduction to Drug Use Investigations and Special Investigations.