S42-7 Drug Safety Measures using the Adverse Drug Reaction (ADR) Report Database of the PMDA (Pharmaceuticals and Medical Devices Agency)

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Regarding ADR reporting in Japan, it is mandatory under the Pharmaceutical Affairs Law that Marketing Authorization Holders (MAHs) who obtained information on ADRs should report ADRs to the PMDA. The ADR reports submitted to PMDA have serious outcomes such as death or are defined as serious by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). There are more than 25,000 ADR reports from MAHs, etc. per year. The ADR Report Database of the PMDA has accumulated such data since April 2004. On the PMDA website, these ADR reports are available in a line-listing including data of suspect drug(s), co-suspect drug(s), adverse event(s), underlying disease(s), age, sex, etc., and can be searched using the specific name of a drug or adverse event. On the other hand, regarding post-marketing safety measures, investigation of signal detection methods in ADR database is in progress using a data mining approach. If the accumulated data include a significantly higher number of reports on a certain adverse reaction to a specific drug, safety measures may be required. Some of the signal detection methods have already been introduced into routine practice in the regulatory authorities worldwide. The PMDA is working toward the establishment of a safety measure procedure using a data mining approach and toward the introduction of the procedure into practice.