S42-3 Drug Safety Information from Overseas Regulatory AgenciesNational Institute of Health Sciences

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Collection and analysis of post-marketing safety information are crucial for ensuring the safety of pharmaceutical products. Our division surveys post-marketing drug safety information issued by overseas regulatory agencies, such as the FDA, the EMEA, and the MHRA and posts it on the home page of our institute as "Overseas Drug Safety Information (in Japanese)" every other week (http://www.nihs.go.jp/dig/jindex.html).

In 2008, following safety concerns have been issued by overseas regulatory agencies: the risk of tumor progression by recombinant human erythropoietins, fibrotic cardiac valvulopathy by anti-Parkinson's drugs and mortality in older adults with dementia by conventional antipsychotic drugs, and the possible association between myocardial infarction and anti-HIV NRTI drugs, atrial fibrillation and bisphosphonates, cancer and ezetimibe/simvastatin, asthma and paracetamol in children, and so on.

In this symposium, we select recent representatives mostly from the information based on the scientific studies published in medical journals, such as the results of clinical studies and case-control studies, and introduce several lines of evidence that supports the safety information issued and the measures taken by the authorities.