S14-3 Safety Information on Psychotropic Drugs from Overseas Regulatory Agencies

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Our division surveys post-marketing drug safety information issued by overseas regulatory agencies, such as FDA (USA), EMEA(EU), and MHRA (UK), and posts it on the homepage of our institute as " Overseas Drug Safety Information (in Japanese)" every other week (http://www.nihs.go.jp/dig/jindex.html).

In 2009, the following safety information on psychotropic drugs has been issued. The risk of suicidal thoughts or behavior associated with antiepileptic drugs was suggested by the FDA, which was based on the findings of the FDA's review on this class of drugs. The risk of congenital malformations in fetuses from women using antiepileptic drugs was noted by the TGA (Australia) and MedSafe (New Zealand). The possible risk of cardiovascular and cerebrovascular disorders, and psychiatric disorders in children using methylphenidate -containing medicines for the treatment of attention deficit/hyperactivity disorder (AD/HD) was indicated by the EMEA. After reviewing the safety of these medicines, the EMEA concluded that the benefits of these medicines continue to outweigh their risks, but that new recommendations on prescribing the medicines and on pre-treatment screening and ongoing monitoring of patients are needed to maximize the safe use of these medicines. Following this recommendation, the MHRA has updated the guidance on safe and effective use of methylphenidate in AD/HD. As to another drug for AD/HD approved in several countries, the FDA and the Health Canada investigated their adverse reaction database and issued safety information.