Recent Amendment of OTC Medicines Sales System: Process and Implication

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The partial revision of Pharmaceutical Affairs Law was adopted by Japan's Parliament and published in June 2006. One of the major pillars of this revision is a comprehensive review of the OTC medicines retailing system. Under the revised Pharmaceutical Affairs Law OTC medicines were classified into three categories based on the extent of their risk as described below, and the classification was implemented on April 1st, 2007.

Category 1 OTC medicines: OTC medicines need special attention because of their action or those for which the period after approval is less than that required by Ministry of Health, Labor and Welfare. Category 2 OTC medicines: Those medicines whose side effects may possibly cause health hazards to the extent of daily life disruption. Category 3 OTC medicines: Those medicines which may not affect our daily activity, but may cause slight physical discomfort. Category 1 medicines need to be handled by pharmacist and information must be given to consumer with written document. OTC medicines in Category 1 and Category 2 can be handled by pharmacist or other registered sales staff.

The background of this amendment and the anticipated problems to be solved before its full implementation will be discussed.