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Japan approves Humira for Crohn's disease patients

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Singapore: Japan's Ministry of Health, Labor and Welfare has approved the use of Humira in induction and maintenance of clinical remission in patients with moderately to severely active Crohn's disease. Abbott Japan and Eisai, also headquartered in the country, received a notification from the ministry that the "all-case surveillance" drug use results survey condition required for approval of the Humira pre-filled syringe 40 mg or 0.8 mL for subcutaneous injection, a fully human anti-TNF-Î± monoclonal antibody, has been lifted.

In Japan, Abbott Japan is the marketing and manufacturing authorization holder for Humira, while Eisai is responsible for distribution. The two companies are working together to promote the product under a one-brand, one-channel, two-promotion scheme.

In October 2010, the ministry approved moderately to severely active Crohn's disease as an additional indication for Humira with the following condition for approval: "To promptly obtain safety and efficacy data on the drug and ensure that appropriate measures are taken to establish its proper use, a post-marketing drug use-results survey of all Crohn's disease patients receiving Humira must be conducted until sufficient data can be collected for a predetermined number of cases."

The ministry lifted this condition for approval based on a review of safety and efficacy data on Humira submitted to it in an interim report outlining analysis results of the all-case surveillance of 704 patients with moderately to severely active Crohn's disease.

Clinical studies of Humira have been carried out extensively to date and a wide literature of clinical data exists on the drug. Today, Humira is administered to more than 600,000 patients worldwide.