

AZ, Takeda, Mitsubishi, Eisai to jointly wipe out *H. pylori* in Japan

03 September 2012 | Regulatory | By BioSpectrum Bureau

AZ, Takeda, Mitsubishi, Eisai to jointly wipe out *H. pylori* in Japan



Singapore: Takeda, AstraZeneca, Mitsubishi Tanabe and Eisai submitted a joint application to Japan's Ministry of Health, Labour and Welfare seeking approval and subsequent coverage under Japanese National Health Insurance (NHI) of *H. pylori* gastritis as an additional indication for the eradication of *H. pylori* by concomitant therapy with four proton pump inhibitors—lansoprazole, omeprazole, rabeprazole sodium and esomeprazole magnesium hydrate.

These are manufactured and marketed by the four companies in Japan under five brand names. This concomitant therapy consists of a proton pump inhibitor, amoxicillin hydrate (marketed under two brand names) and either clarithromycin (marketed under two brand names) or metronidazole (marketed under one brand name).

H. pylori gastritis is also known as chronic active gastritis due to the fact that it causes histological gastric mucosal injury as a result of the persistent infiltration of inflammatory cells in the gastric mucosa due to *H. pylori* infection, and is believed to be associated with the development of various *H. pylori*-related diseases such as gastric and duodenal ulcers.

However, under the Japanese National Health Insurance (NHI) system, the approved indications for eradication of *H. pylori* are currently limited to gastric and duodenal ulcers, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and the stomach after endoscopic resection of early stage gastric cancer.

The companies submitted the latest joint application based on the said published evidence in accordance with the "Handling of Ethical Drugs for Off-label Use", Notification No 4 of the R&D division / notification No 104 of the Evaluation and Licensing Division, dated February 1, 1999. The four companies expect that, once approved, this additional indication will significantly contribute to the prevention and treatment of diseases related to *H. pylori*.