

## **Daiichi Sankyo Espha's TB drugs approved in Japan**

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Japan' Daiichi Sankyo's domestic subsidiary, Daiichi Sankyo Espha Co Ltd. has obtained approval for partial changes concerning a supplementary indication of their synthetic broad-spectrum oral antibacterial agents, Cravit Tablets 250mg and 500mg, Granules 10% (Levofloxacin hemihydrate). These drugs are marketed by Daiichi Sankyo, and Levofloxacin Tablets 250mg DSEP and 500mg DSEP, Granules 10% DSEP, marketed by Daiichi Sankyo Espha, for the treatment of pulmonary and other tuberculosis disorders.

This supplementary indication came as a result of Daiichi Sankyo being asked by Japan's Ministry of Health, Labor and Welfare to develop a drug for tuberculosis following a supplementary indication investigation by the 'Review Committee on

## Unapproved Drugs and Indications with High Medical Needs'.

In addition to this drug providing a new option for patients in need of tuberculosis treatment, as part of its CSR efforts, Daiichi Sankyo says that as a company it is committed to making unapproved and off-label drugs available to the patients who are waiting for them.

In Japan, around 20,000 people are newly diagnosed with tuberculosis each year. Some patients, however, do not continue treatment using first-line drugs because of resistance to or side effects resulting from the drugs. Levofloxacin is the only fluroquinolone-type antibacterial agent approved as an anti-tuberculosis drug in Japan, and it is hoped that it will be an effective treatment taken in combination with other anti-tuberculosis drugs.