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Daiichi seeks approval of Topotecin use in children

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Singapore: Daiichi Sankyo has submitted a supplemental new drug application to Japan's Ministry of Health, Labor and Welfare for an additional indication for Topotecin 40 mg and 100 mg (irinotecan hydrochloride hydrate) for pediatric malignant solid tumor.

The ministry officially requested that Daiichi Sankyo develop Topotecin intravenous drip infusion for this indication, as a result of discussions by the review committee for unapproved or off-label use of drugs with high medical needs on March 23, 2012. It was subsequently determined at the committee meeting held on October 3, 2012, that an application for this additional indication based on evidence in the public domain would be appropriate.

A preliminary evaluation was conducted on October 31 at the meeting of the second committee on new drugs of the Pharmaceutical Affairs and Food Sanitation Council, and the application was permitted.

As a part of its corporate social responsibility effort, Daiichi Sankyo is committed to making unapproved or off-label use of drugs with high medical needs available to patients who are waiting for them to be approved. Working group held by the MHLW that aims to accelerate the development process for drugs not yet approved in Japan but available in Europe and the US.