

Subject: TBT notification (G/TBT/N/JPN/461) by Japan on pharmaceutical product

Kind Attention Mr. N.R. Munjal, Chairman, PHARMEXCIL.

Dear Mr. Munjal,

This has reference to TBT notification (G/TBT/N/JPN/461) dated 28th of June, 2014 which has been issued by the Ministry of Health, Labour and Welfare, Japan. The regulation is with regard to Substances with probable effects on the central nervous system.

HS Code

The HS Code for the product is 30

Draft Regulation

The Minister of Health, Labour and Welfare of Japan proposes to designate the following substances as “Shitei Yakubutsu” (designated substances). Manufacture, import and sale of “designated substances” are banned except for the “proper uses”

- The proposed substances as “Shitei Yakubutsu”

1. **.N-(1-Amino-3-methyl-1-oxobutan2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide**
2. **. Methyl 2- [1-(5-fluoropentyl)-1H-indazole-3-carboxamido] -3-methylbutanoate**

- The “proper uses” for all “Shitei Yakubutsu”, designated based on the Law are as follows

1. To be used for researches or tests at the government, the local governments, agencies thereof, technical colleges, inter-university research institutes, the independent administrative agencies and the local independent administrative agencies
 2. To be used for tests under the Pharmaceutical Affairs Law, and
 3. To be used for forensic use

For more details about the regulation, please find attached the regulation and TBT notification for your reference.

India exports these products to Japan, hence, this approval requirement, if implemented, will significantly impact the registration strategy and timeline of the notified products for India's exports.