NO DCGI APPROVAL REQUIRED FOR CLINICAL TRIALS FOR ACADEMIC PURPOSES

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The Ministry of Health and Family Welfare, vide its notification No. G.S.R. 313(E) dated March 16, 2016, amended Rule 122DA of the Rules to segregate procedures of approval for clinical trials of drugs intended for academic and marketing purposes. As per the amended Rule 122DA, no permission is required to conduct clinical trials for academic research on drug formulations approved by the Ethics Committee. This exception covers clinical trials for new indications, routes of administration, dose or dosage forms of drugs. Prior to this amendment, researchers had to seek approval from DCGI for clinical trials for academic purposes, in the same manner as pharmaceutical companies' application for approval of new drugs. It included many stages and clearance from multiple committees, and hence delayed research and development activities related to drugs developed for treatment of cancer and other such critical medical conditions.

PSA view: This move not only makes clinical trials for academic research on drugs more cost effective and efficient, but also promotes innovation in terms of treatment of critical maladies like AIDS, cancer, etc. The exemption from DCGI approval reduces timelines for research and development activities in the country while maintaining vigilance through Ethics Committees.

Validity of free sale certificates for domestic medical device manufacturers increased

The DCGI has requested state regulators to extend the validity of free sale certificates required by domestic medical device manufacturers for exports so that they expire only alongside the manufacturing license. Free sale certificates which are issued to medical device manufacturers by state licensing authorities were initially valid for two years. In 2015, the DCGI has extended this to five years, subject to validity of manufacturing license. In order to export medical devices, manufacturers need to register with the foreign country and obtain its regulatory approval. These foreign regulators generally ask for a free sale certificate to allow imports. Notified medical devices are regulated as "drugs" under section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 ("Act"). As of now, only 15 medical devices are notified and regulated for import, manufacture and marketing in the country. This proposed extension on free sale certificate validity will apply only to these 15 notified medical devices.

PSA view: This move comes in light of incessant requests from medical device manufacturers with a view to promote exports. The limited validity period of free sale certificates used to restrict registration by domestic manufacturers and exporters with overseas authorities. It also added to re-registration costs of overseas

importers. For medical devices not covered as drugs under the Act, the certificates are issued by the Directorate General of Foreign Trade (DGFT).

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