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LAW OFFICES INDIA

LIFESCIENCES AND HEALTHCARE SECTOR

Regulatory Update – New Drugs and Clinical Trials (Amendment) Rules, 2024

On 19 September 2024, the Ministry of Health and Family Welfare (**MoHFW**) issued a notification amending the New Drugs and Clinical Trials Rules, 2019 (**"NDCT Rules"**). The New Drugs and Clinical Trials (Amendment) Rules, 2024 (the **"NDCT Amendment Rules"**), will come into effect on 01 April 2025. This amendment introduces several critical changes aimed at enhancing the oversight of clinical trials in India, with a particular focus on the role of Clinical Research Organisations (**CROs**) in clinical trials.

Similar to the CROs conducting clinical investigations under the Medical Devices Rules, 2017, the NDCT Amendment Rules have now defined CROs. The definition of CROs under the NDCT Amendment Rules encompasses both commercial and academic bodies involved in clinical trials and bioavailability or bioequivalence studies. One of the major changes brought in by the NDCT Amendment Rules is the mandatory registration requirement for CROs. Earlier, under the NDCT Rules, only bioavailability and bioequivalence study centres were required to register with the Central Licensing Authority (**CLA**). Upon this amendment coming into effect, all CROs will have to register with the CLA before conducting any clinical trial, bioavailability, or bioequivalence study on new or investigational drugs in human subjects.

The NDCT Amendment Rules have also introduced a mechanism to keep oversight on CROs through inspections which includes inspection of the premises with or without prior consent of the CROs. CROs that contravene the provisions of the NDCT Rules as amended by the NDCT Amendment Rules, will face a range of penalties, including warnings, cancellation of registration, or even the rejection of clinical trial results.

The NDCT Amendment Rules aim to establish a structured framework for CRO operations in India, designed to strengthen regulatory compliance within the clinical research sector. While the intent behind the legislation is clear and prudent, the industry's response to these new regulations remains to be seen.