October 2024

New Drugs and Clinical Trials (Amendment) Rules, 2024

The Ministry of Health and Family Welfare has on September 19, 2024, announced significant amendments to the New Drugs and Clinical Trials Rules, 2019 ("**NDCT Rules, 2019**"). The latest changes, encapsulated in the New Drugs and Clinical Trials (Amendment) Rules, 2024 (**"NDCT Rules, 2024**") intend to streamline the approval process for new drugs and clinical trials, improve patient safety protocols, and ensure compliance with global standards.

Key changes in the NDCT Rules, 2024

1. **Definition for Clinical Research Organisation**: The NDCT Rules, 2024 has now introduced a definition for "**Clinical Research Organisation/CROs**" which means the sponsor or a body, commercial or academic or of other category, owned by an individual or an organisation having status of legal entity by whatsoever name called, to which the sponsor may, delegate or transfer in writing, some or all of the tasks, duties or obligations regarding clinical trial or bioavailability or bioequivalence study.

2. **Registration of CROs**: CROs are required to obtain registration from the Central Licensing Authority ("**CLA**") (*as defined in rule 2(i) of the NDCT Rules, 2019*) before conducting any clinical trials or bioavailability and bioequivalence studies involving new or investigational drugs on human subjects.

   CROs must submit their registration applications to the CLA using Form CT-07B along with the prescribed fee of INR 5,00,000 (Indian Rupees five lakh). However, centres that are already registered for conducting bioavailability or bioequivalence studies are deemed to be registered for these purposes under the NDCT Rules, 2024.

3. **Grant of registration**: Upon submission of the necessary documents and information *via* Form CT-07B, the CLA will review the application and conduct enquiries for a period of 45 (forty-five) working days and do either of the following: .

   a) Grant an approval**:** The approval will be granted if the application meets all criteria and the CLA will grant registration using Form CT-07C.

   b) Reject the application**:** The application may be rejected if the application does not meet the requirements by providing written reasoning. In cases of rejection, applicants have the right to request a reconsideration of their application within 60 (sixty) days from the date of rejection, accompanied by the appropriate fee and any additional required documentation. Furthermore, aggrieved applicants can appeal against the decision to the Central Government within 45 (forty-five) days, with the government set to respond within 60 (sixty) days of receiving the appeal.

c) Request for rectification**:** If there are deficiencies, the CLA will notify the applicant, who will then have a specified period to rectify these issues. Post-rectification, the CLA will make a final decision within 90 (ninety) days from the receipt of the corrected application.

The registration for CROs, once granted under rule 38C, is valid for 5 (five) years from the date of its grant, unless suspended or cancelled earlier. To renew this registration, organisations must apply using Form CT-07B along with specified documents before the current registration expires. If this renewal application is submitted before the expiration date, the existing registration remains valid until a decision is made on the renewal. The CLA will review the renewal application and can either renew the registration using Form CT-07C or request rectifications, following the same procedures under rule 38C.

4. **Conditions for registration**:

a) CROs must maintain facilities and qualified staff as outlined in the Ninth Schedule to perform their functions.

b) They can initiate clinical trials or bioavailability or bioequivalence studies only after receiving protocol approval from an Ethics Committee ("**EC**") and permission from the CLA.

c) If a clinical trial site or bioavailability or bioequivalence center lacks its own EC, it can initiate a study after getting protocol approval from an EC at another site or an independent EC registered under Rule 8. The approving EC must be responsible for the study and be located within the same city or within a 50 (fifty) kilometer radius of the trial site or center.

d) The CLA must be informed about any EC approvals for clinical trials or bioavailability or bioequivalence studies.

e) All clinical trials and bioavailability or bioequivalence studies must be registered with the Clinical Trial Registry of India before the enrolment of the first subject.

f) Studies must adhere to the approved protocols, Good Clinical Practices Guidelines, and relevant regulations.

g) If a study is terminated early, reasons must be promptly communicated to the CLA. Additionally, any serious adverse events occurring during the study must be reported to the CLA within 14 (fourteen) days of their occurrence, following specific procedures and formats outlined in the regulations.

h) In cases of injury, disability, or death during a study, the Clinical Research Organisation must provide appropriate medical management and compensation as outlined in Chapter VI. Details of the compensation paid must be reported to the CLA within 30 (thirty) days of receiving the order. Further, any changes in the constitution or ownership of the CRO must be reported within 30 (thirty) days.

i) CROs are required to maintain all study-related data, records, and documents for 5 (five) years post-study completion, or for at least 2 (two) years after the expiration date of the drug batch studied, whichever is later.

j) CROs must allow inspections by any officer authorised by the CLA, with or without prior notice, to review any records or documents related to clinical trials. The CLA also reserves the right to impose additional conditions justified in writing, on specific clinical trials to ensure they meet targeted objectives and standards concerning study design, subject population, subject eligibility, assessments, conduct and treatment of such specific study.

k) Other requirements for the registration of CROs i.e., particulars and documents required to be submitted along with application for registration are as specified in the Ninth Schedule introduced through the NDCT Rules, 2024.

Conclusion

The NDCT Rules, 2024, aims to enhance the clinical trials landscape in India by providing a structured framework for operation of the CROs. By aligning more closely with international standards and addressing critical concerns around patient safety and regulatory efficiency, these amendments enhance India's position as a leading global hub for clinical trials and ensures the protection of patient interests and meets the expectations of domestic stakeholders.

Healthcare Practice

JSA provides a full range of transactional and advisory services in the healthcare sector. We represent clients in the entire spectrum of the health care system, including, hospital networks and individual hospitals, managed care organisations, health insurers, pharmaceutical and biotechnology companies, medical device manufacturers; and major financial investors in the sector. These include domestic as well multinational clients. Our clients in the sector range from start-ups to industry leaders.

JSA also has substantial experience in matters relating to regulation of foods, drugs, medical devices, cosmetics, product packaging, and dangerous chemicals. Our attorneys advise manufacturers on Indian labelling questions, national rules for testing and review of new products, reporting of safety information, and proceedings relating to product withdrawals. We regularly advise clients on regulatory standards governing advertising, the distinction between advertising and labelling and the differing regulatory standards that apply to each, and the roles of the states and self-regulatory mechanisms. JSA has been actively involved in advising clients with respect to regulation of nutrition and health claims in food advertising.

We also have extensive experience in litigating cases in courts and administrative agencies in the healthcare sector.

This Prism has been prepared by:

Bhavya Sriram
Partner

Mahemaa Senthilkumar
Associate

18 Practices and
25 Ranked Lawyers

7 Ranked Practices,
16 Ranked Lawyers

Elite – Band 1 -
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3 Band 1 Practices
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For more details, please contact km@jsalaw.com

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