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India Finalizes Rules Regarding Compensation for Subjects Injured in Clinical Trials and Post-Trial Access to Study Drugs

Attorneys
Mark Barnes
Jamie L. Flaherty

I. Background

Since 2013, India's clinical trials regulatory framework has undergone continuous, significant changes to bolster protections for clinical trial participants. In an effort to clarify these evolving requirements relating to clinical trials, on February 1, 2018, India's Ministry of Health and Family Welfare (the "MoHFW"), in supersession of India's Drugs and Cosmetics Rules, 1945, issued new draft rules pertaining to clinical trials (the "2018 Draft Rules"). The MoHFW has now released finalized rules via notification dated March 19, 2019, entitled the "New Drugs and Clinical Trials Rules, 2019" ("2019 Rules").[1] As with the 2018 Draft Rules, these finalized rules consolidate and clarify the myriad notices, orders, and other regulatory notifications issued by the Indian government over the past few years, and reflect ongoing efforts to improving India's clinical trial regulatory framework.

The 2019 Rules, among other changes, provide clarity through new definitions, add additional provisions regarding research ethics committees, and expedite the application process for new clinical trials, including by limiting the processing time to 30 days for an application to conduct a clinical trial of a new drug that was either discovered in India or will be manufactured and marketed in India.[2] This Alert provides a high-level description of other key provisions of the 2019 Rules.

II. Compensation for Subjects Injured in the Course of Clinical Trials

For several years, India has imposed stringent obligations on the part of the sponsor to provide compensation to clinical trial participants for injuries suffered that are deemed related to the trial. The 2019 Rules preserve these fairly controversial and broad compensation-related requirements, though – in an improvement over past rules – any such compensation for injury will now ultimately be determined by the Drug Controller General of India based on recommendations from an expert committee, instead of based on the decision of an ethics committee, which generally are ill-equipped to make such an assessment. The 2019 Rules also retain the requirement that sponsors provide free medical management to study participants that have experienced an injury per the investigator's opinion or until it is established that the injury is unrelated to the study.

In addition, the 2019 Rules have finalized the inclusion of the helpful compensation formulae that had been developed by the MoHFW (based on certain factors, such as age of the subject), which introduces clarity and defines the limit of financial liability on the part of the sponsor for certain injuries.[3]

III. Recording of Informed Consent Process and Post-Trial Study Drug Access

These finalized rules also preserve another controversial requirement that has been in place for several years, specifically, that investigators maintain an audio-video recording of the informed consent process for vulnerable subjects in clinical trials of new chemical or molecular entities (but requiring audio recording only for cases "of clinical trial of anti-HIV and anti-leprosy drugs").[4]

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[1] New Drugs and Clinical Trials Rules, 2019, Ministry of Health & Fam. Welfare, Notification, G.S.R. 227(E), (March 19, 2019), [*hereinafter*, the "2019 Rules"].
[2] *Id.* at Ch. V, Section 23.
[3] *Id.* at Seventh Schedule.
[4] *Id.* at Third Schedule, Section 2(g).

India also has viewed favorably participant post-trial access to a study drug, with the 2019 Rules finalizing post-access requirements, requiring sponsors to provide post-trial access to a drug at no cost to the trial participant if (1) the investigator has recommended such post-trial access for an individual after completion of a trial, (2) the trial relates to an indication for which no alternative therapy is available and the drug has been found beneficial to the subject by the investigator, (3) the ethics committee has approved the continued access, (4) the subject consents to post-trial use of the investigational drug, and (5) the investigator has certified and the trial subject declares in writing that for such post-trial use the "sponsor shall have no liability for post-trial use of investigational new drug or new drug."[5]

The 2019 Rules also provide a term for orphan drugs, now defined as drugs intended to treat conditions that affect not more than 500,000 persons in India, and contemplate fee waivers for applications to conduct clinical trials for such drugs in India.[6]

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While certain requirements under India's clinical trials regulatory framework might still be in need of further clarification, these changes – and other significant developments set forth in the 2019 Rules – represent an incrementally favorable development in India's clinical trials regulations.

[5] *Id.* at Ch. V, Section 27.
[6] *Id.* at Ch. 1, Section 2(x); Sixth Schedule.