

THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019

¹[GSR 227(E), dt. 19-3-2019]

(As amended vide GSR 778(E) dated 14-10-2022, w.e.f. 14-10-2022)

Whereas the draft of the New Drugs and Clinical Trials Rules, 2018 was published, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i) vide notification number G.S.R. 104(E), dated the 1st February, 2018, by the Central Government, after consultation with the Drugs Technical Advisory Board, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the Official Gazette containing the said notification were made available to the public on the 7th February, 2018;

And whereas, all objections and suggestions received in response to the said draft notification have been duly considered by the Central Government;

And whereas, the Hon'ble Supreme Court of India in Writ Petition(s) (Civil) No. (s). 33/2012 Swathaya Adhikar Manch, Indore and another Versus Union of India and others with W.P.(C) No. 79/2012 (PIL-W), *inter alia*, observed that new clinical trial rules shall be finalised urgently;

Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules, namely:—

CHAPTER I PRELIMINARY

1. Short title, commencement and applicability

(1) These rules may be called the New Drugs and Clinical Trials Rules, 2019.