The MOHFW issues Notification for the latest amendments to the Drugs Rules, 1945

On 24th August 2022, the Ministry of Family Welfare issued a notification following the draft of specific rules further to amend the Drugs Rules, 1945, being published, in accordance with sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide Notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 82(E), dated the 23rd May 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said Notification were made available to the public. Copies of the said Official Gazette were made available to the public on the
23rd May 2022, and the objections and suggestions received from the public were taken into consideration by the Government.

In this particular Notification, through the exercise of powers as stated in Section 12 and Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government of India, with the consultation of the Drugs Technical Advisory Board, issued further amendments to the Drugs Rules, 1945, mentioned as follows -

(i) The amended rules are to be referred to as the Drugs (Seventh Amendment) Rules, 2022.

(ii) These Rules are to be enforced on the date of their publication in the Official Gazette.

(iii) The Rule 75 of the Drugs Rules, 1945, a sub-rule is added following sub-rule (3), which is as follows -

“(3A) The application referred to in sub-rule (3) of rule 75 of these rules, and the application for grant of permission to manufacture a new drug for sale or distribution under rule 80 of the New Drugs and Clinical Trials Rules, 2019 or rule 122B of these rules, as the case may be, shall be made simultaneously.”;

(iv) Sub-Rule 6 is substituted with a new amendment which is as follows -

“Where an application under this rule is for the manufacture of drug formulations falling under the purview of new drug under rule 80 of the New Drugs and Clinical Trials Rules, 2019 or rule 122B, the licence to manufacture for sale or distribution of the drugs shall be granted after approval of the drug as a new drug.”

Official Notification Attached - here

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