

Drugs And Cosmetics (Sixth Amendment) Rules, 2015

[17 July 2015]

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G.S.R. 558(E).-Whereas certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published vide notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare vide number G.S.R. 503(E), dated the 14th July, 2014, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), 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 the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 14th July, 2014;

And, whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 12 read with 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 further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. Rule 1 :-

(1) These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2015.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Rule 2 :-

In the Drugs and Cosmetics Rules, 1945, in rule 105, in sub-rule (2),

(i) in the second proviso, for the words "Provided also that", the words "Provided further that" shall be substituted;

(ii) in the third proviso, for the words "Provided further that", the words "Provided also that" shall be substituted;

(iii) after the third proviso, the following proviso shall be inserted namely:-

"Provided also that Diclofenac injection for human use shall be in single unit dose pack only." ;