

“नई औषधि की प्रत्येक बिक्री योग्य इकाई के साथ उपभोक्ताओं को प्रदान करने के लिए पैकेज सन्निवेश शामिल होगा।”;

3. उक्त नियमों में अनुसूची क के प्ररूप 46 में क्रम संख्या (8) की शर्त के अंत में, निम्नलिखित शब्दों को शामिल किया जाएगा, अर्थात्:—

“नई औषधि की प्रत्येक बिक्री योग्य इकाई के साथ उपभोक्ताओं को प्रदान करने के लिए पैकेज सन्निवेश शामिल होगा।”।

[फा. सं.एक्स-11014/18/2018-डीआर]

सुधीर कुमार, संयुक्त सचिव

नोट : मूल नियम भारत के राजपत्र में दिनांक 21 दिसंबर, 1945 की अधिसूचना संख्या एफ-28-10/45-एच (1) में प्रकाशित किए गए थे तथा अंतिम बार संशोधन अधिसूचना संख्या सा.का.नि. ----(अ) दिनांक -----द्वारा किया गया था।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th August, 2018

G.S.R. 813(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by Section 12 and Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the Gazette of India containing these draft rules are made available to the public.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

- (1) These rules may be called the Drugs and Cosmetics (..... Amendment) Rules, 2018.
- (2) They shall come into force on the first day of January, 2019.
- In the Drugs and Cosmetics Rules, 1945, (hereinafter to be referred as said Rules), in Schedule A, in Form 45, in the condition at serial number (8), at the end the following words shall be inserted, namely:-
“Each saleable unit of the new drug shall accompany by the package insert for providing to the consumer.”;
- In the said rules, in Schedule A, in Form 46, in the condition at serial number (8), at the end the following words shall be inserted, namely:-
“Each saleable unit of the new drug shall accompany by the package insert for providing to the consumer.”.

[F. No. X.-11014/18/2018-DR]

SUDHIR KUMAR, Jt. Secy.

Note: The principal rules were published in the Official Gazette *vide* notification No. F. 28-10/45-H (1), dated 21st December, 1945 and last amended *vide* notification number G.S.R (E), dated