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PART II—Section 3—Sub-section (i)

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स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 29 जून, 2026

सा.का.नि. 530(अ).—औषधि नियम, 1945 में और संशोधन करने के लिए कतिपय नियमों के प्रारूप को औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 12 की उप-धारा (1) और धारा 33 की उप-धारा (1) के अधीन अपेक्षित रूप से, भारत सरकार, स्वास्थ्य और परिवार कल्याण मंत्रालय (स्वास्थ्य और परिवार कल्याण विभाग) की अधिसूचना संख्या सा.का.नि. 758 (अ), तारीख 16 अक्टूबर, 2025 द्वारा, भारत के राजपत्र, असाधारण, भाग 2, खंड 3, उप-खंड (i) में प्रकाशित किया गया था, जिसमें ऐसे व्यक्तियों से, जो उससे प्रभावित होने की संभावना रखते हैं, उस अवधि की समाप्ति से पूर्व, जो उक्त अधिसूचना वाले राजपत्र की प्रतियां जनता को उपलब्ध कराये जाने की तारीख से तीस दिन की थी, आक्षेप और सुझाव आमंत्रित किए गए थे;

और, उक्त राजपत्र की प्रतियां जनता को 18 अक्टूबर, 2025 को उपलब्ध कराई गई थीं;

और, उक्त प्रारूप नियमों के संबंध में जनता से कोई आक्षेप और सुझाव प्राप्त नहीं हुए;

अतः अब केंद्रीय सरकार उक्त अधिनियम की धारा 12 और धारा 33 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए और औषधि तकनीकी सलाहकार बोर्ड से परामर्श के पश्चात् एतद्वारा औषधि नियम, 1945 में और संशोधन करने के लिए निम्नलिखित नियम बनाती है, अर्थात्:—

1. (1) इन नियमों का संक्षिप्त नाम औषधि (आठवाँ संशोधन) नियम, 2026 है।

(2) ये नियम राजपत्र में उनके प्रकाशन की तारीख को प्रवृत्त होंगे।

MINISTRY OF HEALTH AND FAMILY WELFARE**(Department of Health and Family Welfare)****NOTIFICATION**

New Delhi, the 29th June 2026

G.S.R. 530(E).— Whereas a draft of certain rules further to amend the Drugs Rules, 1945 was published, as required under 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. 758 (E), dated the 16th October, 2025, 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 Gazette containing the said notification were made available to the public;

And whereas, copies of the said Gazette were made available to the public on the 18th October, 2025;

And whereas, no objections and suggestions received from the public on the said draft rules;

Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely: —

1. (1) These rules may be called the Drugs (Eighth Amendment) Rules, 2026.
(2) These rules shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs Rules, 1945, —
 - (i). in rule 75, in sub-rule (3), after the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs,” the words “Cell or Stem Cell derived products, Gene therapeutic products or Xenografts,” shall be inserted;
 - (ii). in rule 75A, in sub-rule (1A), after the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs”, the words “Cell or Stem Cell derived products”, ‘Gene therapeutic products or Xenografts’” shall be inserted;
 - (iii). in rule 76, for the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs” wherever may occur, the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs, Cell or Stem Cell derived products, Gene therapeutic products or Xenografts,” shall be substituted;
 - (iv). in rule 76A, for the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs”, the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs, Cell or Stem Cell derived products, Gene therapeutic products or Xenografts,” shall be substituted;
 - (v). in SCHEDULE A, —
 - (a) in Form 27D, —
 - (A) in the heading, for the words, letters and brackets “RECOMBINANT DNA (R-DNA) DERIVED DRUGS”, the words, letters and brackets “RECOMBINANT DNA (R-DNA) DERIVED DRUGS/ CELL OR STEM CELL DERIVED PRODUCTS, GENE THERAPEUTIC PRODUCTS OR XENOGRAFTS,” shall be substituted;
 - (B) after the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs,” the words “Cell or Stem Cell derived products, Gene therapeutic products or Xenografts,” shall be inserted;
 - (b) in Form 27DA, —
 - (A) in the heading, for the words, letters and brackets “RECOMBINANT DNA (R-DNA) DERIVED DRUGS”, the words, letters and brackets “RECOMBINANT DNA (R-DNA) DERIVED DRUGS/ CELL OR STEM CELL DERIVED PRODUCTS, GENE THERAPEUTIC PRODUCTS OR XENOGRAFTS,” shall be substituted;
 - (B) after the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs,” the words “Cell or Stem Cell derived products, Gene therapeutic products or Xenografts,” shall be inserted;
 - (c) in Form 28D, —

- (A) in the heading, for the words, letters and brackets “RECOMBINANT DNA (R-DNA) DERIVED DRUGS”, the words, letters and brackets “RECOMBINANT DNA (R-DNA) DERIVED DRUGS/ CELL OR STEM CELL DERIVED PRODUCTS, GENE THERAPEUTIC PRODUCTS OR XENOGRAFTS,” shall be substituted;
- (B) after the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs,”, the words “Cell or Stem Cell derived products, Gene therapeutic products or Xenografts,” shall be inserted;
- (d) in Form 28DA, —
- (A) in the heading, for the words, letters and brackets “RECOMBINANT DNA (R-DNA) DERIVED DRUGS”, the words, letters and brackets “RECOMBINANT DNA (R-DNA) DERIVED DRUGS/ CELL OR STEM CELL DERIVED PRODUCTS, GENE THERAPEUTIC PRODUCTS OR XENOGRAFTS,” shall be substituted;
- (B) after the words, letters and brackets “Recombinant DNA (r-DNA) derived drugs,”, the words “Cell or Stem Cell derived products, Gene therapeutic products or Xenografts,” shall be inserted;

[F. No. X.11014/07/2025-DR-Part(2)]

HARSH MANGLA, Jt. Secy.

Note: The Drugs Rules, 1945 were published in the Official Gazette *vide* notification No. F. 28-10/45H(1), dated the 21st December, 1945 and last amended *vide* notification number G.S.R. 506(E), dated 22nd June, 2026