CDSCO

Cell and gene therapeutic products added to r-DNA licence rules

G.S.R. 530(E) of June 29, 2026 adds cell or stem cell derived products, gene therapeutic products and xenografts to the r-DNA manufacturing licence rules.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) issued notification G.S.R. 530(E), dated June 29, 2026, making the Drugs (Eighth Amendment) Rules, 2026. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 477, dated June 30, 2026. The Central Government made the rules under sections 12 and 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board. They come into force on the date of their publication in the Official Gazette. The notification is signed by Harsh Mangla, Jt. Secy., under F. No. X.11014/07/2025-DR-Part(2).

KEY FACTS

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G.S.R. 530(E), the Drugs (Eighth Amendment) Rules, 2026

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The rules add three kinds of product beside "Recombinant DNA (r-DNA) derived drugs" in the Drugs Rules, 1945: "Cell or Stem Cell derived products", "Gene therapeutic products" and "Xenografts". The words go into rule 75(3), which covers applications for a licence to manufacture for sale or for distribution in Form 27D, and rule 75A(1A), which covers loan licence applications in Form 27DA. They also replace the r-DNA wording in rule 76, wherever it occurs, and in rule 76A. Those two rules issue the licence in Form 28D and the loan licence in Form 28DA. The headings and text of all four forms in Schedule A change the same way.

The notification does not mention the Central Licence Approving Authority (CLAA) and does not amend rule 68A; CDSCO lists it as "Notification regarding Inclusion of additional items under CLAA in Drugs Rules 1945". In the Drugs Rules (CDSCO's copy dated July 1, 2024), rule 2(b) defines the CLAA as the Drugs Controller, India, or the Joint Drugs Controller (India) or the Deputy Drugs Controller (India) appointed by the Central Government. Under rule 68A, the CLAA grants licences to manufacture the drugs the Central Government specifies for that rule by notification in the Official Gazette. The application goes to the licensing authority, which verifies it, has the establishment inspected under rule 79 and, if satisfied, forwards a report; the CLAA then grants or rejects it.

In Schedule A, Form 27D asks that a copy of the application, with its enclosures, also be sent to the CLAA and to the concerned Zonal or Sub-Zonal Officers of CDSCO. Form 28D's signature line reads "Licensing Authority/Central Licence Approving Authority", and Form 28DA's names both authorities too. The conditions of both licences name both authorities for reporting changes and for adding items. Under rules 75(3) and 75A(1A), an application covers up to ten items for each category of drugs in Schedule M, with a licence fee of six thousand rupees and an inspection fee of one thousand five hundred rupees for every inspection; under rules 75(5) and 75A(3), each further item adds a fee of three hundred rupees.

A draft of these rules was published as G.S.R. 758(E), dated October 16, 2025, and copies of that Gazette were made available to the public on October 18, 2025. The notification records that no objections and suggestions were received from the public. The draft ended each added phrase with "etc."; the final rules do not. The notification does not define the three kinds of product,

says nothing about licences already granted or applications already pending, and amends no other rule or form.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	G.S.R. 530(E), the Drugs (Eighth Amendment) Rules, 2026
Dated	June 29, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 477, June 30, 2026
Takes effect	On the date of publication in the Official Gazette; the Gazette is dated June 30, 2026
Applies to	Licences and loan licences to manufacture for sale or for distribution of Cell or Stem Cell derived products, Gene therapeutic products or Xenografts
Rules amended	Rules 75(3), 75A(1A), 76 and 76A of the Drugs Rules, 1945
Forms amended	Form 27D (application) and Form 28D (licence); Form 27DA (loan licence application) and Form 28DA (loan licence), in Schedule A
Fees (rules 75 and 75A)	Up to ten items for each Schedule M category; licence fee of six thousand rupees; inspection fee of one thousand five hundred rupees for every inspection; three hundred rupees for each item beyond ten (rules 75(5) and 75A(3))
Draft	G.S.R. 758(E), October 16, 2025; no objections and suggestions received
Signed by	Harsh Mangla, Jt. Secy.
File number	F. No. X.11014/07/2025-DR-Part(2)

The notification (PDF, 716 KB)

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