June 22, 2026

CDSCO

Schedule H2 to cover four drug categories from 2027 and 2028

G.S.R. 506(E) adds all vaccines, antimicrobials, NDPS Act narcotics and psychotropics, and anticancer drugs to Schedule H2 of the Drugs Rules, 1945.

G.S.R. 506(E) IS A NOTIFICATION of the Ministry of Health and Family Welfare (Department of Health and Family Welfare), dated June 22, 2026, making the Drugs (Seventh Amendment) Rules, 2026. It appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 455, dated June 22, 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 follow draft rules published as G.S.R. 757(E), dated October 16, 2025, whose Gazette copies were made available to the public on October 18, 2025; the objections and suggestions received were considered. CDSCO lists the same file as a "Notification regarding amendment under Drugs Rules to include more categories under Schedule H2".

KEY FACTS

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G.S.R. 506(E), the Drugs (Seventh Amendment) Rules, 2026



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The rules change Schedule H2 of the Drugs Rules, 1945. Its existing Table is numbered "Table 1", and a new "Table 2", headed "Therapeutic Category of drug formulations", is inserted after it. Table 2 has four entries: "All Vaccines"; "All Antimicrobials"; "All Narcotic Drugs and Psychotropic Substance, listed under the Narcotic Drugs and Psychotropic Substance Act, 1985 and rules made thereunder"; and "All Anticancer drugs". Table 1, as G.S.R. 823(E) of November 17, 2022 inserted it, lists 300 brand names of drug formulations.

The rules come into force on July 1, 2027, except serial number 2 of Table 2, all antimicrobials, which comes into force on July 1, 2028. The draft had left the start date to be specified at final publication, and its third entry read "All Narcotic and Psychotropic drugs listed under the Narcotic and Psychotropic drugs Act, 1985".

The notification does not restate what a Schedule H2 listing requires. Schedule H2's heading refers to sub-rules (6) and (7) of rule 96 of the Drugs Rules, 1945, which G.S.R. 823(E) inserted with effect from August 1, 2023. Sub-rule (6) requires manufacturers of drug formulation products as specified in Schedule H2 to print or affix a Bar Code or Quick Response Code on the primary packaging label. If the primary package label lacks space, the code goes on the secondary package label. The code stores data or information legible with a software application to facilitate authentication. Under sub-rule (7), the data must include a unique product identification code, the proper and generic name of the drug, the brand name, the name and address of the manufacturer, the batch number, the date of manufacturing, the date of expiry and the manufacturing licence number. G.S.R. 554(E), dated August 18, 2025, added qualitative details of excipients to that list from March 1, 2026.

The notification does not define the four categories and makes no provision for stock made or labeled before its dates. It is signed by Harsh Mangla, Joint Secretary, under F. No. X.11014/07/2025-DR. Its note records the last amendment of the Drugs Rules, 1945 as G.S.R. 496(E), dated June 18, 2026. Its e-Gazette ID is CG-DL-E-25062026-273811.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	G.S.R. 506(E), the Drugs (Seventh Amendment) Rules, 2026
Dated	June 22, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 455, June 22, 2026
Gazette ID	CG-DL-E-25062026-273811
Draft	G.S.R. 757(E), October 16, 2025; copies made available to the public on October 18, 2025
Amends	Drugs Rules, 1945: Schedule H2, the existing Table numbered "Table 1" and a new "Table 2" inserted
Applies to	Drug formulations in four therapeutic categories: all vaccines; all antimicrobials; all narcotic drugs and psychotropic substances listed under the Narcotic Drugs and Psychotropic Substance Act, 1985 and rules made thereunder; all anticancer drugs
Takes effect	July 1, 2027
All antimicrobials (serial number 2)	July 1, 2028
What Schedule H2 requires	Rule 96(6) and (7), Drugs Rules, 1945 (G.S.R. 823(E), November 17, 2022, in force August 1, 2023): manufacturers must print or affix a Bar Code or Quick Response Code on the primary packaging label, or the secondary package label if space is inadequate, storing the particulars in rule 96(7)
Signed by	Harsh Mangla, Jt. Secy.
File number	F. No. X.11014/07/2025-DR

Schedule H2, Table 2: categories and start dates

Serial Number	Therapeutic Category of drug formulations	In force from
1	All Vaccines	July 1, 2027
2	All Antimicrobials	July 1, 2028
3	All Narcotic Drugs and Psychotropic Substance, listed under the Narcotic Drugs and Psychotropic Substance Act, 1985 and rules made thereunder	July 1, 2027

4	All Anticancer drugs	July 1, 2027

The notification (PDF, 664 KB)

Source: Gazette of India, CG-DL-E-25062026-273811.

Checked against the official copy on October 28, 2026.

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Read online: indusdesk.com/cdsco/insights/schedule-h2-to-cover-four-drug-categories-from-2027-and-2028/