CDSCO

Drug licence applicants may be debarred for fake documents

G.S.R. 706(E) lets drug licensing authorities debar applicants found guilty of submitting misleading, fake or fabricated documents or information.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) issued notification G.S.R. 706(E), dated July 30, 2026, making the Drugs (Eleventh Amendment) Rules, 2026. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 642, dated August 5, 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, and they come into force on the date of their publication in the Official Gazette. They amend the Drugs Rules, 1945, last amended by G.S.R. 607(E) of July 8, 2026. The notification is signed by Harsh Mangla, Jt. Secy., under F. No. X.11014/07/2025-DR.

KEY FACTS

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Ministry of Health and Family Welfare (Department of Health and Family Welfare)

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Notification G.S.R. 706(E), the Drugs (Eleventh Amendment) Rules, 2026

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A new sub-rule (bb) in rule 2 defines "debarment" as "the prohibition, exclusion, or disqualification of any person, firm, or entity from engaging in the import of drugs, manufacture for sale or for distribution, sell, stock or exhibit or offer for sale, or distribute, for a specified period or permanently as a consequence to the violation of statutory provisions". The rules then insert seven new rules, each headed "Debarment of applicant under this Part": 29B after rule 29A, 66B after 66A, 84F after 84E, 93A after 93, 122DBA after 122DB, 122Q after 122P and 150L after 150K.

Each new rule says that "Whoever himself or, any other person on his behalf, or applicant is found to be guilty of submitting misleading, or fake, or fabricated documents or information under this part, may, after giving him an opportunity to show cause as to why such an order should not be made, in writing, stating the reasons thereof", be debarred "for such period as may be deemed fit". Rules 29B and 66B give the power to the "Licensing Authority", rule 122DBA to the "Licencing Authority", and rules 84F, 93A, 122Q and 150L to the "Central Licensing Approving Authority or Licencing Authority". Under every new rule except 122DBA, an applicant aggrieved by the order may appeal "to that Government" within thirty days from the receipt of the order, and that Government may pass such orders as may be considered appropriate, after such enquiry as it considers necessary and after giving an opportunity of being heard. Rule 122DBA has no appeal provision.

The rules do not name the Parts. In CDSCO's compilation of the Drugs and Cosmetics Rules, 1945, as amended up to December 31, 2016, rule 29A sits in Part IV (import and registration), 66A in Part VI (sale of drugs other than homoeopathic medicines), 93 in Part VIII (manufacture for examination, test or analysis), 122DB in Part XA (import or manufacture of new drugs for clinical trials or marketing), 122P in Part XB (collection, storage, processing and distribution of whole human blood and blood components, and manufacture of blood products) and 150K in Part XV(A) (approval of institutions that test drugs, cosmetics and raw materials for licensed manufacturers). Rule 84E was added after that compilation; it falls between rules 84B and 85, both in Part VII (manufacture for sale or for distribution of drugs other than homoeopathic medicines).

A draft, G.S.R. 756(E) of October 16, 2025, was made available to the public on October 28, 2025, with thirty days for objections and suggestions, which the Central Government considered. It proposed the same seven rules; the definition in rule 2(bb) and the words "under this part" after "documents or information" were added in the final rules. The rules set no minimum or maximum period of debarment, do not say which Government "that Government" is, and do not say how a debarment affects a licence or registration already granted or an application pending. They amend only the Drugs Rules, 1945.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Notification G.S.R. 706(E), the Drugs (Eleventh Amendment) Rules, 2026
Dated	July 30, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 642, August 5, 2026
Takes effect	The date of publication in the Official Gazette; the Gazette is dated August 5, 2026
Amends	Drugs Rules, 1945: rule 2 (new sub-rule (bb)) and new rules 29B, 66B, 84F, 93A, 122DBA, 122Q and 150L
Applies to	"Whoever himself or, any other person on his behalf, or applicant" is found guilty of submitting misleading, fake or fabricated documents or information under the Part concerned
Who may debar	The "Licensing Authority" (29B, 66B), the "Licencing Authority" (122DBA) or the "Central Licensing Approving Authority or Licencing Authority" (84F, 93A, 122Q, 150L)
Before an order	An opportunity to show cause why the order should not be made
Period	"for such period as may be deemed fit"; the definition covers a specified period or permanently
Appeal	"to that Government", within thirty days from the receipt of the order; rule 122DBA has none
Draft	G.S.R. 756(E), October 16, 2025, made available to the public on October 28, 2025
File number	F. No. X.11014/07/2025-DR
Signed by	Harsh Mangla, Jt. Secy.

The seven new debarment rules

New rule	Inserted after	Part of the Drugs Rules, 1945 (CDSCO compilation to December 31, 2016)	Who may debar	Appeal within 30 days
29B	Rule 29A	Part IV: Import and registration	"Licensing Authority"	Yes
66B	Rule 66A	Part VI: Sale of drugs other than homoeopathic medicines	"Licensing Authority"	Yes
84F	Rule 84E	Part VII: Manufacture for sale or for distribution of drugs other than homoeopathic medicines (rule 84E was added after the compilation; it falls between rules 84B and 85, both in Part VII)	"Central Licensing Approving Authority or Licencing Authority"	Yes
93A	Rule 93	Part VIII: Manufacture for examination, test or analysis	"Central Licensing Approving Authority or Licencing Authority"	Yes
122DBA	Rule 122DB	Part XA: Import or manufacture of new drug for clinical trials or marketing	"Licencing Authority"	No provision
122Q	Rule 122P	Part XB: Collection, storage, processing and distribution of whole human blood and human blood components, and manufacture of blood products	"Central Licensing Approving Authority or Licencing Authority"	Yes
150L	Rule 150K	Part XV(A): Approval of institutions for carrying out tests on drugs, cosmetics and raw materials on behalf of licensees	"Central Licensing Approving Authority or Licencing Authority"	Yes

The notification (PDF, 759 KB)

Source: Gazette of India, CG-DL-E-05082026-275233.

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