CDSCO

16 fixed dose combinations banned for human use

S.O. 3068(E) to S.O. 3083(E) of June 11, 2026 prohibit the manufacture, sale or distribution of 16 fixed dose combinations for human use, with immediate effect.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) issued 16 notifications, S.O. 3068(E) to S.O. 3083(E), all dated June 11, 2026, under section 26A of the Drugs and Cosmetics Act, 1940. They appear together in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), No. 2962, dated June 15, 2026; the e-Gazette copy, CG-DL-E-19062026-273649, was digitally signed on June 19, 2026. Each notification prohibits the manufacture, sale or distribution of one fixed dose combination (FDC) for human use, with immediate effect. All 16 are signed by Harsh Mangla, Joint Secretary, under F. No. X.11035/53/2014-DFQC(Pt.- III).

KEY FACTS

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Notifications S.O. 3068(E) to S.O. 3083(E), under section 26A of the Drugs and Cosmetics Act, 1940

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CDSCO · June 11, 2026

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Six of the FDCs contain aloe vera or aloe extract: Aloe vera + Jojoba oil + Wheat germ oil + Tea tree oil; Aloe Extract + Allantoin + Alphatocopherol Acetate + D-Penthenol + Vitamin A; Aloe Extract + Vitamin E + Dimethicone + Glycerine; Aloe Vera + Jojoba Oil + Vitamin E; Aloe vera + Orange oil; and Aloe vera + Vitamin E + Herbal. Four combine amoxicillin or cefuroxime with serratiopeptidase: Amoxicillin + Serratiopeptidase + Lactobacillus Sporogenes; Amoxicillin + Serratiopeptidase; Amoxicillin + Cloxacillin + Lactic acid bacillus + Serratiopeptidase; and Cefuroxime + Serratiopeptidase. Two are Dicyclomine + Paracetamol + Clidinium Bromide, one of them with Chlordiazepoxide added. The other four are Acetyl Salicylic Acid + Ethoheptazine, Paracetamol + Lignocaine, Gliclazide + Chromium Picolinate and Cefadroxyl + Probenecid. The table gives each with its S.O. number.

Each notification sets out the same steps. The Central Government is satisfied that the FDC "is likely to involve risk to human beings when safer alternatives to the said drug are available". An Expert Committee examined it in 2021. The Drugs Technical Advisory Board (DTAB) agreed in principle with that committee and recommended that its Sub-Committee examine all irrational FDCs in detail. The Sub-Committee gave manufacturers and stakeholders a chance to present data through public notices. Its report dated December 28, 2024 said that, in the larger public interest, it is necessary to prohibit the FDC as there is no therapeutic justification for the fixed dose combination of these ingredients. The DTAB agreed, and the Government acted on its recommendations.

The Expert Committee's findings differ by FDC. For 15 of them, it said the available data and peer reviewed scientific evidence do not support the FDC's rationality and considered it irrational. For Cefadroxyl + Probenecid, it found no pharmacokinetic data to substantiate adding probenecid in regard to dose titration, said a pharmacokinetic study was needed to determine the doses of probenecid, and, in present circumstances, did not recommend it. For the four serratiopeptidase FDCs, it found no sound clinical evidence of concurrent use of amoxicillin or cefuroxime with serratiopeptidase and said the combination is not as per standard therapeutic guidelines. For the two dicyclomine FDCs, it said combining dicyclomine with another anti-cholinergic agent like clidinium "does not seem to be justified". For Gliclazide + Chromium Picolinate, it said national

and international standard treatment guidelines for type 2 diabetes mellitus do not recommend chromium picolinate. For Aloe vera + Vitamin E + Herbal, it noted the product "is not defined as well as characterized". For Paracetamol + Lignocaine, the Sub-Committee's report also said "there is a possibility of risk with the fixed dose combination".

The notifications prohibit manufacture, sale or distribution. None of them mentions import, and none gives strengths, dosage forms, brands or a period to clear existing stock. They cover human use only, and they do not give the date of the DTAB meeting that agreed with the Sub-Committee. On July 21, 2026, CDSCO posted a one-page "List of 16 FDCs banned dated 11.06.2026" (June 11, 2026) on its FDC page, with the same 16 FDCs and S.O. numbers; it changes nothing. On October 28, 2026, CDSCO's Gazette notifications, public notices and circulars lists and its FDC page showed no stay or withdrawal of any of the 16.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Notifications S.O. 3068(E) to S.O. 3083(E), under section 26A of the Drugs and Cosmetics Act, 1940
Dated	June 11, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), No. 2962, June 15, 2026
Gazette ID	CG-DL-E-19062026-273649; the e-Gazette copy was digitally signed on June 19, 2026
Applies to	The manufacture, sale or distribution of 16 fixed dose combinations for human use, one in each notification
Takes effect	With immediate effect, as each notification states
Import	Not mentioned
Reason given	Likely to involve risk to human beings when safer alternatives are available; no therapeutic justification for the combination of these ingredients
Based on	An Expert Committee's examination in 2021; the DTAB Sub-Committee's report dated December 28, 2024; the DTAB's recommendations
Transition period	Not stated
Related	CDSCO's "List of 16 FDCs banned dated 11.06.2026", posted on its FDC page on July 21, 2026: the same 16 FDCs and S.O. numbers

Status	No stay or withdrawal on CDSCO's Gazette notifications, public notices and circulars lists or its FDC page on October 28, 2026
Signed by	Harsh Mangla, Jt. Secy.
File number	F. No. X.11035/53/2014-DFQC(Pt.- III)

The 16 fixed dose combinations prohibited for human use

Notification	Fixed dose combination
S.O. 3068(E)	Acetyl Salicylic Acid + Ethoheptazine
S.O. 3069(E)	Aloe vera + Jojoba oil + Wheat germ oil + Tea tree oil
S.O. 3070(E)	Amoxicillin + Serratiopeptidase + Lactobacillus Sporogenes
S.O. 3071(E)	Dicyclomine + Paracetamol + Clidinium Bromide + Chlordiazepoxide
S.O. 3072(E)	Amoxicillin + Serratiopeptidase
S.O. 3073(E)	Aloe Extract + Allantoin + Alphatocopherol Acetate + D-Penthenol + Vitamin A
S.O. 3074(E)	Aloe Extract + Vitamin E + Dimethicone + Glycerine
S.O. 3075(E)	Aloe Vera + Jojoba Oil + Vitamin E
S.O. 3076(E)	Aloe vera + Orange oil
S.O. 3077(E)	Aloe vera + Vitamin E + Herbal
S.O. 3078(E)	Dicyclomine + Paracetamol + Clidinium Bromide
S.O. 3079(E)	Paracetamol + Lignocaine
S.O. 3080(E)	Gliclazide + Chromium Picolinate
S.O. 3081(E)	Amoxicillin + Cloxacillin + Lactic acid bacillus + Serratiopeptidase
S.O. 3082(E)	Cefadroxyl + Probenecid
S.O. 3083(E)	Cefuroxime + Serratiopeptidase

The notifications under section 26A of the drugs and cosmetics act, 1940 (PDF, 1.4 MB)

Source: Gazette of India, CG-DL-E-19062026-273649.

Checked against the official copy on October 28, 2026.

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