



Union Ministry of Health and Family Welfare Prohibits Manufacture, Sale and Distribution of 16 Fixed Dose Combinations (FDCs) in Public Interest

**Decision aimed at safeguarding public health and ensuring
availability of only scientifically justified drug combinations**

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In a significant step towards safeguarding public health and promoting the rational use of medicines, the Ministry of Health and Family Welfare has issued notifications under Section 26A of the Drugs and Cosmetics Act, 1940, prohibiting the manufacture for sale, sale and distribution for human use of 16 Fixed Dose Combinations (FDCs). The notifications have come into force with immediate effect.

The decision follows directions of the Hon'ble Supreme Court, which had mandated a comprehensive review of Fixed Dose Combinations available in the country. In compliance with these directions, the Drugs Technical Advisory Board (DTAB) constituted an Expert Committee to examine various FDCs and identify those that are irrational, lack therapeutic justification, or may pose risks to human health.

Based on the scientific assessment and recommendations of the Expert Committee, the Government has taken action against 16 FDCs that were found to lack therapeutic justification and whose continued use was not considered beneficial in relation to the potential risks involved. The prohibited FDCs belong to various therapeutic categories, including certain dermatological preparations, analgesic and antispasmodic medicines, and antibiotic-based formulations.

The Ministry noted that this action is in line with the Government's continuing efforts to ensure that only safe, effective and scientifically validated medicines are available to the public. In previous instances as well, several irrational FDCs were prohibited following detailed scientific review, reinforcing the commitment of the Government towards patient safety and evidence-based healthcare.

Accordingly, the manufacture for sale, sale, distribution and supply of the identified 16 FDCs for human use shall stand prohibited with immediate effect across the country.

All State Drug Controllers, regulatory authorities and enforcement agencies have been directed to ensure strict implementation and compliance with the notifications. Manufacturers, importers, distributors and other stakeholders have also been advised to take necessary corrective measures to comply with the provisions of the law.

The e-Gazette regarding the same can be accessed through this link: <https://egazette.gov.in/WriteReadData/2026/273649.pdf>

The detailed list of the prohibited Fixed Dose Combinations are as follows:

S.No.	Composition of the FDC	Recommendations
1	Acetyl Salicylic acid + Ethoheptazine	Recommended for prohibition under Section 26A of Drugs & Cosmetics Act, 1940
2	Aloe Extract + Allantoin + Alphatocopherol Acetate +D-Penthenol + Vitamin A	
3	Aloe Extract +Vitamin E + Dimethicone + Glycerine	
4	Aloe Vera +Jjoba Oil +Vitamin E	
5	Aloe vera + Orange oil	
6	Aloe vera + Jojoba oil + Wheat germ oil + Tea tree oil	
7	Aloe vera + Vitamin E + Herbal	
8	Dicyclomine + Paracetamol + Clidinium Bromide	
9	Dicyclomine +Paracetamol + Clidinium Bromide + Chlordiazepoxide	
10	Gliclazide + Chromium Picolinate	
11	Paracetamol + Lignocaine	
12	Amoxicillin + Serratiopeptidase+ Lactobacillus Sporogenes	
13	Amoxicillin + Cloxacillin + Lactic acid bacillus + Serratiopeptidase	
14	Amoxicillin + Serratiopeptidase	
15	Cefadroxyl + Probenecid	
16	Cefuroxime + Serratiopeptidase	

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