

16 fixed-dose combination medicines banned in India; antibiotics and skin creams among affected

The decision of the ministry follows directions of the Supreme Court, which mandates a comprehensive review of Fixed Dose Combinations (FDCs) available in the country



The Ministry of Health and Family Welfare has prohibited the manufacture for sale, sale and distribution for human use of 16 Fixed Dose Combinations (FDCs). Image credit/iStock.

The Ministry of Health and Family Welfare has prohibited 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 prohibited FDCs belong to various therapeutic categories, including certain dermatological preparations, analgesic and antispasmodic medicines, and antibiotic-based formulations.

The banned combinations include penicillin-class antibiotics. A combination of acetylsalicylic acid (aspirin) and ethoheptazine is an analgesic formulation historically used to manage mild to moderately severe pain. Several combinations containing Aloe Vera as one of the ingredients are also included in the list. This includes the combination of ingredients (Aloe Extract, Allantoin, Alpha Tocopherol Acetate, D-Panthenol, and Vitamin A) is formulated for topical use, primarily in skin creams and lotions.

The decision of the ministry follows directions of the 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 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.

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