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Health Ministry bans manufacture, sale and distribution of 16 Fixed Dose Combinations (FDCs)

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Ensuring the availability of only scientifically appropriate drug combinations

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

This decision has been taken following the directions of the Supreme Court, which mandated a comprehensive review of the fixed dose combinations available in the country.

In compliance with these directives, the Drug Technical Advisory Board (DTAB) constituted an expert committee to investigate various FDCs and identify FDCs that are irrational, lack medical justification, or may pose a risk to human health.

All State Drug Controllers, Regulatory Authorities and Enforcement Agencies have been directed to ensure strict implementation and compliance of 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 following is a detailed list of restricted fixed dose combinations:

- Acetyl salicylic acid + ethoheptazine
- Aloe vera extract + allantoin + alphatocopherol acetate + D-panthenol + vitamin A
- Aloe vera extract + vitamin E + dimethicone + glycerin
- Aloe Vera + Jojoba Oil + Vitamin E
- Aloe vera + orange oil
- Aloe vera + jojoba oil + wheat germ oil + tea tree oil
- Aloe vera + vitamin E + herbal
- Dicyclomine + Paracetamol + Clidinium Bromide
- Dicyclomine + Paracetamol + Clidinium Bromide + Chlordiazepoxide
- Glyclavazide + Chromium Picolinate
- Paracetamol + lignocaine
- Amoxicillin + Serratiopeptidase + Lactobacillus sporogenes
- Amoxicillin + cloxacillin + lactic acid bacillus + serratiopeptidase
- Amoxicillin + Serratiopeptidase
- Cefadroxyl + probenecid
- Cefuroxime + Serratiopeptidase