

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 1203
TO BE ANSWERED ON 9TH FEBRUARY, 2024**

FIXATION OF DOSE FOR COMMON COLD DRUGS

1203. SHRI V.K. SREEKANDAN:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether it is a fact that the Drugs Controller General of India has directed manufacturers of common cold drug fixed dose combination of chlorpheniramine maleate IP2 mg with phenylephrine HCL IP 5 mg per ml drops to carry a warning to not use the combination in children below certain years of age in the country;
- (b) if so, the details thereof;
- (c) whether the manufacturers have been directed by the Government to put such warnings on label and promotional literature as well in the country and if so, the details thereof;
- (d) whether any decision has come out after the recommendation by the Subject Expert Committee; and
- (e) if so, the details thereof

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)**

(a) to (e): Based on the recommendations of Subject Expert Committee, Central Drugs Standard Control Organization (CDSCO) has issued circular on 18.12.2023 requesting all State/UTs Drugs Controllers to direct all the manufacturers of the fixed dose combination (FDC) of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml under their jurisdiction to mention warning "FDC should not be used in children below 4 years of age" on label and package insert/Promotional Literature of the drug.
