2632: SHRIMATI RAKSHA NIKHIL KHADSE:
SHRI MANOJ KOTAK:

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

(a) whether the Government has proposed to impose ban on certain combination of drugs as per the recommendations of the expert panel constituted in the country;
(b) if so, the details thereof along with the list of banned combination of drugs; and
(c) the reasons specified by the expert panel for each of the drugs banned?

ANSWER

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

(a) to (c): The Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) has recently prohibited the manufacture for sale, sale or distribution for human use of 14 Fixed Dose Combinations (FDCs) vide gazette notification dated 02.06.2023 vide S.O No. 2394(E) to 2407(E) on the basis of recommendation of expert committee, that there is no therapeutic justification for such FDCs and the FDCs may involve risk to human beings and hence, in the larger public interest, it is necessary to prohibit the manufacture for sale, sale or distribution of such FDCs which were agreed by Drugs Technical Advisory Board. The List of 14 banned FDCs is enclosed as Annexure - ‘A’.

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Annexure - ‘A’

List of 14 Fixed Dose Combinations prohibited for manufacture for sale, sale or distribution for human use vide Gazette notification No. S.O No. 2394(E) to 2407(E) dated 02.06.2023

1. Nimesulide + Paracetamol dispersible tablets
2. Amoxicillin + Bromhexine
3. Pholcodine + Promethazine
4. Chlorpheniramine maleate + Dextromethorphan + Guaifenesin + Ammonium chloride + Menthol
5. Chlorpheniramine Maleate + Codeine syrup
6. Ammonium Chloride + Bromhexine + Dextromethorphan
7. Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol
8. Dextromethorphan + Chlorpheniramine + Guaifenesin + Ammonium Chloride
9. Paracetamol + Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin
10. Salbutamol + Bromhexine
11. Chlorpheniramine +Codeine phosphate +Menthol syrup
12. Phenytoin + Phenobarbitone sodium
13. Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol
   (100mg + 40mg + 2.5mg + 0.9mg), (125mg + 55mg + 4mg + 1mg), (110mg + 46mg + 3mg + 0.9mg) & (130mg + 55mg + 3mg + 0.5mg) per 5ml syrup