

F.No 04-01/2013-DC (Misc-13-PSC) Part-II
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, New Delhi

Dated: 14.09.2018

To

All State/UT Drug Controllers

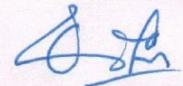
Subject: Prohibition of 328 Fixed Dose Combinations by the Central Government vide Gazette notification nos. S.O.4379 (E) to S.O.4706(E) –regarding

Sir,

The Central Government vide Gazette notification nos. S.O.4379(E) to S.O.4706(E) dated 07.09.2018 has prohibited 328 Fixed Dose combinations for manufacture, sale or distribution with immediate effect under Section 26A of Drugs & Cosmetics Act, 1940 based on the recommendations of DTAB as there is no therapeutic justification for the ingredients contained in these 328 FDCs or and these FDCs may involve risk to human beings as mentioned in the notifications. The copy of these notifications is available on the CDSCO website.

In view of above notifications, you are requested to direct the concerned manufacturer, distributor and wholesaler/retailer under your jurisdiction to stop the manufacture, sale or distribution of these FDCs with immediate effect and it is also requested that all the associations of manufacturers as well as chemists active in your jurisdiction may be directed to inform their members for compliance to these notifications as per Drugs & Cosmetics Act and Rules thereunder.

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Copy for information and compliance by your members:-

1. All Associations in Indian Drug / Pharmaceuticals Association Forum.
2. All India Organisation of Chemists and Druggists Association and other similar associations.
3. Indian Medical Association.

CC:

- 1.PPS to JS(R), Ministry of Health & Family welfare, Nirman Bhawan, New Delhi.
2. All India Drugs Control Officers Confederation (AIDCOC).
3. CDSCO Website.