

File No.4-01/2013-DC (Misc. 13-PSC)  
Directorate General of Health Services  
Office of Drugs Controller General (India)  
(FDC Division)

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated:

28 MAR 2014

To,  
All State/UT Drugs Controllers

**Subject:** Approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG(I)-regarding.

Sir,

This is in continuation to this office letter dated: 15.01.2013, 05.07.2013, 02.09.213 and 03.02.2014 on the subject cited above.


In this regard, you are requested to inform manufacturers of such FDCs to make presentation before the office of DCG(I) as and when directed and such presentations shall mandatorily contain following information:

1. Name of product with composition and indication.
2. Rationale.
3. Pharmacokinetic/Pharmacodynamic interactions and Pharmacokinetic rationality (with half life details of individual drugs, dosage schedule of individual drug alongwith reference etc.
4. Published data regarding safety and efficacy of applied FDC.
5. Original data generated by the applicant on applied FDC, if any.
6. PMS data generated by the applicant on applied FDC, if any.
7. Regulatory status of FDC in-other countries, if any.
8. Similar FDC approved, if any by DCG(I).
9. Further studies planned, if any.

You are requested to communicate the manufacturers to compile & present the data in above format while presenting their proposals before the office of DCG(I). You are also requested to instruct the manufacturers to bring Drug samples in original pack as well as package insert while coming for presentation.

Action taken in the matter may kindly be intimated to this office

Yours faithfully,

  
(Dr. G. N. Singh)

Drugs Controller General (India)

**Copy to:-**

1. PPS to DGHS, Dept. of Health and Family Welfare, Nirman Bhawan, New Delhi
2. PPS to ASDG, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
3. PS to JS, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
4. All Zonal/sub Zonal offices of CDSCO.
5. Members of all the Expert committees constituted for the purpose of evaluation of such FDCs.
6. Manufacturing Associations: IPA, IDMA, OPPI, SPICS.