F. No. 4-01/2013-DC(Misc13-PSC)
Directorate of General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi
(O/o Drugs Controller General (I))

FDA Bhawan,
Kotla Road, New Delhi
Dated: 15 JAN 2013

To,

1. **All State / UTs 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,

The grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term 'new drug' in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India) had been raised in many forums from time to time. The Parliamentary Standing Committee of the Ministry of Health and Family Welfare in its 59th report on the functioning of CDSCO have also observed that the some of the State Licensing Authorities have issued manufacturing licenses for a very large number of FDCs without prior clearance from CDSCO. This has resulted in the availability of many FDCs in the market which have not been tested for efficacy and safety. This can put patients at risk.

The Ministry of Health and Family Welfare had issued repeated statutory directions under Section 33P to the State Governments to instruct their respective drug licensing authorities to refrain from granting licenses for manufacture of new drugs and FDCs covered under the definition of the term 'new drug' without due approval of the Drugs Controller General (India). The last such direction was issued vide letter No. X11011/1/2011-DFQC dated 1st October, 2012 wherein the State / UT Governments were directed to instruct their respective Drug Licensing Authorities to abide by the provisions prescribed under the Drugs and Cosmetics Rules for grant of manufacturing licenses for drugs falling under the definition of the term 'new drug' and not to grant licenses for manufacture for sale or for distribution or for export of such new drugs except in accordance with the procedures laid down under the said rules i.e. without prior approval of the Drugs Controller General (India).

Earlier, in 2007, direction was issued to the State Drugs Controllers to withdraw 294 FDCs which were licensed without approval of DCG (I). However, the manufacturers Association got stay order from the Madras High Court. The matter is still sub-judice. Action in respect of the aforesaid 294 FDCs will be taken after the outcome of the court case in Madras High Court.

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.12, without the permission of DCG(I), it has been decided that the DCG(I) will ask all the State Drugs Controllers to ask the concerned

manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.

As regards the new FDCs, if any, licensed by the State Licensing Authorities after 01.10.2012 without approval of DCG(I), the same will be considered for being prohibited for manufacturing and marketing in the country.

In view of above, you are requested to ask the concerned manufacturers in your State to prove the safety and efficacy of the FDCs as mentioned above before the office of DCG(I) within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.

Action taken in the matter may kindly be communicated to the undersigned in due course.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy forwarded to:

1. All zonal and sub-zonal offices of CDSCO
2. Under Secretary, Drugs, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi