**F. No. 04-146/2007-DC (Part-I)**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**(FDC Division)**

**FDA Bhawan, Kotla Road,**
**New Delhi**
**Dated:** 27/8/2021

**To,**

**All State/UT Drugs Controller**

**Subject:- Manufacturing and Marketing of certain FDCs as per directions of Hon'ble High Court, Maharashtra, Nagpur Bench - regarding.**

Sir,

As you are aware while reviewing the directions of the Hon'ble High Court, Maharashtra, Nagpur bench on following FDCs which are already approved by DCG(I) in specific dosage forms and strengths, DTAB in its meeting held on 27.08.2019 also referred these FDCs to the Prof. Kokate Committee :-

| Sr. No. | Fixed Dose Combinations (FDCs) |
|---|---|
| 1. | Cefixime + Cloxacillin |
| 2. | Cefixime + Cloxacillin + Lactobacillus |
| 3. | Cefadroxil + Clavulanic acid |

As per the report of DTAB dated 13.04.2021 and recommendations of subcommittee of DTAB as approved, the above FDCs have been considered as **rational** with certain conditions.

As regard to the FDC of Cefixime + Cloxacillin and FDC of Cefixime + Cloxacillin + Lactobacillus, these have been considered as rational if cloxacillin is in sustained release form in twice daily doses schedule. The indication of the FDC should be restricted to skin and soft tissue infections.

As regard to the FDC of Cefadroxil + Clavulanic acid, firms should prove the efficacy of the combination by conducting in-vitro study in GLP complied laboratory for all the approved indications with respect to the infections caused by susceptible microorganisms including S. aureus. The study should compare cefadroxil alone and in FDC. Accordingly the study protocol should be submitted for approval within 3 months of the notification.

In view of above, you are requested to direct all the manufacturers of above FDCs to manufacture and market the above FDCs at S. No. 2 & 3 only for the indication as

mentioned above. Further as regard to the FDC at S.No.1, you are requested to direct manufacturers to submit the protocol for conducting in-vitro study to prove the efficacy of this combination to this office for approval.

Yours faithfully,

**(Dr. V. G. Somani)**
**Drugs Controller General (India)**

**Copy to:-**

1. PS to JS(R), Ministry of Health and family Welfare, Nirman Bhawan, New Delhi
2. CDSCO Zonal and Sub-Zonal offices
3. Drug Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE/Indian Drug/ Pharmaceuticals Association Forum
4. Website of CDSCO