INDIAN DRUG MANUFACTURERS' ASSOCIATION

102, POONAM CHAMBERS, 'A' WING, DR. A. B. ROAD, WORLI, MUMBAI 400 018, INDIA

Phone : 91- 22 - 24974308
91- 22 - 24944624
Fax : 91- 22 - 24950723

E-mail : idma1@idmaindia.com
accounts@idmaindia.com
Website : www.idma-assn.org

PARTNERS IN GLOBAL HEALTHCARE

5th March 2015

To,
Mr. O S Sadhwani
Jt. Commissioner (HQ)
Food & Drug Administration Maharashtra
Opp. RBI, Bandra Kurla Complex
Bandra (East), Mumbai 400 051

Subject:- Fixed Dose Combination (FDC) of Cefixime (200/200/100) + Azithromycin (250/500/125)

Dear Mr. Sadhwani,

This is to inform you that the State-Licensing Authority (SLA) Approved FDCs prior to September 2012 (post-1988) were to be regularized by the DCG(I) after submitting data on safety and efficacy by the concerned manufacturers. Accordingly for the said FDC of cefixime + azithromycin various companies such as Macleods, Alkem, Mankind, Akums, FDC and others had submitted dossiers to DCG(I) with the necessary data. The scrutiny of the dossiers submitted for over 6000 FDCs have been undertaken by a special committee operational under Prof Kokate. We understand that the report of Prof Kokate has been submitted to the concerned Ministry and the same is yet to be decided upon possibly by the DTAB.

In the meanwhile, pending the DTAB decision, those FDCs for which the data has been submitted by the concerned manufacturers, most of which have been in existence for years, needs to be made available. Especially the FDC of cefixime + azithromycin needs to be persisted with since it has been mentioned in the DCG(I) correspondence to the manufacturer that said combination is 'useful for certain population of patients with multi-resistant typhoid fever or moderate-to-severe lower respiratory tract infections'.

We would therefore request you to allow the existing manufacturers to continue manufacturing and marketing the said product till such time the DTAB report is officially made available.

Thanking You,

Yours Sincerely,

7/3/15

S V Veerramani
President

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