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File No.4-01/2011-DC (Pt. Deanxit)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

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FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 10 JAN 2013

To
All the States/UTs Drugs Controller

Sub: To established the safety and efficacy of the FDC of Flupenthixol + Melitracen on Indian population-regarding.

Sir,

The FDC of Flupenthixol + Melitracen tablets was approved by this Directorate on 28.10.1998 for manufacturing and marketing in the country. However, concerns have been raised on the safety and efficacy of the drug. Concerns have been also raised that there must be some very good reasons for Danish Medicine Agency (Denmark) not to approve a domestically developed drug where an anti-depressant drug would perhaps be in greater demand as compared to India. Curiously, FDC of Flupenthixol + Melitracen tablets is allowed to be produced and exported but not allowed to be used in Denmark. The drug is not marketed in major developed countries such as United States, Britain, Ireland, Canada, Japan, Australia etc.

The issue of safety and efficacy of the FDC is under examination in consultation with the experts committee.

In view of concerns raised on the drug, it has been decided that the manufacturer of the drug shall be instructed to establish the safety and efficacy of the FDC of Flupenthixol + Melitracen tablets within 6 months, failing which the drug would be considered for being prohibited for manufacture and marketing in the country.

In view of above, you are requested to instruct the manufacturers of the FDC of Flupenthixol + Melitracin under your jurisdiction to establish safety and efficacy of the drug within the period of six months before this Directorate, failing which the drug would be considered for being prohibited for manufacture and marketing in the country.

Yours faithfully,


(Dr. G. N. Singh)

Drugs Controller General (India)

Copy to:-

1. US (D), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. All Zonal/Sub zonal offices of CDSCO.