

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

No.X.11053/1/2009-D

Date : 01-9-2009

To
All State Drugs Controllers/Union Territories

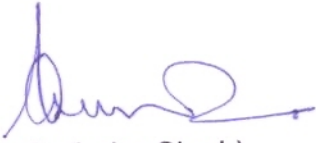
Sir,

Sub: implementation of WHO Certification Scheme by CDSCO -reg.

A considered view has been taken that Certificate of Pharmaceutical Products (COPP) and Certificate of GMP under WHO Certification shall be taken over by the National Regulatory Authority ie DCG (I) office. The WHO has time and again expressed concerns on the implementation of WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

The matter was discussed in the 40th meeting of DCC held at New Delhi on 29-06-2009 and the States were informed that this activity would henceforth be taken over by CDSCO in a period of 3 months and WHO informed accordingly.

Now, the directorate has decided to implement WHO Certification Scheme by CDSCO from 1st October 2009 and COPPs will be issued by Offices of CDSCO after inspection of manufacturing facilities by CDSCO regulatory officials.



(Dr.Surinder Singh)

Drugs Controller General (I)

- CC:
- 1.Shir D.Panda, Joint Secretary, Ministry of Health, Nirman Bhavan, New Delhi.
 - 2.Shri ArunJha, Joint Secretary, Department of Pharmaceuticals, New Delhi
 - 3.Smt Gaitri I.K, Joint Secretary, Ministry of External Affairs, New Delhi.
 - 4.Shri Rajeev Kher, Joint Secretary, Ministry of Commerce, New Delhi.
 - 5.Mr.L.Belgharbi, WHO, Geneva.
 - 6.Mr.S.J.Hybayeb, WR, Nirman Bhavan, New Delhi
 - 7.Mr.Anil Chawala, SEARO, WHO, New Delhi.
 8. All Zonal and Sub-Zonal offices of CDSCO
 9. Manufacturing Associations (IDMA, OPPI, IPA, BDMA, SPIC, CIPI, FOPE).
 - 10.Pharmexcil, Ameer Pet, Hyderabad.