File No. DCGI/MISC/2014 (223)
Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
(Office of DCGI)

FDA Bhavan, Kotla Road,
New Delhi-110002.
Dated: 10th December, 2014

NOTICE

As you are aware that Ministry of Health & Family Welfare, Government of India is taking proactive measures to strengthen the regulatory framework in the country at the Central and State level. The Expenditure Finance Committee note has been put on the website of Ministry of Health & Family Welfare and Central Drugs Standards Control Organization. In this regard, you are hereby requested to forward your comments/suggestion to the Ministry of Health & Family Welfare **by 22.12.2014.**

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

To

1. All State/UT Drugs Controllers
2. Dr. R.A. Mashelkar, Padmabhushan, National Chemical Laboratory, Pune.
3. Prof. Ranjit Roy Chaudhury, Padmashree, Professor of Pharmacology, New Delhi
4. Dr. Nitya Anand, Former Director, CDRI, Lucknow.
5. Dr. M.K. Bhan, Former, Secretary, Department of Biotechnology, New Delhi
6. Dr. Ashwini Kumar/ Dr. Prem Kumar Gupta, Former Drugs Controller India
7. President, Pharmacy Council of India, New Delhi.
8. Dr.(Mrs.) Jayashree Gupta, Consumer India, New Delhi
9. Mr. Bejon Misra, Partnership for Safe Medicines, New Delhi
10. Ms. Leena Menghaney, MSF Assess Counting, New Delhi
11. Dr. Mira Shiva, Founder Coordinator & Co-Convenor, All India Drug Action Network New Delhi
12. IPA/IDMA/OPPI/FOPE/BDMA/CIPI/AIMED/ADMI/ISCR/ACRO/SME/FICCI/CII/ ASSOCHEM/Indian Pharma Forum/AIDCOC/SAMA and Others

Copy to:

Director (Drugs), MoHFW, Nirman Bhawan, New Delhi.

Ministry of Health and Family Welfare

Strengthening of Drug Regulatory System in India viz. (i) Central Drugs Standard Control Organisation (CDSCO); and (ii) States' Drug Regulatory System.

The Department of Health and Family Welfare proposes to implement: (i) a Central Sector Scheme for Strengthening the Central Drugs Standard Control Organisation (CDSCO); and (ii) a Scheme for strengthening of the State Drug Regulatory System during the residual period of Twelfth Five Year Plan (2012-2017) at an estimated cost of Rs.900 crore and Rs.850 crore (excluding States' share) respectively. The proposed strengthening of structures will facilitate expeditious consideration and faster decision making and testing of medical products wherever required and serve the objective of the quality, safety and efficacy of drugs and other medical and cosmetics products.

2) Strengthening of CDSCO entails the following components:

(i) Strengthening of Drug safety infrastructure at CDSCO, establishment of a Training Academy and installing e-Governance mechanism and networking of CDSCO and State Drugs Control Departments;

(ii) Construction of new drug testing laboratoriesand up-gradation of existing Central Laboratories;

(iii) Creation of new laboratory and regulatory posts and providing basic and advanced training to the officials.

3) Strengthening of State Drug Regulatory System entails the following components:

(i) Strengthening of Drug Safety Infrastructure at State level;

(ii) Setting up of new laboratories and strengthening of existing State level laboratories;

(iii) Creation of new laboratories and regulatory posts andproviding basic and advanced training of officials.

4) The CDSCO implements the provisions of the Drug and Cosmetics Act, 1940 and the Rules framed thereunder in respect of the matters falling within the purview of the Central Government and the State Drugs Control Departments are responsible for regulating matters under the purview of the State Governments. To ensure proper implementation of the above Act and the Rules uniformly in a transparent manner throughout the country, the enforcement structures at the Centre and in all the States / UT's need to be strengthened and upgraded. Funds to the States / UTs are to be released after a Memorandum of Understanding (MoU) is signed between the respective State/ UT Government and the CDSCO regarding objectives and timelines for completion of activities, etc.

5) The brief details of the Scheme are being placed in public domain with a view to elicit the comments/ views of the Stakeholders including the general public. The comments/ views may be forwarded to Under Secretary (Drugs), Room no. 527 "C" Wing, NirmanBhawan, New Delhi - 110011or e- mailed at *anita.tripathi76@nic.in*before 22.12.2014.

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