

File No. 12-01/14-DC Pt.47
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, New Delhi-110002

Date: 03.07.2014

ORDER

SUBJECT: Creation of cell for co-ordination with institutes like ICMR for sponsoring various studies- regarding


The Ministry of Health & Family Welfare had constituted an Expert Committee under the Chairmanship of Prof. Ranjit Roy Chaudhury to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs. The Expert Committee submitted its report to the Ministry of Health & Family Welfare. The actions proposed to be taken on the recommendations of the Expert Committee were finalized by the Ministry of Health & Family Welfare.

As per the report, the CDSCO may need information continuously on post-marketing Surveillance of drugs, rational use of medicines, drug utilization studies and adverse drug reaction monitoring etc. It will be useful if a research unit is created within the Central Drugs Standard Control Organization (CDSCO). This unit would initiate and sponsor studies in these areas to be able to get the needed information to help in decision-making.

Pursuant to the actions in this regard as decided by the Ministry, a cell is constituted in CDSCO comprising following officials to co-ordinate with agencies such as ICMR for the conduct of various studies.

- 1) Dr. A. Ramkishan , Deputy Drugs Controllers (India), CDSCO H.Q
- 2) Shri Somnath Basu, Asstt. Drugs Controller (India), CDSCO, H.Q
- 3) Shri. M. Balakumar, Drugs Inspector, CDSCO H.Q

The members of the cell will co-ordinate with agencies such as ICMR, for the conduct of specific studies for the Post-marketing surveillance of drugs, Rational use of medicines, Drug utilization studies, Adverse drug reaction monitoring etc. that would enable CDSCO for continued evaluation of drugs marketed in India and to take regulatory actions on continued use such drugs in the country.


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

To

All officers concerned / JDC (I), DDC (I), H.Q & Zonal officers

Copy to:

US (D), MOHFW, Nirman Bhawan, N. Delhi