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

Dated: 03.07.2014

ORDER

SUBJECT: Clinical Trial on Medical Device- 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.

Clinical Trial of Medical Device is different in nature as compared to that of Drugs or Vaccine. In case of Medical Device, there is no concept of conducting Phase I Clinical trial to assess safety, tolerability of the Medical Device. However, in pursuant to the decision of the Ministry of Health and Family Welfare, it has been decided that the procedures for the Clinical Trials approval, accreditations of Investigators, sites, Ethics Committee and such other conditions would be similar to the Clinical Trials of New Drugs/Vaccines

All concerned are hereby directed to comply with the above decision.

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

To:

1. **IDMA / IPA / OPPI / ISCR / ACRO**
2. **NDAC / MDAC Members**

CC to:

US(D), Ministry of Health and Family Welfare