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: Placebo controlled trials - 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 mentioned in the report, Placebo-controlled trials are fairly uncommon these days, although there will always be a case for such trials in special circumstances. Since other remedies are usually available, the drug to be tested is compared to the existing therapy. There is thus no reason to deprive a patient of a drug in such placebo controlled trial. The pharmaceutical companies, the Investigators, the drugs regulator and the ECs all would have to ensure that the design used in a placebo controlled clinical trial is appropriate, efficient and ethical.

In view of the above, all the sponsors/CROs/Clinical trial applicants/Ethics Committees are required to ensure that the design used in a placebo controlled clinical trial is appropriate, efficient and ethical. The NDAC members are also requested to ensure that only those placebo control trials, design of which are appropriate, efficient and ethical considered for approval.

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

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

CC to:

US (D), Ministry of Health and Family Welfare