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: Number of subjects in Phase III Global Clinical 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.

Pursuant to above, it has been decided that if Indians have participated in Phase III Global Clinical Trials, the number of participants would have be adequate for considering approval of the drug in India.

In view of above, all the NDAC experts are requested to evaluate applications of such new drugs NDAC adhering to the above said requirement.

(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