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: Waiver of Clinical Trial in Indian population for approval of New Drugs- 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 finalised by the Ministry of Health & Family Welfare.

In pursuance to above, it has been decided that waiver of Clinical Trial in Indian population for approval of new drugs, which have already been approved outside India, can presently be considered only in cases of national emergency, extreme urgency, and epidemic and for orphan drugs for rare diseases and drugs indicated for conditions/diseases for which there is no therapy.

(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