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: Requirements of local trial for a generics or similar biologics (Bio-similars) in other country like USA for its approval in the country-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.

In pursuance to above, in regard to consideration of requirements of local trial for a generics or similar biologics (Bio-similars) in other country like USA for its approval in the country, it has been decided that the drugs considered generics and similar biologics (biosimilars) in other countries like USA that have been marketed in such countries for more than four years and have a satisfactory report would be approved for marketing in India after abbreviated trials.

In view of above, all the NDAC experts are requested to evaluate applications of such new drugs which are considered generics and similar biologics (biosimilars) in other countries like USA are evaluated keeping in view the above requirements.

(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