File No. 12-01/14-DC (Pt. 47)
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, New Delhi 110002

Dated 10.11.2015

CIRCULAR

Subject:- Requirement of approval of Review Committee on Genetic Manipulation (RCGM) under Department of Biotechnology for r-DNA derived drugs like Insulin, Monoclonal antibody, etc. – regarding.

To deliberate stakeholders concerns and the way forward relating to some issues on conduct of clinical trials in India, two meetings were held on 20.08.2015 and 06.10.2015 under the Chairmanship of Secretary, Ministry of Health and Family Welfare in which experts including Secretary, D/o Health Research & Director General, ICMR and Director General Health Services were present.

As regards requirement of approval of Review Committee on Genetic Manipulation (RCGM) under Department of Biotechnology for r-DNA derived drugs like Insulin, Monoclonal antibody, etc., it was decided in the meeting that the applicant may submit parallel application to RCGM and DCG (I) seeking approval to conduct clinical trial. However, DCG (I) shall complete the scrutiny of application and issue permission, only after RCGM clearance was received.

This is communicated for information and necessary compliance by all concerned.

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

To:-

i) All stakeholders through website of DCG (I).
ii) Zonal and Sub-zonal offices of CDSCO/ all officers of CDSCO (HQ).

Copy to:-

i) PS to Secretary, Ministry of Health and Family Welfare
ii) PPS to DGHS,
iii) PPS to JS(R).