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

Dated 03.08.2016

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 trial 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 and Director General, ICMR and Director General of 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. PPS to secretary
II. PPS to DGHS
III. PPS to AS (Food and drugs)
IV. PS to JS (R)