

Protocol – IV Import and marketing of Pharma Products in Bulk for making Finished Formulation where the End Product is a LMO

Application

GEAC (Examines data generated in the Country of origin and other countries where the product has been tested and accords “in principle” approval for limited import for conduct of clinical trials. GEAC to inform DCGI and directs the applicant to setup IBSC)

Institutional Biosafety Committee (IBSC)

RCGM (Approves activity, recommends to DCGI for clinical trials and forward views to GEAC on containment facilities)

DCGI
(Approves human CT)

GEAC examines information on containment facilities and data on clinical trials

Approval

Human CT conducted

Approval

DCGI (Approves market authorization under Drugs & Cosmetics Act and Rules based on clinical trials data)

GEAC (Examines environmental risk versus benefits and accords approval for environmental release under Rule 1989 of EPA)

DCGI- Post release monitoring