

MINUTES OF THE 197th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 07.01.2021 BY VIDEO CONFERENCING

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 197th meeting and initiated the process of the meeting. The list of participants is given at Annexure-I.

2. The Committee adopted the minutes and recommendations of the 196th meeting of the RCGM held on 24.12.2020.

3. On action taken report, the Member-Secretary informed that during the 196th meeting of the RCGM, a total of 32 applications including information items were considered and the Secretariat is in the process of issuing requisite permit letters based on the recommendations of the RCGM.

4. Proposals considered

4.1 Applications in the area of pharmaceuticals

The committee considered application to conduct preclinical toxicity studies on anti-CD 19 CAR-T cells product, Anakinra biosimilar, Pegylated Recombinant *E. coli* asparaginase, recombinant measles vectored 2019-nCoV (SARS-CoV-2) vaccine, SARS-CoV-2 receptor binding domain-based vaccines candidates and AAV gene therapy product; pre-clinical toxicity study reports on Tenecteplase biosimilar, Tocilizumab biosimilar, simian adenovirus (ChAd36-SARS-CoV-S) vectored vaccine for COVID-19 and Chimeric Antigen Receptor CAR-T cells technology for cancer treatment; progress report on change in required biosafety level from BSL-3 to enhanced BSL-2. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

4.2 Applications in the area of Agriculture

The Committee considered application to receive GE cotton line expressing *MSc14* gene; on conduct confined field trial for event selection for GE cotton lines expressing *Cry2Ai* gene. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

5. IBSC Reports

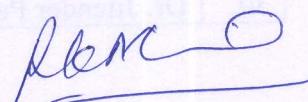
The Committee considered minutes submitted by four IBSCs, Nil annual compliance reports and Nil medical surveillance report, appropriate decision was taken by the RCGM.

6. Other items

The Committee considered Draft document on biosafety of biorepositories, ratification of IBSC related matter, appropriate decision was taken by the RCGM.

No other transaction took place and the meeting ended with vote of thanks to the chair.

The Minutes are approved.



(Dr. Rakesh Kumar Mishra)
Chairman, RCGM

Annexure-I

List of Participants:		
1.	Dr. Rakesh Kumar Mishra, Director-CCMB, Hyderabad	Chairman
2.	Dr. Amita Aggarwal, Professor, SGPIMS, Lucknow	Co-Chair (Pharma)
3.	Dr. Anand Kumar Kondapi, School of Life Science, University of Hyderabad, Hyderabad	Member
4.	Dr. Gururaj Katti, Former Principal Scientist & Head, ICAR- IIRR, Hyderabad	Member
5.	Dr. P. V. Mohanan, Scientist 'G', SCTIMST, Thiruvananthapuram	Member
6.	Dr. R. Uma Shaanker, University of Agricultural Sciences, Bengaluru	Member
7.	Dr. Chandish R. Ballal, Former Director, National Bureau of Agricultural Insect Resources, Bangalore	Member
8.	Dr. Neelam S. Sangwan, Head, Department of Biochemistry, Central University of Haryana, Mahendergarh	Member
9.	Dr. Pradyumna Kumar Singh, CSIR-National Botanical Research Institute, Lucknow	Member
10.	Dr. S.K. Rath, Principal Scientist, CSIR- CDRI, Lucknow	Member
	Dr. K.G.Tirumurugaan, Professor, TANUVAS, Chennai	Member
11.	Dr. Rajesh Gokhale, National Institute of Immunology, New Delhi	Member
12.	Sh. Jayant Ganga Khedkar, Asst Drugs Controller(India), CDSCO	Nominee-CDSCO
13.	Dr. Geeta Jotwani, Scientist F	Nominee-ICMR
14.	Dr. Nitin K. Jain, Scientist 'F', DBT	Member Secretary
15.	Dr. Sangeeta Agarrwal, CSO, BSU, New Delhi	Special Invitee
16.	Dr. Gandharva Nagpal, Scientist 'C', DBT	Secretariat Member
Biosafety Support Unit:		
17.	Dr. Pranjali Vishwakarma, Scientist	
18.	Dr. Reema Sharma, Scientist	
19.	Dr. Govind Kumar Rai, Scientist	
20.	Dr. Poonam Vishwakarma, Scientist	
21.	Dr. Shipra Shahi, Scientist	
22.	Dr. Manpreet Kaur, Scientist	
Others:		
23.	Dr. Praveen Agarwal, M/s. Gennova Biopharmaceutical Limited, Pune	
24.	Dr Rajesh kumar Singh, M/s. Gennova Biopharmaceutical Limited, Pune	
25.	Dr Narendra Deshmukh, M/s. Intox Pvt. Ltd., Pune	
26.	Dr. Balareddy, M/s. Hetero Biopharma Limited, Telangana	
27.	Dr Rajendra Kumar, M/s. Hetero Biopharma Limited, Telangana	
28.	Dr. Kapil Maithal, M/s. Cadila Healthcare Limited, Ahmedabad	
29.	Dr Ayan Dey, M/s. Cadila Healthcare Limited, Ahmedabad	
30.	Dr. Jitender Patel, M/s. Cadila Healthcare Limited, Ahmedabad	