

MINUTES OF THE 214th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 02.09.2021 BY VIDEO CONFERENCING

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 214th 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 213th meeting of the RCGM held on 19.08.2021

3. On action taken report, the Member-Secretary informed that during the 213th meeting of the RCGM, a total of 15 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 applications to import Adenovirus serotype 5 and recombinant Adenovirus, analytical reagents for testing of Gam-COVID Vac combined vector vaccine; to conduct pre-clinical toxicity study of Natalizumab biosimilar; pre-clinical toxicity study reports on FIX- novel gene therapy product, recombinant Insulin Isophane, Pertuzumab biosimilar, Tocilizumab biosimilar; preclinical CMC data of anti-CD19 CAR-T cells along with request for waiver of preclinical toxicity studies; RCGM requirement for recombinant DNA products developed outside India by a contract development and manufacturing organization. After deliberation on each application including information items, appropriate decisions were taken by the RCGM.

4.2 Applications in the area of Agriculture

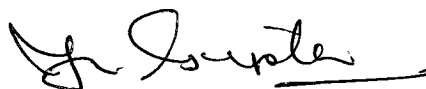
The Committee considered information items and after deliberation, appropriate decisions were taken by the RCGM.

5. IBSC Reports

The Committee considered minutes submitted by six IBSCs, nil annual compliance report and nil medical surveillance report, and appropriate decisions were taken by the RCGM.

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

The Minutes are approved.

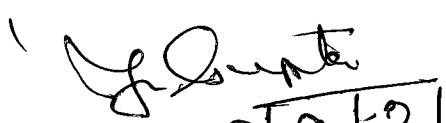


(Prof. Y.K. Gupta)
Chairman, RCGM

9/9/21.

Annexure-I

List of Participants:		
1.	Prof. Y.K. Gupta, Former Director IITR, Lucknow and President, AIIMS, Bhopal	Chairman
2.	Dr. Alka Sharma, Scientist 'G' & Head Regulation, DBT	Member
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. Vinay Nandicoori, Director, CSIR-CCMB, Hyderabad	Member
6.	Dr. P. V. Mohanan, Scientist 'G', SCTIMST, Thiruvananthapuram	Member
7.	Dr. R. Uma Shaanker, University of Agricultural Sciences, Bengaluru	Member
8.	Dr. Neelam S. Sangwan, Head, Department of Biochemistry, Central University of Haryana, Mahendergarh	Member
9.	Dr. S.K. Rath, Principal Scientist, CSIR- CDRI, Lucknow	Member
10.	Dr. Rajnish Kumar Chaturvedi, CSIR-Indian Institute of Toxicology Research, Lucknow	Member
11.	Dr. Pradyumna Kumar Singh, CSIR-National Botanical Research Institute, Lucknow	Member
12.	Dr. Kavita Lole, Scientist, National Institute of Virology, Pune. Nominee - ICMR	Member
13.	Dr. Ajit Kumar Shasany, Director, ICAR-National Institute for Plant Biotechnology, New Delhi. Nominee - ICAR	Member
14.	Sh. Jayant Ganga Khedkar, Astt Drugs Controller (India), CDSCO. Nominee - CDSCO	Member
15.	Sh. Tarun Kathula, Director Biosafety & Member Secretary-GEAC, Ministry of Environment, Forest and Climate Change, Government of India. Nominee - MoEF & CC	Member
16.	Dr. Naryanam Srikanth, Deputy Director General, Central Council For Research In Ayurvedic Sciences, Ministry Of Ayush. Nominee - Ministry of Ayush	Member
17.	Dr. Neelima Mishra, Scientist 'G', Science and Engineering Research Board, New Delhi. Nominee - DST	Member
18.	Sh. Sanjeev Arora, Deputy Director, Ministry of Home Affairs. Nominee - MHA	Member
19.	Dr. Nitin K. Jain, Scientist 'F', DBT, New Delhi	Member Secretary
20.	Dr. Sangeeta Agarrwal, CSO, BSU, New Delhi	Special Invitee
21.	Dr. Gandharva Nagpal, Scientist 'C', DBT, New Delhi	Secretariat Member
Biosafety Support Unit:		
22.	Dr. Poonam Vishwakarma, Scientist	
23.	Dr. Govind Kumar Rai, Scientist	
24.	Dr. Manpreet Kaur, Scientist	
25.	Dr. Reema Sharma, Scientist	
Others:		


 9/9/21

26.	Dr. Ramnath RL., M/s. Reliance Bio, Mumba
27.	Mr. Girish Masand, M/s. Reliance Bio, Mumbai
28.	Dr. Praveen Rao, M/s. Reliance Life Sciences Pvt. Ltd., Mumbai
29.	Dr. Lakshmikanth Gandikota, M/s. Intas Pharmaceuticals Limited, Ahmedabad
30.	Mr. Akash Savaliya, M/s. Intas Pharmaceuticals Limited, Ahmedabad
31.	M/s. Charnit Jashal, M/s. Intas Pharmaceuticals Limited, Ahmedabad
32.	Mr. Chintan Patel, M/s. Cadila Pharmaceuticals Limited, Ahmedabad
33.	M/s. Durgabhavani Kuchibhatla, M/s. Virchow Biotech Private Limited, Hyderabad

1

J. D. D. D.
9/9/21