MINUTES OF THE 205th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 29.04.2021 BY VIDEO CONFERENCING

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the **205**th 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 204th meeting of the RCGM held on 15.04.2021
- 3. On action taken report, the Member-Secretary informed that during the 204th meeting of the RCGM, a total of 17 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 *Komagataella phaffii* expressing CoV RBD spytag variants and corresponding RBD Spytag proteins, reagents for Chimpanzee adenovirus expressing Spike protein of SARS-CoV-2 South African variant, virus seed for component-I &II, HEK 293, Ad26 and Ad5 cell lines, Working cell bank (HEK 293) and Working viral banks - rAD5 and rAD26; pre-clinical toxicity study of Denosumab biosimilar, Ustekinumab biosimilar, protein subunit vaccine against SARS-CoV-2 virus; pre-clinical toxicity study reports on ranibizumab biosimilar, Infliximab biosimilar. After deliberation on each application including information items, appropriate recommendations were made by the RCGM.

4.2 Applications in the area of Agriculture

The Committee considered application to receive seeds of GE cotton Event. After deliberation on each application including information items, appropriate recommendations were made by the RCGM.

5. IBSC Reports

The Committee considered minutes submitted by eight IBSCs, Nil annual compliance reports and Nil medical surveillance report, and appropriate recommendations were made by the RCGM.

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6. Other items

The Committee deliberated on the justification submitted for not performing Necropsy on Day 2 after last dose in Non rodent study and additional data pertaining to the Rodent study for a C5 application, and appropriate recommendations were made 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

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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. Kuldeep Singh, Director, ICAR- NBPGR, New Delhi	Co-Chair (Agri)	
4.	Dr. Anand Kumar Kondapi, School of Life Science, University	Member	
	of Hyderabad, Hyderabad	1,10111001	
5.	Dr. Gururaj Katti, Former Principal Scientist & Head, ICAR-IIRR, Hyderabad	Member	
6.	Dr. P. V. Mohanan, Scientist 'G', SCTIMST,	Member	
7	Thiruvananthapuram	N/ 1	
7.	Dr. R. Uma Shaanker, University of Agricultural Sciences,	Member	
8.	Bengaluru Dr. Neelam S. Sangwan, Head, Department of Biochemistry,	Member	
0.	Central University of Haryana, Mahendergarh	Member	
9.	Dr. Pradyumna Kumar Singh, CSIR-National Botanical	Member	
).	Research Institute, Lucknow	Wichioci	
10.	Dr. S.K. Rath, Principal Scientist, CSIR- CDRI, Lucknow	Member	
11.	Dr. Chandish R. Ballal, Former Director, National Bureau of	Member	
11.	Agricultural Insect Resources, Bangalore	1,10111001	
12.	Dr. K.G. Tirumurugaan, Professor, TANUVAS, Chennai	Member	
13.	Dr. Rajnish Kumar Chaturvedi, CSIR-Indian Institute of	Member	
	Toxicology Research, Lucknow		
14.	Sh. Jayant Ganga Khedkar, Astt Drugs Controller(India),	Nominee-CDSCO	
	CDSCO		
15.	Sh. Tarun Kathula, Director Biosafety, MoEFCC & Member	Nominee-MoEF &	
	Secretary-GEAC	CC	
16.	Dr. Geeta Jotwani, Scientist F	Nominee-ICMR	
17.	Sh. Sanjeev Arora, Deputy Director, Ministry of Home Affairs	Nominee-MHA	
18.	Dr. Nitin K. Jain, Scientist 'F', DBT	Member Secretary	
19.	Dr. Sangeeta Agarrwal, CSO, BSU, New Delhi	Special Invitee	
20.	Dr. Gandharva Nagpal, Scientist 'C', DBT	Secretariat Member	
Biosafety Support Unit:			
21.	Dr. Govind Kumar Rai, Scientist		
22.	Dr. Reema Sharma, Scientist		
23.	Dr. PoonamVishwakarma, Scientist		
24.	Dr. Manpreet Kaur, Scientist		
25.	Dr. Renu Arora, Scientist		
	Others:		
26.	Ms. Alka Mankad, DEO-IV, DBT		
27.	Mr. Dinesh B, M/s. Biocon Biologics Limited, Bangalore		
28.	Mr. Raghu Chitta, M/s. Biocon Biologics Limited, Bangalore		
29.	Mr. Praveen Reddy, M/s. Biocon Biologics Limited, Bangalore		
30.	Dr. Nagaraj G, M/s. Biocon Biologics Limited, Bangalore		
31.	Dr. Arindam Saha, M/s. Biocon Biologics Limited, Bangalore		

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32.	M/s. Sushma Hegde, M/s. Biocon Biologics Limited, Bangalore
33.	M/s. Shruthi Prasad, M/s. Biocon Biologics Limited, Bangalore
34.	Mr. Ramakrishnan, M/s. Novel/ M/s. Biocon Biologics Limited, Bangalore
35.	Dr. Harish Pai, M/s. Biocon Biologics Limited, Bangalore
36.	Dr. Muralidhar Reddy M, M/s. Clonz biotech private limited, Hyderabad
37.	Dr. Sanjeev Gupta, M/s. Ipca Laboratories, Mumbai
38.	Dr. Ramnath L., M/s. Reliance Bio, Mumbai

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