

MINUTES OF THE 187th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 13.08.2020 BY VIDEO CONFERENCING

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 187th 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 186th meeting of the RCGM held on 23.07.2020.

3. On action taken report, the Member-Secretary informed that during the 186th meeting of the RCGM, a total of 37 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 Research virus seed material [SARS-CoV2-V candidate], reagents for simian adenovirus vectored vaccine; to export strains of *Mycobacterium tuberculosis*; to receive whole blood samples from Covid-19 recovered individuals; to conduct preclinical toxicity studies on Aflibercept biosimilar, Filgrastim biosimilar, Corona Virus Vaccine, Tocilizumab biosimilar; pre-clinical toxicity study reports on Ranibizumab biosimilar; study on de-centralized CAR-T cell manufacturing and treatment of relapsed and refractory B cell acute leukemia's and lymphoma's. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

4.2 Applications in the area of Agriculture

After deliberation on information items, appropriate decision was taken by the RCGM.

5. IBSC Reports


The Committee considered minutes submitted by three IBSCs, appropriate decision was taken by the RCGM.

6. Other items

The Committee considered the request of M/s Aurobindo Pharma Limited for the change in company name of R&D location from Biological R&D centre to Biologics R&D centre, request of M/s Serum Institute of India Pvt. Ltd., Pune on containment facility required for handling Covid-19 strain and also discussed regulatory reforms for streamlining RCGM activities and regulatory approval process, and 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

List of Participants:

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| 1. | Dr. Rakesh Kumar Mishra, Director-CCMB, Hyderabad | Chairman |
| 2. | Dr. Amita Aggarwal, SGPIMS, Lucknow | Co-Chair (Pharma) |
| 3. | Dr. Kuldeep Singh, Director, ICAR- NBPGR, New Delhi | Co-Chair (Agri) |
| 4. | Dr. Gururaj Katti, Principal Scientist & Head, ICAR- IIRR, Hyderabad | Member |
| 5. | Dr. S.K. Rath, Principal Scientist, CSIR- CDRI, Lucknow | Member |
| 6. | Dr. P. V. Mohanan, Scientist 'G', SCTIMST, Thiruvananthapuram | Member |
| 7. | Dr. Pradyumna Kumar Singh, CSIR-National Botanical Research Institute, Lucknow | Member |
| 8. | Dr. Anand Kumar Kondapi, School of Life Science, University of Hyderabad, Hyderabad | Member |
| 9. | Dr. R. Uma Shaanker, University of Agricultural Sciences, Bengaluru | Member |
| 10. | Dr. Guhan Jayaraman, Indian Institute of Technology, Madras | Member |
| 11. | Dr. Chandish R. Ballal, Director, National Bureau of Agricultural Insect Resources, Bangalore | Member |
| 12. | Dr. Rajesh S. Gokhale, National Institute of Immunology, New Delhi | Member |
| 13. | Dr. Neelam S. Sangwan, Head, Department of Biochemistry, Central University of Haryana, Mahendergarh | Member |
| 14. | Dr. Rajnish Kumar Chaturvedi, CSIR-Indian Institute of Toxicology Research, Lucknow | Member |
| 15. | Dr. K.G. Tirumurugan, Professor, TANUVAS, Chennai | Member |
| 16. | Sh. Tarun Kathula, Director Biosafety, MoEFCC & Secretary-GEAC | Nominee-MoEF & CC |
| 17. | Dr. Geeta Jotwani, Scientist F | Nominee-ICMR |
| 18. | Dr. Alka Sharma, Scientist-G, & Nodal Officer (Biopharma), DBT, New Delhi | Member |
| 19. | Dr. A.K. Rawat, Scientist- G & Nodal Officer (Agri.), DBT, New Delhi | Member |
| 20. | Dr. Sangeeta Agarwal, CSO, BSU, New Delhi | Special Invitee |
| 21. | Dr. Nitin K. Jain, Scientist-F, DBT | Member Secretary |
| 22. | Dr. Gandharva Nagpal, Scientist C, DBT | Secretariat Member |

Biosafety Support Unit:

23. Dr. Govind Kumar Rai, Scientist
24. Dr. Poonam Vishwakarma, Scientist
25. Dr. Manpreet Kaur, Scientist

Others:

26. Dr. Vikram Mathews, Christian Medical College, Vellore
27. Dr. Akshaya S. Odak, Lupin Limited, Pune
28. Dr. Sudharti Gupta, Lupin Limited, Pune
29. Mr. Vishal Pavitrakar, Lupin Limited, Pune
30. Representatives of M/s. Bharat Biotech International Limited, Hyderabad
31. Representatives of M/s. Hetero Hetero Biopharma Limited, Telangana

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