

MINUTES OF THE 161st MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 14.11.2017 IN THE DEPARTMENT OF BIOTECHNOLOGY

Dr. B. Sesikera, Chairman, RCGM extended a formal welcome to the members of RCGM for the 161st 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 160th meeting of the RCGM held on 26.09.2017.

3. On action taken report, RCGM Secretariat informed that during the 160th meeting of the RCGM, a total of 51 applications including information items was considered and the Secretariat is in the process of issuing the 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 in the area of pharmaceuticals to import recombinant anti RANKL monoclonal antibody, Filgrastim, Nivolumab, Pembrolizumab, anti-CTLA4 antibody, influenza virus strains, overlapping peptides of Zika Env & NS1 protein, Human Insulin, and Scrapie infected N2A cell line; to transfer mouse-adapted Dengue virus serotype 2 cultures; to receive mouse-adapted Dengue virus serotype cultures; to export Anti RANKL antibody producing CHO cell lines, GBR 910 drug substance, recombinant fully human anti RANKL monoclonal antibody, anti CTLA4 and Anti PD-1 antibodies, and recombinant *Pichia pastoris* strain; to conduct pre-clinical toxicity studies on Recombinant PEG-Interferon Beta-1a, and Bevacizumab; pre-clinical toxicity study report on recombinant Natalizumab; monovalent and bivalent vaccine composed of *P. falciparum* fusion proteins, and recombinant Insulin Glargine; and request for extension of the validity of the permission to conduct PCT studies on rh-GCSF. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

2.2 Applications in the area of Agriculture

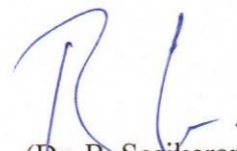
The Committee considered applications in the area of agriculture to import recombinant DNA vectors, *AtPAP2* gene bearing binary construct, *HPT* gene, pGPro3 vector and recombinant *Agrobacterium* harbouring viral elements; to conduct event selection trial on transgenic rice, cotton, maize and inspection reports of Central Compliance Committees on site visits to BRL-1 trials on transgenic maize. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

The Committee also deliberated on 'Requirement of stability data while submitting report of pre-clinical toxicity on recombinant biotherapeutics' and was updated on public consultation on "Regulations and guidelines on biosafety of recombinant DNA research and biocontainment, 2017".

The next meeting of the RCGM was scheduled on 09.01.2018. No other transaction took place and the meeting ended with vote of thanks to the Chair.

The minutes are approved.

Date: 06.12.2017 ,
Place: Bangalore


(Dr. B. Sesikeran)
Chairman, RCGM

ANNEXURE-I

List of Participants:

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| 1. | Dr. B. Sesikeran, NIN, Hyderabad | - Chairman |
| 2. | Dr. S.R. Bhat, Emeritus Scientist, NRCBP, New Delhi | - Co-Chairman |
| 3. | Dr. Shailaja Hittalmani, UAS, Bangalore | - Member |
| 4. | Dr. Vanga Siva Reddy, New Delhi | - Member |
| 5. | Dr. S.N. Sudhakara Babu, DOR, Hyderabad | - Member |
| 6. | Dr. Gururaj Katti, IIRR, Hyderabad | - Member |
| 7. | Dr. A.K. Kondapi, Professor, University of Hyderabad, Hyderabad | - Member |
| 8. | Dr. Sanjeev Galande, Professor, IISER, Pune | - Member |
| 9. | Dr. Debendra K. Sahoo, IMTECH, Chandigarh | - Member |
| 10. | Dr. Madhumita Biswas, New Delhi | - Nominee-MoEF&CC |
| 11. | Dr. Vijay Kumar, Scientist-G, | - Nominee-ICMR |
| 12. | Dr. P.K. Chakrabarty (ADG-ICAR) ICAR, New Delhi | - Nominee-ICAR |
| 13. | Dr. Jayant Gangakhedkar, ADGI, CDSCO, New Delhi | - Nominee-CDSCO |
| 14. | Dr. S.R. Rao, Scientist-H, DBT | - Member Secretary |
| 15. | Dr. Amit Parikh, Scientist-E, DBT | - Member |

Biosafety Support Unit:

16. Dr. G.R. Soni, Chief (Bio-Pharma)
17. Dr. Sangeeta Agarwal, Chief (Agriculture)
18. Dr. Poonam Vishwakarma, Scientist
19. Dr. Sapna, Scientist
20. Dr. Reema Sharma, Scientist
21. Dr. Abhijit Poddar, Scientist

Other representatives:

22. Dr. Tulasi Ramu C., M/s GeneSys Biologics Pvt. Ltd, Telangana
23. Dr. Venkat Reddy Y, M/s. GeneSys Biologics Pvt. Ltd, Telangana
24. Dr. Sujana Dhar, M/s. Genesys Biologics Pvt. Ltd., Hyderabad
25. Dr. Yokesha K., CEFT, Sri Ramachandra University, Chennai
26. Mr. Harinarayana Rao, M/s. Reliance Life Sciences Pvt. Ltd., Navi, Mumbai
27. Mr. Girish Masand, M/s. Reliance Life Sciences Pvt. Ltd., Navi, Mumbai
28. Dr. Sanjay Singh, M/s. Sun Pharmaceutical Industries Ltd , Vadodara
29. Dr. Madhav Marathe, M/s. Sun Pharmaceutical Industries Ltd , Vadodara
30. Dr. Satish T. Panchal, M/s. Sun Pharmaceutical Industries Ltd , Vadodara
31. Mr. Sandip Bose, M/s. Sun Pharmaceutical Industries Ltd , Vadodara
32. Mr. C. Srinivas Reddy, M/s. Sun Pharmaceutical Industries Ltd , Vadodara
33. Mr. Mohd. Hasan Rizwi, M/s. Sun Pharmaceutical Industries Ltd , Vadodara
34. Mr. Suresh S., M/s. Biocon Limited, Bengaluru
35. Mr. Sriram A. V., M/s. Biocon Limited, Bengaluru
36. Ms. Amita Nawani, M/s. Biocon Limited, Bengaluru
37. Mr. Pawan kumar, M/s. Biocon Limited, Bengaluru
38. Mr. Saurav Gupta, M/s. Zydus Cadila, Ahmedabad
39. Mr. Sudhakar Jhadhav, M/s. Jai Research Foundation, Vapi ,Gujrat
40. Dr. Darpesh Gohel, M/s. Jai Research Foundation, Vapi, Gujrat
41. Dr. Paushali Mukherjee, ICGB, New Delhi
42. Dr. Rushdi Shakri, ICGB, New Delhi
43. Prof. V. S. Chauhan, ICGB, New Delhi
44. Dr. Rajender Jena, Malaria Vaccine Development Programme, New Delhi
45. Dr. Kavita Singh, Malaria Vaccine Development Programme, New Delhi