

## **MINUTES OF THE 168<sup>th</sup> MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 09.10.2018 IN THE DEPARTMENT OF BIOTECHNOLOGY**

Since the Chairman, RCGM could not attend the meeting, the Co-Chairman (Pharma), RCGM extended a formal welcome to the members of RCGM for the 168<sup>th</sup> 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 167th meeting of the RCGM held on 21.08.2018.

3. On action taken report, the Member Secretary informed that during the 167th meeting of the RCGM, a total of 79 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 to import synthetic DNA constructs expressing Natalizumab, Eculizumab, Aflibercept & Secukinumab, recombinant *Zika virus* vaccine strains, rabbit polyclonal serum anti-ZIKV-NS3 & NS5 antibodies, CHO cell line expressing ZTS-00508841, anti-IL-4R antibodies, Tildrakizumab, Denosumab & IgG1 antibody, attenuated Dengue serotype, fully human IgG1 anti TNF  $\alpha$ -antibody drug substance, IgG2 Anti RANKL mAb drug substance & IgG2 Anti RANKL mAb protein intermediates, M-NFS-60 cell line, and genetically modified murine Sp2/0 cells expressing antibody against IL-12 and IL-23; to export CHO cell-line expressing Follicle Stimulating Hormone, Trastuzumab & Bevacizumab, MCB & WCB of Recombinant Insulin Glargine Cell Bank; to receive Liraglutide; to transfer Working Cell Banks and Master Cell Bank of recombinant *Saccharomyces cerevisiae* expressing Liraglutide; to conduct MTD study on anti-VEGF molecule; to conduct preclinical toxicity study on recombinant Insulin Glargine; and pre-clinical study reports on recombinant Dengue Tetravalent Vaccine, Dengue Monoclonal antibody, Darbepoetin, and Liraglutide. 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 applications to import *Cry I Ab* protein; to obtain approval on biosafety protocols related to purified, *Cry I Ab* protein, over-expressed in *E. coli*; and to conduct confined field trial on transgenic cotton. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

#### 4.3 Other items

Representative of NBPGR, New Delhi made a presentation on Plant Quarantine measures, storage mechanism and issues on import of transgenic seeds & plants by National Bureau of Plant Genetic Resources.

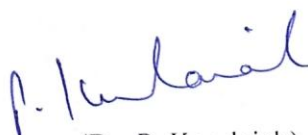
The Committee recommended the extension of the project titled "Establishment of Biosafety Support Unit" for one year within the sanctioned budget.

The Committee was also apprised that DBT has constituted an Apex Committee to work out general principles and guidelines on genome editing technologies, applications and regulations and to identify specific Sub-Committees for data requirements.

The next meeting of the RCGM was scheduled on 20.11.2018. No other transaction took place and the meeting ended with vote of thanks to the Chair.

The minutes are approved.

Date: 24.10.2018  
Place: Bangalore

  
(Dr. P. Kondaiah)  
Acting Chairman, RCGM

## ANNEXURE-I

### List of Participants:

- |  |                    |
|--|--------------------|
| 1. Dr. P. Kondaiah, IISc, Bangalore                        | - Acting Chairman  |
| 2. Dr. S.R. Bhat, Emeritus Scientist, NRCPB, New Delhi     | - Co-Chairman      |
| 3. Dr. Shailja Hittalmani, Former Dean, UAS, Bangalore     | - Member           |
| 4. Dr. Vanga Siva Reddy, CSO, BSU, New Delhi               | - Member           |
| 5. Dr. S.N. Sudhakara Babu, ICAR-, Hyderabad               | - Member           |
| 6. Dr. Vishwanathan Chinnusamy, IARI, New Delhi            | - Member           |
| 7. Dr. Gururaj Katti, Principal Scientist, IIRR, Hyderabad | - Member           |
| 8. Dr. S.K.Rath, Principal Scientist, CSIR-CDRI, Lucknow   | - Member           |
| 9. Dr. Kulbhushan Tikoo, NIPER, Mohali                     | - Member           |
| 10. Dr. A.K. Kondapi, University of Hyderabad, Hyderabad   | - Member           |
| 11. Dr. Debendra K. Sahoo, IMTECH, Chandigarh              | - Member           |
| 12. Dr. Vijay Kumar, ICMR, New Delhi                       | - Member           |
| 13. Dr. Sanjay Kumar, Nominee-CSIR, New Delhi              | - Member           |
| 14. Dr. Gurinderjit Randhawa, Nominee-NBPGR                | - Member           |
| 15. Dr. S.R. Rao, Scientist-H, DBT                         | - Member Secretary |
| 16. Dr. Rajalakshmi Muralidharan, Scientist-F, DBT         | - Member           |

### Biosafety Support Unit:

17. Dr. G. R. Soni, Chief (Bio-Pharma)
18. Dr. Sangeeta Agarwal, Chief (Agriculture)
19. Dr. Poonam Vishwakarma, Scientist
20. Dr. Swati Ohja, Scientist
21. Dr. Samir Dhurai, Scientist

### Other representatives:

22. Dr. C. N. Ramchand, M/s. Saksin Life Sciences, Chennai
23. Dr. Reema Arora, M/s. Saksin Life Sciences, Chennai
24. Dr. Ravikant Harit, M/s. Saksin Life Sciences, Chennai
25. Dr. Supriya, M/s. Saksin Life Sciences, Chennai
26. Dr. S. K. Dhar, M/s. CFFTE, Chennai
27. Mr. S. Raje Kishan, M/s. Saksin Life Sciences, Chennai
28. Dr. M. Sarvanakumar, M/s. Rasi Seeds, Salem, Tamil Nadu
29. Dr. K.S. Mohan, M/s. Rasi Seeds, Salem, Tamil Nadu
30. Dr. P. Karnan, M/s. Rasi Seeds, Salem, Tamil Nadu
31. Mr. Pramod Kumar, M/s. Serum Institute of India Pvt. Ltd, Pune
32. Dr. C. D. Kamat, M/s. Serum Institute of India Pvt. Ltd, Pune
33. Mr. Peddi Srinivas Reddy, M/s. Serum Institute of India Pvt. Ltd, Pune
34. Dr. Bhagwat Gunale, M/s. Serum Institute of India Pvt. Ltd, Pune
35. Mr. Ramnath.R., M/s. Reliance Life Science, Mumbai, Navi Mumbai
36. Dr. M. K. Sahil, M/s. Wockhardt Ltd, Aurangabad
37. Dr. Amarnath Chaterjee, M/s. Wockhardt Ltd, Aurangabad
38. Dr. Shravan Kumar Singh, M/s. Wockhardt Ltd, Aurangabad



39. Dr. V.V. Dange, M/s. Indian Institute of Toxicology, Pune
40. Dr. R. M. Bhide, M/s. Indian Institute of Toxicology, Pune
41. Mr. S. Prathap Kumar, M/s. Stelis Biopharma, Bangalore
42. Mr. G. Rajanarendra, M/s. Stelis Biopharma, Bangalore
43. Dr. Anand Khedkar, M/s. Stelis Biopharma, Bangalore
44. Mr. Kamalpreet, M/s. Stelis Biopharma, Bangalore
45. Mr. Santosh Kumar, M/s. Stelis Biopharma, Bangalore
46. Mr. Jatin Vimal, M/s. Levim Biotech, Chennai
47. Mr. S. Raman, M/s. Levim Biotech, Chennai
48. Mr. Srinivasa Rao Kandula, M/s. RCC Laboratories India Ltd, Hyderabad
49. Dr. J. Jose, M/s. RCC Laboratories India Ltd, Hyderabad