

## **MINUTES OF THE 169<sup>th</sup> MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 20.11.2018 IN THE DEPARTMENT OF BIOTECHNOLOGY**

The Chairman, RCGM extended a formal welcome to the members of RCGM to the 169<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 168<sup>th</sup> meeting of the RCGM held on 09.10.2018.

3. On action taken report, the Member Secretary informed that during the 168<sup>th</sup> meeting of the RCGM, a total of 96 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 CHO cell lines expressing AMG 133 molecule, Rituximab and Denosumab, Insulin Aspart synthetic cDNA, Insulin Glargine synthetic cDNA, Insulin Lispro synthetic cDNA, Insulin Degludec synthetic cDNA, Liraglutide synthetic cDNA, Herpes Simplex virus, CHO cell lines expressing monoclonal antibody expected to bind to the canine IL-4R protein, research cell banks of *Pichia pastoris* expressing Dengue Subunit VLP-based tetravalent and DENV-2 Envelope proteins, working cell bank expressing Erythropoietin, master cell bank expressing Bevacizumab, internal control reagents of S19 Polio Virus materials, Mewo cells infected with recombinant live attenuated *Varicella zoster* virus vaccine strain, and MR766 challenge Zika virus; to transfer working cell banks of recombinant CHO cell lines expressing Trastuzumab, and working cell banks of recombinant *E. coli* expressing Peg-filgrastim; Dengue viruses and anti-dengue 4G2 mAb, and Ranibizumab drug substance and drug product; to export working cell banks and master cell banks of recombinant *Pichia pastoris* expressing Human Insulin; to receive working cell banks of recombinant CHO cell lines expressing Trastuzumab, Dengue Viruses, polyclonal anti-dengue vaccine candidate sera, Ranibizumab drug product & drug Substance; to conduct preclinical toxicity study on recombinant Cetuximab, and human albumin; pre-clinical toxicity study reports of recombinant Insulin Glargine, Streptokinase, and Liraglutide; request for waiver of pre-clinical toxicity study on recombinant Insulin aspart Mix 30; and request for renewal of validity of the permission to conduct preclinical toxicity studies on recombinant human Insulin, recombinant Insulin Lispro, and recombinant Insulin Glargine. 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 transgenic corn seeds; to export seeds of transgenic *Setaria viridis* and *Arabidopsis*; and to transfer transgenic tomato seeds. The Committee also considered confined field trial report for event selection of water use efficient rice and low glucosinolate *Brassica juncea* transgenic lines; and inspection report on event selection trial of Nitrogen use efficient rice. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

### 4.3 Other items

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

The minutes are approved.

Date: Hyderabad  
Place: 17.12.2018

  
(Dr. B. Sesikeran)  
Chairman, RCGM



**List of Participants:**

1. Dr. B.Sesikaran, NIN, Hyderabad
2. Dr. S.R. Bhat, Emeritus Scientist, NRCPB, New Delhi
3. Prof. P. Kondaiah, Chairman, IISc, Bangalore
4. Dr. Shailaja Hittalmani, Emeritus Scientist, UAS, Bangalore
5. Dr. Vanga Siva Reddy, CSO, BSU New Delhi
6. Dr. S.N. Sudhakara Babu, DOR, Hyderabad
7. Dr. Gururaj Katti, Principal Scientist, IIRR, Telangana
8. Dr. S.K. Rath, Principal Scientist, CSIR-CDRI, Lucknow
9. Dr. Kulbhushan Tikoo, Professor & Head, NIPER, Mohali
10. Dr. Debendra K. Sahoo, IMT, Chandigarh
11. Dr. Amita Aggarwal, SGPIMS, Lucknow
12. Dr. Ambikanandan Misra, MSUB, Gujarat
13. Dr. Jayant Gangakhedkar, ADGI, CDSCO
14. Dr. Gurinderjit Randhawa, NBPGR, New Delhi
15. Dr. Rajalakshmi Muralidharan, Scientist- F, DBT

- Chairman
- Co-Chairman
- Member
- Member
- Member
- Member
- Member
- Member
- Member
- Member
- Member
- Member
- Nominee-DCG(I)
- Nominee- NBPGR
- Member

**Biosafety Support Unit:**

16. Dr. G.R. Soni, Chief (Bio-Pharma)
17. Dr. Sangeeta Agarwal, Chief (Agriculture)
18. Dr. Swati Ojha, Scientist
19. Dr. Anuradha Gupta, Scientist
20. Dr. Samir Dhurai, Scientist

**Other representatives:**

21. Dr. R.M. Bhide, M/s. Indian Institute of Toxicology, Pune
22. Dr. Saptarshi Paul, M/s. Epygen Biotech Pvt. Ltd., Navi Mumbai
23. Dr. Punri Bansal, M/s. Epygen Biotech Pvt. Ltd., Navi Mumbai
24. Dr. V.V. Dange, M/s. Indian Institute of Toxicology, Pune
25. Mr. Nikhil Sathe, M/s. Indian Institute of Toxicology, Pune
26. Mr. A.K. Pradhan, University of Delhi, Delhi
27. Dr. Naveen C. Bisht, University of Delhi, Delhi
28. Dr. Deepak Pental, University of Delhi, Delhi
29. Dr. Durga Bhavani Konga, M/s. Virchow Biotech Pvt Ltd, Hyderabad
30. Dr. Naveen Anubrolu, M/s. Virchow Biotech Pvt. Ltd, Hyderabad
31. Dr. Rajyashri K R, M/s. Shilpa Medicare limited, Hubli, Karnataka
32. Mr. Vinay, M/s. Shilpa Medicare Limited, Hubli, Karnataka
33. Dr. Ravi Kumar, M/s. Shilpa Medicare Limited, Hubli, Karnataka
34. Dr. Narendra Deshmukh, M/s. Intox Pvt. Ltd., Pune
35. Mrs. Disha Dadke, M/s. Aurobindo Biologics, Hyderabad
36. Mr. Sivakesava Reddy, M/s. Aurobindo Biologics, Hyderabad
37. Dr. Pankaj Bihani, M/s. Mahyco Pvt. Ltd., Jalna, MS
38. Dr. Srinivasulu Yeruva, M/s. Sajjala Biolabs Pvt. Ltd., Hyderabad
39. Mrs. S. Lakshmi, M/s. Sajjala Biolabs Pvt. Ltd., Hyderabad
40. Mr. P Madan Pueit, M/s. Sipra Labs Pvt. Ltd., Hyderabad