

MINUTES OF THE 162nd MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 09.01.2018 IN THE DEPARTMENT OF BIOTECHNOLOGY

Dr. B. Sesikaran, Chairman, RCGM extended a formal welcome to the members of RCGM for the 162nd 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 161st meeting of the RCGM held on 14.11.2017.

3. On action taken report, RCGM Secretariat informed that during the 161st meeting of the RCGM, a total of 110 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 Etarnercept RCB, Anti RANKL antibody process intermediates, drug substance, and drug product, CHO cells expressing antibody against RANKL Ligand, recombinant human Anti Her2 antibody product intermediates, S19 Polio Virus Strains, and Aflibercept clones; to transfer recombinant Dengue Monoclonal Antibody, Insulin Lispro, and Dengue Tetravalent vaccine; to receive Dengue Monoclonal Antibody, Dengue Tetravalent vaccine, Insulin Lispro, Bevacizumab and Avastin; to export CHO cells producing anti-RANKL antibody process intermediates, drug substance and drug product, Anti HER2 antibody intermediates, drug substance and drug product, and monovalent & combination IPV drug product; to conduct pre-clinical toxicity studies on Recombinant Insulin Glargine, Liraglutide and Human Albumin; pre-clinical toxicity study report on recombinant Bevacizumab; and request for extension of the validity of the permission to conduct PCT studies on recombinant Darbepoetin. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

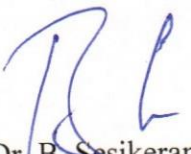
4.2 Applications in the area of Agriculture

The Committee considered applications in the area of agriculture to receive transgenic rice seeds and banana plants; to import recombinant *Saccharomyces cerevisiae* strain; to conduct event selection trial on transgenic cotton; to undertake testing of three GM cotton events; and request for extension of the validity of the permission to conduct BRL-I trial, seed production and biosafety studies on transgenic maize. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

The next meeting of the RCGM was scheduled on 20.02.2018. No other transaction took place and the meeting ended with vote of thanks to the Chair.

The minutes are approved.

Date: 09.02.2018
Place: Bangalore


(Dr. B. Sesikeran)
Chairman, RCGM

ANNEXURE-I

List of Participants:

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| 1. Dr. B. Sesikeran, Former Director, NIN, Hyderabad | - Chairman |
| 2. Dr. S.R. Bhat, Emeritus Scientist, NRCPB, New Delhi | - Co-Chairman |
| 3. Prof. P. Kondaiah, Chairman, IISc., Bangalore | - Member |
| 4. Dr. Shailaja Hittalmani, UAS, Bangalore | - Member |
| 5. Dr. S.J. Rahman, Principal Scientist and Head, PJTSAU, Hyderabad | - Member |
| 6. Dr. Vanga Siva Reddy, CSO, BSU, New Delhi | - Member |
| 7. Dr. S.N. Sudhakara Babu, DOR, Hyderabad | - Member |
| 8. Dr. Viswanathan Chinnusamy, ICAR- IARI, New Delhi | - Member |
| 9. Dr. Gururaj Katti, Principal Scientist & Head, IIRR, Telangana | - Member |
| 10. Dr. S.K. Rath, Principal Scientist, CSIR-CDRI, Lucknow | - Member |
| 11. Dr. Debendra K. Sahoo, IMTECH, Chandigarh | - Member |
| 12. Prof. Amita Aggarwal, SGPIMS, Lucknow | - Member |
| 13. Prof. Ambikanandan Misra, Univ. of Baroda, Vadodra | - Member |
| 14. Dr. Vijay Kumar, Scientist G, ICMR, New Delhi | - Nominee -ICMR |
| 15. Dr. Murali Krishna, MoEF&CC, New Delhi | - Nominee-MoEF&CC |
| 16. Dr. P.K.Chakrabarty (ADG-ICAR) ICAR, New Delhi | - Nominee-ICAR |
| 17. Mr. Fatim Khan, New Delhi | - Nominee - DCG(I) |
| 18. Dr. Gurinderjit Randhawa, NBPGR, New Delhi | - Nominee-NBPGR |
| 19. Dr. S.R. Rao, Scientist-H, DBT | - Member Secretary |
| 20. Dr. Rajalakshmi Muralidharan, Scientist- F, DBT | - Member |
| 21. Dr. Sanjay Kalia, Scientist-D, DBT | - Member |

Biosafety Support Unit:

22. Dr. G.R. Soni, Chief (Bio-Pharma)
23. Dr. Sangeeta Agarwal, Chief (Agriculture)
24. Dr. Poonam Vishwakarma, Scientist
25. Dr. Reema Sharma, Scientist
26. Dr. Govind Kumar Rai, Scientist

Other representatives:

27. Dr. Sridhar Kottakota, Lupin Biotech, Ghotawad, Pune
28. Mr. Arun Sachdeva, Lupin Ltd, New Delhi
29. Dr. Vishal, Lupin Ltd., Pune
30. Dr. Amol Kale, INTOX, Pune
31. Dr. Nazia Sulthana, Levim Biotech, Chennai
32. Dr. Srikar Raman, Levim Biotech, Chennai
33. Dr. Prakash V, Bioseed Research India, Hyderabad
34. Dr. Dwarkesh Parihar, Bioseed Research India, Hyderabad
35. Dr. Giri Raghavanatu, Lazuline Biotech, Hyderabad
36. Dr. B. Ramesh, Lazuline Biotech Pvt. Ltd., Hyderabad
37. Dr. Sasikumar, Lazuline Biotech Pvt. Ltd., Hyderabad