MINUTES OF THE 172nd MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 16.05.2019 IN THE DEPARTMENT OF BIOTECHNOLOGY

The Chairman, RCGM extended a formal welcome the members of the RCGM for the 172nd 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 171st meeting of the RCGM held on 29.03.2019.

3. On action taken report, the Member-Secretary informed that during the 171st meeting of the RCGM, a total of 116 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 stable cell pool expressing di-SFV antibody, CHO cell line expressing AMG 447 molecule, CHO cell line expressing antibody molecule, research cell banks expressing MBP047 and MBP087 antibody, genetically modified Influenza strain X-327, Western Pacific Strain of stable Dengue (DENV1) VLP expressing 293F cell lines, American strain of stable Dengue (DENV2) VLP expressing 293F cell lines, Singapore8120/95 strain of stable Dengue (DENV3) VLP expressing 293F cell lines, ThD4 0476 97 strain of stable Dengue (DENV4) VLP expressing 293F cell lines, STHdhQ7/Q7, STHdhQ7/Q111 and STHdhQ111/Q111 cells, Research cell bank, Master cell bank and Working cell bank of CHO cells, Plasmid pD2535, genetically modified Influenza strain X-327; to export research cell bank of GBL1204, master and working seed of recombinant Chikungunya virus; to receive Chimeric Antigen Receptor T cell; to transfer Drug Product anti-VEGF FAB, recombinant Liraglutide Drug substance, Cetuximab and Erbitux®; to conduct preclinical toxicity studies on modified Brucella abortus S19 vaccine strain, Similar Biologic of Pertuzumab, recombinant Insulin glargine, Pneumococcal Conjugate Vaccine, Inactivated Hepatitis A vaccine, biosimilar Adalimumab, recombinant fowl pox vaccines, Hepatitis E (rDNA) Vaccine; pre-clinical toxicity study reports on recombinant Bevacizumab; request for waiver of non-clinical toxicology studies of GBR 1302. After detail 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 male sterile mutant maize, two applications of transgenic corn, Bt insecticidal proteins, Medicago truncatula insertion mutant; to receive transgenic rice seeds, transgenic cotton events var. Coker 312; report on event selection trial of transgenic rice event; report on harvest and termination of event selection trial of transgenic rice. After detail deliberation on each application including information items, appropriate decision was taken by the RCGM.

4.3. Other items

The committee considered revised applications to conduct preclinical studies on Recombinant Insulin Glargine and Rituximab and appropriate decision was taken by the RCGM.
The next meeting of the RCGM was scheduled on 01.07.2019.

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

The Minutes are approved.

(Dr. B. Sesikaran)
Chairman, RCGM
List of Participants:
1. Dr. B. Sesikeran, Former Director, NIN Hyderabad
2. Prof. P Kondaiah, IISc, Bangalore
3. Dr. S.R. Bhat, Emeritus Scientist, NRCPB, New Delhi
4. Dr. Shailaja Hittalmani, Emeritus Scientist, UAS, Bangalore
5. Dr. Vanga Siva Reddy, CSO, BSU, New Delhi
6. Dr. S.N. Sudhakar Babu, Principle Scientist, IIOR, Hyderabad
7. Dr. Vishwanth Chinnamary, IARI, New Delhi
8. Dr. Gururaj Katti, Principal Scientist, IIRR, Hyderabad
9. Dr. S.K. Rath, Principal Scientist, CSIR-CDRI, Lucknow
10. Dr. Kulbhushan Tikko, Professor & Head NIPER, Mohali
11. Dr. A.K. Kondapi, University of Hyderabad, Hyderabad
12. Dr. Debendra K. Sahoo, IMTECH, Chandigarh
13. Dr. Anita Aggarwal, SGPIMS, Lucknow
14. Dr. Rajesh Rastogi, MoEF&CC, New Delhi
15. Dr. P K Chakrabarty, ICAR, New Delhi
16. Dr. Sanjay Kumar, IHB, Palampur
17. Dr. Gurinderjit Randhawa, NBPG, New Delhi
18. Dr. S.R. Rao, Scientist-II, DBT
19. Dr. Alka Sharma, Scientist-G, DBT
20. Dr. Rajalakshmi Muralidharan, Scientist-F, DBT
21. Dr. Nitin Jain, Scientist-E, DBT

Biosafety Support Unit:
22. Dr. Sangeeta Agarwal, Chief (Agriculture)
23. Dr. Poonam Vishwakarma, Scientist
24. Dr. Pranjali Vishwakarma, Scientist

Other representatives:
25. Dr. S. Karnan, M/s. Rasi Seeds Pvt. Ltd., Salem, Tamil Nadu
26. Dr. T. Jayaprakash, M/s. Rasi Seeds Pvt. Ltd., Salem, Tamil Nadu
27. Dr. K.S. Mohan, M/s. Rasi Seeds Pvt. Ltd., Salem, Tamil Nadu
28. Dr. Anurag Khera, M/s. Glenmark Pharmaceuticals Ltd., Mumbai
29. Dr. Pawan Sancheti, M/s. Glenmark Pharmaceuticals Ltd., Mumbai
30. Dr. Harsh, M/s. Glenmark Pharmaceuticals Ltd., Mumbai
31. Dr. Kishan Khera, M/s. Glenmark Pharmaceuticals Ltd., Mumbai
32. Dr. J. Nair, M/s. Glenmark Pharmaceuticals Ltd., Mumbai
33. Dr. Devendra Mali, M/s. Sun Pharmaceutical Industries Ltd., Vadodara, Gujarat
34. Dr. Satish, M/s. Sun Pharmaceutical Industries Ltd., Vadodara, Gujarat
35. Dr. Jitendra H. Patel, M/s. Cadila Healthcare Limited, Zydus Research Centre, Ahmedabad, Gujarat
36. Dr. Sanjay Bandopadhyay, M/s. Cadila Healthcare Limited, Zydus Research Centre, Ahmedabad, Gujarat
37. Dr. Harish Chandra, M/s. Cadila Healthcare Limited, Zydus Research Centre, Ahmedabad, Gujarat
38. Dr. Yognanth Rajvedran, M/s. Cadila Healthcare Limited, Zydus Research Centre, Ahmedabad, Gujarat
39. Dr. Sudeep, M/s. Unichem Laboratories Limited, Goa
40. Dr. Mohnish, M/s. Unichem Laboratories Limited, Goa
41. Dr. Ramanath, M/s Reliance Life Sciences, Navi Mumbai
42. Dr. Rajan S., M/s. Biological E. Limited, Hyderabad
43. Dr. Ramesh, Matur, M/s. Biological E. Limited, Hyderabad
44. Dr. B. Mohana Subramanian, M/s. Biological E. Limited, Hyderabad
45. Dr. Rajendra Burki, M/s. Biological E. Limited, Hyderabad
46. Dr. Vikas Vij, M/s. Biological E. Limited, Hyderabad
47. Dr. Ravi Kumar, M/s. Biological E. Limited, Hyderabad
48. Dr. Anil Kalidas, M/s. Shilpa Medicare Ltd., Hubli, Karnataka
49. Dr. Rajyashri, M/s. Shilpa Medicare Ltd., Hubli, Karnataka
50. Dr. M. Sarvanam, M/s. Vipragen Biosciences Pvt. Ltd., Karnataka
51. Dr. Viney, M/s. Vipragen Biosciences Pvt. Ltd., Karnataka