

MINUTES OF THE 163rd MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 20.02.2018 IN THE DEPARTMENT OF BIOTECHNOLOGY

Since the Chairman, RCGM could not attend the meeting, the Co-Chairman (Bio-Pharma), RCGM chaired the meeting and extended a formal welcome to the members of the RCGM for the 163rd meeting and initiated the process of the meeting. The list of participants is given at Annexure-I.

2. Proposals considered:

2.1 Applications in the area of Pharmaceuticals

The Committee considered applications in the area of pharmaceuticals to import recombinant CHO Cell lines expressing IgG1 antibody, Adalimumab and Infliximab, Thymalfasin gene with suitable vector, ORF clone set of *Mycobacterium tuberculosis*, dengue virus, Rv3615c:ESAT-6:CFP10 fusion protein, and *E. coli* strains; to receive *Plasmodium falciparum* strains, *Leishmania donovani* culture, Darbepoetin and Bevacizumab Drug Substance; to export recombinant Rituximab, Trastuzumab, Bevacizumab, Adalimumab, Granulocyte Colony Stimulating Factor, Interferon beta, Darbepoetin, Follicle Stimulating Hormone, Human Chorionic Gonadotropin, Growth hormone, TNK Tissue Plasminogen Activator, Abciximab, Omalizumab, Ranibizumab, Cetuximab, Aflibercept, Etanercept, Reteplase, Interferon alpha Infliximab, Erythropoietin, Ramucirumab, and CHO Cell lines expressing Infliximab & Adalimumab; and to transfer *Leishmania donovani* culture, Darbepoetin, and Bevacizumab Drug Substance. The Committee also considered applications to conduct pre-clinical toxicity studies on Rituximab, Streptokinase, and Trastuzumab; pre-clinical toxicity study report on Ustekinumab. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

2.2 Applications in the area of Agriculture

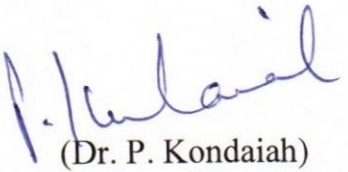
The Committee considered applications in the area of agriculture to export, transfer and receive transfer transgenic rice seeds; and to conduct event selection trial on transgenic cotton. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

The next meeting of the RCGM was scheduled on 03.04.2018. No other transaction took place and the meeting ended with vote of thanks to the Chair.

The minutes are approved.

Date: 20.03.2018

Place: Bangalore


(Dr. P. Kondaiah)
Acting Chairman, RCGM

ANNEXURE-I

List of Participants:

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| 1. Prof. P. Kondaiah, IISc., Bangalore | - Acting Chairman |
| 2. Dr. S.R. Bhat, Emeritus Scientist, NRCPB, New Delhi | - Co-Chairman |
| 3. Dr. Shailaja Hittalmani, UAS, Bangalore | - Member |
| 4. Dr. Vanga Siva Reddy, CSO, BSU New Delhi | - Member |
| 5. Dr. S.N. Sudhakara Babu, DOR, Hyderabad | - Member |
| 6. Dr. S.K. Rath, Principal Scientist, CSIR-CDRI, Lucknow | - Member |
| 7. Dr. Kulbhushan Tikoo, Professor & Head, NIPER, Mohali | - Member |
| 8. Dr. Debendra K. Sahoo, IMTECH, Chandigarh | - Member |
| 9. Dr. A.K. Kondapi, Professor, UoH, Hyderabad | - Member |
| 10. Dr. P.K. Chakrabarty (ADG-ICAR) ICAR, New Delhi | - Nominee-ICAR |
| 11. Dr. Jayant Gangakhedkar, ADGI, CDSCO, New Delhi | - Nominee-CDSCO |
| 12. Mr. Fahim Khan, Drug Inspector, CDSCO, New Delhi | - Nominee-CDSCO |
| 13. Dr. Vijay Kumar, Scientist G, ICMR, New Delhi | - Nominee- ICMR |
| 14. Dr. S.R. Rao, Scientist-H, DBT | - Member Secretary |
| 15. Dr. Rajalakshmi Muralidharan, Scientist- F, DBT | - Member |
| 16. Dr. Sanjay Kalia, Scientist-E, 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. Reema Sharma, Scientist
21. Dr. Jyoti Batra, Scientist

Other representatives:

22. Dr. S.H. Rao, Reliance Life Sciences, Navi Mumbai
23. Dr. Girish Masand, Reliance Life Sciences, Navi Mumbai
24. Dr. Dwarkesh Parihar, Bioseed Research India, Hyderabad
25. Dr. Rishikesh Gupta, Epygen Biotech, Navi Mumbai
26. Dr. R.M. Bhide, Indian Institute of Toxicological Research, Pune
27. Dr. Debayan Ghosh, Epygen Biotech, Navi Mumbai
28. Dr. Saptarshi Paul, Epygen Biotech, Navi Mumbai
29. Dr. Sandhya Agarwal, Metahelix Life Sciences, Bangalore
30. Dr. Nagraj Kampt, Metahelix Life Sciences, Bangalore
31. Dr. A. Naveen, Virchow Biotech Pvt Ltd, Telangana
32. Dr. J. Gopinath, Virchow Biotech Pvt Ltd, Telangana
33. Dr. Murali K.R. Tummuru, Virchow Biotech Pvt Ltd, Telangana
34. Dr. Darshan Koticha, Virchow Biotech Pvt Ltd, Telangana,
35. Dr. V. Peejmaroha, Virchow Biotech Pvt Ltd, Telangana
36. Dr. M. Saravanam, Vipragen Biosciences Pvt Ltd., Mysore
37. Dr. Kishore Nalan, Aurobindo Pharma Ltd., Telangana
38. Dr. Disha Dadke, Aurobindo Pharma Ltd., Telangana
39. Dr. Ankireddy Sivakesaver Reddy, Aurobindo Pharma Ltd., Telangana
40. Dr. P. Santosh Kumar, Eurofins Advinus Ltd., Bengaluru