

**MINUTES OF THE 156<sup>th</sup> MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 21.3.2017 IN THE DEPARTMENT OF BIOTECHNOLOGY**

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 156<sup>th</sup> 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 transfer laboratory-adapted Dengue virus serotype 1, 2, 3, 4 and mouse-adapted DENV-2; to conduct pre-clinical toxicity study on recombinant Human Insulin, Insulin Glargine, and Liraglutide; Pre-clinical study reports on Denosumab, Trastuzumab, Trastuzumab Emtansine, Liraglutide, Romiplostim, Darbepoetin Alfa and rCRM<sub>197</sub> & EpCRM<sub>197</sub>. 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 transgenic brinjal seeds; to transfer transgenic banana plants and transgenic cotton seeds, to import plasmid pCAS47; for approval of protocols to conduct toxicity and allergenicity studies on transgenic cotton, to include additional location to conduct confined field trial of transgenic maize hybrid; for approval of protocols for Assessment of nutrition composition in grain and forage of transgenic maize and to study the effect of transgenic maize on soil microflora. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

Presentation on "Assessment process of analytical biosimilarity of biosimilars followed by US-FDA" was made by BSU. The Committee also reviewed the scientific progress made in the project entitled "National containment/ quarantine facility for transgenic planting material" by National Bureau of Plant Genetic Resources (NBPGR), New Delhi for the year 2016.

The next meeting of the RCGM was scheduled on 09.05.2017. No other transaction took place and the meeting ended with vote of thanks to the Chair.

The minutes are approved.

Date: 31.03.2017  
Place: Hyderabad

  
(Dr. B. Sesikeran)  
Chairman, RCGM



**List of Participants:**

- |  |                          |
|--|--------------------------|
| 1. Dr. B. Sesikera, Former Director, NIN, Hyderabad                | - Chairman               |
| 2. Dr. S.R. Bhat, Emeritus Scientist, NRCPB, New Delhi             | - Co-Chairman (Agri.)    |
| 3. Prof. P. Kondaiah, IISC, Bangalore                              | -Co-Chairman (BioPharma) |
| 4. Prof. Shailaja Hittalmani, Head, UAS, Bangalore                 | -Member                  |
| 5. Dr. S.J.Rahman, Principal Scientist & Head, PJTSAU, Hyderabad   | -Member                  |
| 6. Dr. Vanga Siva Reddy, CSO, BSU, New Delhi                       | -Member                  |
| 7. Dr. S. N. Sudhakara Babu, Principal Scientist, DOR, Hyderabad   | -Member                  |
| 8. Dr. Natarajan Sakthivel, Professor, PU, Puducherry              | -Member                  |
| 9. Dr. Vishwanathan Chinusamy, Head, ICAR-IARI, New Delhi          | -Member                  |
| 10. Dr. Gururaj Katti, IIRR, Hyderabad                             | -Member                  |
| 11. Dr. S.K.Rath, Principal Scientist, CSIR-CDRI, Lucknow          | -Member                  |
| 12. Dr. Kulbhushan Tikoo, NIPER, Mohali, Punjab                    | -Member                  |
| 13. Prof. A. K. Kondapi, UOH, Hyderabad                            | -Member.                 |
| 14. Prof. Sanjeev Galande, IISER, Pune                             | -Member                  |
| 15. Dr. Debendra K. Sahoo, IMTECH, Chandigarh                      | -Member                  |
| 16. Prof. Amita Aggarwal, SGPIMS, Lucknow                          | -Member                  |
| 17. Prof. Ambikanandan Misra, Dean, University of Baroda, Vadodara | -Member                  |
| 18. Dr. Madhumita Biswas, Director, GEAC                           | -Nominee, MoEFCC         |
| 19. Dr. Vijay Kumar, Scientist G& Head (BMS), ICMR, New Delhi      | -Nominee, ICMR           |
| 20. Dr. V. G. Somani, JDC (India), CDSCO, DGHS, New Delhi          | -Nominee, DCG(I)         |
| 21. Dr. Shashi Bhalla, Nominee of Director- NBPGR, New Delhi       |                          |
| 22. Dr. Saranya P, Scientist-C, MoEFCC                             |                          |
| 23. Dr. S.R.Rao, Scientist-G, DBT                                  | -Member Secretary        |
| 24. Dr. Rajalakshmi Muralidharan, Scientist-E, DBT                 | -Member                  |
| 25. Dr. Amit Parikh, Scientist-D, DBT                              | -Member                  |

**Biosafety Support Unit:**

26. Dr. Sangeeta Agarwal, Chief (Agriculture)
27. Dr. G.R. Soni, Chief (Bio-Pharma)
28. Dr. Poonam Vishwakarma, Scientist
29. Dr. Pooja Srivastava, Scientist
30. Dr. Sandeep Soni, Scientist

**Other Representatives:**

31. Dr. Gurinderjit Randhawa, Principal Scientist, ICAR-NBPGR, New Delhi
32. Dr. Bhawna Gupta (Associate Director), Dr. Reddy's Laboratories Ltd.
33. Dr. J. Sreenivasaha, Senior Scientist, Dr. Reddy's Laboratories Ltd.
34. Dr. Sanjeev Gupta, IPCA Laboratories Ltd.
35. Mr. Pankaj Chaudhari, IPCA Laboratories Ltd.
36. Dr. ArunSachdeva, Lupin Pvt. Ltd., Pune.
37. Dr. Akshay S. Odak, Lupin Pvt. Ltd., Pune
38. Dr. Narendra Deshmukh, INTOX Pvt. Ltd., Pune

39. Dr. Vishal Pavitrakar, Lupin Pvt Ltd., Pune
40. Mr. Vikram V.J. (Regulatory Affairs), Biological E. Pvt. Ltd.
41. Dr. Pradip Das, Biological E. Pvt. Ltd.
42. Dr. K.Vivek Babu, Biological E. Pvt. Ltd.
43. Dr.AkshayGoel, Biological E. Pvt. Ltd.
44. Dr. Vivek Kushwaha, M/s Anthem Biosciences Ltd.
45. Dr. Sanganesh Purania, M/s Anthem Biosciences Ltd.
46. Dr. Prasad Shivarudraiah, M/s Anthem Biosciences Ltd.
47. Dr. Pushpadhary Mall, M/s Anthem Biosciences Ltd.
48. Dr. Balareddy, M/s. Hetero Drugs, Ltd.
49. Dr. Rajendra Kumar, M/s Hetero Drugs, Ltd.
50. Dr. Chandrakant Patel, M/s. Hetero Drugs, Ltd.
51. Dr. Harish Shandilya, M/s Enzene Biosciences Pvt. Ltd.
52. Dr. Himanshu Gadgil, M/s Enzene Biosciences Pvt. Ltd.