

## MINUTES OF THE 178<sup>th</sup> MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 11.12.2019 IN THE DEPARTMENT OF BIOTECHNOLOGY

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 178<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 177<sup>th</sup> meeting of the RCGM held on 11.11.2019.

3. On action taken report, the Member-Secretary informed that during the 177<sup>th</sup> meeting of the RCGM, a total of 26 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 master cell banks and working cell banks of Ipilimumab, working cell banks of Denosumab, Omalizumab and Xolair; applications to export Rituximab in-process samples; to receive RSV vaccine strain; to conduct preclinical toxicity studies on Omalizumab biosimilar, Pertuzumab biosimilar, Trastuzumab biosimilar, Ranibizumab biosimilar, Pneumococcal Conjugate Vaccine; preclinical toxicity study reports on live attenuated tetravalent recombinant Dengue vaccine. 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 information items, appropriate decisions were taken by the RCGM.

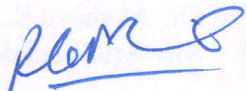
#### 4.3. Other items

The Committee considered the merger of M/s. Monsanto India Limited with M/s. Bayer Crop Science Limited, draft guideline on "General Principles and framework for regulation and principles of risk assessment of Genome edited products/organism", Regulatory Reforms to Improve Drug Development Process in India, status of *Wolbachia* based Vector Control Strategy for control of Dengue/Chikungunia transmitted by *Aedes aegypti* and appropriate decision was taken by the RCGM.

The next meeting of the RCGM was scheduled on 09.01.2020

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

The Minutes are approved.

  
(Dr. Rakesh Kumar Mishra)  
Chairman, RCGM

**List of Participants:**

- |     |   |                       |
|-----|---|-----------------------|
| 1.  | Dr. Rakesh Kumar Mishra, Director, CCMB, Hyderabad                                | - Chairman            |
| 2.  | Dr. Pradhyumna Kumar Singh, CSIR-NBRI, Lucknow                                    | - Member              |
| 3.  | Prof. (Dr.) Neelam S. Sangwan, Senior Principal Scientist, CIMAP,<br>Lucknow      | - Member              |
| 4.  | Dr. R. Uma Shanker, UAS Bengaluru   | - Member              |
| 5.  | Dr. S.K. Rath, Principal Scientist, CSIR-CDRI, Lucknow                            | - Member              |
| 6.  | Dr. Rajesh S. Gokhale, NII, New Delhi   | - Member              |
| 7.  | Dr. GuhanJayaraman, IIT-M, Chennai  | - Member              |
| 8.  | Dr. K. G. Tirumurugaan, Professor, Madras Veterinary College,<br>TANUVAS, Chennai | - Member              |
| 9.  | Sh. TarunKathula, Director & Member Secretary-GEAC                                | - Nominee-MoEF&<br>CC |
| 10. | Dr. GeetaJotwani, Scientist F   | - Nominee- ICMR       |
| 11. | Dr. Shilpi Paul, Scientist E, SERB  | - Nominee-DST         |
| 12. | Dr. Alka Sharma Scientist-G, & Nodal Officer (Biopharma), DBT                     | - Member              |
| 13. | Dr.Vanga Siva Reddy, CSO, BSU, New Delhi  | - Special Invitee     |
| 14. | Dr. Nitin K. Jain, Scientist-F, DBT   | - Member Secretary    |

**RCGM Secretariat:**

15. Dr. GandharvaNagpal, Scientist-C, DBT

**Biosafety Support Unit:**

16. Dr. Sangeeta Agarwal, Chief (Agriculture)  
17. Dr. Poonam Vishwakarma, Scientist  
18. Dr. Reema Sharma, Scientist  
19. Dr. Manpreet Kaur, Scientist

**Other representatives:**

20. Dr. Rajendra Lingala, Indian Immunologicals Ltd., Hyderabad  
21. Dr. Y Venugopal, Indian Immunologicals Ltd., Hyderabad  
22. Dr. Santosh Kumar, Eurofins Advinus Limited  
23. DarshakTerajas, Eurofins Advinus Limited  
24. M/s. Chandrika Patel, Kashiv Biosciences Pvt. Ltd, Gujarat  
25. Mr. Om Narayan, Kashiv Biosciences Pvt. Ltd, Gujarat  
26. Dr. Prayag N. Shah, Kashiv Biosciences, LLC, USA  
27. Dr. Vishal Pavitrakar, Lupin Ltd.  
28. Dr. Bhaskarjyoti Prasad, Lupin Ltd.  
29. Dr. Akshaya S. Odak, Lupin Ltd.  
30. Mr. ArunSachdeva , Lupin Ltd.