

INDIAN PHARMACOPOEIA COMMISSION

(Ministry of Health & Family Welfare, Govt. of India)
Sector-23, Raj Nagar, Ghaziabad-201002

MINUTES OF 47th MEETING OF THE SCIENTIFIC BODY OF IPC

Date of Meeting : 3rd July 2021
Mode of Meeting : Video Conferencing
Chairperson : Prof. N. K. Ganguly

The list of participants is appended as Enclosure-I.

Welcome and Opening of the Meeting

Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC welcomed the Chairperson and members of the Scientific Body for the 47th meeting of the SB through video conferencing. He thanked all the members of the Scientific Body for their suggestions and guidance for strengthening the IPC activities. With the permission of Prof. N. K. Ganguly, Chairperson-Scientific Body, Dr. Raghuvanshi gave a presentation on the major activities of the IPC after the 46th meeting of the Scientific Body.

Prof. N. K. Ganguly took note of the key achievements of the IPC since the last meeting of the Scientific Body and appreciated the efforts of IPC towards publication and release of Indian Pharmacopoeia (IP) Addendum 2021, development of new IP Reference Substances (IPRS) and Impurity Standards, publication of 6th edition of the National Formulary of India (NFI), expansion of Pharmacovigilance Programme of India (PvPI) and Materiovigilance Programme of India (MvPI), National and International cooperations, and training activities through webinars.

Thereafter, the Member Secretary presented the agenda in following sequence and decisions of the Scientific Body are recorded as below:

Item 1. Confirmation of the Minutes of the 46th Meeting of the Scientific Body held on 6th March 2021

Confirmed.

Item 2. Action Taken Report on the Minutes of the 46th Meeting of the Scientific Body held on 6th March 2021

Noted by the Scientific Body.

MAIN AGENDA

Item 3. Progress Report of AR&D Division

Noted.

It was suggested by the Scientific Body that the effective date of the IP Addendum 2021 may be extended by three months in consideration of the impact of the current COVID-19 pandemic on the pharma industry.

Scientific Body also suggested working on the standards of COVID-19 related new drugs like Molnupiravir.

Item 4. Progress Report of Reference Standard Division

Noted.

Scientific Body appreciated efforts for procurement of new IPRS and Impurity Standards through tendering process. It was agreed to draft new monographs for their inclusion in the next IP edition.

Item 5. Progress Report of Microbiology Division

Noted.

Scientific Body appreciated the General Chapter on 'Approach to Alternative Microbiological Methods' and approved for its inclusion in the next edition of IP. Scientific Body also took note of the webinar conducted on this topic and desired that more webinars should be organized to create awareness about IP standards.

Item 6. Progress Report of Phytopharmaceutical Division

Noted.

Scientific Body noted that some confusion prevails in the Phytopharmaceuticals Gazette Notification, such as qualitative/quantitative aspects and number of marker compounds, whether all the markers should be present in one plant or two or more etc. In order to address this issue, IPC is in the process of drafting a General Chapter on 'Phytopharmaceuticals Drugs' and a meeting with Prof. Ramesh K. Goyal shall be planned to discuss the issue.

Scientific Body also approved for new General Chapter on Essential Oils and monographs under Phytopharmaceuticals Ingredient (PPI) category (namely *Andrographis paniculata* raw herbs for phytopharmaceutical drugs and *Silybum marianum* extract for phytopharmaceutical drugs).

Item 7. Progress Report of Biologics Section

Noted.

Scientific Body suggested that IPC should collaborate with other national Institutes in the area of standards setting and it was appraised to the Scientific Body that IPC is closely working with NIB-NOIDA and CDL-Kasauli in this area. Scientific

Body noted efforts for IP digitization and appreciated the same.

Item 8. Progress Report of National Formulary of India (NFI)

Noted.

Item 9. Mutual Cooperation with National and International Organizations

Noted.

Item 10. Progress Report of Quality Assurance (QA) Division

Noted.

Item 11. Progress Report of Pharmacovigilance Programme of India (PvPI)

Noted.

Scientific Body suggested initiating Focused Pharmacovigilance of new drugs as well as COVID-19 vaccines. It was also suggested to utilize IT tools for data mining.

It was also suggested to integrate the Pharmacovigilance data of the PvPI and AEFI to have complete picture of the adverse events due to vaccines in the country.

Scientific Body strongly recommended making PvPI as permanent mandate of the IPC and detailed proposal in this regard shall be submitted to the MoH&FW. Also, the activities of the PvPI shall be audited by an external agency.

Item 12. Progress Report of Materiovigilance Programme of India (MvPI)

Noted.

Scientific Body appreciated new draft monographs on Medical Devices and directed that before finalizing these monograph a meeting with concerned organizations namely IPC, CDSCO, BIS to be organized for consensus.

Item 13. Progress Report of Publication Division

Noted.

Scientific Body noted that efforts have been initiated to digitize IP and suggested that IPC should decrease the number of printed copies of the IP.

Item 14. Progress of the Advance Level Research Centre (ALRC)

Noted.

Scientific Body suggested to keep a close monitoring on the progress of ALRC.

Item 15. Any Other Agenda Item with Permission of the Chairperson

Scientific Body also suggested:

- ▶ Implementation of Flexible Complementary Scheme for IPC scientists,
- ▶ Making business development plan for advertisement of IPC products across globe,
- ▶ To check monograph of Prussian Blue for its inclusion in IP,
- ▶ To explore the possibility of publishing IP with different volumes for different categories of products.

Meeting ended with vote of thanks to the Chairperson and Members of the Scientific Body of IPC by the Member Secretary.

List of Scientific Body Members Participated through Video Conferencing

1. Prof. N. K. Ganguly, Former DG-ICMR and Chairperson, Scientific Body-IPC
2. Prof. Sanjay Singh, Vice Chancellor, BBAU-Lucknow
3. Prof. Ramesh Kr. Goyal, Vice Chancellor, DPSRU-Delhi
4. Dr. D. Srinivasa Reddy, Director, IIIM-Jammu
5. Dr. A. K. Singh, Former Director General (LS), DRDO-Delhi
6. Dr. Amulya K. Panda, Former Director, NII-Delhi (attended physically)
7. Dr. Ram A. Vishwakarma, Former Director, IIIM-Jammu
8. Mr. A. K. Pradhan, DDC(I), CDSCO-Delhi (attended physically)
9. Dr. Raman M. Singh, Director, CDTL-Mumbai (attended physically)
10. Dr. Naresh Bhatnagar, Professor, IIT-Delhi
11. Prof. Naveet Wig, Head-Deptt. of Medicine, AIIMS-Delhi
12. Dr. Nithya Gogtay, Deptt. of Clinical Pharmacology, KEM-Mumbai
13. Dr. Arun K. Mishra, Head-Global Regulatory Affairs, Unilever-Gurugram (attended physically)
14. Dr. Sunil Gairola, Director-QC, Serum Institute-Pune
15. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram (attended physically)
16. Prof. Vinod Kumar Dixit, Former Dean, Dr. Hari Singh Gaur Univ., Sagar
17. Dr. Praveen Khullar, Head-Global Development Centre, Sanofi-Goa
18. Dr. Hemant K. Sharma, Senior Vice President, Aurobindo Pharma-Hyderabad
19. Dr. Nitin Bhatia, Assistant Vice President, Intas Pharma-Ahmedabad
20. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director-IPC and Member Secretary (attended physically)

Leave of Absence

1. Mr. Salim Veljee, Former Commissioner, FDA-Goa
2. Dr. Rakesh N. Tirpude, Assistant Commissioner, FDA-Maharashtra
3. Dr. V. Satyanarayana, Managing Director, Sipra Labs-Hyderabad