INDIAN PHARMACOPOEIA COMMISSION

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

Minutes of 54th Meeting of the Scientific Body (SB) of IPC

Date of Meeting : April 13, 2024
Chairperson : Dr. V. M. Katoch

The list of participants is appended as Enclosure-I.

Welcome and Opening of the Meeting

The 54th meeting of the Scientific Body of IPC started with a welcome address by Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director. With the permission of the Chairperson, Dr. Raghuvanshi made a presentation on the progress and key achievements made by the IPC since the last meeting of the Scientific Body.

Scientific Body took note of the key achievements of the IPC and appreciated the inauguration of the ALRC by the Hon'ble Prime Minister, release of the IP Addendum 2024 by the Hon'ble Union Health Minister, recognition of the IP in Nicaragua and Bhutan, increase in the number of IP Reference Standards (IPRS) and Impurity Standards, conducting Proficiency Testing (PT) Program, expansion of Pharmacovigilance and Materiovigilance Programmes of India, signing of MoUs with USP and International Patients' Union, International training on Materiovigilance for Bhutan, workshop on scientific writing conducted by Dr. Bikash Medhi, scientific publications, and revenue generation.

Scientific Body took note of the exponential progress of the IPC in the last three years and congratulated its Secretary-cum-Scientific Director and scientific staff. Keeping in view very limited opportunities for career growth of scientific staff, the Scientific Body strongly recommended the implementation of the Modified Flexible Complimentary Scheme (MFCS) for the scientific staff of the IPC at the earliest. Scientific Body noted and appreciated the steps being taken by IPC in this regard.

Thereafter, the main agenda was presented in following sequence and the decisions of the Scientific Body were recorded as below:

- Item 1. Confirmation of the Minutes of 53rd Meeting of the SB held on December 30, 2023

 The minutes were confirmed by the Scientific Body.
- Item 2. Action Taken Report on the Minutes of 53rd Meeting of the SB held on December 30, 2023

Noted by the Scientific Body.

MAIN AGENDA

Item 3. Progress of AR&D and Phytopharmaceuticals Divisions

Scientific Body noted work progress of AR&D Division w.r.t. development of monographs for the next IP 2026, activities related to recognition of the IP in foreign countries, IPC's participation in the Pharmacopoeial Discussion Group (PDG), development of IP on-line portal, organizing Expert Working Group (EWG) meetings,

student training, and publication. While reviewing the monograph list, Scientific Body suggested including a greater number of monographs of rational Fixed Dose Combinations (FDCs) in the next IP 2026.

Item 4. Progress of Biologics Section

Scientific Body noted the work progress of Biologics Division during the index period w.r.t. development and upgradation of General Chapters and monographs of biologics and veterinary products for the IP 2026, activities related to alternative to animal methods, EWG and stakeholders' meetings, conducting PT program, analytical testing, and student training. Signing and renewal of MoUs between IPC and other Institutes was also noted. Scientific Body suggested that deliberations should be done with experts and stakeholders to adopt alternatives to animal testing using 3R principles.

Item 5. Progress of Microbiology Division

Scientific Body noted the progress made by Microbiology Division w.r.t. development and upgradation of General Chapters for the IP 2026, analytical testing, conducting PT round, meetings of the EWG, student training, and publications.

Item 6. Progress of Reference Standard Division

Scientific Body noted progress of the Division for the development of new IPRS and Impurity standards, lot changes of the reference standards, analysis of drugs (including cough syrups), and revenue generation. It was suggested by the Scientific Body that new Institutes may be identified who can help IPC in developing IPRS and Impurity standards.

Item 7. Progress of Quality Assurance (QA) Division

Scientific Body noted progress of the Division in maintaining accreditation certifications, conducting PT programmes, internal quality checks, and training provided to students. Scientific Body suggested conducting more PT rounds particularly for MSMEs and International laboratories. CDSCO may be contacted for issuing an advisory to MSMEs to participate in PT rounds to enhance credibility of their test results. Specific training modules for Mission Karmyogi in the areas of pharmacovigilance and materiovigilance may also be developed and sent for uploading on the portal.

Item 8. Progress of Pharmacovigilance Programme of India (PvPI)

Scientific Body noted the progress of PvPI for reporting of ADRs, expansion of AMCs across India, issuing drug safety alerts, and stakeholders' meetings. Scientific Body strongly felt the need to constitute a Scientific Committee to specifically review the pharmacovigilance activities and guide on the future direction of the PvPI to ensure its contribution in formulating policies for the improved healthcare in the country. It was also suggested to organize brainstorming sessions with the experts to explore the possibility of focused pharmacovigilance in the areas of diabetes, hypertension, and cancer.

Item 9. Progress of Materiovigilance Programme of India (MvPI)

Progress of MvPI activities was noted by the Scientific Body for integration with public health programme, reporting of MDAEs, expansion of MDMCs across India, proposal of MvPI to become certification body, Internation training programme conducted for Bhutan, and activities related to WHO Collaborating Centre.

Item 10. Progress of Publication Division

Noted and appreciated by the Scientific Body.

Item 11. Revenue Generation

Noted and appreciated by the Scientific Body.

Item 12. Creation of Industrial Research Chairs and Endowed Research Chairs

Scientific Body appreciated and approved this proposal as the same will attract fresh brains and will help IPC in strengthening its research activities. IPC was advised to formulate a policy in compliance with the standard guidelines for its approval by the Ministry of Health and Family Welfare.

Item 12. Any Other Item with Permission of the Chairperson

None.

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

Enclosure-I

List of Scientific Body Members Participated

- Dr. V. M. Katoch, Former DG-ICMR cum Secretary-Department of Health Research and Chairperson, Scientific Body-IPC (connected through VC)
- 2. Prof. Sanjay Singh, Vice Chancellor, BBAU-Lucknow (connected through VC)
- 3. Dr. Hemant Koshia, Commissioner-Food and Drug Control Administration-Ahmedabad
- 4. Dr. Inder Pal Singh, Deptt. of Natural Products, NIPER-Mohali
- 5. Dr. Amulya K. Panda, Former Director, NII-Delhi (connected through VC)
- 6. Dr. A. K. Singh, Former Director General (LS), DRDO-New Delhi
- 7. Mr. A. K. Pradhan, JDC(I), CDSCO-New Delhi
- 8. Dr. Bikash Medhi, Deptt. of Pharmacology, PGIMER-Chandigarh
- 9. Prof. Sanjeev Sinha, Deptt. of Medicine, AIIMS-Delhi (connected through VC)
- **10.** Sh. Zoher Sihorwala, Head-Global Regulatory Affairs, Wockhardt-Aurangabad (connected through VC)
- 11. Dr. Sunil Gairola, Executive Director, Serum Institute-Pune (connected through VC)
- 12. Dr. C. Hariharan, Director, RDTL-Guwahati (connected through VC)
- 13. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration-Mumbai (connected through VC)
- 14. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI-New Delhi (connected through VC)
- 15. Dr. Ravi P. Singh, Provost. Adani University-Ahmedabad (connected through VC)
- **16.** Dr. D. J. Kalita, Head-Technical and Regulatory, Zenex Animal Health India Pvt. Ltd.-Ahmedabad (connected through VC)
- 17. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director-IPC and Member Secretary

Leave of Absence

- 1. Dr. D. Srinivasa Reddy, Director, IICT-Hyderabad
- 2. Dr. Naresh Bhatnagar, Deptt. of Mechanical Engg., IIT-Delhi
- 3. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER-Mohali
- 4. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram