INDIAN PHARMACOPOEIA COMMISSION

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

Minutes of 55th Meeting of the Scientific Body (SB) of IPC

Date of Meeting : August 3, 2024 Chairperson : Dr. V. M. Katoch

The list of participants is appended as Enclosure-I.

Welcome and Opening of the Meeting

The 55th 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.

The Scientific Body appreciated the key achievements of the IPC including development of IP Online portal, recognition of the IP in Mozambique and Sri Lanka, increase in the number of IP Reference Standards (IPRS) and Impurity Standards, expansion of Pharmacovigilance and Materiovigilance Programmes of India, signing of MoUs with CSIR-IMTech, recognition of Materiovigilance Programme of India (MvPI) as certification body by the Quality Council of India (QCI), scientific publications, and revenue generation.

The Scientific Body applauded exponential progress of the IPC in all its mandates in the last three years and congratulated its Secretary-cum-Scientific Director and scientific staff. Keeping in view the contribution and achievements of IPC's work in the healthcare system, the Scientific Body strongly recommended expedited implementation of the Modified Flexible Complimentary Scheme (MFCS) for the scientific staff of the IPC at the earliest so that they remain motivated.

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 54th Meeting of the SB held on April 13, 2024

 The minutes were confirmed by the Scientific Body.
- Item 2. Action Taken Report on the Minutes of 54th Meeting of the SB held on April 13, 2024

Noted by the Scientific Body.

MAIN AGENDA

Item 3. Progress of AR&D and Phytopharmaceuticals Divisions

The 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 to harmonize Colistimethate sodium monographs of the IP with USP/BP.

Item 4. Progress of Reference Standard Division

The Scientific Body noted the 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 IPC should review the process for IPRS development and identify new Institutes who can help IPC in developing remaining IPRS and Impurity standards.

Item 5. Progress of Biologics Section

The 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. The Scientific Body emphasised that utmost care needs to be taken while taking decisions related to 'Alternatives to Animal Methods in IP'.

Item 6. Progress of Microbiology Division

The Scientific Body noted the progress made by Microbiology Division w.r.t. Development of new General Chapter (Disinfectant and Antiseptics), digital IP, signing MOU with CSIR-IMTech, Chandigarh and functioning of new Microbiology Laboratory in Advance Level Research Center (ALRC). The Scientific Body also noted the progress made by division w.r.t analytical testing and conducting in Proficiency Testing Program (PTP) in biological domain as per requirement of NABL for ISO/IEC 17043:2023 as PT provider.

Item 7. Progress of Quality Assurance (QA) Division

The Scientific Body noted the progress of the Division in maintaining accreditation certifications as per ISO standards, conducting PT programmes, internal quality checks, and trainings provided to students.

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

The Scientific Body noted the progress of PvPI for reporting of ADRs, expansion of AMCs across India, issuing drug safety alerts, and stakeholders' meetings. The Scientific Body suggested to establish AMCs in Lakshadweep and Nagaland. It was also suggested to review the performance of low reporting AMCs.

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, QCI recognizes MvPI as certification body, and activities related to WHO Collaborating Centre.

Dr. Sanjay Singh introduced about his university's role in promoting the education for differently able students and expressed interest to work with IPC in possible areas.

Since assistive devices used in blindness and deafness are notified as medical devices, IPC may explore this area for future collaborations.

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 Research Chairs at IPC

The Scientific Body appreciated the policy document created by IPC's Working Group on this subject and suggested that:

- o Honorarium should be kept same for all chairs,
- Guidelines from DST, ICMR, UGC, INSA may also be referred before finalizing the policy document,
- Yearly renewal of the Research Chairs should be based on assessment of deliverables.

Item 13. 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. D. Srinivasa Reddy, Director, IICT-Hyderabad (connected through VC)
- 4. Dr. Hemant Koshia, Commissioner-Food and Drug Control Administration-Ahmedabad
- 5. Dr. A. K. Singh, Former Director General (LS), DRDO-New Delhi
- **6.** Dr. Amulya K. Panda, Former Director, NII-Delhi (connected through VC)
- 7. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER-Mohali (connected through VC)
- 8. Dr. Inder Pal Singh, Deptt. of Natural Products, NIPER-Mohali (connected through VC)
- 9. Dr. Bikash Medhi, Deptt. of Pharmacology, PGIMER-Chandigarh
- **10.** Mr. A. K. Pradhan, JDC(I), CDSCO-New Delhi (connected through VC)
- 11. Sh. Zoher Sihorwala, Head-Global Regulatory Affairs, Wockhardt-Aurangabad
- 12. Dr. Sunil Gairola, Executive Director, Serum Institute-Pune (connected through VC)
- **13.** Dr. C. Hariharan, Director, RDTL-Guwahati (connected through VC)
- 14. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration-Mumbai (connected through VC)
- 15. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI-New Delhi (connected through VC)
- 16. Dr. Ravi P. Singh, Provost. Adani University-Ahmedabad (connected through VC)
- 17. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram (connected through VC)
- 18. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director-IPC and Member Secretary

Leave of Absence

- 1. Prof. Sanjeev Sinha, Deptt. of Medicine, AIIMS-Delhi
- 2. Dr. Naresh Bhatnagar, Deptt. of Mechanical Engg., IIT-Delhi
- 3. Dr. D. J. Kalita, Head-Technical and Regulatory, Zenex Animal Health India Pvt. Ltd.-Ahmedabad