INDIAN PHARMACOPOEIA COMMISSION

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

Minutes of 57th Meeting of the Scientific Body of the IPC

Date of Meeting : May 13, 2025
Chairperson : Dr. V. M. Katoch

The list of participants is appended as Enclosure-I.

Welcome and Opening of the Meeting

The 57th meeting of the IPC Scientific Body started with a welcome address by Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director.

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

Item 1. Introduction and Brief Presentation by the Member Secretary

Dr. Raghuvanshi presented the progress and key achievements made by the IPC since the last meeting of the Scientific Body. The Scientific Body noted and appreciated the key achievements of the IPC, including the successful conduct of the 15th International Meeting of World Pharmacopoeias (IMWP), recognition of the IP in Sri Lanka and Fiji, increase in the number of IP Reference Standards (IPRS) and Impurity Standards, expansion of Pharmacovigilance and Materiovigilance Programmes of India, audit activities initiated for medical devices, scientific publications, and revenue generation.

Scientific Body took note of the exponential progress of the IPC in the last four years. Keeping in view very limited opportunities for career growth of scientific staff, the Scientific Body once again recommended the implementation of the Modified Flexible Complimentary Scheme (MFCS) for the scientific staff of the IPC at the earliest.

Item 2. Confirmation of the Minutes of the 56th Meeting of the SB held on December 23, 2024

Confirmed by the Scientific Body.

Item 3. Action Taken Report on the Minutes of the 56th Meeting of the SB held on December 23, 2024

Noted by the Scientific Body.

MAIN AGENDA

Item 4. Progress of AR&D and Phytopharmaceuticals Divisions

The Scientific Body noted the work progress of the 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 Online portal, and organizing Expert Working Group (EWG) meetings.

Scientific Body suggested to share list of new drug substances and impurities for their establishment by the Reference Standards Division.

Item 5. Progress of Microbiology Division

The Scientific Body noted the progress made by the Microbiology Division w.r.t. the development of a new General Chapter on Disinfectants and Antiseptics, ongoing work related to the PDG, functioning of the new Microbiology Laboratory at the Advanced Level Research Centre (ALRC), and analytical testing. It was suggested that prior to the inclusion of *Candida albicans* testing for patches and medicated plasters, relevant data should be obtained from stakeholders.

Scientific Body agreed with the proposal to constitute an expert committee to identify gaps in the process of creating a biobank of microbial reference cultures for pharmaceutical analysis at IPC and recommended that the expert committee should operate in a time-bound manner. It was also directed that gap analysis in comparison with other microbial culture collections should be presented in the next Scientific Body meeting.

Item 6. Progress of Biologics Section

The Scientific Body noted the work progress of the Biologics Division 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 proficiency testing (PT) program, analytical testing, signing of MoU with National Institute of Pharmaceutical Education and Research (NIPER), Mohali, and student training.

Scientific Body suggested that monograph omissions in IP 2026 should be recorded as monograph modernizations that are carried out in-line with the current regulatory requirements. For smooth execution of the MoU with NIPER, Mohali, it was suggested to share impurities list for their synthesis.

Item 7. Progress of Reference Standard Division

The Scientific Body acknowledged the progress made by the Division in the development of new IPRS and impurity standards, updates related to lot changes in reference standards, drug analysis, and revenue generation. The Scientific Body noted that IPC has already developed most of the reference standards identified as priority and is now focusing on impurities. Scientific Body expressed satisfaction on the achievements. Particular emphasis was placed on the development of new impurity standards. The Scientific Body further advised directing focused efforts toward engaging state authorities to promote the adoption and use of these impurity standards and IPC should write letters to Drug Control Authorities in this regard.

Item 8. 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 training provided to students. The Scientific Body recommended aligning efforts with the Prime Minister's Internship Scheme to enhance capacity building and engagement of young professionals. It was also emphasized that the contribution of the IPC should be duly acknowledged in the publications made by trainee students.

Item 9. Progress of Pharmacovigilance Programme of India (PvPI)

The Scientific Body noted the progress of PvPI for reporting of Adverse Drug Reaction (ADR), expansion of ADR Monitoring Centres across India, issuing drug safety alerts, and stakeholders' meetings. The Scientific Body noted that PGI, Chandigarh has made ADR Reporting Form mandatory for patient admission and PvPI should make efforts to promote adoption of this practice in other hospitals also.

Scientific Body also directed that the PvPI proposal for the next 5 years should be circulated to its members prior to its submission to the Ministry of Health & Family Welfare at the earliest.

Item 10. 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, activities as WHO Collaborating Centre, and capacity building in North East States. Scientific Body appreciated efforts of the MvPI for initiating audit scheme of the medical device manufacturing firms.

Scientific Body suggested that MvPI should organize webinars to create awareness about its publications among key stakeholders. Scientific Body also took note of the medical device testing facility being developed at IPC and suggested to make priority list of medical devices.

Item 11. Progress of Publication Division

The Scientific Body suggested to present the impact of expos and marketing initiatives, along with details of IPC publications in the next meeting. Additionally, it was recommended to utilize the services of 'Anuvadini' under the Ministry of Education, Government of India for Hindi translation of IPC annual report. Scientific Body also desired that IPC annual reports should also be shared with its members.

Item 12. Enhancement of Objectives (Mandate) of the IPC

Scientific Body approved to enhance IPC Objectives (Mandate) by including following new function:

"To conduct systematic examination and analysis of the quality of drugs and medical devices referred to the IPC in accordance with the Drugs & Cosmetics Act and Rules framed thereunder."

Item 13. Revenue Generation

Noted by the Scientific Body.

Item 14. Any Other Item with the 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.

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Enclosure-I

List of Scientific Body Members Participated

1. 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, Dr Shakuntala Misra University Lucknow; Former VC, 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. A. K. Singh, Former Director General (LS), DRDO-New Delhi (connected through VC)
6. Sh. Zoher Sihorwala, Head-Global Regulatory Affairs, Wockhardt-Aurangabad
7. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER-Mohali (connected through VC)
8. Dr. Bikash Medhi, Deptt. of Pharmacology, PGIMER-Chandigarh (connected through VC)
9. Mr. A. K. Pradhan, Former JDC(I), Advisor, CDSCO-New Delhi
10. Dr. Sunil Gairola, Executive Director, Serum Institute-Pune (connected through VC)
11. Dr. C. Hariharan, Director, CDTL-Mumbai (connected through VC)
12. Dr. D. J. Kalita, Head-Technical and Regulatory, Zenex Animal Health India Pvt. Ltd.-Ahmedabad (connected through VC)
13. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram (connected through VC)
14. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director-IPC and Member Secretary

Leave of Absence

1. Dr. D. Srinivasa Reddy, Director, IICT-Hyderabad
2. Prof. Sanjeev Sinha, Deptt. of Medicine, AIIMS-Delhi
3. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration-Mumbai
4. Dr. Amulya K. Panda, Former Director, NII-Delhi
5. Dr. Naresh Bhatnagar, Deptt. of Mechanical Engg., IIT-Delhi
6. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI-New Delhi
7. Dr. Ravi P. Singh, Provost. Adani University-Ahmedabad