

INDIAN PHARMACOPOEIA COMMISSION

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

Minutes of the 56th Meeting of the Scientific Body (SB) of IPC

Date of Meeting : December 23, 2024

Chairperson : Dr. V. M. Katoch

The list of participants is appended as Enclosure-I.

Welcome and Opening of the Meeting

The 56th meeting of the IPC Scientific Body started with a welcome address by Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director. 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 launch of the IP Online portal, recognition of the IP in foreign countries, establishment of the IP Reference Standards (IPRS) and Impurity Standards, expansion of Pharmacovigilance and Materiovigilance Programmes of India along with scientific publications, and revenue generation.

Dr. V. M. Katoch appreciated all round progress of IPC and mentioned that the work carried out by the IPC has made significant contributions to the healthcare system of the country. He reiterated that there is need to expedite the process for implementation of the Flexible Complimentary Scheme (FCS) for career progression of the scientific staff.

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

Item 1. Confirmation of the Minutes of the 55th Meeting of the SB held on August 3, 2024

These minutes were earlier circulated to members and no comments were received. The SB confirmed the minutes.

Item 2. Action Taken Report on the Minutes of the 55th Meeting of the SB held on August 3, 2024

Noted by the Scientific Body.

MAIN AGENDA

Item 3. 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, launch of the IP Online portal, activities related to recognition of the IP in foreign countries, IPC's participation in the Pharmacopoeial Discussion Group (PDG), organizing Expert Working Group (EWG) meetings, and research publications. While reviewing the monograph list, the Scientific Body suggested that the development of phytopharmaceutical monographs, which are already in the pipeline, should also be considered. Also, the thermostability data should be checked in the IP for harmonization.

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 in the reference standards, analysis of drugs, and revenue generation. Emphasis was placed by the Scientific Body on raising issues for the quality specifications of the new drugs by the IPC to CDSCO prior to granting the market authorization. Moreover, it was advised to gather and analyze state-wise data on IPRS and impurities sales which may be presented in the next meeting.

Item 5. 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 PT program, analytical testing, and student training.

Item 6. Progress of Microbiology Division

The Scientific Body noted the progress made by the Microbiology Division w.r.t. development of a new general chapter of 'Disinfectant and Antiseptics', functioning of the new Microbiology Laboratory in Advance Level Research Center (ALRC), analytical testing and participation in the Proficiency Testing Program (PTP), and maintaining NABL accreditation as per requirement for ISO/IEC 17025:2017 as testing in the biological domain. Scientific body suggested forming a committee with members from bodies like the Institute of Microbial Technology (IMTech) and the Department of Biotechnology (DBT) to identify the gap(s) while working towards creating a biobank of microbial cultures for pharmaceutical analysis at IPC.

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 training 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 check the PvPI data for additional beneficial effects of the drugs so that the same can be utilized for repurposing of the drugs. Need was felt to increase stakeholder engagement for compliance with the newly released guidance document. Further, webinars should be organized to improve the functioning of zero reporting AMCs. PvPi should also analyze gaps towards achieving maturity Level 4 in WHO NRA assessment.

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, inclusion

of Medical Device Division in IPC's organizational structure, and activities related to WHO Collaborating Centre. Scientific Body suggested to review the status of zero reporting MDMCs.

Item 10. Progress of Publication Division

The Scientific Body suggested conducting a market analysis for the promotion of IP Online and assessing the current status and future requirements for the hardcopy in order to ensure that a substantial number of required documents are published.

Item 11. Revenue Generation

Noted by the Scientific Body.

Item 12. Any Other Item with Permission of the Chairperson

There was no additional agenda item.

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

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. 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 (connected through VC)
6. Dr. Amulya K. Panda, Former Director, NII-Delhi (connected through VC)
7. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER-Mohali
8. Dr. Inder Pal Singh, Deptt. of Natural Products, NIPER-Mohali
9. Dr. Bikash Medhi, Deptt. of Pharmacology, PGIMER-Chandigarh
10. Mr. A. K. Pradhan, JDC(I), CDSCO-New Delhi
11. Dr. Sunil Gairola, Executive Director, Serum Institute-Pune (connected through VC)
12. Dr. C. Hariharan, Director, CDTL-Mumbai (connected through VC)
13. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration-Mumbai (connected through VC)
14. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram (connected through VC)
15. 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. Sh. Zohar Sihorwala, Head-Global Regulatory Affairs, Wockhardt-Aurangabad
3. Dr. Naresh Bhatnagar, Deptt. of Mechanical Engg., IIT-Delhi
4. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI-New Delhi (connected through VC)
5. Dr. Ravi P. Singh, Provost. Adani University-Ahmedabad (connected through VC)
6. Dr. D. J. Kalita, Head-Technical and Regulatory, Zenex Animal Health India Pvt. Ltd.-Ahmedabad