INDIAN PHARMACOPOEIA COMMISSION

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

Minutes of 52nd Meeting of the Scientific Body (SB) of IPC

Date of Meeting : August 12, 2023

Chairperson : Dr. V. M. Katoch

The list of participants is appended as Enclosure-I.

Welcome and Opening of the Meeting

At the outset, Dr. Rajeev Singh Raghuvanshi welcomed the Chairperson and members of the Scientific Body for 52nd meeting of the Scientific Body of the IPC. With the permission of Dr. V. M. Katoch, Chairperson-Scientific Body, Dr. Raghuvanshi made a presentation on the 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 efforts made by IPC towards development of monographs for the next IP Addendum 2024, global recognition of IP, development of new IP Reference Substances (IPRS) and Impurity Standards, expansion of Pharmacovigilance and Materiovigilance Programmes of India, and revenue generation. It was emphasized by the Scientific Body that IPC resources should also be utilized for exploring new thrust areas so as to help countering new age challenges in the healthcare system of India. Scientific Body also felt that there is need to publicize the achievements of the IPC and success of the IPC may be shared with neighboring countries. Further, it was suggested that IPC scientists should focus on publishing their work in scientific journals.

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

Item 1. Confirmation of the Minutes of 51st Meeting of the SB held on March 25, 2023

Minutes were confirmed by the Scientific Body.

Item 2. Action Taken Report on the Minutes of the 51st Meeting of the SB held on March 25, 2023

Noted by the Scientific Body.

MAIN AGENDA

Item 3. Progress of AR&D Division

Scientific Body noted work progress of AR&D Division w.r.t. development of monographs for IP Addendum 2024, inclusion of tests on dissolution and related substances, IPC's participation in Pharmacopoeia Discussion Group (PDG) pilot expansion, and organizing IPC Interactive Meet. IP recognition in Suriname was appreciated by the Scientific Body. Proposal on directly publishing 10th edition of IP 2026 after the publication of IP Addendum 2024 was approved by the Scientific Body.

Item 4. Progress of Biologics Section

Scientific Body noted the work progress of Biologics Division during the index period w.r.t. development and revision of human and veterinary vaccine biological monographs and General Chapters, organizing EWG meetings, and scientific

publications. Signing and renewal of MoUs between IPC and other Institutes was also noted.

Action Points: Scientific Body suggested following action points:

- To constitute a sub-group for reviewing impurity specifications in biological monographs since the same vary from manufacturer to manufacturer due to variations in the host cells and manufacturing process,
- Proficiency Testing (PT) programme should be initiated in the domain of biological derived pharmaceuticals (including immunological products).

Item 5. Progress of Microbiology Division

Scientific Body noted the progress made by the Microbiology Division w.r.t. upgradation and development of General Chapters and monographs for IP Addendum 2024, analytical testing, EWG meetings, and scientific publications. Scientific Body appreciated the expansion of the scope in biological domain (i.e. test for specified microorganisms) as per ISO/IEC 17043:2010 as PT provider.

Item 6. Progress of Phytopharmaceuticals Division

Scientific Body noted development of monographs and General Chapters on phytopharmaceuticals for the IP Addendum 2024. Progress made by the Division w.r.t. signing of MoU with CSIR-CIMAP, EWG meetings and scientific publications was also noted.

Action Points: Following action points were suggested by the Scientific Body:

- To conduct training and awareness programmes on phytopharmaceuticals in different parts of the country,
- Creating a think tank to identify gap areas in the field of phytopharmaceuticals.

Item 7. Progress of Reference Standard Division

The work for the development of new IP reference standards and impurity standards, lot changes of the reference standards, analysis of drugs, and revenue generation was reviewed by the Scientific Body. Scientific Body applauded that the Division has developed more than 1200 reference standards and made available to the stakeholders.

Action Points: Scientific Body suggested following action points:

- Library of reference standards needs to be increased and a sub-group under the leadership of Dr. D. Srinivasa Reddy may be created to deliberate on the requirements,
- Inputs of the manufacturers should also be taken into consideration while developing new standards.

Item 8. Progress of Quality Assurance (QA) Division

Scientific Body noted progress of the Division in the area of maintaining certification and accreditation activities, conducting proficiency testing (PT) programmes, internal quality checks, and trainings provided to students.

Action Points: Following action points were suggested by the Scientific Body:

- Training programmes should be conducted throughout the year and on-line training programmes should also be designed so that time and resources are optimally utilized,

- ITEC programmes should be designed for overseas participants.

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

Scientific Body noted the progress report of PvPI for reporting of ADRs, expansion of AMCs across India, issuing drug safety alerts, and stakeholders meetings. It was noted that PvPI has made a significant progress in expanding the programme across India.

Action Points: Scientific Body suggested following action points:

- PvPI should celebrate Pharmacovigilance Week by becoming patient and society centric and engaging with them so that reporting by individuals can be increased. Special sessions may be conducted for educating school going children as well as in academic Institutions,
- An expert group needs to be created to explore the possibility of initiating cosmetovigilance under the ambit of PvPI,
- PvPI should also focus on vigilance of biosimilars/biologicals since many products are being approved for marketing in off-patent regime.

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, and training programmes conducted.

Item 11. Progress of Publication Division

Noted by the Scientific Body.

Item 12. Revenue Generation

Noted and appreciated by the Scientific Body.

Item 13. Any Other Item with Permission of the Chairperson

None.

Meeting ended with 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, BBAU-Lucknow
3. Dr. D. Srinivasa Reddy, Director, IICT-Hyderabad (connected through VC)
4. Mr. A. K. Pradhan, JDC(I), CDSCO-Delhi
5. Dr. A. K. Singh, CEO, Biotech Park-Lucknow
6. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration-Mumbai (connected through VC)
7. Dr. C. Hariharan, Director, RDTL-Guwahati (connected through VC)
8. Dr. Amulya K. Panda, Former Director, NII-Delhi (connected through VC)
9. Dr. Bikash Medhi, Deptt. of Pharmacology, PGIMER-Chandigarh
10. Dr. Inder Pal Singh, Deptt. of Natural Products, NIPER-Mohali (connected through VC)
11. Prof. Sanjeev Sinha, Deptt. of Medicine, AIIMS-Delhi (connected through VC)
12. Dr. Sunil Gairola, Executive Director, Serum Institute-Pune
13. Sh. Zoher Sihorwala, Head-Global Regulatory Affairs, Wockhardt-Aurangabad
14. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram
15. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director-IPC and Member Secretary

Leave of Absence

1. Dr. Naresh Bhatnagar, Deptt. of Mechanical Engg., IIT-Delhi
2. Dr. Hemant Koshia, Commissioner-Food and Drug Control Administration-Ahmedabad
3. Dr. Ravi P. Singh, Secretary General, Quality Council of India-New Delhi
4. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER-Mohali
5. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI-New Delhi
6. Dr. D. J. Kalita, Head-Technical and Regulatory, Zenex Animal Health India Pvt. Ltd.-Ahmedabad