

INDIAN PHARMACOPOEIA COMMISSION

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

Minutes of 51st Meeting of the Scientific Body of IPC

Date of Meeting : March 25, 2023

Chairperson : Dr. V. M. Katoch

The list of participants is appended as Enclosure-I.

Welcome and Opening of the Meeting

Dr. Rajeev Singh Raghuvanshi welcomed the Chairperson and Members of the Scientific Body of the IPC for the 51st meeting of the Scientific Body. With the permission of Dr. V. M. Katoch, Chairperson-Scientific Body, Dr. Raghuvanshi gave a presentation on the major activities and achievements of the IPC since the last meeting of the Scientific Body. Dr. Raghuvanshi also informed the Scientific Body that Government of India is taking quality of medicines very seriously and a Chintan Shivir was organized by the Ministry of Health and Family Welfare in Hyderabad where a session was dedicated on Indian Pharmacopoeia (IP) which makes IPC at the centre stage in the drug regulatory framework in the country.

Dr. Katoch congratulated Dr. Raghuvanshi for his appointment as the Drugs Controller General of India and added that continuing in his both roles, Dr. Raghuvanshi will be able to achieve maximum by overall strengthening the drug regulatory systems in India. Dr. Katoch and Members of the 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, development of new IP Reference Substances (IPRS) and Impurity Standards, expansion of Pharmacovigilance and Materiovigilance Programmes of India, and revenue generation.

Thereafter, Dr. Raghuvanshi presented the agenda in following sequence and decisions of the Scientific Body were recorded as below:

Item 1. Confirmation of the Minutes of 50th Meeting of the Scientific Body held on September 28, 2022

Minutes were confirmed by the Scientific Body.

Item 2. Action Taken Report on the Minutes of the 50th Meeting of the Scientific Body held on September 28, 2022

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, inclusion of tests on related substances and dissolution. It was apprised to the Scientific Body that draft monographs for next IP Addendum have been published on IPC website for inviting public comments. Scientific Body suggested that whenever IPC is developing an API monograph, its formulation monograph should also be published in the same edition/addendum. IP monographs should be screened, and any missing formulation monographs(s) should be included as a priority.

IPC's participation in expansion pilot of Pharmacopoeia Discussion Group (PDG) along with other PDG pharmacopoeias (i.e., USP, Ph. Eur., and JP) was appreciated by the Scientific Body.

Item 4. Progress of Phytopharmaceuticals Division

Scientific Body noted development of monographs and General Chapters on phytopharmaceuticals for the next IP Addendum. Scientific Body enquired about the markers being selected for the phytopharmaceuticals monographs to which it was appraised that IPC is developing monographs by including one principal bioactive marker and other phytoconstituents which may have bioactivity. Progress made by the Division w.r.t. EWG meetings and scientific publications was also noted.

Item 5. Progress of Microbiology Division

Scientific Body noted the progress made by the Division w.r.t. upgradation and development of General Chapters and monographs including the new General Chapter on “Guidelines on the Bacterial Endotoxin Tests” for the next IP Addendum.

Progress made by Division w.r.t. analytical testing, EWG meetings, and scientific publications was noted. 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 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 participation in International conference. It was suggested by the Scientific Body to constitute a sub-group on biologicals (with NIB as a member) to publish a white paper on the subject.

Item 7. Progress of Reference Standard Division

The work for the development of new Reference Substances and impurity standards, retesting of current and revenue generated through analysis of drugs was reviewed by the Scientific Body. Scientific Body applauded that the Division has developed more than 500 Impurity standards. It was suggested that IPC should monetize its analytical services by offering them to industry, academia and others.

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, inter-laboratory collaborative studies, and trainings provided to students and stakeholders. Scientific Body suggested that while conducting the PT on dissolution testing, IPC should keep in mind the issues faced by the WHO in their PT. It was also suggested that IPC should conduct PT on immunological assays.

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

Scientific Body noted the progress report of PvPI for reporting of ADRs and expansion of AMCs across India. It was noted that PvPI has made a significant progress in expanding the programme across India but analyzing the pharmavigilance data in unbiased way is a challenge.

It was suggested by the Scientific Body that there is a need to connect with the consumers to increase direct reporting of ADRs to the PvPI. Need was felt that efforts should be made for focused pharmacovigilance wherein key drugs need to be identified

and timelines should be decided for this activity. Dr. Bikash Medhi informed that a protocol is being developed for the same which will be shared with the IPC.

It was also suggested by the Scientific Body that IPC should think of Cosmetovigilance in India. Scientific Body also suggested that PvPI should coordinate with the Ministry of AYUSH for vigilance data generated for AYUSH drugs which will help assessing the comprehensive picture of the pharmacovigilance in India as many consumers use both modern and AYUSH systems, sometime together and on other occasions sequentially especially in chronic conditions.

Item 10. Progress of Materiovigilance Programme of India (MvPI)

Progress of MvPI activities was noted by the Scientific Body for reporting of MDAEs and expansion of MDMCs across India. Scientific publication in high impact journal was appreciated by the Scientific Body.

Item 11. Progress of Publication Division

Noted by the Scientific Body.

Item 12. Revenue Generation

Noted and appreciated by the Scientific Body.

Item 13. Future Targets and Vision of the IPC

Scientific Body took note of the proposed targets of IPC and approved the same.

Item 14. Any Other Item with Permission of the Chairperson

None.

The meeting ended with 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, BBAU-Lucknow (connected through VC)
3. Dr. D. Srinivasa Reddy, Director, IIIM-Jammu (connected through VC)
4. Mr. A. K. Pradhan, JDC(I), CDSCO-Delhi
5. Dr. Hemant Koshia, Commissioner-Food and Drug Control Administration-Ahmedabad
6. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration-Mumbai (connected through VC)
7. Dr. C. Hariharan, Director, RDTL-Guwahati
8. Dr. A. K. Singh, CEO, Biotech Park-Lucknow
9. Dr. Amulya K. Panda, Former Director, NII-Delhi (connected through VC)
10. Dr. Bikash Medhi, Deptt. of Pharmacology, PGIMER-Chandigarh (connected through VC)
11. Dr. Inder Pal Singh, Deptt. of Natural Products, NIPER-Mohali (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. Sh. Ganadhish Kamat, Former Executive Vice President, Dr. Reddy's Laboratory-Hyderabad (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. Naresh Bhatnagar, Deptt. of Mechanical Engg., IIT-Delhi
2. Dr. Ravi P. Singh, Secretary General, Quality Council of India-New Delhi
3. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER-Mohali
4. Prof. Sanjeev Sinha, Deptt. of Medicine, AIIMS-Delhi
5. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI-New Delhi