

Indian Pharmacopoeia Commission

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

Minutes of 49th Meeting of The Scientific Body of IPC

Date of Meeting : May 26, 2022

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 newly constituted Scientific Body (SB) for the 49th 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.

Dr. Katoch and members of SB took note of the key achievements of the IPC and appreciated the efforts made by IPC towards publication of Indian Pharmacopoeia (IP 2022), publication and release of National Formulary of India (NFI 2021), development of new IP Reference Substances (IPRS) and Impurity Standards, expansion of Pharmacovigilance Programme of India (PvPI) and Materiovigilance Programme of India (MvPI). It was appreciated that IPC is contributing significantly for public health and there is need to make more efforts so that public can relate with the organization. Dr. Katoch also suggested that IPC should plan to manage its resources for expansion of its activities to take up new challenges in mandated areas.

Thereafter, the Member Secretary presented the agenda in following sequence and decisions of the Scientific Body are recorded as below:

Item 1. Confirmation of the Minutes of 48th Meeting of the Scientific Body held on January 08, 2022

Minutes were confirmed by the Scientific Body.

Item 2. Action Taken Report on the Minutes of the 48th Meeting of the Scientific Body held on January 08, 2022

Noted by the Scientific Body.

MAIN AGENDA

Item 3. Progress Report of AR&D Division

Scientific Body noted status of publication of IP 2022. Also, status of monograph development and their revision w.r.t. test for Related substances and impurity limits was noted. It was noted that efforts for bringing out IP on-line platform would help stakeholders for accessing the IP digitally.

Publication of next IP edition/addendum was discussed and Scientific Body suggested that IPC may continue with publication cycle of new IP edition every four year and addenda may be published in between two editions to keep the IP standards updated. Decision on increasing the frequency of new editions of IP may be taken once the IP on-line platform is ready for users.

It was also suggested that IPC should look into harmonizing excipient monographs with other pharmacopoeia particularly w.r.t. impurity limits in monographs. It was informed to the Scientific Body that IPC has applied for expansion pilot of Pharmacopoeia Discussion Group (PDG) and this activity is being taken up with other PDG pharmacopoeia (i.e., USP, Ph. Eur., and JP).

Scientific Body also suggested to perform gap analysis regarding absence of tests for Dissolution and Related substances in IP monographs and such monographs should be upgraded on priority basis. Also, there is need to relook into the publication of amendment list and errata in light of the regulatory implications. Separate discussion with the experts may be done to take a decision in this regard.

Item 4. Progress Report of Reference Standard Division

Scientific Body noted significant increase in the number of IPRS and Impurity standards developed by the Division. Efforts made for procurement of new IPRS and Impurity standards through tendering process were also noted.

It was suggested by the Scientific Body to perform gap analysis for remaining IPRS to be developed for making them available to the stakeholders.

Item 5. Progress Report of Microbiology Division

Scientific Body noted the progress made by Division and suggested that for repository of the Reference Cultures may be established with the help of NCCS-Pune. On the issue of revision of endotoxin limit in Remdesivir injection (0.6 EU/mg), it was decided not to change existing limits in this monograph.

Item 6. Progress Report of Phytopharmaceuticals Division

Noted by the Scientific Body and it was suggested that immunomodulatory properties of the PPI monographs may be checked.

Item 7. Progress Report of Biologics Section

Scientific Body noted the progress of Biologics Division and suggested that references should be cited while drafting general chapters which will help reviewers to offer their comments on the text. It was also desired that progress report of the general chapters should also be brought to the notice of the Scientific Body.

Scientific Body specifically desired to develop monograph standards on vaccine platforms which will not only help new manufacturers to develop new vaccines but also help ensuring their quality. A separate sub-group of experts may be constituted for this specific activity.

Item 8. Progress Report of National Formulary of India (NFI)

Scientific Body suggested that efforts should be made to create more awareness about NFI among the stakeholders and digital platforms may be used for this purpose. Dr. Bikash Medhi suggested that his publication on this subject may be referred for this activity.

Item 9. Mutual Cooperation with National and International Organizations

Noted by the Scientific Body.

Item 10. Progress Report of Quality Assurance (QA) Division

Scientific Body noted progress of the Division w.r.t. accreditation activities, proficiency testing programmes, ILC, and trainings provided to students and stakeholders.

Item 11. Progress Report of Pharmacovigilance Programme of India (PvPI)

Scientific Body noted the expansion plan of PvPI and suggested to integrate PvPI activities with the Primary Health Centres across India. It was also suggested to enroll new AMCs in Ladakh and Nagaland with the help of Dr. Bikash Medhi.

In addition, Scientific Body suggested that there is need to plan focused activities under the PvPI to ensure that outcomes of the PvPI have direct impact on public health. This may include, but not limited to, identifying India-specific ADRs from PvPI database to make recommendations for necessary regulatory actions. Priority may be considered for

treatment of diseases like cancer, other chronic diseases with long term use of drugs, that too in unusual inadequately researched combinations and expansion of human resources including outside experts for in-depth and timely analysis.

Item 12. IPC as WHO Collaborating Centre for Pharmacovigilance

Noted and appreciated by the Scientific Body.

Item 13. Progress Report of Materiovigilance Programme of India (MvPI)

Scientific Body noted expansion of MvPI and increase in the reporting of MDAEs to the programme.

Item 14. Progress Report of Publication Division

Noted by the Scientific Body.

Item 15. Any Other Agenda Item with Permission of the Chairperson

There was no other agenda.

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. Hemant Koshia, Commissioner-Food and Drug Control Administration-Ahmedabad
4. Mr. A. K. Pradhan, JDC(I), CDSCO-Delhi (Connected through VC)
5. Dr. A. K. Singh, CEO, Biotech Park-Lucknow
6. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration-Mumbai
7. Dr. C. Hariharan, Director, CDL-Kolkata
8. Dr. Amulya K. Panda, Former Director, NII-Delhi
9. Dr. Bikash Medhi, Deptt. of Pharmacology, PGIMER-Chandigarh (Connected through VC)
10. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER-Mohali (Connected through VC)
11. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram
12. Sh. Ganadhish Kamat, Former Executive Vice President, Dr. Reddy's Laboratory-Hyderabad
13. Dr. Sunil Gairola, Executive Director, Serum Institute-Pune
14. Sh. Zoher Sihorwala, Head-Gobal Regulatory Affairs, Wockhardt-Aurangabad
15. Dr. D. J. Kalita, Head-Technical and Regulatory, Zenex Animal Health India Pvt. Ltd.-Ahmedabad
16. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director-IPC and Member Secretary

Leave of Absence

1. Dr. D. Srinivasa Reddy, Director, IIIM-Jammu
2. Dr. Ravi P. Singh, Secretary General, Quality Council of India-New Delhi
3. Dr. Naresh Bhatnagar, Deptt. of Mechanical Engg., IIT-Delhi
4. Prof. Sanjeev Sinha, Deptt. of Medicine, AIIMS-Delhi
5. Dr. Inder Pal Singh, Deptt. of Natural Products, NIPER-Mohali
6. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI-New Delhi