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

Minutes of 50th Meeting of the Scientific Body of IPC

Date of Meeting : September 28, 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 Scientific Body (SB) for the 50th 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 Scientific Body took note of the key achievements of the IPC and appreciated the efforts made by IPC towards publication of Indian Pharmacopoeia (IP 2022), 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 over the years IPC has continuously progressed and made significant contributions in public health sector of the country. Scientific Body suggested that IPC should prepare long term plan also with medium and short term goals with defined targets. It was also suggested that there is need to properly utilize the resources for IPC's expansion plans and future goals in mandated areas. Dr. Katoch emphasized to think differently while defining the future targets and new areas shall be identified for IPC's growth.

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 49th Meeting of the Scientific Body held on May 26, 2022

Minutes were confirmed by the Scientific Body.

Item 2. Action Taken Report on the Minutes of the 49th Meeting of the Scientific Body held on May 26, 2022

Noted by the Scientific Body.

MAIN AGENDA

Item 3. Progress Report 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 have been published on IPC website for inviting public comments and many more monographs are under development for next IP Addendum. IPC's participation in expansion pilot of Pharmacopoeia Discussion Group (PDG) along with other PDG pharmacopoeia (i.e., USP, Ph. Eur., and JP) was appreciated by the Scientific Body. AR&D Division has identified the IP monographs requiring upgradation w.r.t. test for dissolution and related substances. Scientific Body suggested to consult pharma manufacturers for sourcing of monograph specifications and Mr. Ganadhish Kamat offered that he will help in this regard.

Item 4. Progress Report 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 members applauded that the Division has developed more than 1000 IPRS and Impurity standards for the stakeholders which is third highest among global pharmacopoeias.

Item 5. Progress Report of Microbiology Division

Scientific Body noted the progress made by the Division w.r.t. upgradation and development of General Chapters for IP, analytical testing, and publications. Scientific Body appreciated for granting the approval by NABL for ISO/IEC 17043:2010 as PT provider in biological domain (i.e. microbiological assay of gentamicin sulphate).

Item 6. Progress Report of Phytopharmaceuticals Division

Scientific Body noted monograph and general chapter development of phytopharmaceuticals for the next IP Addendum. Signing of MoU with PCIM&H for developing monographs under 'One Herb One Standard' initiative was appreciated.

Item 7. Progress Report of Biologics Section

Scientific Body noted the work progress of Biologics Division during the index period. Scientific Body approved proposals for amendments in **Vaccines for human use** (i.e. Cell Substrates for the Production of Vaccines for Human Use, General Requirements Vaccines, Inactivated Hepatitis A Vaccine (Adsorbed)), **Biotechnology derived therapeutic products** (i.e. Pegfilgrastim, Erythropoietin Concentrated Solution, Insulin Aspart, Insulin Glargine), **Blood and blood related products** (i.e. Anti-A Blood Grouping Serum, Anti-Human Globulin, Dried Human Antihaemophilic Fraction, Fibrin Sealant Kit, Human Coagulation Factor VIII (rDNA), Human Normal Immunoglobulin for Intravenous Use, Incorporation of Other Kit Based Alternate Method).

Item 8. Progress Report of Veterinary Products in India

Scientific Body noted the development of monographs and general chapters for veterinary products and approved proposals for amendments in Veterinary products.

Item 9. Mutual Cooperation with National and International Organizations

Signing of MoU with PCIMH was noted by the Scientific Body.

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

Scientific Body noted progress of the Division in the area of maintaining certification and accreditation activities, conducting proficiency testing programmes, inter-laboratory collaborative studies, and trainings provided to students and stakeholders.

Item 11. Progress Report 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 suggested by the Scientific Body to send letter to National Centre for Disease Control (NCDC)-New Delhi and JIPMER-Puducherry to sensitize them about sharing of anti-microbial resistance (AMR) data of AMR containment programme with the PvPI.

In addition, Scientific Body also suggested sending letter to the Chairman of National Medical Commission (NMC) for submission of ADRs by all hospitals and medical colleges under purview of NMC to PvPI. NMC should be requested to integrate the

Pharmacovigilance Committee of hospitals and medical colleges with the PvPI Committee.

Dr. Bikash Medhi emphasized the need to start veterinary pharmacovigilance in the country. Being a policy decision the same needs thorough discussion before its implementation. Scientific Body also suggested incentivizing the high performing AMCs to encourage them.

Item 12. IPC as WHO Collaborating Centre for Pharmacovigilance

Activities under the WHO Collaborating Centre for Pharmacovigilance were noted by the Scientific Body. Development of e-ITEC course under Indian Technical and Economic Cooperation (ITEC) with the support of Ministry of External Affairs was appreciated.

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

Progress of MvPI activities was noted by the Scientific Body. Dr. Naresh Bhatnagar requested to share the list of medical device related recommendations submitted by IPC to CDSCO.

Item 14. Progress Report of Publication Division

Scientific Body noted progress of Publication Division for printing status of IP 2022, sales data of IPC publications, and articles published by the Division.

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

Dr. Rajeev Singh Raghuvanshi presented analytical data of dissolution testing generated in IPC laboratory on marketed products highlighting the need for strengthening overall drug regulatory mechanism to ensure availability of quality medicinal products in the country. Scientific Body took note of the presentation made and opined that first an Expert Committee may be constituted by the IPC to examine the findings of IPC's analysis. Thereafter, recommendations of the Expert Committee may be submitted to the Scientific Body to seek guidance on further course of action in the matter.

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 (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. Dr. Naresh Bhatnagar, Deptt. of Mechanical Engg., IIT-Delhi (Connected through VC)
7. Dr. Bikash Medhi, Deptt. of Pharmacology, PGIMER-Chandigarh
8. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER-Mohali
9. Dr. Inder Pal Singh, Deptt. of Natural Products, NIPER-Mohali
10. Dr. C. Hariharan, Director, RDTL-Guwahati (Connected through VC)
11. Sh. Ganadhish Kamat, Former Executive Vice President, Dr. Reddy's Laboratory-Hyderabad
12. Sh. Zoher Sihorwala, Head-Gobal Regulatory Affairs, Wockhardt-Aurangabad (Connected through VC)
13. Dr. D. J. Kalita, Head-Technical and Regulatory, Zenex Animal Health India Pvt. Ltd.-Ahmedabad (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, IIIM-Jammu
2. Dr. Ravi P. Singh, Secretary General, Quality Council of India-New Delhi
3. Dr. Amulya K. Panda, Former Director, NII-Delhi
4. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration-Mumbai
5. Prof. Sanjeev Sinha, Deptt. of Medicine, AIIMS-Delhi
6. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI-New Delhi
7. Dr. Sunil Gairola, Executive Director, Serum Institute-Pune
8. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram