

INDIAN PHARMACOPOEIA COMMISSION

(Ministry of Health & Family Welfare, Govt. of India)

Sector-23, Raj Nagar, Ghaziabad-201002

MINUTES OF 43rd MEETING OF THE SCIENTIFIC BODY OF IPC

Date of Meeting : 29th May, 2020
Mode of Meeting : Video Conferencing
Chairperson : Prof. N. K. Ganguly

The list of participants is appended (Enclosure-I)

Opening of the Meeting

Dr. Jai Prakash, Secretary-cum-Scientific Director (I/c), IPC welcomed the Chairperson and members of the Scientific Body for the 43rd meeting of the Scientific Body through video conferencing. He thanked all the members of the Scientific Body for critically reviewing the activities of IPC and their suggestions for further strengthening the same. He requested Prof. N. K. Ganguly to open the meeting and the same was accepted by the Chairperson.

Prof. N. K. Ganguly, Chairperson-Scientific Body appreciated the success of IPC in the field of setting standards of Indian Pharmacopoeia (IP), development of IPRS and impurities, publication of National Formulary of India (NFI), Pharmacovigilance Programme of India (PvPI), national and international co-operations, and certification/accreditation of IPC laboratory.

Thereafter, Prof. Ganguly took note of the key achievements of the IPC since the last meeting of the Scientific Body and appreciated that IPC has been doing constant progress in every field even during the tough time of COVID-19 pandemic.

Afterwards, the Member Secretary presented the agenda to the Scientific Body.

Item 1. Confirmation of the Minutes of the 42nd Meeting of the Scientific Body (SB) held on 22nd February, 2020

The minutes of the 42nd meeting of the Scientific Body had been circulated to the Scientific Body members through email vide IPC letter No. IPC/7041 dated 28.02.2020 and no comments were received; therefore, the minutes of the 42nd meeting of the Scientific Body were confirmed.

Item 2. Action Taken Report on the Minutes of the 42nd Meeting of SB held on 22nd February, 2020

Noted and approved by the Scientific Body.

Main Agenda

Item 3. Role of IPC in COVID-19 Pandemic

Scientific Body deliberated this important agenda and desired to constitute two separate Working Groups for addressing the issue of setting standards for Drugs as well as Devices including PPE, masks etc. These Groups are to be chaired by Dr. A. K. Singh (DG-LS, DRDO) and Dr. Naresh Bhatnagar (Deptt. of Mechanical Engg., IIT-Delhi) respectively. Prof. Ramesh Kumar Goyal (Vice Chancellor, DPSRU), Dr. D. Srinivasa Reddy (Sr. Principal Scientist, NCL-Pune), Dr. Arun K. Mishra (M/s Unilever), and Dr. Shobha

Baroor (Ex-HOD, Microbiology, AIIMS-Delhi) were suggested as members of these Groups and other members may be opted by the Chairs. Two representatives from IPC (one each in respective committees) should also be included.

Item 4. Replacement of Scientific Body Members

Scientific Body opined that before making any decision on the replacement of the members of the Scientific Body, the reasons for continuing absence from meetings of the Scientific Body may be sought from such members.

Item 5. Progress Report of Indian Pharmacopoeia (IP) and AR&D Division

I. Monographs Drafted for IP Addendum 2021

Scientific Body appreciated the work of monograph development for IP Addendum 2021 and approved for its publication after incorporating valid comments received from the stakeholders.

II. Stakeholders' Representations for Extension of Publication of IP Addendum 2021

Scientific Body took note of five representations from the stakeholders wherein they have stated that due to the nationwide lockdown monograph verification at sites is currently not possible and sourcing/ testing of the drug substances and drug products is delayed owing to difficulty in procuring key consumables, reference standards, impurities and requested for extension of publication of IP Addendum 2021 (up to 6 months) so that they can review all impacted materials/products and confirm the compliance to provide comments. Considering the inability of the stakeholders' to verify the draft monographs of the IP Addendum 2021 due to current COVID-19 pandemic, Scientific Body accepted the proposal for extension by six months.

III. Amendment List 05 to IP 2018

Scientific Body reviewed the content of the Amendment List 05 and approved its release for the stakeholders.

IV. Meetings of Expert Working Groups

Scientific Body appreciated that IPC organized meetings of the Expert Working Groups even during the COVID-19 pandemic and noted the progress made.

V. Meetings with Stakeholders

Noted by the Scientific Body.

Item 6. Progress Report of Microbiology Division

Scientific Body noted and appreciated the work done by Microbiology Division in the areas of drug analysis, work related to IP, and skill development. Scientific Body also desired to take opinion of a virologist expert to support the development of standards for COVID-19 related drugs.

Item 7. Progress Report of Phytopharmaceutical Division

Scientific Body noted and appreciated the work done by Phytopharmaceutical Division in the areas of setting standards, development of DNA fingerprinting methods, undertaking revision of Guidance Manual, and organizing virtual meetings. It was also suggested to consult Dr. Debabrata Kanungo on the matters of pesticides, Dr. Ram Vishwakarma on COVID-19 related therapies, and Sh. A. K. Pradhan on the standards of

phytopharmaceuticals. Scientific Body also suggested to have an ethanobotanist to help IPC in setting standards of herbs and phytopharmaceuticals..

Item 8. Progress Report of Biologics Section

Work done by Biologics Section was also noted and appreciated by the Scientific Body. The proposal for deletion of test for Abnormal Toxicity was also discussed and Scientific Body approved the proposal. Scientific Body also suggested to have opinion of Dr. Sunil Gairola on the proposed amendments in Japanese Encephalitis Vaccine Inactivated Adsorbed and Haemophilus Type b Conjugate Vaccine with justification before taking final decision.

Item 9. Progress Report of Reference Standard Division

The work for the development of IP Reference Substances (IPRS) and Impurity Standards, analysis of New Drug Substances, and revenue generated by the Reference Standard Division was reviewed and appreciated by the Scientific Body.

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

Scientific Body noted the work progress of the QA Division in the area of maintaining certification and accreditation, training programmes, and review of reports and quality documents. Scientific Body noted the new proposal on NQAAS, and PT programmes.

Item 11. Progress Report of National Formulary of India (NFI)

The work of NFI was presented and Scientific Body noted and appreciated the progress.

Item 12. Progress Report of Pharmacovigilance Programme of India (PvPI)

The activities of PvPI were presented and Scientific Body Members appreciated the progress of the PvPI. It was suggested that a letter in this regard to be sent to the Chairperson-Governing Body to convey the achievement of PvPI on the quality and quantity of ADR reports. A separate letter should also be sent to Marketing Authorization Holders on quality of reports. Scientific Body also suggested including Artificial Intelligence in ADRMS software for PvPI data mining.

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

The progress made under MvPI w.r.t. reporting of suspected adverse events associated with medical devices was noted. It was further suggested that in order to arrive at meaningful conclusions reporters are required to provide follow up information and root cause analysis for such reports. The necessary action should be taken by MvPI in future.

Item 14. Progress Report of Publication Division

All developments including laying down of Annual Report of IPC for the financial year 2018-19 in both the Houses of Parliament were noted by the Scientific Body.

Item 15. Any Other Agenda Item with Permission

There was no other agenda.

Meeting ended with thanks to the Chairman and Members of the Scientific Body of IPC by the Member Secretary.

List of Scientific Body Members Participated through Video Conferencing

1. Prof. N. K. Ganguly, Former DG-ICMR and Chairperson, Scientific Body-IPC
2. Dr. A. K. Singh, Director General (LS), DRDO-Delhi
3. Prof. Sanjay Singh, Vice Chancellor, BBAU-Lucknow
4. Prof. Ramesh Kr. Goyal, Vice Chancellor, DPSRU-Delhi
5. Dr. Raman M. Singh, Director, CDTL-Mumbai
6. Mr. A. K. Pradhan, DDC(I), CDSCO-Delhi
7. Dr. Naresh Bhatnagar, Professor, IIT-Delhi
8. Dr. D. Srinivasa Reddy, Sr. Principal Scientist, NCL-Pune
9. Dr. Sunil Gairola, Director-QC, Serum Institute-Pune
10. Dr. Arun K. Mishra, Head-Global Regulatory Affairs, Unilever-Gurugram
11. Dr. Hemant K. Sharma, Senior Vice President, Aurobindo Pharma-Hyderabad
12. Dr. Nitin Bhatia, Assistant Vice President, Intas Pharma-Ahmedabad
13. Dr. Jai Prakash, Secretary-cum-Scientific Director (I/c)-IPC and Member Secretary

Leave of Absence

1. Dr. Ram A. Vishwakarma, Director, IIIM-Jammu
2. Dr. Amulya K. Panda, Director, NII-Delhi
3. Prof. Naveet Wig, Head-Deptt. of Medicine, AIIMS-Delhi
4. Dr. Nithya Gogtay, Deptt. of Clinical Pharmacology, KEM-Mumbai
5. Dr. Rakesh N. Tirpude, Assistant Commissioner, FDA-Maharashtra
6. Mr. Salim Veljee, Former Commissioner, FDA-Goa
7. Prof. Vinod Kumar Dixit, Former Dean, Dr. Hari Singh Gaur Univ., Sagar
8. Dr. Praveen Khullar, Head-Global Development Centre, Sanofi-Goa
9. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram
10. Dr. V. Satyanarayana, Managing Director, Sipra Labs-Hyderabad

IPC Staff who assisted the meeting

1. Dr. V. Kalaiselvan, P.S.O.
2. Dr. Anil K. Teotia, P.S.O.
3. Dr. Robin Kumar, P.S.O.
4. Dr. Anuj Prakash, S.S.O.
5. Dr. Meenakshi Dahiya, S.S.O.
6. Dr. M. Kalaivani, S.S.O.
7. Dr. Gaurav Pratap Singh, S.S.O.
8. Dr. Shashi Bhushan, S.S.O.
9. Dr. Manoj K. Pandey, S.O.
10. Dr. Pawan K. Saini, S.O.
11. Dr. K. K. Singh, L.I.O.