

INDIAN PHARMACOPOEIA COMMISSION
(Ministry of Health & Family Welfare, Govt. of India)
Sector-23, Raj Nagar, Ghaziabad-201002

MINUTES OF 44th MEETING OF THE SCIENTIFIC BODY OF IPC

Date of Meeting : 28th July, 2020
Mode of Meeting : Video Conferencing
Chairperson : Prof. N. K. Ganguly

The list of participants is appended (Enclosure-I)

Welcome and 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 44th meeting of the Scientific Body through video conferencing. He thanked all the members of the Scientific Body for their suggestions for continual strengthening of IPC activities in the field of pharmaceutical analysis and vigilance. Dr. Jai Prakash requested the Chairperson of Scientific Body to open the meeting.

Prof. N. K. Ganguly, Chairperson-Scientific Body took note of the key achievements of the IPC since the last meeting of the Scientific Body and appreciated the efforts of IPC towards setting standards of COVID-19 related drugs and devices.

Thereafter, the Member Secretary presented the agenda to the Scientific Body in following sequence and decisions of the Scientific Body are recorded.

Item 1. Confirmation of the Minutes of the 43rd Meeting of the Scientific Body (SB) held on 29th May, 2020

The minutes of the 43rd meeting of the Scientific Body had been circulated to the Scientific Body members through email vide IPC letter No. IPC/7041 dated 05.06.2020 and no comments were received; therefore, the minutes of the 43rd meeting of the Scientific Body were confirmed.

Item 2. Action Taken Report on the Minutes of the 43rd Meeting of SB held on 29th May, 2020

Noted and approved by the Scientific Body.

MAIN AGENDA

Item 3. Progress Report of AR&D Division

I. New Monographs of COVID-19 Related Drugs

Scientific Body appreciated the drafting of new monographs of COVID-19 related drugs and suggested to invite comments of the stakeholders before finalizing the same for their inclusion in IP Addendum 2021.

II. Amendment List-07 to IP 2018

Scientific Body reviewed the content of the Amendment List-07 and no comments were received from the members. Scientific Body approved Amendment List-07 for its release to the stakeholders.

III & IV. Meetings of Expert Working Groups & Stakeholders Meetings
Noted by the Scientific Body.

Item 4. 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 meetings of the Expert Working Groups.

Item 5. Progress Report of Phytopharmaceutical Division

Work done by the Phytopharmaceutical Division in the areas of monograph development, retesting of BRS, and webinars on herbal monographs was noted and appreciated by the Scientific Body.

Also, development of new monographs for COVID-19 related herbal/phytopharmaceuticals products was discussed and it was suggested by the Scientific Body to take comments from the stakeholders before finalizing such monographs for their inclusion in the IP.

Scientific Body also noted the work done for General Monograph development, meetings of the stakeholders, and MoU with similarly placed organizations. It was suggested to include short note on Phytopharmaceutical Ingredient category in the General Monograph.

Item 6. Progress Report of Biologics Section

Scientific Body also noted and appreciated the work done by Biologics Section for making amendments in the relevant monographs and organizing Expert Working Groups meetings.

Item 7. Progress Report of Reference Standard Division

Scientific Body took note of the work done for the development of IP Reference Substances & Impurity Standards particularly for COVID-19 related drugs and the same was well appreciated. Work done for the analysis of New Drug Substances was also reviewed and noted.

Item 8. 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.

Item 9. Progress Report of National Formulary of India (NFI)

The work of NFI was presented and Scientific Body noted and appreciated the progress made by the Expert Committees in finalizing the content for the next edition of NFI. The guidance and contribution of Prof. Y.K. Gupta for NFI has been commendable.

Item 10. Progress Report of Pharmacovigilance Programme of India (PvPI)

The activities of PvPI w.r.t. the ADRs associated with the use of Hydroxychloroquine and its use in ICMR's revised advisory on COVID-19 were presented to the Scientific Body and the members well appreciated the efforts of the PvPI and the progress made.

Item 11. Progress Report of Materiovigilance Programme of India (MvPI)

Scientific Body took note of the meeting of the Working Group-Devices and the progress made under MvPI w.r.t. reporting of suspected adverse events associated with PPEs and other medical devices.

Item 12. Progress Report of Publication Division
Noted by the Scientific Body.

Item 13. Any Other Agenda Item with Permission
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 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. Ram A. Vishwakarma, Director, IIIM-Jammu
6. Dr. Raman M. Singh, Director, CDTL-Mumbai
7. Dr. Naresh Bhatnagar, Professor, IIT-Delhi
8. Dr. D. Srinivasa Reddy, Sr. Principal Scientist, NCL-Pune
9. Mr. Salim Veljee, Former Commissioner, FDA-Goa
10. Dr. Sunil Gairola, Director-QC, Serum Institute-Pune
11. Dr. Arun K. Mishra, Head-Global Regulatory Affairs, Unilever-Gurugram
12. Dr. Praveen Khullar, Head-Global Development Centre, Sanofi-Goa
13. Dr. Hemant K. Sharma, Senior Vice President, Aurobindo Pharma-Hyderabad
14. Dr. Nitin Bhatia, Assistant Vice President, Intas Pharma-Ahmedabad
15. Dr. Jai Prakash, Secretary-cum-Scientific Director (I/c)-IPC and Member Secretary

Leave of Absence

1. Dr. Amulya K. Panda, Director, NII-Delhi
2. Prof. Naveet Wig, Head-Deptt. of Medicine, AIIMS-Delhi
3. Dr. Nithya Gogtay, Deptt. of Clinical Pharmacology, KEM-Mumbai
4. Mr. A. K. Pradhan, DDC(I), CDSCO-Delhi
5. Dr. Rakesh N. Tirpude, Assistant Commissioner, FDA-Maharashtra
6. Prof. Vinod Kumar Dixit, Former Dean, Dr. Hari Singh Gaur Univ., Sagar
7. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram
8. Dr. V. Satyanarayana, Managing Director, Sipra Labs-Hyderabad

Special Invitees

1. Prof. Y.K. Gupta, Former HOD, Deptt. of Pharmacology, AIIMS-New Delhi and Principal Advisor (Projects), THSTI-Faridabad
2. Sh. J.L. Sipahimalani, Member, Expert Working Group-IP Review