INDIAN PHARMACOPOEIA COMMISSION

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

MINUTES OF 45th MEETING OF THE SCIENTIFIC BODY OF IPC

Date of Meeting : 27th October 2020
Mode of Meeting : Video Conferencing
Chairperson : Prof. N. K. Ganguly

The list of participants is appended as 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 45th meeting of the Scientific Body through video conferencing. He thanked all the members of the Scientific Body for their suggestions and guidance for continual strengthening of IPC activities. 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 drug standards in Indian Pharmacopoeia (IP), development of IP Reference Substances, National Formulary of India (NFI), Pharmacovigilance Programme of India (PvPI), Materiovigilance Programme of India (MvPI), and training activities.

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

Item 1. Confirmation of the Minutes of the 44th Meeting of the Scientific Body held on 28th July 2020

The minutes of the 44th meeting of the Scientific Body had been circulated to the Scientific Body members through email vide IPC letter No. IPC/7041 dated 29.07.2020 and no comments were received; therefore, the minutes of the 44th meeting of the Scientific Body were confirmed.

Item 2. Action Taken Report on the Minutes of the 44th Meeting of Scientific Body held on 28th July 2020

Noted and approved by the Scientific Body.

MAIN AGENDA

Item 3. Progress Report of AR&D Division

I. Manuscript of Addendum 2021 to IP 2018

Scientific Body appreciated the drafting of new drug monographs for inclusion in the IP Addendum 2021. Content of the IP Addendum 2021 was presented before the Scientific Body and the same was approved for its printing and publication.

II. Proposed Amendments for Inclusion in Addendum 2021

Scientific Body reviewed the content of the proposed amendments for their inclusion in the IP Addendum 2021 and approved the same. It was desired that the impurity status in the Diltiazem API and formulation monographs may be rechecked before publication in IP Addendum 2021.

III. Extension in the Implementation of Amendment in Ticagrelor Monograph

It was appraised to the Scientific Body that normally extension for implementation of specific amendment is not given; however, considering the current challenging time due to COVID-19, Scientific Body approved one time extension of six months in the implementation of amendment in Ticagrelor monograph issued in Amendment List-07.

IV. Effective Date of Amendment List

Scientific Body approved the proposal of extended implementation period of maximum six months for those amendments which require sufficient time for method validation, process/formulation development, and sourcing of Reference Standard/Impurities.

V, VI, VII. Meetings and Webinars

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, ILC testing, work related to IP, meetings of the Expert Working Groups, and webinars.

Item 5. Progress Report of Phytopharmaceutical Division

Scientific Body reviewed the draft General Notice for Phytopharmaceutical Ingredient category and suggested to revise the same in line with the current Drugs and Cosmetics Rules and comments from the CDSCO should also be invited before its approval.

The work done for DNA barcodes was also noted and it was desired that the same should also be reviewed by the members of Scientific Body before approval.

Work done by the Phytopharmaceutical Division in the areas of retesting of IP Reference Standards (IPRS), trainings, and webinars was noted and appreciated by the Scientific Body.

Item 6. Progress Report of Biologics Section

Scientific Body took note of the appreciation letter received from Smt. Maneka Sanjay Gandhi, MP-Lok Sabha regarding deletion of abnormal toxicity test from monographs of Vaccines and Immunosera for Human Use in Amenddment List-06 to IP 2018.

It was opined by the Scientific Body that amendment in the Heparin sodium IP 2018 monograph may be accepted provided the same does not affect the safety of the end product.

Proposed amendment in the Infectious Bursal Disease Vaccine, Live was accepted by the Scientific Body.

Scientific Body also noted the work done by Biologics Section regarding successful closing of the query on Streptokinase, making amendments in the relevant monographs, and organizing Expert Working Groups meetings.

Item 7. Progress Report of Reference Standard Division

Scientific Body noted the work done for the development of IPRS, Impurity Standards, lot change, and retesting of IPRS. Work done for the analysis of New Drug Substances was also noted.

Request from M/s Kamal Udyog regarding authorization for sale and distribution of IPRS was also discussed. Scientific Body desired that in order to address the current challenges in this matter and to enhance the sale of IPRS in India and abroad, IPC shall create a

guideline for expression of interest and set up a process for empanelment of authorized distributors in consultation with Finance Division.

Scientific Body appreciated that the revenue generated from the sale of IPRS is commendable despite the challenging time due to COVID-19 and efforts should be made to enhance the same in days to come.

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)

Scientific Body noted the work of NFI and appreciated the progress made in this regard. It was also desired that the content for the next edition of NFI should be finalized at the earliest so that the same may be printed by January 2021.

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

The activities of PvPI were presented and Scientific Body Members appreciated the progress of the PvPI. Scientific Body suggested to validate the ADRMS software before its use and PvPI staff should also be trained to use this software.

Scientific Body appreciated the trainings imparted by PvPI in the field of pharmacovigilance and desired that PvPI should charge a reasonable fee for its training programmes and the same shall be brought to the notice of the Governing Body.

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

Scientific Body noted the progress of MvPI and directed that a letter should be written to the DCG(I) to have the opinion of CDSCO on the matter of setting standards for the medical devices. Other standards (such as BIS) may also be referred so that the duplicacy of the work can be avoided.

Item 12. Progress Report of Publication Division

Noted by the Scientific Body. Scientific Body directed to put up the revenue generation to the Governing Body.

Item 13. Any Other Agenda Item with Permission

I. Monographs of COVID-19 Related Drugs

Scientific Body desired that the monographs of the COVID-19 related drugs (i.e. Favipiravir, Remdesivir) may be included in the IP Addendum 2021 after confirming their approval status in India from the CDSCO as none of these drugs have been unequivocally established to be the standard treatment for Covid-19. The draft monographs should be kept ready.

II. Proposed Revision in Monograph Inclusion/Exclusion Criteria of IP

Scientific Body took note of the revised criteria for inclusion/exclusion of the monographs in the IP and desired that the same may be adopted after consulting the CDSCO regarding the approval status of the drugs in India.

Existing Inclusion Criteria	Proposed Revised Inclusion Criteria
▸ Drugs approved by CDSCO ▸ Drugs used in NHPs of India ▸ Drugs listed in the NLEM	▸ Drugs approved by CDSCO through normal regulatory process ▸ Drugs approved by CDSCO for emergency use, such as

▸ FDCs approved by CDSCO and recommended by the IPC Experts ▸ Drugs considered appropriate by IPC	in Covid-19 pandemic, Swine flu etc. ▸ Drug permitted by CDSCO as off label use/research purpose in extraordinary situations ▸ Drugs listed in NLEM ▸ Drugs listed in National Health Programs ▸ FDCs approved by CDSCO and recommended by the IPC Experts ▸ Any drug in public interest recommended by Expert Working Group and approved by the Scientific Body of IPC
Existing Exclusion Criteria	Proposed Revised Exclusion Criteria
▸ Drugs banned in India ▸ Obsolete drugs ▸ Drugs considered inappropriate by IPC	▸ Drugs banned in India ▸ Drugs/Formulation showing adverse benefit-risk profile ▸ Drugs which have not been banned but rarely used or have lost relevance ▸ Drugs considered inappropriate by IPC

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 through Video Conferencing

1. Prof. N. K. Ganguly, Former DG-ICMR and Chairperson, Scientific Body-IPC (attended physically)
2. Prof. Sanjay Singh, Vice Chancellor, BBAU-Lucknow
3. Dr. Amulya K. Panda, Director, NII-Delhi
4. Prof. Ramesh Kr. Goyal, Vice Chancellor, DPSRU-Delhi
5. Dr. D. Srinivasa Reddy, Director, IIIM-Jammu
6. Dr. Ram A. Vishwakarma, Former Director, IIIM-Jammu
7. Mr. A. K. Pradhan, DDC(I), CDSCO-Delhi
8. Dr. Raman M. Singh, Director, CDTL-Mumbai
9. Mr. Salim Veljee, Former Commissioner, FDA-Goa
10. Prof. Vinod Kumar Dixit, Former Dean, Dr. Hari Singh Gaur Univ., Sagar
11. Dr. Sunil Gairola, Director-QC, Serum Institute-Pune
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. A. K. Singh, Director General (LS), DRDO-Delhi
2. Dr. Naresh Bhatnagar, Professor, IIT-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. Dr. Arun K. Mishra, Head-Global Regulatory Affairs, Unilever-Gurugram
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 (attended physically)
2. Dr. Rishendra Verma, Member, Expert Working Group-Veterinary Products