INDIAN PHARMACOPOEIA COMMISSION

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

MINUTES OF 46th MEETING OF THE SCIENTIFIC BODY OF IPC

Date of Meeting : 6th March 2021
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. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC welcomed the Chairperson and members of the Scientific Body for the 46th meeting of the Scientific Body through video conferencing and requested the Chairperson of Scientific Body to open the meeting.

Prof. N. K. Ganguly, Chairperson-Scientific Body congratulated Dr. Rajeev Singh Raghuvanshi for his new role and conveyed that Scientific Body would keep on guiding IPC for 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.

Prof. Ganguly also took note of the key achievements of the IPC since the last meeting of the Scientific Body and appreciated IPC's role during COVID-19 pandemic including submission of ADR data of Hydroxychloroquine on weekly basis to ICMR. It was suggested that IPC has important role to play in ensuring the quality of medicines and patient safety across the country and therefore IPC should plan to fulfill the future needs of the country particularly w.r.t. establishment of Reference Standard library, conducting skill development (short-term and long-term), modernization of analytical capabilities, and extension of IPC activities in foreign countries. In addition, IPC needs to take appropriate measures to develop human resources and permanent staff should be engaged in the core activities of PvPI thereby stopping multitasking.

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 45th Meeting of the Scientific Body held on 27th October 2020
Confirmed.

Item 2. Action Taken Report on the Minutes of the 45th Meeting of Scientific Body held on 27th October 2020
Noted by the Scientific Body.

MAIN AGENDA

Item 3. Progress Report of AR&D Division
Noted.

Scientific Body took note of the voluntarily withdrawal of Lorcaserin by the manufacturer from USA and Indian market based on the safety clinical trial and possible risk of cancer associated with Lorcaserin and approved for omission of monographs of 'Lorcaserin Hydrochloride Hemihydrate' and 'Lorcaserin tablets' from the Indian Pharmacopoeia (IP).

In the matter of 'Valproic Acid Capsules' Scientific body noted that the product is neither banned in India nor there are no safety concerns associated with it; and therefore, there is no need to omit such monographs from the IP.

Subsequently, to safe guard the public health, manufacturer has also voluntarily withdrawn the distributed product from the Indian market.Scientific Body suggested that to set standards under the category of 'Vitamins, Minerals, Amino Acids, Fatty Acids etc.' appropriate consultations be done with subject experts as these standards may overlap with the Nutraceuticals category of the FSSAI.

Issue of standards of Medical Devices also came for discussion to which Scientific Body opined that duplication of the work by different organizations in the country (like BIS) may be avoided and CDSCO, being the enforcement organization, shall be consulted in this matter.

Also, there is need to speed up in this area to make available standard quality Medical Devices in the country and to avoid import of possible sub-standard quality products. Medical Devices containing drugs as major component may be prioritized for this activity.

Item 4. Progress Report of Microbiology Division

Noted.

Item 5. Progress Report of Phytopharmaceutical Division

Noted.

Scientific Body approved the General Notice on Phytopharmaceutical Drugs. It was also opined that duplicacy of the work with AYUSH should be avoided.

The draft MoU between IPC and CSIR-CMAP was also discussed and it was suggested that IPC may consider the scope of the activities under the MoU which are feasible.

Item 6. Progress Report of Biologics Section

Noted and approved.

Scientific Body suggested that IPC should collaborate with NIB and NII in the field of Biologics standards. Also, product variations due to host cells shall be considered while setting these standards.

Item 7. Progress Report of Reference Standard Division

Noted.

Scientific Body directed that the prices of the Reference Standards and Impurities available for sale from IPC should be decided in consultation with the subject experts.

Also, the laboratory activities may be audited by external experts to enhance the confidence of the users of the Reference Standards. The list of Reference Standards and Impurities available at IPC may be circulated to all Pharma Associations to create more awareness.

Scientific Body also suggested increasing the revenue generation after induction of more Impurities in IPC's catalogue.

Item 8. Progress Report of Quality Assurance (QA) Division

Noted.

Scientific Body directed to increase the number of training programmes for students and stakeholders using virtual platforms. Also, IPC may start PhD programmes in affiliation with Universities (such as DIPSRU) after recognition of its laboratory facilities.

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

Noted.

Scientific Body advised for creating awareness among healthcare professionals for wider circulation and acceptance of NFI. Cost of NFI needs to be at par with International trend.

Item 10. Mutual Co-operation with National and International Organizations

Noted.

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

Noted.

Scientific Body directed increasing the number of AMCs across the country and IT tools should be employed for the purpose of managing PvPI activities across the country. Also, biostatistics tools shall be employed for analyzing the PvPI data.

Also, PvPI should continue with organizing trainings to the staff and stakeholders at regular intervals. It was also suggested to have a sensitization programme involving State Governments so that pharmacovigilance can become part of healthcare systems of the States.

It was also directed that, as PvPI has completed its 10 years at IPC, a detailed proposal for strengthening the PvPI as a core activity with permanent staff of IPC should be submitted to the MoH&FW.

Evaluation of PvPI activities by International agency (such as WHO) may be done after approval of the MoH&FW.

Item 12. Progress Report of Materiovigilance Programme of India (MvPI)

Noted.

Scientific Body suggested taking help from LV Prasad Eye Institute, Hyderabad for standards of ocular devices to which it was informed that IPC is already consulting with Dr. Santosh G. Honavar in this matter.

Item 13. Progress Report of Publication Division

Noted.

Item 14. Any Other Agenda Item with Permission

Scientific Body also suggested:

- Implementation of Flexible Complementary Scheme for IPC scientists,
- Digitizing IPC processes for seamless functions,
- Making business development plan for advertisement of IPC products across globe,
- Reconstitution of the Expert Working Groups for induction of new subject experts, and
- Development of IPC Vision 2030 to meet challenges in next decade

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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. Dr. A. K. Singh, Director General (LS), DRDO-Delhi (attended physically)
3. Prof. Sanjay Singh, Vice Chancellor, BBAU-Lucknow
4. Dr. Amulya K. Panda, Director, NII-Delhi (attended physically)
5. Prof. Ramesh Kr. Goyal, Vice Chancellor, DPSRU-Delhi (attended physically)
6. Dr. D. Srinivasa Reddy, Director, IIIM-Jammu
7. Dr. Naresh Bhatnagar, Professor, IIT-Delhi
8. Mr. A. K. Pradhan, DDC(I), CDSCO-Delhi
9. Dr. Raman M. Singh, Director, CDTL-Mumbai
10. Dr. Ram A. Vishwakarma, Former Director, IIIM-Jammu
11. Dr. Rakesh N. Tirpude, Assistant Commissioner, FDA-Maharashtra
12. Dr. Arun K. Mishra, Head-Global Regulatory Affairs, Unilever-Gurugram (attended physically)
13. Prof. Vinod Kumar Dixit, Former Dean, Dr. Hari Singh Gaur Univ., Sagar
14. Dr. Praveen Khullar, Head-Global Development Centre, Sanofi-Goa
15. Dr. Nitin Bhatia, Assistant Vice President, Intas Pharma-Ahmedabad
16. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director-IPC and Member Secretary

Leave of Absence

1. Prof. Naveet Wig, Head-Deptt. of Medicine, AIIMS-Delhi
2. Dr. Nithya Gogtay, Deptt. of Clinical Pharmacology, KEM-Mumbai
3. Mr. Salim Veljee, Former Commissioner, FDA-Goa
4. Dr. Sunil Gairola, Director-QC, Serum Institute-Pune
5. Dr. Hemant K. Sharma, Senior Vice President, Aurobindo Pharma-Hyderabad
6. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram
7. Dr. V. Satyanarayana, Managing Director, Sipra Labs-Hyderabad

Special Invitee

1. Dr. Anup Anvikar, Director, NIB-NOIDA