

FOR IPC USE ONLY

INDIAN PHARMACOPOEIA COMMISSION

Minutes of the Meeting	No. of Meeting	Day, Date & Time	Venue
Scientific Body of the IPC	41 st	Saturday, 20 th July, 2019	RS Iyer Hall, IPC-Ghaziabad

The list of participants is appended (Enclosure-I)

Opening of the Meeting:

Dr. G. N. Singh, Secretary-cum-Scientific Director-IPC, welcomed the members of the Scientific Body and special invitees for the 41st meeting of the Scientific Body. He thanked all the members of the Scientific Body for continuously reviewing the activities of IPC and their suggestions for further strengthening.

With the permission of the Chair, Dr. Singh gave a presentation on the major achievements of the IPC since its inception in 2005. He acknowledged that under the leadership and guidance of the Scientific Body IPC could reach to milestones in the field of drug standardization and pharmacovigilance. Dr. Singh briefed about the major success stories in publication of IP and monograph development, making available IPRS and impurities to the stakeholders, publication of NFI, pharmacovigilance, international co-operations, certification and accreditation of IPC facilities, and infrastructure development. Despite limited resources and manpower, IPC made big achievements under the leadership of Dr. G. N. Singh and the same were greatly appreciated and applauded by the Chairman and members of the Scientific Body. It was noted that IPC has made significant contributions in the areas of anti-retroviral, herbal, phytopharmaceutical and biologics standards as well as establishment of world class system of pharmacovigilance.

Prof. N. K. Ganguly, Chairman-Scientific Body, took note of the key achievements of the IPC since the last meeting of the Scientific Body and appreciated that IPC has been doing good progress in every field. Prof. Ganguly reiterated that in order to further strengthen its activities in the area of ensuring the quality of medicines and patient safety across the country, appropriate measures must be taken to develop human resources and infrastructure.

Afterwards, the Scientific Body took-up the main agenda.

Item No. 1:

Confirmation of the Minutes of 40th Meeting of the Scientific Body held on 27th March, 2019

The minutes had been circulated to the members. No comments had been received so the minutes are confirmed.

Item No. 2:**Action taken report on the minutes of last meeting**

Approved.

Main Agenda**Item No. 3: Progress Report of Indian Pharmacopoeia (IP)**

The Scientific Body appreciated the release of IP Addendum 2019 to IP 2018 by the Hon'ble Health Minister Dr. Harsh Vardhan on 5th July, 2019.

Also, the Scientific Body took a note of the progress for the development of monographs for the next IP Addendum 2020. The proposed list of drugs for monograph development was also discussed and the same was approved for its inclusion in next IP Addendum/Edition.

Scientific Body noted the progress of the technical meetings and the major outcomes of these meetings. Members appreciated that IPC has initiated IP Expert Working Groups meetings through video conferencing and recommended that video conferencing facility shall be strengthened so that more stakeholders can contribute in monograph development.

Item No. 4: Progress Report of Microbiology Division

The Scientific Body noted the activities of the Microbiology Division including the testing of New Drug Samples and IPRS, outcomes of technical meetings, and participation in ILC study.

Item No. 5: 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 and it was suggested to rationalize the testing fee for NDS samples so that the revenue generation may be further increased. Dr. G. N. Singh appraised that IPC has initiated the process for procurement of the Reference Standards and/or Impurity Standards from various leading manufacturers in order to suffice the need of the country and the Scientific Body recommended that these purchases are to be made on urgent basis as impurities are of utmost importance for ensuring quality of drugs in the country.

Item No. 6: Progress Report of Quality Assurance Division

Scientific Body appreciated the work of the Division in the area of maintaining certification and accreditation, organizing PT studies for international laboratories, and providing training to various stakeholders. It was suggested to rationalize the training fee in order to generate more revenue from this activity. It was suggested to expand the training to stakeholders from across India as well as other countries.

Item No. 7: Progress Report of National Formulary of India (NFI)

The work of NFI was presented and Scientific Body noted and appreciated the progress. It was briefed about the series of Subject Expert Committee's meetings and its outcomes. The list of 20 most commonly used medicines was also brought to the notice and it was decided that the list should be circulated to the members for review.

Item No. 8: Working Relationships with National and Other Institutes of Repute

Scientific Body noted the work of MoU between IP and CSIR-IICT and CSIR-CCMB for creating a facility for development of Reference Standards and Impurity Standards. It was suggested that IPC shall have similar MoU with DRDO and NII-New Delhi in the areas of mutual co-operation.

Item No. 9: Progress Report of Biologics Section

Scientific Body noted the progress of Biologics Section. The matter of deletion of test for abnormal toxicity was also discussed and it was recommended that a committee comprising of Dr. Amulya Panda, Mr. A. K. Pradhan and representatives from industry may further review the matter in two months time so that the animal toxicity test may be deleted from the individual vaccine monographs wherever possible.

The issue of snake venom antiserum also came for discussion to which it was suggested that NII-New Delhi should also be taken on board during the deliberations on this matter.

Item No. 10: Progress Report of Pharmacovigilance Programme of India (PvPI)

The activities of PvPI were presented and Scientific Body Members reiterated that PvPI has important role to play in the public health under the current regulations. It was desired that the activities of PvPI should be strengthened across country and the statistical analytical tools along with trained manpower should be utilized for churning out the huge data collected under the PvPI.

Item No. 11: Progress Report of Materiovigilance Programme of India (MvPI)

The progress made under MvPI was noted and it was suggested to gradually increase the Medical Device Adverse Events Monitoring Centres across the country.

As artificial intelligence is going to play an important role in medical products safety monitoring, both MvPI and PvPI will have to prepare tools and roadmap accordingly to meet the future challenges.

Item No. 12: Progress Report of Phytopharmaceutical Division

Progress of the Division was informed to the Scientific Body and the same was appreciated.

Item No. 13: Price of Addendum 2019 to IP 2018

Approved by the Scientific Body.

Item No. 14: Status of Sale and Distribution of IPC Publications

Details of sale and distribution of IP publications were noted.

Item No. 15: Other Agenda Items

With the permission of the Chair following agenda items were also discussed:

(i) Decision on Albendazole Dissolution by Hon'ble Delhi High Court

Dr. G. N. Singh briefed to the Scientific Body that vide its order dated 04.07.2019 Hon'ble Delhi High Court has dismissed the petitions in the matter of inclusion of dissolution test in albendazole tablets by IPC in the Amendment List-003 dated 02.01.2019. Scientific Body members appreciated the role of IPC in upgrading the

standard of albendazole tablets and suggested that, in order to avoid confusion in such cases that may arise in future, IPC shall again issue a notice to the concerned stakeholders on IPC's policy on the effective date of the IP Editions, IP Addenda and Amendment Lists issued from time to time. The same shall also be put on IPC website to give wider publicity among stakeholders.

(ii) Decision on DEGEE by Hon'ble Delhi High Court

Dr. Singh also briefed that vide its order dated 04.07.2019 Hon'ble Delhi High Court has dismissed the petitions in the matter of use of DEGEE in parenteral preparation. In view of above order Scientific Body suggested that IPC shall not include such requirements in the excipient monographs and have consonance with regulatory decisions taken by CDSCO.

(iii) Global Recognition of IP

Scientific Body took a note of the concept paper on global recognition of IP being considered by the Ministry of Health & Family Welfare and suggested to circulate the same to all members for their comments/inputs. Further, IPC should expedite its efforts towards the availability of online version of IP to the stakeholders as this would also help in global recognition of IP.

(iv) Neutraceuticals Standards

Scientific Body noted that there are grey areas between standards for food, drugs and plant products and the same are currently being looked after by different organizations. It is important to have harmonized standards so that the public health concerns can be better addressed by ensuring the availability of quality products in the market. Therefore, Scientific Body suggested that IPC, being standard setting organization, shall coordinate with FSSAI to work out a mechanism for setting harmonized standards for neutraceuticals.

(v) Revenue Generation

It was appreciated by the members of the Scientific Body that IPC is earning a good amount of revenue through its various services. It was recommended that IPC shall make efforts to increase the revenue generation in order to become a revenue independent Institute. In this regard IPC should make a proposal on utilization of the earned revenue for its own infrastructure development/upgradation, providing incentives to the scientific staff and strengthening the manpower. This proposal shall be submitted to the Government for its approval.

Meeting ended with thanks to the Chairman and Members of the Scientific Body.

List of Scientific Body Members Participated

1. Prof. N. K. Ganguly
2. Dr. A. K. Singh
3. Dr. Amulya K. Panda
4. Prof. Ramesh Kr. Goyal
5. Mr. A. K. Pradhan
6. Dr. R. M. Singh
7. Dr. Nithya Gogtay
8. Dr. Arun K. Mishra
9. Dr. V. Satyanarayana
10. Dr. Nitin Bhatia
11. Dr. G. N. Singh

Leave of absence was granted to

1. Prof. Sanjay Singh
2. Dr. Ram A. Vishwakarma
3. Dr. Naresh Bhatnagar
4. Dr. D. Srinivasa Reddy
5. Prof. Vinod Kumar Dixit
6. Prof. Naveet Wig
7. Dr. Rakesh N. Tirpude
8. Dr. Sunil Gairola
9. Dr. Praveen Khullar
10. Dr. Hemant K. Sharma
11. Mr. Salim Veljee
12. Dr. Anil Kumar Tyagi

Special Invitees

1. Dr. Reba Chhabra
2. Mr. Vinod Arora
3. Dr. B. K. Sharma

IPC Staff who attended the meeting

1. Dr. Jai Prakash
2. Dr. V. Kalaiselvan
3. Dr. Anil K. Teotia
4. Dr. Robin Kumar
5. Dr. Meenakshi Dahiya
6. Mr. Alok Sharma
7. Dr. Gaurav Pratap Singh
8. Dr. Shashi Bhushan
9. Dr. Manoj K. Pandey
10. Dr. Pawan K. Saini
11. Dr. K. K. Singh
12. Mr. Abhinav Paliwal