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INDIAN PHARMACOPOEIA COMMISSION

Minutes of the Meeting	No. of Meeting	Day, Date & Time	Venue
Scientific Body of the IPC	40 th	Wednesday, 27 th March, 2019	India International Centre, New Delhi

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 40th meeting of the Scientific Body. He thanked all the Members of the Scientific Body for critically reviewing the activities of IPC and their suggestions for strengthening the IPC.

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 members appreciated that IPC has been doing good progress in the field of pharmaceutical analysis and vigilance. Members noted and lauded that IPC has successfully organized the 5th Asia Pacific Pharmacovigilance Training Course. 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 including the timely promotion of eligible staff and filling up of vacant posts. Members noted and appreciated the publications provided to them (i) Annual Report of IPC; (ii) Guidance Document on Materiovigilance Programme; (iii) IPC Newsletter; and (iv) Report on 5th Asia Pacific Pharmacovigilance Training Course.

Scientific Body members also took note of the progress of the construction of 'Advance Level Research Centre' and Dr. G. N. Singh informed that after due deliberations the technical specifications of equipments have been submitted to HLL for their tender. It was suggested by Scientific Body to consider the training component in the tender document itself. Members desired that the existing IPC infrastructure shall be continued for conventional analytical works and training while the newly developed infrastructure shall be used for the pharmacopoeial work including validation/verification of monographs, development of Reference Standards and other advance research activities under taken by the Commission.

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

Item No. 1:

Confirmation of the Minutes of 39th Meeting of the Scientific Body held on 22nd December, 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 noted the work carried out by the Analytical Research and Development Division for the development of Indian Pharmacopoeia. The contents of the proposed Amendment List 004 were apprised to the Scientific Body members and it was informed that the contents have been compiled by the IP Technical Secretariat based on the queries and/or suggestions of the stakeholders and thoroughly reviewed by the IP Review Group members. Scientific Body accorded the approved the same as Amendment List as 4 instead of 004. Prof. Y. K. Gupta suggested to categorize the IP amendments as minor/major and procedure for dealing with such amendments be keep in place.

It was also informed the Scientific Body that the contents of Amendment Lists 001, 002, 003, 004 and Errata 001 have been incorporated in the IP Addendum 2019 and the same has been submitted for printing.

Scientific Body noted the technical meetings and the major outcomes of these meetings. Members suggested that meetings for different IP Expert Working Groups should be regularly organized by IPC to that Dr. Nitin Bhatia suggested to convene the meeting of Veterinary Expert Group aslo.

Details on Interactive Meet were presented before the Scientific Body to that Prof. Y. K. Gupta suggested to summarize the objectives and the outcomes of such events in in line with IPC mandate.

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, Reference Substances and trainings/seminars organized. Members appreciated the signing of MoU between IPC and IMTECH, Chandigarh for the supply of the microbial cultures to stakeholders. Members also desired that IPC shall adhere to the clauses of the MoUs signed with other institutes and keep on working in the agreed areas of mutual interest.

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 members. It was also appraised by Dr. G. N. Singh that IPC has initiated the process for empanelment of the manufacturers for supply of Reference Standards and/or Impurity Standards to IPC. Members suggested that the IPC activities must be presented in quantitative terms in comparison with the past period so that Scientific Body can better assess the progress made by different Divisions of IPC. Dr. G. N. Singh suggested that a committee comprising of Pro. Y. K. Gupta, Dr. Raman M. Singh and Dr. Jai Prakash (co-ordinator) be constituted to review the progress of Reference Standard Division and to give their inputs for further strengthening the IPC activities in this area.

Item No. 6: Progress Report of Quality Assurance Division

Scientific Body members appreciated the fact that IPC is the only WHO Pre-qualified Laboratory in public sector in India. The audit of the IPC facilities by the WHO auditors and the non-conformances observed were also presented. Members suggested to categorize the nonconformities as minor/major for their resolution. Dr. Meenakshi also informed that Quality Assurance Division has been engaged in various activities including maintaining various accreditations for different IPC activities, providing trainings to students, reviewing of reports, revising SOPs and planning the Proficiency Testing (PT) studies.

Scientific Body suggested that a total of 04 PT rounds (03 chemical and 01 biological) should be organized in one year and state/central drug testing labs, CDSCO approved labs and international labs should also be invited for participation in these PT rounds. Also, PT round may be planned for anti-TB, anti-malarial drugs. It was also suggested that instead of awareness programmes, trainings/seminars on the themes of IPC functions may organized for stakeholders. Also, IPC shall make a policy for selection of students for carrying their training/project studies in the area of pharmaceutical analysis and vigilance.

The Members were of the opinion that since IPC is a WHO-Prequalified laboratory (PQL), a letter from IPC to be sent to WHO regarding Proficiency and other testing facilities as well as services available at IPC for disseminating this information to its member states.

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

The work of NFI was presented and Scientific Body reiterated that IPC should make efforts for promoting the visibility of NFI among its key stakeholders.

Item No. 8:

1. Working Relationships with National and Other Institutes

Dr. G.N. Singh informed that IPC has moved forward for signing the MoUs with CSIR-IICT and CSIR-CCMB for creating a facility for development of Reference Standards and Impurity Standards. Scientific Body appreciated the efforts of IPC. The Members further suggested to establish strong functional relationship with other national laboratories/ institutions working in the area of Commission's interest.

2. Proposal for "Centre for Pharmaceutical and Biotherapeutics Impurities: Development of Reference Standards" between IPC, CSIR-CCMB and CSIR-IICT

The proposal was discussed threadbare by the Members of SB and in view of the utmost importance it has for the present and future, the SB approved the proposal unanimously for implementation.

Item No. 9: Progress Report of Biologics Section

Scientific Body noted the activities of Biologics Section. Dr. Sunil Gairola informed the members that European Pharmacopoeia has already deleted the test of abnormal toxicity and he will share further details with IPC. Mr. Amresh Tumbagi opined that the provision of abnormal toxicity is required in IP for the enforcement of standard by regulatory authorities and Govt. labs.

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 a proper system be developed to regulate monetary performance and progress of AMCs be put in place so that nonperforming centres can be delisted which in turn will improve the completeness score for ICSRs.

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

The progress and Adverse Events reporting under MvPI was noted, so far the reported adverse events were voluntary in nature. However, it is important from public health point of view specially when large number of medical devices are becoming part of regulation from safety, performance and quality parameters adherence.

Item No. 12: Progress Report of Phytopharmaceutical Division

It was informed to the Scientific Body that subsequent to the phytopharmaceuticals regulation/amendment in Drugs & Cosmetics Rules 1945, IPC has established/establishing a linkage with similarly place organizations. Members suggested the progress of such collaborations required to be monitored continuously. Also in order to discuss the road map, a meeting is proposed to be organized in Lucknow and CSIR labs such as CDRI, NBRI, CMAP, IIM and other institutes may be invited for the said meeting and Prof. Sanjay Singh agreed to host this meeting.

Item No. 13: Status of Sale and Distribution of IP Publications

Details of sale and distribution of IP publications were noted.

Item No. 14: Compliance of IP Status of Sale and Distribution of IP Publications

Details of sale and distribution of IP publications were noted.

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. Prof. Sanjay Singh
3. Mr. A. K. Pradhan
4. Dr. R. M. Singh
5. Dr. D. Srinivasa Reddy
6. Dr.Naresh Bhatnagar
7. Prof. Naveet Wig
8. Dr. Rakesh N. Tirpude
9. Dr.Nithya Gogtay
10. Dr. Sunil Gairola
11. Dr. V. Satyanarayana
12. Dr. Nitin Bhatia
13. Dr. G. N. Singh

Leave of absence was granted to

1. Dr. A. K. Singh
2. Dr. Amulya K. Panda
3. Dr. Ram A. Vishwakarma
4. Prof. Ramesh Kr. Goyal
5. Prof. Vinod Kumar Dixit
6. Dr. Praveen Khullar
7. Dr.Arun K. Mishra
8. Dr.Hemant K. Sharma
9. Mr. SalimVeljee
10. Dr. Anil Kumar Tyagi

Special Invitees

1. Prof. Y. K. Gupta
2. Sh. Amaresh Tumbagi
3. Dr. B. K. Sharma
4. Dr. V. Vijaykumar

IPC Staff who attended the meeting

1. Dr. Jai Prakash
2. Dr. V. Kalaiselvan
3. Dr.Robin Kumar
4. Dr.Meenakshi Dahiya
5. Dr.GauravPratap Singh
6. Dr. K. K. Singh
7. Mr.Chandan Kumar
8. Mr. Abhinav Paliwal