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INDIAN PHARMACOPOEIA COMMISSION

| Minutes of the Meeting | No. of Meeting | Day, Date & Time | Venue |
|-------------------------------|-----------------------|-------------------------------------|------------------------------|
| Scientific Body of the IPC | 39 th | Saturday, 22 nd Dec 2018 | 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 Chairman and all the Members of the Scientific Body and special invitees to the 39th meeting of the Scientific Body. He thanked all the Members of the Scientific Body for continuously reviewing the scientific activities of IPC and providing their support and guidance for continual improvement.

Prof. N. K. Ganguly, Chairman-Scientific Body appreciated that IPC is playing an important role in the healthcare sector of the country and it should plan its activities keeping in mind the future challenges. Prof. Ganguly expressed that IPC should further strengthen its activities in the area of ensuring the quality of medicines and patient safety across the country because these activities have immense impact on the public health. IPC should strengthen the analytical capabilities and a Committee of Dr. Panda and Dr. Khullar will review the specifications of new equipments for their purchase. He appreciated that during its short journey IPC has emerged as an important Institute in the country and its achievements with limited manpower and resources are commendable. IPC should make efforts to develop standards for immunotherapeutics through collaborations with national laboratories. Also IPC should relook to study in the grey areas for monograph development including cosmetics (baby products) vs food vs medicines.

Secretary-cum-Scientific Director, IPC requested Chairman, Scientific Body to take-up the main agenda one by one.

Item No. 1:

Confirmation of the Minutes of 38th Meeting of the Scientific Body held on 15th Sept 2018

The minutes had been circulated to the members. No comments had been received so the minutes are confirmed with the permission of Chair.

Item No. 2:

Action taken report on the minutes of last meeting

Approved.

Main Agenda

Item No. 3: Scientific Body Members Agenda

Discussion agenda on the dissolution of immediate release tablets received from Dr. Hemant Kumar Sharma was discussed in the meeting and Dr. G.N. Singh suggested that the proposal may further be deliberated in IP Review Group meetings and Dr. Sharma and Prof. R.K. Goyal may also be invited in the meeting for discussions.

Item No. 4: Progress Report of Indian Pharmacopoeia (IP)

(I) Release of Amendment List 003 and Errata List 002 to IP 2018

Amendment List 003 and Errata List 002 to IP 2018 came for discussion and it was apprised to the Scientific Body members that these amendments and errata are compiled by the IP Technical Secretariat and thoroughly reviewed in the IP Review Group meetings. Scientific Body discussed the Amendment List 003 and Errata List 002 to IP 2018 and noted that the same are required for continuous up-gradation of IP standards. Scientific Body desired to merge the Errata List with Amendment List and based on the recommendations of the IP Review Group the list was approved for its release as Amendment List with the exceptions of: revisiting the limits in Folic acid and deleting the disintegration test from Ferrous fumarate monograph as these products are important for national programs. Scientific Body also desired that IPC shall engage proof reader on contractual basis for editing the contents of IP to minimize the errors. It was also suggested that all the IP monographs should be screened for inclusion of test for dissolution wherever the test is missing.

(II) Other Proposed Amendments

(i) Secondary Spot in TLC

Scientific Body noted the recommendations of the Expert Committee on General Chapters and the IP Review Group and approved the proposed amendment for its release along with the Amendment List. The related text should emphasize on valid justification also.

(ii) Dissolution Test in Albendazole Tablets

Scientific Body reviewed the efforts made by IPC to ensure the quality of Albendazole Tablets by including the test for dissolution. Proposed dissolution method was approved for its release in the Amendment List.

(iii) Dissolution Test in Lapatinib Tablets Monograph

Test results of the analysis on the Lapatinib Tablets, OGD recommendations and approval sought from the IP Review Group were presented before the Scientific Body. Proposal for amendment was approved for its release along with the Amendment List.

(iv) Amendment in General Chapter on Containers (6.2)

Scientific Body took a note of the recommendations of the Dr. Y. K. Gupta Committee as well as the proceedings of another Expert Committee constituted by IPC to further examine the issue. Scientific Body extensively deliberated the issue and recommended that the matter be examined with subject experts under chairmanship of Dr. R. A. Mashelkar in light of the Maharashtra Govt. orders and in consultations with consumer activist groups to take appropriate decision.

(III) Checklists for Monograph Inclusion and Amendments

The checklists developed by AR&D Division for the purpose of 'Monograph Inclusion' and 'Requests for IP Amendments' were approved with minor modifications. The same should be uploaded on IPC website and circulated to IP stakeholders for its implementation.

(IV) Other Activities

For the purpose of strengthening the process of IP monograph development and resolving the queries received from the stakeholders IPC has drafted SOPs and the same were approved for implementation within ten days. Members desired that IPC should gradually move towards online IP monograph submission and proposals for IP amendments.

Also, development of the IR spectra by AR&D Division along with the method verification done for various categories of drugs was highly appreciated. Mr. Pradhan suggested that Buclizine hydrochloride monograph should be discussed in IP Review Group before making any amendment with respect to proposed deletion of category. Scientific Body recommended for up-gradation of the analytical lab facilities of IPC by procuring modern high-end equipment which would be essential for testing and standardizing the newly developed drugs in coming days. The equipments costing more than 25 lacs be put up to the Scientific Body for their inputs to have broader view on technical needs of the pharma sector.

Item No. 5: Progress Report of Microbiology Division

(I) Drug Samples Analysed

Scientific Body desired that IPC should strengthen its activities in the field of pharmaceutical microbiology by adopting the advanced methods and technologies for rapid analysis after their validation and verification.

(II) Memorandum of Understanding between CSIR-IMTech, Chandigarh and IPC

Scientific Body Members reviewed the clauses of the draft MoU between CSIR-IMTech and IPC and taking into consideration the importance of requirement of reference microbial cultures for pharmaceutical analysis, Scientific Body approved for the execution of MoU between two Institutes.

(III) Meeting of Microbiology Experts Working Group for IP

Members noted the proceedings of the Microbiology Expert Working Group meeting on the up-gradation of microbiological monographs in IP 2018 and noted the efforts of the Expert Working Group for strengthening the standards. Scientific Body recommended that the BET limits should be relooked before their release along with the Amendment List. Also, the list of equipment for Microbiology Division was approved for further procurement process.

Item No. 6: Progress Report of Materiovigilance Programme of India (MvPI)

Progress of Materiovigilance Programme of India (MvPI) was presented and Scientific Body desired that, in order to ensure the availability of safe medical devices to the patients, the activities of MvPI should be further strengthened by engaging more Institutes as AMCs across the country.

Scientific Body in principle agreed and approved for certification by IPC to Medical Device Adverse Event Monitoring Centre (MDMC) and for constitution of Medical Devices Adverse Events Causality Assessment Group based on the medical devices in question. Pharmacologist should also be included as member in the Assessment Group.

Item No. 7: Progress Report of Pharmacovigilance Programme of India (PvPI)

(I) Progress Report of PvPI

The progress of the Pharmacovigilance Programme of India (PvPI) along with different activities being carried out was presented. Scientific Body Members expressed that PvPI has important role to play in the public health sector under the current regulations. PvPI annual report, information profile of PvPI and Newsletter were brought to the notice of Scientific Body Members and was appreciated.

(II) Overseas Training Programme in Pharmacovigilance

Members noted that PvPI has made efforts towards the skill development by providing training in the area of pharmacovigilance. Scientific Body lauded the training programme on 'Pharmacovigilance and Regulatory Aspects' to be organized by IPC for participants from SEARN countries.

(III) Enrolment of New AMC Under PvPI

In order to further strengthen the patient safety across the country, Scientific Body in principle approved for enrolment of new AMCs under the PvPI in phased manner and desired that demographic parameters should also be considered for enrolment of such AMCs.

Item No. 8: Progress Report of Reference Standard Division

Scientific Body noted the progress in development of new IPRS, impurity standards and revenue generated through analysis of medicines; however, considering the scope of drug standardization Division needs to further strengthen the infrastructure facilities and collaborate with other similarly placed institutes in the area of standard development.

Scientific Body Members also desired that IPC should make further efforts to ensure continuous supply of the reference substances and impurities to the stakeholders so that quality of medicine in the country is ensured and a letter may be written to DCG(I) for the same. In order to achieve the same IPC proposed for the development of Mobile App and empanelment of laboratories for IPRS development and Scientific Body gave in principle approval for the same.

Item No. 9: Progress Report of Quality Assurance Division

Members noted that the Quality Assurance Division has been engaged in various activities including maintaining various accreditations for different IPC activities, providing trainings to students, reviewing of reports, developing SOPs and planning the PT studies.

Scientific Body also congratulated IPC for successful completion of the '6thWHO Biannual Interregional Seminar for Quality Control Laboratories (QCLs) Involved in WHO Pre-qualification' and desired that IPC should plan more of such events to collaborate with other International agencies also.

Item No. 10: Progress Report of National Formulary of India (NFI)

Work progress of NFI was noted and a Monograph/Chapter/Appendix inclusion checklist was prepared by IPC and Scientific Body approved the same for its implementation.

Members also desired that IPC should make efforts for promoting the visibility of NFI among its key stakeholders including State Drug Controllers. Members also agreed on the proposal of harmonization among different NFIs in the country in coordination with states authorities.

Item No. 11: Progress Report of Biologics Section

(I) New General Chapters Under Preparation

Approval granted for drafting of new chapters for inclusion in next IP edition.

(II) Vaccines and Immunoserum, for human use

Scientific Body discussed the issue and approved for inclusion of test for Mycoplasma in Live Viral vaccine monographs in line with the recommendations of the WHO TRS.

Issue of OPV contamination with strain type 2 also came for discussion and Members suggested that IPC should wait for outcome from CDL, Kasauli and DCG(I) as it is regulatory in nature.

(III) DST Project Under Drugs and Pharmaceuticals Research Programme (DPRP)

Progress of the project was noted and Members expressed satisfaction on the work done and approved the purchase of equipments under this project as per schedule.

Item No. 12: Progress Report of Phytopharmaceutical Division

Scientific Body reviewed the work of Phytopharmaceutical Division being carried out for up-gradation of existing IP monographs and inclusion of new monographs. Scientific Body approved for publication of second edition of the Guidance Manual for phytopharmaceutical drugs. Members expressed their satisfaction on the efforts of the Division in the field of trainings, skill development and collaborations with similarly placed Institutions and desired that these efforts should be continued to further strengthen the regulatory pathway for phytopharmaceutical drugs in India.

Item No. 13: Working Relationships with National and Other Institutes

IPC's activities towards strengthening working relations with other national laboratories, industry, academia, civil society were appreciated by Members. It was emphasised that IPC may play important role in the field of public health through collaborative approach and IPC should keep on strengthening these working relationship to further enhance its activities in its entrusted areas.

Scientific Body desired that the project proposal with IICT under DPRP may be reviewed by the peer committee and then referred to MoHFW for their consent before its submission to DST.

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

Scientific Body noted the details of sale and distribution of IP publications and suggested that IPC should take necessary steps to ensure that each manufacturer and stakeholder shall use the authentic copy of IPC publication i.e. IP, NFI, Guidance Document etc.

Item No. 15: Any Other Item with Approval of the Chairman

pH of Enrofloxacin injection for Veterinary Use

Dr. Nitin Bhatia raised the issue of pH of Enrofloxacin injection and Scientific Body approved the change amendment of pH from 9-11 to 9-12.

Prof. Ganguly reiterated that IPC has been engaged in multidisciplinary areas and appropriate measures must be taken to develop human resources and infrastructure capabilities to address the future needs of the country. Also, the proposal of implementation of FCS scheme for the scientific staff of IPC should be taken up with MoHFW.

Scientific Body recommended that in order to enhance the quality of training programmes, the registration fee for such programmes may be rationalized and resource persons should also be incentivized. Mr. S. Dey and Mr. P.C.P. Mohapatra will prepare the proposal in this regard for its approval.

Chairman also desired that Members and IPC Scientists should be well prepared for the agenda presented and to be discussed in next meeting of the Scientific Body.

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. Mr. A. K. Pradhan
5. Dr. R. M. Singh
6. Prof. Ramesh Kr. Goyal
7. Dr. D. Srinivasa Reddy
8. Dr. Naresh Bhatnagar
9. Dr. Praveen Khullar
10. Dr. Arun K. Mishra
11. Dr. Hemant K. Sharma
12. Dr. Sunil Gairola
13. Dr. Nitin Bhatia
14. Dr. Anil Kumar Tyagi
15. Dr. G. N. Singh

Leave of absence was granted to

1. Dr. Ram A. Vishwakarma
2. Prof. Sanjay Singh
3. Dr. V. Satyanarayana
4. Prof. Vinod Kumar Dixit
5. Dr. Rakesh N. Tirpude
6. Prof. Naveet Wig
7. Dr. Nithya Gogtay
8. Mr. Salim Veljee

Special Invitee

1. Dr. B. K. Sharma

IPC Staff who attended the meeting

1. Dr. Jai Prakash
2. Dr. V. Kalaiselvan
3. Dr. A. K. Teotia
4. Dr. Robin Kumar
5. Dr. Meenakshi Dahiya
6. Dr. Anuj Prakash
7. Mr. Alok Sharma
8. Dr. M. Kalaivani
9. Dr. Shashi Bhushan
10. Dr. Gaurav Pratap Singh
11. Dr. Manoj Pandey
12. Dr. Pawan Kr. Saini
13. Ms. Ritu Tiwari
14. Dr. Prasad Thota
15. Dr. Ajay Kumar Bishnoi

16. Dr. R.S. Ray
17. Dr. Shantrunajay Shukla
18. Mr. Mukesh Kumar
19. Ms. Anubhuti Goyal
20. Mr. S. Dey
21. Mr. L. M. Vijaya Prasad
22. Mr. Harish Kumar
23. Mr. Munendra Kumar Poonia