IPC released the Guidance Manual for Developing Herbal Monographs and Quality Manual for Pharmacovigilance Programme of India (PvPI)

The Guidance Manuals for Monographs Development of Herbs and Herbal Products including Phytopharmaceutical Drugs & Quality Manual for Pharmacovigilance Programme of India (PvPI) published by Indian Pharmacopoeia Commission (IPC) were released by Shri C K Mishra, Secretary, Ministry of Health and Family Welfare, Government of India during the governing body meeting of IPC held on 4th October 2016 at Nirman Bhawan, New Delhi. Shri Mishra appreciated the efforts of IPC for such documents.

Guidance Manuals for Monographs Development of Herbs and Herbal Products including Phytopharmaceutical Drugs deals with processes involved in developing quality monographs for botanicals / herbs. Indian Pharmacopoeia Commission has been working for over 10 years to develop objectively assessable quality standards for herbs, processed herbs and herbal drugs with a view to provide monographs to the stakeholders. Now 150 monographs of this area are included in Indian Pharmacopoeia (IP)-2014 and its two Addenda published so far. The scientists of the country, during this process, have evolved various standard operating procedures for the monograph development. These monographs included in IP have received wide acceptance globally and some of these monographs now appear in pharmacopoeias of other nations with or without further changes. IP felt the need to share this information to stimulate greater work in this area.

There had been criticism that quality monographs on herbs and botanicals have been removed from earlier editions of IP. With the resurgence of use of herbs in health care and emerging phytopharmaceuticals as drugs, there was a need to provide objectively assessable quality specifications for them. IPC is taking the initiative to form a separate working group of scientists for this work at the Commission’s laboratory supported and guided by an
eminent expert committee on herbs and herbal product as IP is a regulatory book of standards. This guidance manual compiles the learnings of the process of developing monographs to help the industry and scientists and other stakeholders working in this area.

The manual covers various steps in the monograph development – criteria, SOPs for Monograph development, SOP for botanical reference substance, SOP for phytochemical reference substances (marker compounds), SOP for extracts, SOP for herbal product monographs, SOP for photography of the candidate material of the monograph. It also includes a non-exhaustive list of suppliers who can provide marker compounds. Other organizations in India namely Ayurvedic Pharmacopoeia Committee, Indian Council of Medical Research have contributed immensely to this area. The manual acknowledges and provides information on these publications.

It is to the credit of many scientists in India who have contributed to the work of IP and achieved the above results in the last few years, most of which are done without any financial grants from IPC. The publication of this manual should help in speeding up this work to provide quality herbals including phytopharmaceutical drugs in consumer interest covering a larger number of herbs.

The efforts of the Secretary-cum-Scientific Director, IPC, Dr DBA Narayana, Chairman of the Herbals Committee of IPC, Dr Jai Prakash, Senior Principal Scientific Officer, IPC and the associated team are noteworthy.

Quality Manual for Pharmacovigilance Programme of India (PvPI) aims to ensure systems, standard operating procedures etc to perform the various activities of PvPI was prepared by National Coordination Centre (NCC) for PvPI. This was approved by the Quality Review Panel of PvPI. While speaking on the occasion, Secretary, Health appreciated
the efforts of PvPI team at NCC and across India. He stressed the need of a such quality manual in ensuring harmonized systems and procedure to perform all the elements of PvPI.

The feedback on both these Manuals can be sent to the Secretary-cum-Scientific Director, IPC.

Email : ipclab@vsnl.net

Shri C K Mishra, Secretary (Ministry of Health & Family Welfare, Govt of India) released the Guidance Manuals for Monographs Development of Herbs and Herbal Products including Phytopharmaceutical Drugs in Governing Body Meeting of IPC on 4th October 2016 at Nirman Bhawan, New Delhi.
Shri C K Mishra, Secretary (Ministry of Health & Family Welfare, Govt of India) released the Quality Manual for Pharmacovigilance Programme of India (PvPI) in Governing Body Meeting of IPC on 4th October 2016 at Nirman Bhawan, New Delhi.