

## **Manuals under RTI Act, 2005**

### **Manual 3- Procedure followed in Decision Making Process**

#### **3.1 What is the procedure followed to take a decision for various matters?**

So far as Administrative and Financial matters are concerned rules like Central Civil Services Rules, Fundamental Rules and Supplementary Rules and General Financial Rules (GFR), Bye-laws of IPC are referred to and the procedures laid down therein are followed. In case of scientific matters, IP is published in fulfillment of the requirements of the Drugs and Cosmetics Act 1940, and the rules thereunder. National Formulary of India is also published in order to promote rational use of generic medicines.

#### **3.2 What are the documented procedures/laid down procedures/Defined Criteria/Rules to arrive at particular decision for important matters? What are different levels through which a decision process moves?**

The rules mentioned above are followed. The various levels through which decision making process moves are Assistants and Administrative officer(AO)/ Finance & Accounts Officer (FAO) in case of Administrative and financial matters. For scientific and technical matters, Pharmacopoeial/Pharmacovigilance Associates (as the case may be), Scientific Assistant, Scientific Officer (SO), Senior Scientific Officer (SSO), Principal Scientific Officer (PSO), Senior principal Scientific Officer (Sr. PSO), Secretary-cum-Scientific Director after approval with Expert Committees and Scientific Body of IPC are various levels through which decision making process moves.

#### **3.3 What are the arrangements to communicate the decision to the public?**

- The Commission generally communicates the administrative matters like Expression of Interests (EOI), recruitment, procurement related tenders etc. to the public through newspaper advertisement or upload on IPC website [www.ipc.gov.in](http://www.ipc.gov.in).
- The scientific matters like any corrections/upgradations in the General Chapters and Monographs of IP which are deliberated by the Experts Committee and approved by the Secretary-cum Scientific Director of IPC for its implementation are released in form of “Amendment List” and uploaded on IPC website also.

- For the procurement of IP Reference Substances (IPRS) and IP impurity standards the list is available on the IPC website. The stakeholder may download the supply order form from the website, fill it completely and send your completed supply order form along with demand draft to IPC.
- The publications of IPC can be procured through from the office of the Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Raj Nagar, Ghaziabad 201 002 (UP). The publications are as listed below-
  - Indian Pharmacopoeia 2018
  - Guidance Manual for Compliance of Indian Pharmacopoeia (IP), 2012
  - Guidance Manual for Monographs Development of Herbs & Herbal Products Including Phytopharmaceuticals Drugs, 2016
  - National Formulary of India 2016
- The NCC-PvPI communicates the administrative matters like Establishment of AMCs under PvPI, recruitment, procurement related tenders etc. to the public through newspaper advertisement or upload on PvPI website <http://www.pvpi.in/>. The concerned institution (AMC) is also informed.
- The publications of NCC-PvPI, IPC can be procured through from the office of the Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector 23, Raj Nagar, Ghaziabad 201 002 (UP). The publications are as listed below-
  - Quarterly Newsletters
  - Annual Report
  - Guidance Document : Guidance Documents for spontaneous adverse drug reaction reporting, Pharmacovigilance guidance document for marketing authorization holder of Pharmaceutical Products, Reference Manual for Medical Devices.
- The other mechanisms in PvPI:-
  - ADR PvPI Mobile –app
  - SMS facility for Drug Alert
  - Toll Free Helpline 18001803024
  - Consumer ADR Reporting Email: [pvpi.compat@gmail.com](mailto:pvpi.compat@gmail.com)

### **3.4 Who is the final authority that vets the decision?**

In case of Administrative and financial matters the decision are vetted by Secretary-cum-Scientific Director, IPC. In case of scientific matters the decision is taken by Secretary-cum-Scientific Director, IPC after approval by Chairman-Scientific Body.

**3.5 Please provide information separately in the following format for important matters on which the decision is taken by the public authority.**

Subject on which the decision is to be taken	Development of Standards for IP
Guidelines/Direction, if any	Monograph Inclusion/ exclusion criteria is followed
Process of Execution	As stated under para 4.2 above
Designation of the officers involved in decision making	Scientific Officer (SO), Senior Scientific Officer (SSO), Principal Scientific Officer (PSO), Senior principal Scientific Officer (Sr. PSO), Secretary-cum-Scientific Director
Contact numbers of above mentioned officers	0120-2783400, 2783401, 2783392
If not satisfied by the decision, where and how to appeal	The person may contact to Office of The Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission Ministry of Health & Family Welfare Govt. of India Sector-23, Raj Nagar, Ghaziabad-201 002. Tel.:0120-2783400, 2783401, 2783392, FAX: 0120-2783311 E.mail: lab.ipc@gov.in