Manuals under RTI Act, 2005

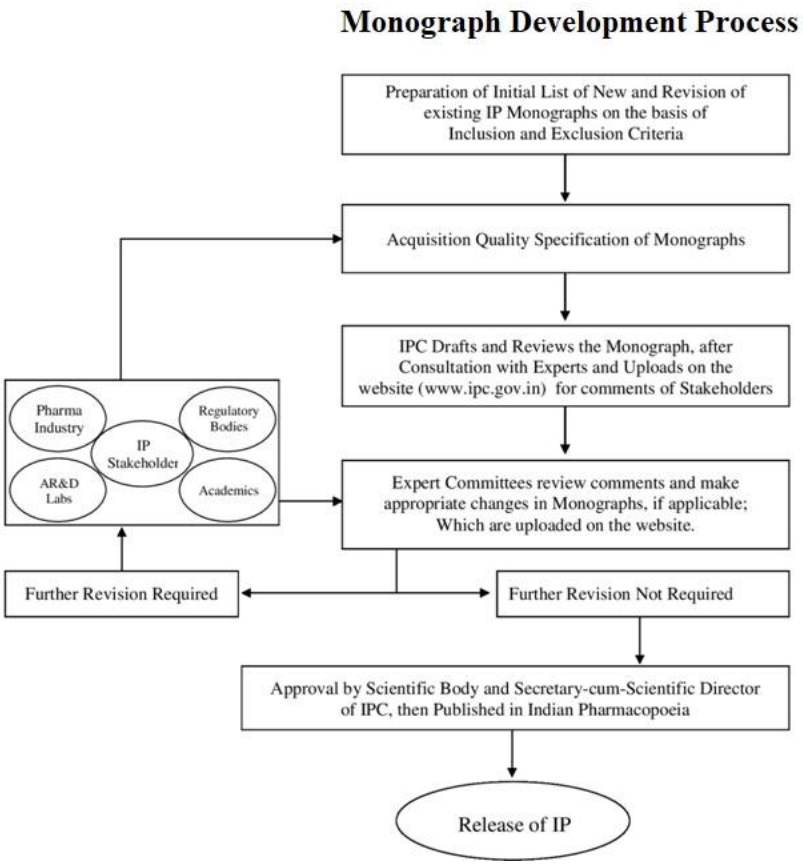
Manual 4-Norms set by it for the discharge of its functions.

Details of the Norms/Standards set by the department for execution of various activities/programs.

Indian Pharmacopoeia (IP) is published by the Indian Pharmacopoeia Commission (IPC) in accordance with the principles and designed plan decided by the Scientific Body of the IPC. To establish transparency in setting standards, the contents of the new monographs, general chapters or any revision and other information are publicized on the website of IPC. The feedback and comments of stakeholders are reviewed by relevant Expert committees to ensure the feasibility and practicability of the standards and methods revised.

1) Development of new monographs in Indian Pharmacopoeia

IPC works in close coordination with all the stakeholders of IP for the development of monographs. Public reviews and comments are given special attention while the development of IP standards. The principle of "openness, justice and fairness" is kept in mind during compiling and editing the contents of the Indian Pharmacopoeia. The methodology adopted is appended below:



The stakeholders can submit the proposal of inclusion of new monograph in IP by submitting the "***IP monograph Submission Checklist***"

2) Amendments/ Revisions/ Up-gradations in Existing Monographs

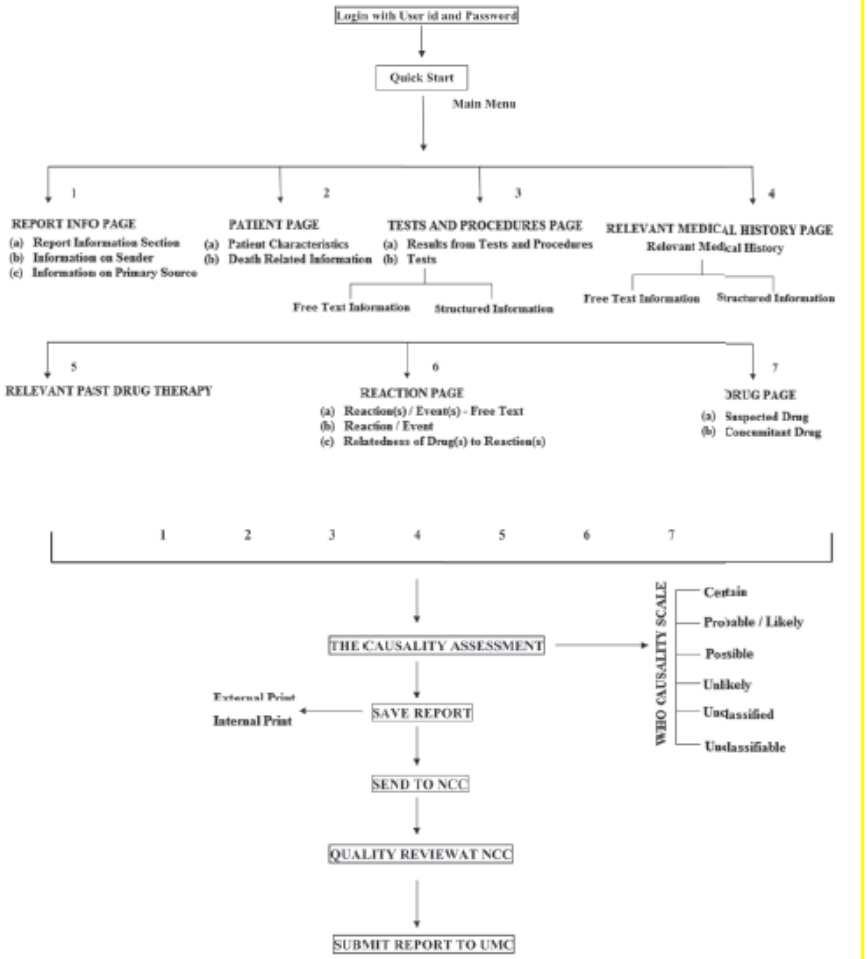
The Typographical Errors, Minor Technical Issues, Major Technical Issues are compiled by the Technical Secretariat and put up to the IP Review Group for their suggestions and comments. After review by the Expert Committee, the amendment list is prepared by the Technical Secretariat and submitted to Scientific Body members and finally approved by the Secretary-cum-Scientific Director.

The amendment list is circulated to all concerned authorities and is also uploaded on IPC website (www.ipc.gov.in)

3) Pharmacovigilance Programme of India (PvPI):

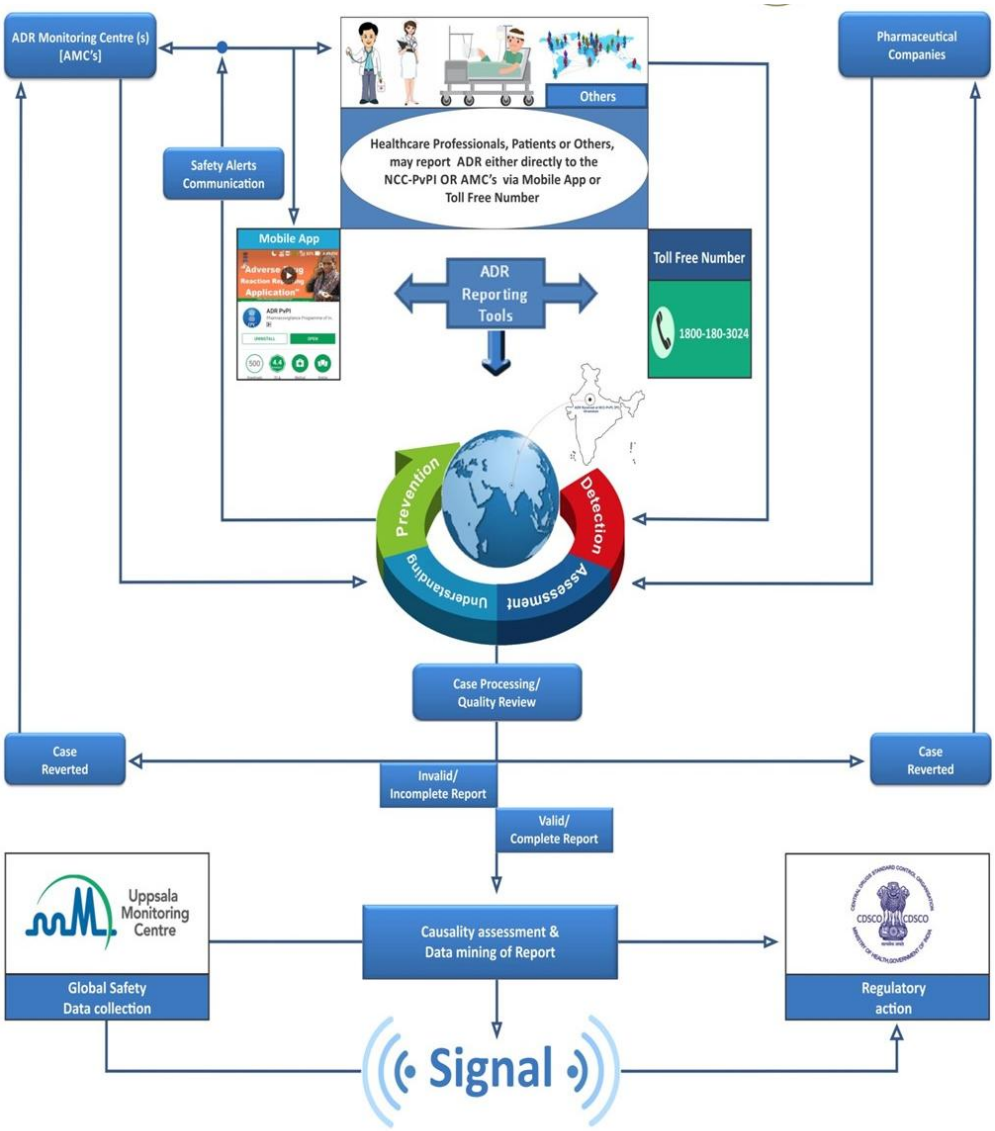
a) Participation of PvPI in International Drug Monitoring Programme

NCC-PvPI collects, collates and evaluates spontaneous reporting of ADRs due to use of medicine, vaccines, medical devices, etc. from all healthcare professionals and consumers/patients. To monitor ADRs, ADR Monitoring Centers (AMCs) have been set in India, which sends reports to NCC-PvPI. The methodology adopted for spontaneous reporting as below:



b) Signal Detection from Indian Data base

Signal detection and clinical assessment of Individual Case Safety Reports (ICSRs) form a vital domain of Pharmacovigilance. NCC – PvPI is engaged in identifying potential signals from Indian specific ICSRs with technical assistance by experts in the signal review panel (SRP).


ADR Monitoring Centre (s) [AMC's]
Pharmaceutical Companies
Others
Healthcare Professionals, Patients or Others, may report ADR either directly to the NCC-PvPI OR AMC's via Mobile App or Toll Free Number
Safety Alerts Communication
Mobile App
ADR Reporting Tools
Toll Free Number
1800-180-3024
Prevention
Detection
Assessment
Understanding
Case Processing/ Quality Review
Case Reverted
Case Reverted
Invalid/ Incomplete Report
Valid/ Complete Report
Uppsala Monitoring Centre
Global Safety Data collection
Causality assessment & Data mining of Report
CDSCO
Regulatory action
Signal