Guidance Document

Process for Development of Indian Pharmacopoeia Monographs

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Indian Pharmacopoeia Commission

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Disclaimer

This Guidance Document is compiled by the Indian Pharmacopoeia Commission (IPC) after consultations with the 'Core Expert Committee' constituted by the IPC for this purpose. The information contained herein represents the current best practices in the field of pharmacopoeial sciences to demonstrate compliance with the existing regulatory requirements. The guidance provided in this document is not intended to alter or modify or supplement or in any other way change the contents of the Indian Pharmacopoeia (IP), but is intended to provide general guidance to all users of the IP to help in ensuring proper compliance with the IP requirements when standards of drugs are to be determined. The content of this document shall be treated as non-mandatory guidance and the information contained herein is subject to review by the IPC. Approaches and methods other than those described in this Guidance Document may be adopted if found suitable and justified. Where provisions of the law exist, the law as prevailing at the relevant time shall apply.

Introduction

The inclusion of monographs in IP and their further amendments due to scientific advancements is taken up by IPC from time-to-time. The same is reviewed by specialized Expert Working Groups having members from regulatory authorities, drug control laboratories, pharmaceutical manufacturers, research institutions and other stakeholders. The principle of "openness, justice and fairness" is followed while compiling, verifying, and editing the contents of the IP monographs. Stakeholders contributing in the process for IP monograph development and their amendments are given in Figure 1.

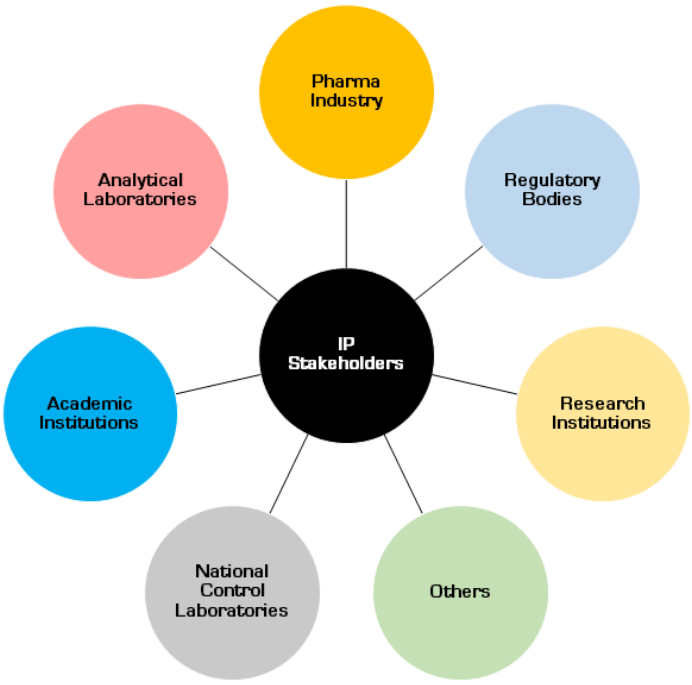

Figure 1. Stakeholders of IP

Process for IP Monograph Development

The process for IP monograph development includes following six steps and is summarized in Figure 2:

Step 1: Preparation of Initial List of Monographs for Inclusion in IP

The scientific staffs of IPC prepare an initial list of APIs and dosage forms for which monographs are to be developed for their inclusion in IP. This list is then thoroughly deliberated in the relevant Expert Working Groups of the IPC. The list of monographs accepted by the Expert Working Groups is then put up to the Scientific Body of the IPC for its review and approval.

Inclusion and Exclusion Criteria for IP

Inclusion Criteria

- Drugs used in National Health Programs of India
- Drugs listed in National List of Essential Medicines (NLEM)
- Drugs approved by CDSCO
- Fixed Dose Combinations approved by CDSCO and recommended by the IPC Experts
- Drugs considered appropriate by the IPC

Exclusion Criteria

- Drugs banned in India
- Obsolete drugs
- Drugs considered inappropriate by the IPC

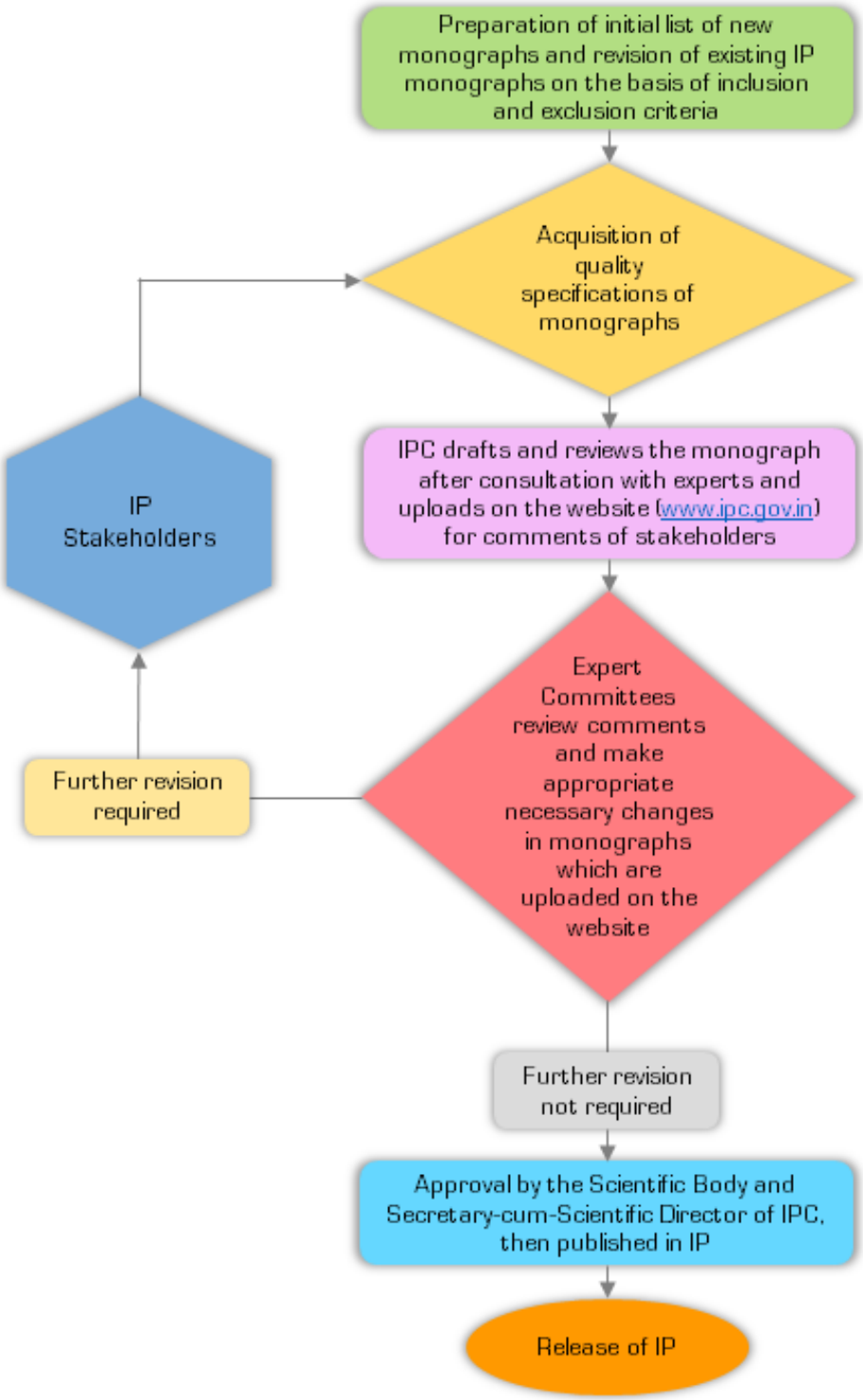

Figure 2. Public Review and Comments Process for IP Monograph Development

Step 2: Acquisition of Monographs from the Stakeholders

The quality specifications of the APIs and/or dosage forms are obtained from the stakeholders along with 'Monographs Inclusion Request Form' which is displayed on IPC website (www.ipc.gov.in) and is re-presented below:

Monograph Inclusion Request Form

1.	Name of the Molecule		
2.	Therapeutic Category		
3.	Name of Monograph		
4.	Is it approved by CDSCO in India? (please tick)		API
			Dosage Form
			Both
			Any Other
5.	In case of Dosage Form, provide details with respect to for how long product is being marketed in India?		
6.	Name of Manufacturers		
7.	Benchmark-International Product/Company		
	Category (Please tick)		National Health Programs of India
			National List of Essential Medicines, India
			Fixed Dose Combination
			Any Other
8.	Comparative status of proposed monograph in different pharmacopoeias		
9.	Justification for deviation of Innovators specification		
10.	Route of Synthesis (If applicable)		
11.	Analytical Method Validation Data		
12.	Stability Data including data about forced degradation studies		
13.	Rationale of Inclusion of Monograph:		
Reviewers Remarks:			
1. _____ 2. _____			
Authorized by:			
1. _____			

Note: *Duly filled in and approved form is submitted to IPC along with details on test samples for method verification, specifications, STP, WS, reference standard, impurity standard, validation data, stability data, and candidate material for the development of IPRS.*

In addition to the drug monographs, recommendations on IP General Chapters, if any, may also be submitted to IPC. At the time of monograph development, stakeholders are also encouraged to donate candidate material for the development of IPRS.

Step 3: Drafting of Monographs in IP Format

IPC scientific staffs draft the monograph(s) in IP format. Simultaneous verification and/or validation of test methods are performed at the IPC. Different Expert Working Groups examine and review the monographs for their suitability in terms of the technical contents and feasibility of testing.

Step 4: Obtaining Public Comments

The draft monograph(s) are displayed on the IPC website for a minimum period of 45 days and given wider publicity by circulating the list of proposed monographs for inviting public comments.

Step 5: Review of Comments

The comments obtained from stakeholders are examined by the scientific staff of IPCand/or Expert Working Groups. Further revision, if required, is carried out by IPC staff and monograph(s) are again displayed on IPC website and circulated to the stakeholders. In case, no further revision is required, the monograph is accepted and processed for its publication. The galley proof of the entire manuscript is reviewed by the IPC scientific staffand Expert Working Groups. Other requirements such as obtaining ISBN and copyright related provisions are complied with before final publication of the IP.

Step 6: Release of IP

The final print of IP, bearing the official seal of IPC and a unique identification number, is released by the competent authority for use by the stakeholders. IP becomes effective from such date as specified and approved by the Secretary-cum-Scientific Director of the IPC.

Reference

1. The Indian Pharmacopoeia, 2018