



THE INDIAN PHARMACOPOEIA COMMISSION (IPC)

By

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Member Secretary

INTRODUCTION

As per the Drugs and Cosmetics Act 1940, the **Indian Pharmacopoeia** is the legally recognized book of **Standards** for the quality of drug substances and preparations included therein.

PUBLICATION OF IP



<u>Edition</u>	<u>Year</u>
I	1955
II	1966
III	1985
IV	1996
Addenda	2000
	2000 (Vet. Suppl)
	2002
	2005
New	Due in 2007

FORMATION

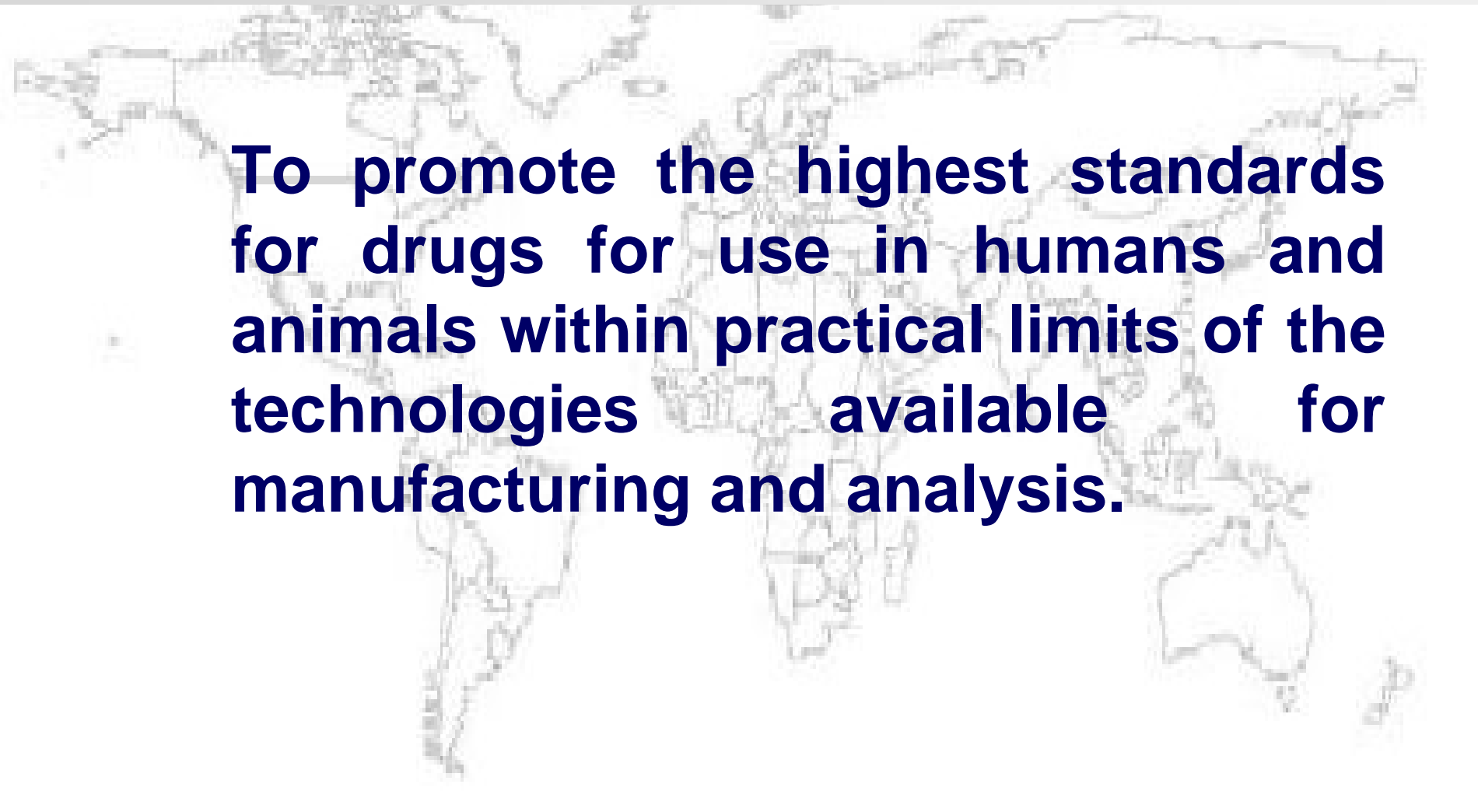


The Indian Pharmacopoeia Commission has been established as an Autonomous Institution under Ministry of Health & Family Welfare on 09th Dec. 2004.

MISSION

To promote public health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers.

VISION



To promote the highest standards for drugs for use in humans and animals within practical limits of the technologies available for manufacturing and analysis.

MANDATE

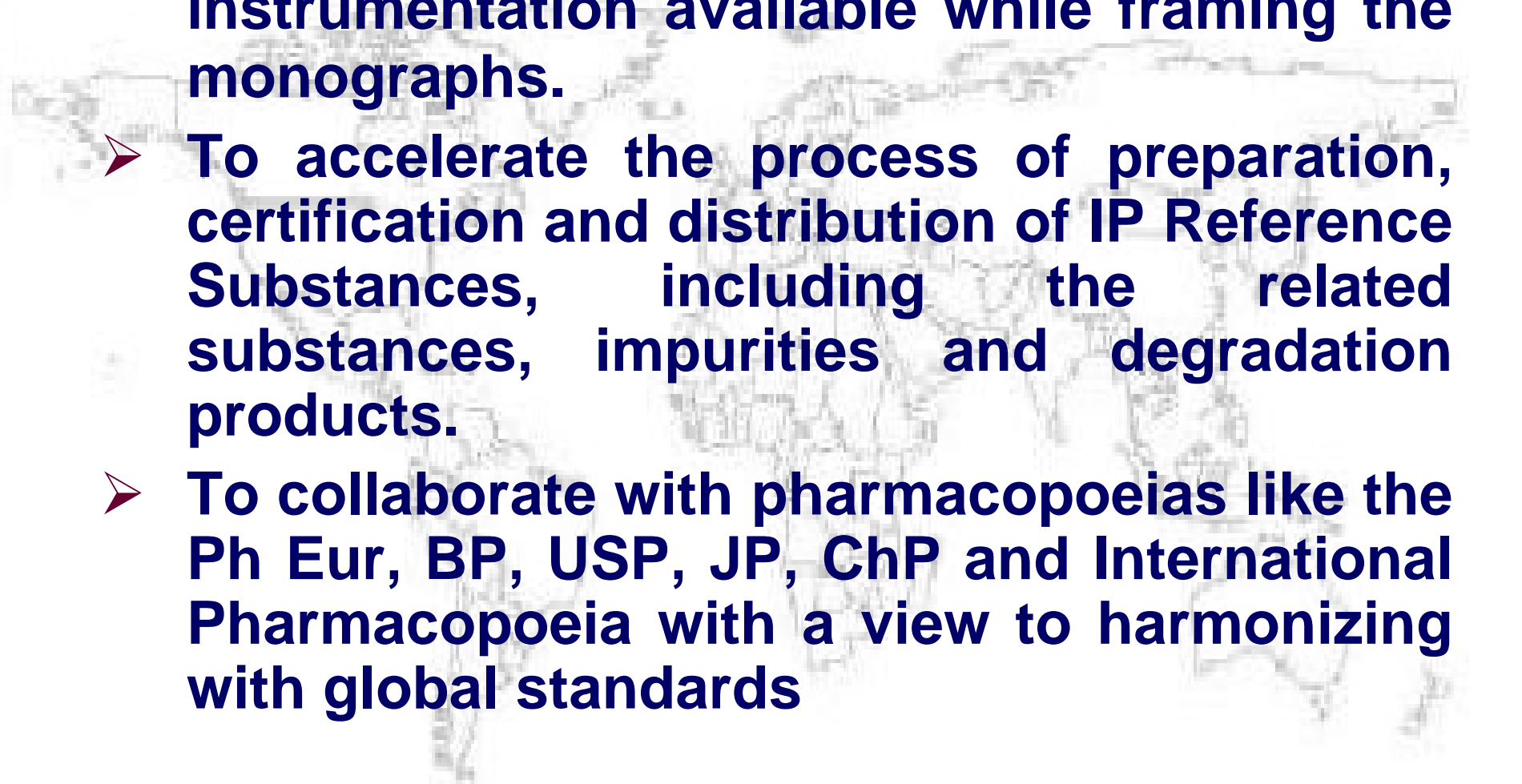
- **To bring new editions and supplements of the Indian Pharmacopoeia at regular intervals**
- **To accelerate the process of preparation, certification and distribution of IP Reference Substances**
- **To establish working relations with other Pharmacopoeial Agencies**

Objectives

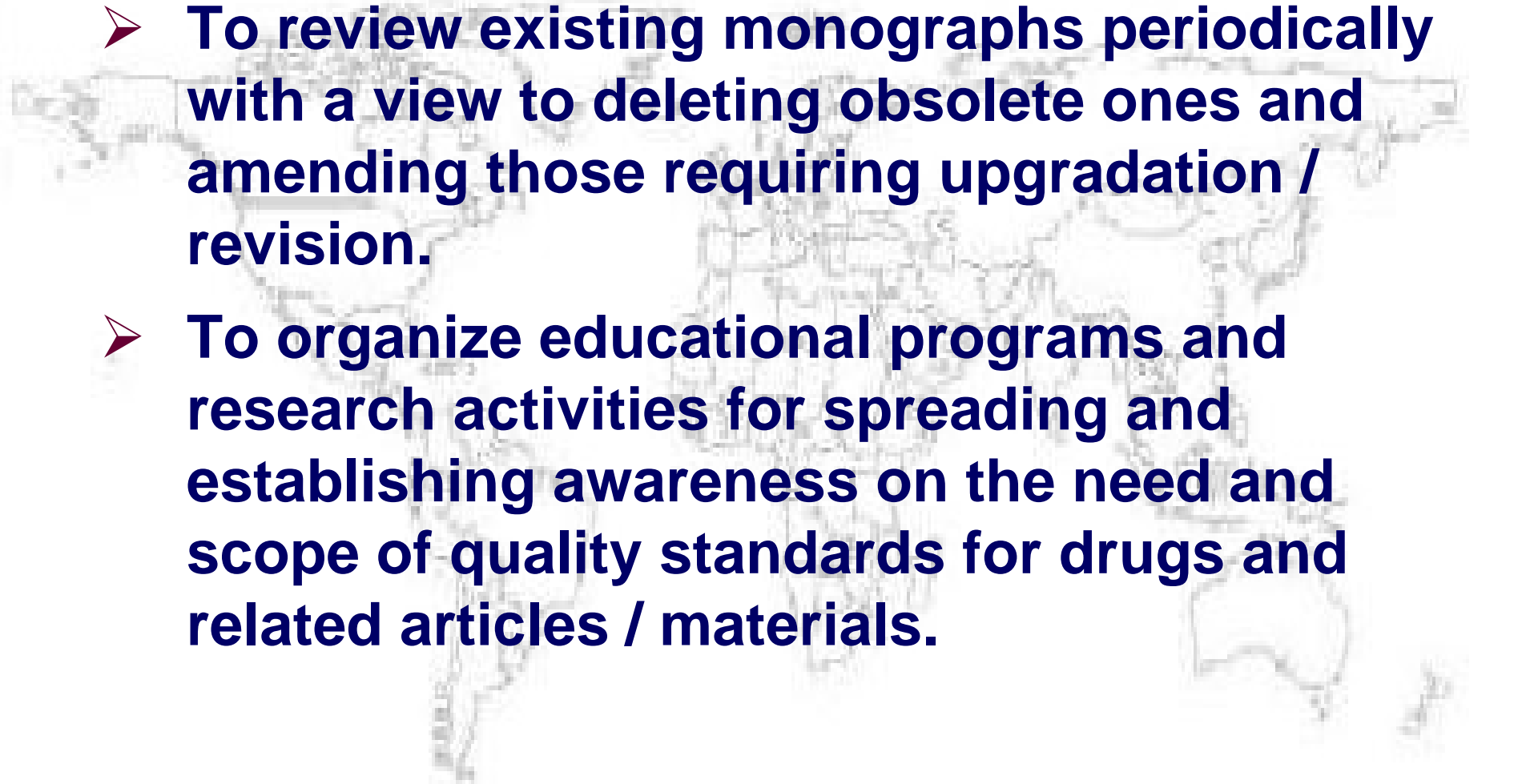
- To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, excipients and dosage forms as well as medical devices, and to keep them updated by revision on a regular basis.
- To develop monographs for herbal drugs, both raw drugs and extracts/formulations therefrom.
- To accord priority to monographs of drugs included in the National Essential Drugs List and their dosage forms.

Contd...

- **To prepare monographs for products that have normally been in the market for not less than 2 years except for certain special categories of new drugs like antiretrovirals, antituberculosis and anticancer drugs and their formulations introduced more recently, which may be accorded priority attention.**
- **To give special attention to the methods of manufacture used by the indigenous industry in selecting the pharmacopoeial tests for monitoring the toxic impurities of the concerned drug.**

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- **To take note of the different levels of sophistication in analytical testing/instrumentation available while framing the monographs.**
 - **To accelerate the process of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products.**
 - **To collaborate with pharmacopoeias like the Ph Eur, BP, USP, JP, ChP and International Pharmacopoeia with a view to harmonizing with global standards**

Contd...

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- **To review existing monographs periodically with a view to deleting obsolete ones and amending those requiring upgradation / revision.**
 - **To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles / materials.**

Location

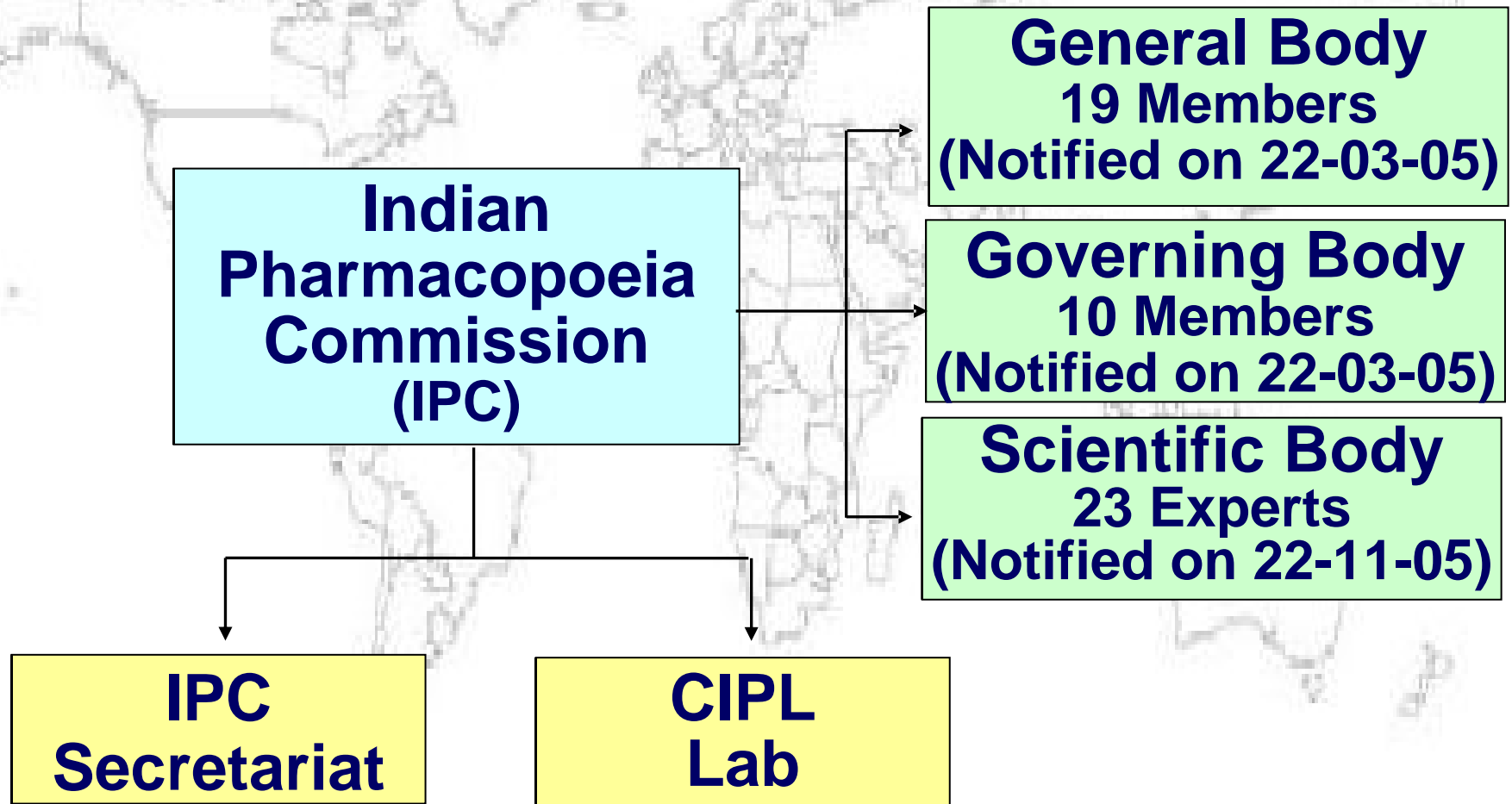
The Office of the Commission is situated at the Central Indian Pharmacopoeia Laboratory Campus, Sector-23, Rajnagar, Ghaziabad-201 002, India.

It is an ultra modern premise having state-of-the art infrastructure and excellent facilities.

Supporting Structure for the Indian Pharmacopoeia Commission



COMPOSITION



COMPOSITION

SCIENTIFIC BODY - Consists of 23 Experts

Executive Committee – 01 (Members – 05)

Expert Committees – 21 (Members – 4 to 5)

MAJOR DECISIONS (S.B.)

- IP Addendum 2005
- Plan for distribution and marketing
- Web-site
(www.ipc.gov.in)
- Work plan for IPRS
- Priority items (133)
- IPRS Label Scheme
- Identified items
 - Active Drugs
 - Dosage Forms
 - National Priority Drugs



NEW EDITION

□ **Upgradation**

- **General Notices** **contents**
- **Monographs** **: 1265**
- **Appendices** **: 300**
- **Veterinary Monographs** **: 80**
- **General Analytical Methods** **: 300**

NEW EDITION



□ Additions	<u>Monographs</u>
• Vaccines and Other Biological Products	: 51
• Biotechnological Products	: 12
• Blood and Blood Products	: 32
• Medicinal Plants	: 20

NEW EDITION

Monographs

- **New Drugs**
Active : **100**
Formulations : **300**
- **Antituberculosis/
Antiasthmatic Drugs** : **35**
- **Antiretroviral Drugs** : **20**


I. P. REFERENCE SUBSTANCES



<u>Item</u>	<u>Nos.</u>
• Chemicals	: 600
• Biologicals	: 30
• Microbiologicals	: 8
• Phytochemicals	: 40

Priority Works

- **New edition of Indian Pharmacopoeia in 2007**
- **Early availability of IP Reference Substances**
- **International collaborations with USP, BPC, EDQM, WHO etc for acceptance of IP globally**



**World is becoming closer and
cooperation is the way of
success.**



THANKS