To Further Internationalization of Japanese Pharmacopoeia

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Office of Standards and Guidelines Development,

Pharmaceuticals and Medical Devices Agency (PMDA)

1. Introduction: What is JP?

Introduction: Legal Status of JP

- Article 2 -

The term “drug” in this Law refers to the following items:

1. Items recognized in the **Japanese Pharmacopoeia.**
2. Items (excluding quasi-drugs or cellular and tissue-based products) which are intended for use in the diagnosis, cure or prevention of disease in humans or animals, and which are not equipment or instruments.
3. Items (excluding quasi-drugs or cosmetics) which are intended to affect the structure or functions of the body of humans or animals, and which are not equipment or instruments.

Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics

Introduction: Legal Status of JP

- Article 56 -

No drug which comes under any of the following items shall be sold or given, or manufactured, imported, stored, or exhibited for the purpose of sale or giving:

1. **The quality or properties are not in conformity with the standards established by Japanese Pharmacopoeia (JP)**

Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics

Pharmaceuticals and Medical Devices Agency

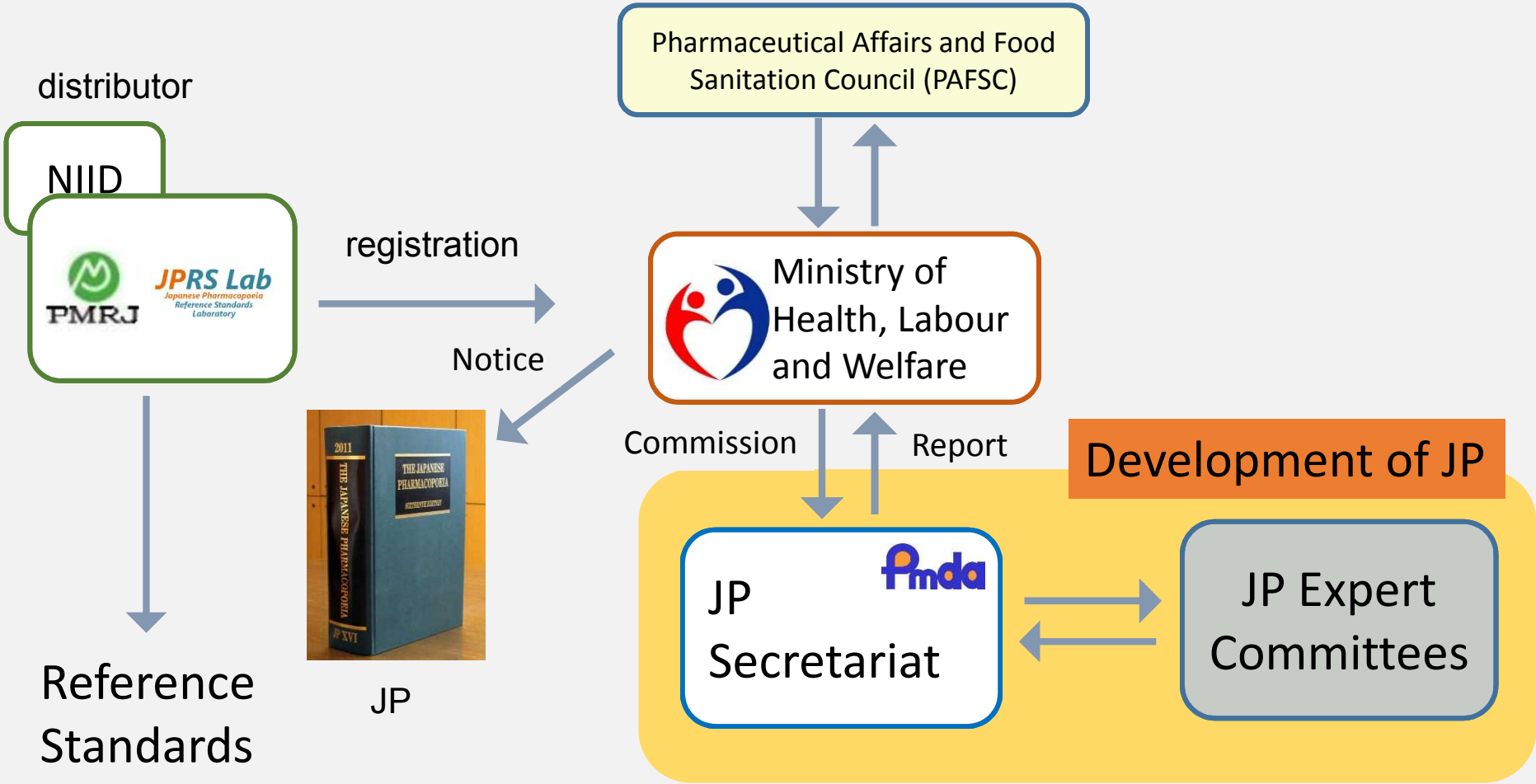
History of JP Edition

Edition	Date of publication	Number of monographs
JP 1	1886.6.25	468
↓	↓	↓
JP 16	2011.3.31	1764
Suppl. I	2012.9.27	1837
Partial rev.	2013.5.31	1837
Suppl. II	2014.2.28	1896
↓	↓	↓
JP 17	2016.3	1962

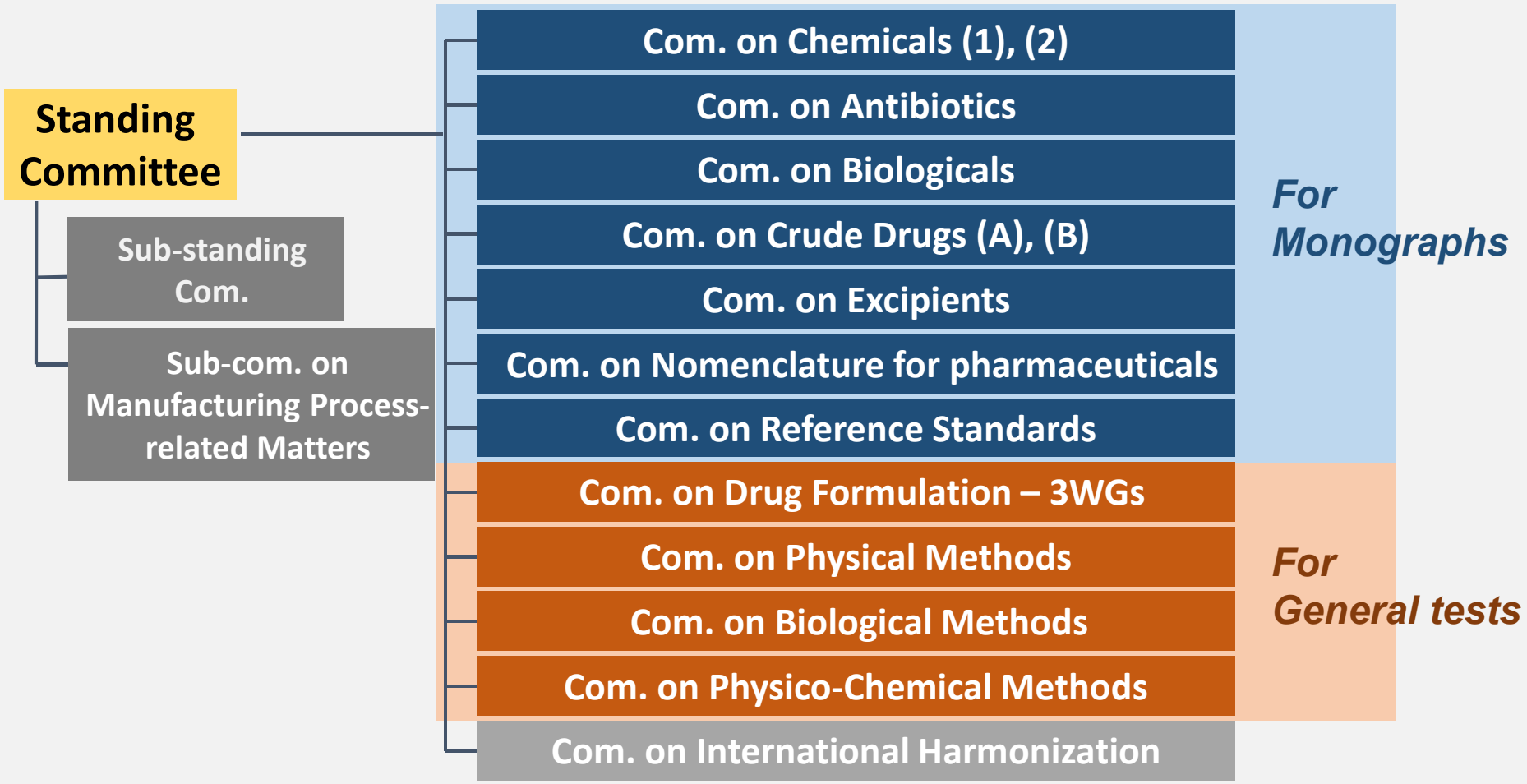
Structure of Japanese Pharmacopoeia

- Main Body (Mandatory part)
  1. General Notices - general rules for drafting, interpreting, and utilizing the Japanese Pharmacopoeia
  2. General Rules for Crude Drugs - general rules for drafting, interpreting, and utilizing the official monographs of crude drugs
  3. General Rules for Pharmaceutical dosage forms - common rules and interpretation about preparations
  4. General Tests, Processes and Apparatus - highly common test methods
  5. Official Monographs - specifications and test methods per drug
  6. Infrared Reference Spectra and Ultraviolet-visible Reference Spectra
- General Information

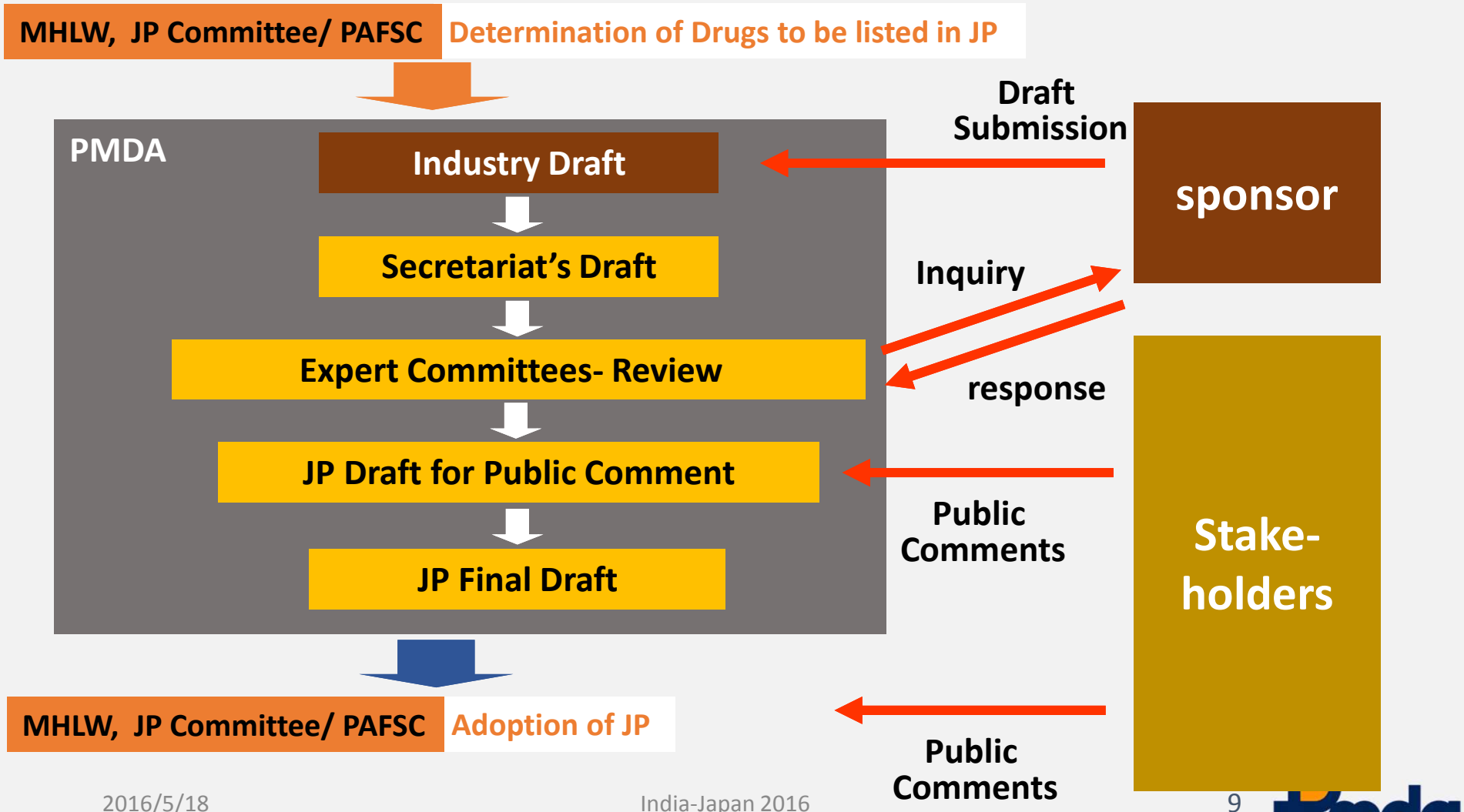
Structure of JP development and implementation



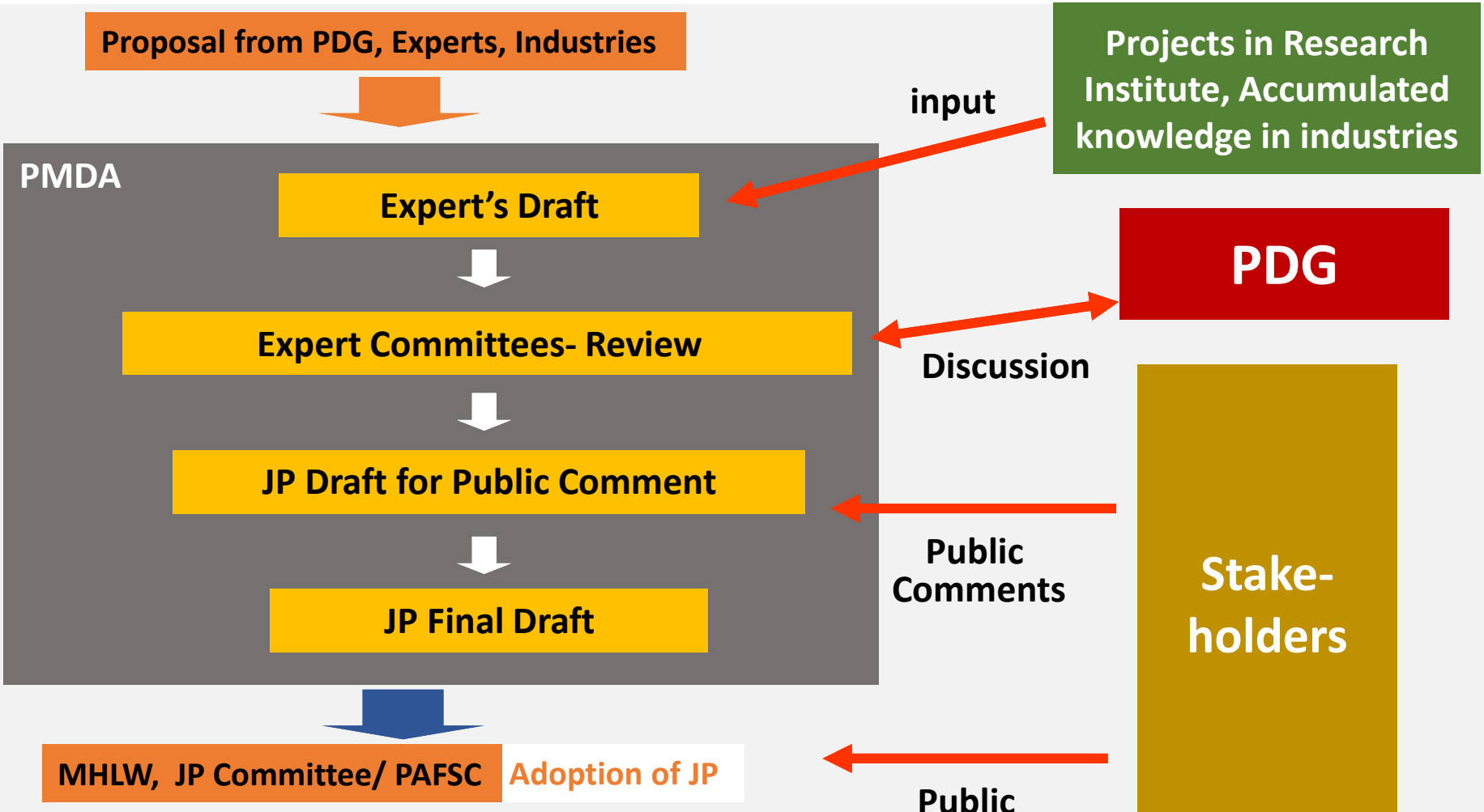
Organization of JP Expert Committees



Methodology of developing JP monographs *with high transparency*



Methodology of developing JP General tests *with harmonization*



Top Sales Drugs in Japan: Many drugs are originated from Japan

rank	Drug substance
1	Clopidogrel Sulfate
2	Valsartan
3	Candesartan Cilexetil
4	Sitagliptin Phosphate Hydrate
5	Olmesartan Medoxomil
6	infliximab (genetical recombination)
7	Ketoprofen
8	Bevacizumab（Genetical Recombination）
9	Lansoprazole
10	Donepezil Hydrochloride
11	Leuprorelin Acetate
12	Telmisartan
13	Loxoprofen Sodium Hydrate
14	Olanzapine
15	Darbepoetin Alfa (genetical recombination)

rank	Drug substance
16	Atorvastatin Calcium Hydrate
17	Tacrolimus Hydrate
18	Rabeprazole Sodium
19	Fexofenadine Hydrochloride
20	Etanercept（genetical recombination）
21	Rosuvastatin Calcium
22	Celecoxib
23	Montelukast Sodium
24	Teriparatide Acetate
25	Ethyl Icosapentate
26	Cilostazol
27	Imatinib Mesilate
28	Pemetrexed Sodium Hydrate
29	Vildagliptin
30	Aripiprazole

Sales based on https://nk.jiho.jp/servlet/nk/related/html/1226663477655.html

Pharmaceuticals and Medical Devices Agency

Top Sales in Japan vs Listing in JP

rank	Drug substance	
1	Clopidogrel Sulfate	JP16-2
2	Valsartan	JP16-1
3	Candesartan Cilexetil	JP16
4	Sitagliptin Phosphate Hydrate	To be listed
5	Olmesartan Medoxomil	JP16-2
6	infliximab (genetical recombination)	
7	Ketoprofen	JP12
8	Bevacizumab（Genetical Recombination）	
9	Lansoprazole	JP17
10	Donepezil Hydrochloride	JP16
11	Leuprorelin Acetate	JP16-2
12	Telmisartan	JP16-2
13	Loxoprofen Sodium Hydrate	JP12-2
14	Olanzapine	To be listed
15	Darbepoetin Alfa (genetical recombination)	

rank	Drug substance	
16	Atorvastatin Calcium Hydrate	JP16
17	Tacrolimus Hydrate	JP15-2
18	Rabeprazole Sodium	JP16
19	Fexofenadine Hydrochloride	JP16
20	Etanercept（genetical recombination）	To be listed
21	Rosuvastatin Calcium	To be listed
22	Celecoxib	
23	Montelukast Sodium	JP17
24	Teriparatide Acetate	
25	Ethyl Icosapentate	JP15
26	Cilostazol	JP15
27	Imatinib Mesilate	
28	Pemetrexed Sodium Hydrate	To be listed
29	Vildagliptin	
30	Aripiprazole	

Sales based on https://nk.jiho.jp/servlet/nk/related/html/1226663477655.html

2. Internationalization of JP

Policies on Drafting of JP 17th Edition

1. Providing all drugs essential for health care and medical treatment
2. Improving quality by introducing the latest science and technology
3. Promoting internationalization
4. Timely updating and revising as necessary and facilitating smooth administrative operation
5. Ensuring transparency in process and disseminating JP

Administrative Notice, September 13, 2011, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare

Background: Gap between JP standards and ICH standards

- ICH-Q guidelines (Q1, Q3, Q5, Q6 etc) addresses the marketing approval of new drug products, and in JP styles are not properly subject to ICH-Q guidelines.
- The specification of the new drug products are changed to JP styles especially in impurity test, as listed in JP monographs.

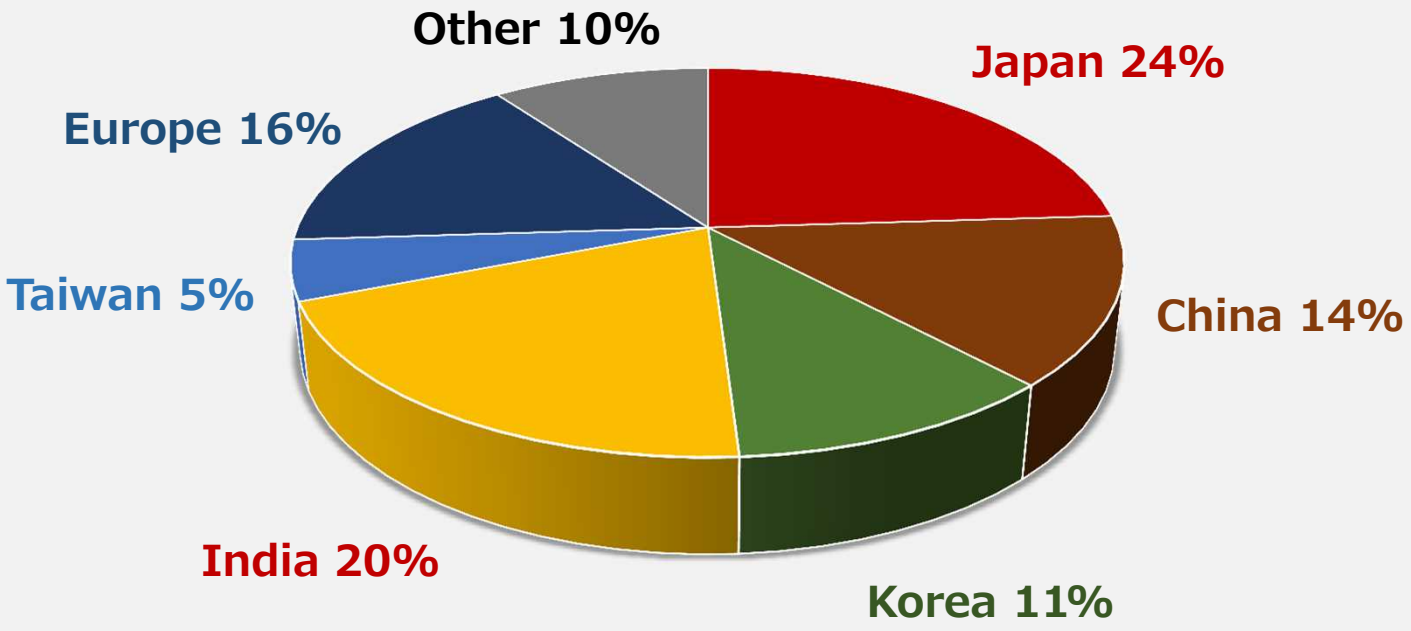
The style of JP monograph are reevaluated for new drugs to fit in.

Trend 1 : Globalization

Globalization of Raw Materials of Drug

Registration of the Drug Master File (DMF) by manufacturers

PMDA, 2011-2014. August



Issues of Globalization

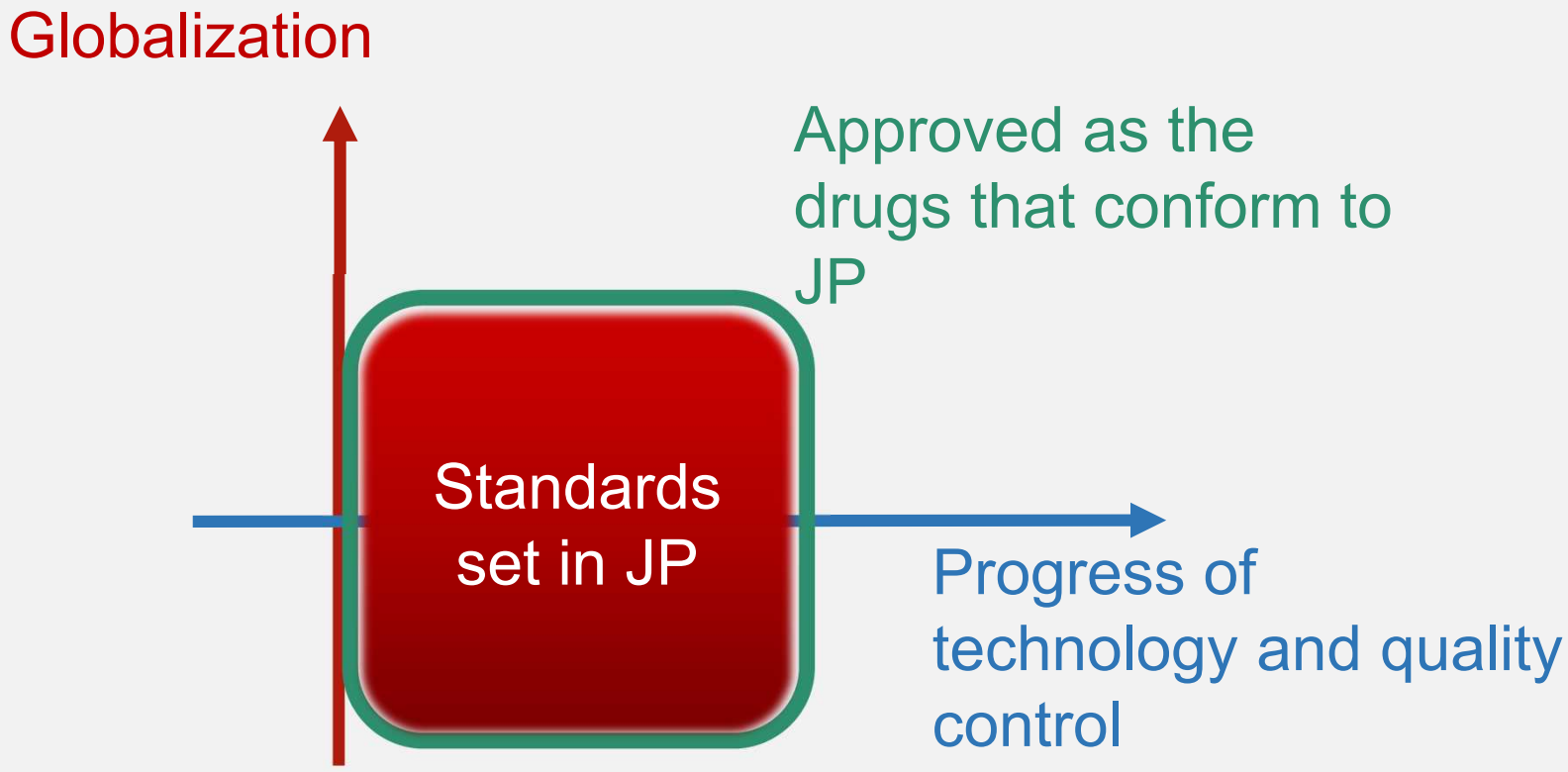
- A JP test standard could pose an obstacle to procurement of drug substances from the countries or regions outside of Japan.
- As the supply chains of drug substances are diversified, a risk with raw materials would be directly linked to the Japanese clinical practice.
- Gaps of the policies between JP and other pharmacopoeia could be difficult to understand for people outside of Japan, and could potentially cause mistaken notion of conformity with JP standards.

Trend 2: Diversification and Progress of Quality Control

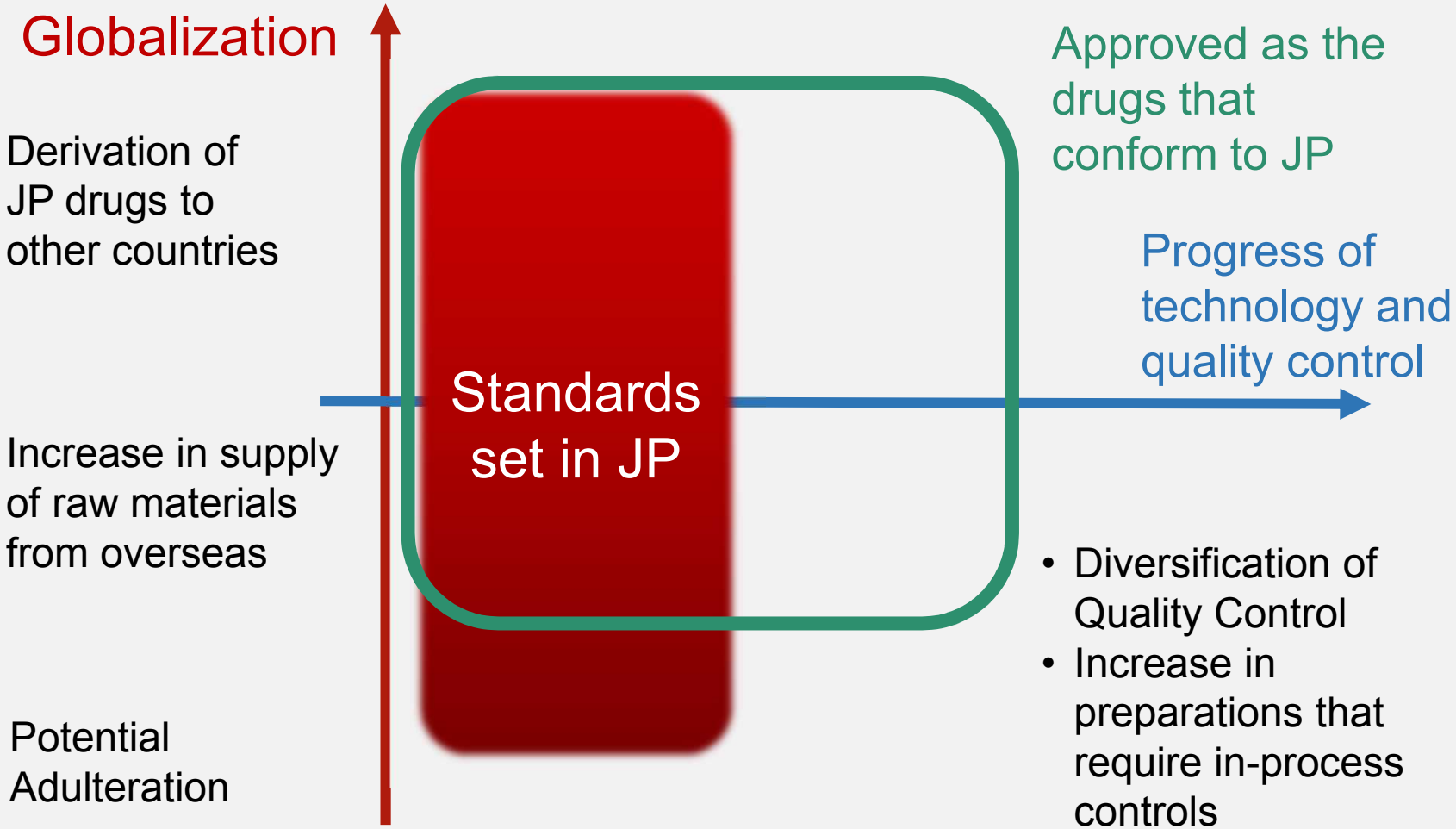
- A certain period of time has past after application of ICH Q8-Q11.
- The new drugs (e.g. biological products) that require the process controls have increased.
- The formulation development and control of generic drugs have been diversified.

The style of JP monograph are reevaluated for drugs with multiple variety of process-controls to fit in.

Japanese Pharmacopoeia in the Past



Japanese Pharmacopoeia of the 17th edition



Major Revision Points in JP17

- New policies of specification setting of impurities in JP monographs
- New articles about production and quality control
- Introduction of new headings of “Production” and “Potential adulteration”
- Comprehensive regulation of residual solvents.
- Revision of Containers and Packages
- Revision related to the Biological methods

New policies of specification setting of impurities in JP monographs

- **The purity test using the reference standards of impurities**
  - Chromatographic method using the reference standards of impurities will be adapted in the Purity test.
- **The second test method for the purity test**
  - For the drugs manufactured by a different chemical syntheses and thus having a different impurity profile, the Second Test Method may be adopted in the Purity test.

New articles about production and quality control

- **Following articles are to be adopted in General Information**
  - “Basic concepts of quality assurance of drug substances and drug products”, which is based on ICH-Q6A and Q6B philosophy
  - “Basic concepts of quality risk managements”, which is based on ICH-Q9 philosophy

Revision regarding the Reference Standards

- **Adoption of a new concept for Reference Standards were discussed, considering the consistency with other pharmacopoeias**
  - Requirements to set the Reference Standards used for the tests other than the Assay in the Official Monograph
  - Requirements for the specification of the Reference Standards used for non-Assay tests
  - Consideration of influence on the distributors of Reference Standards
- **Revision of General Test, <9.01> Reference Standards**

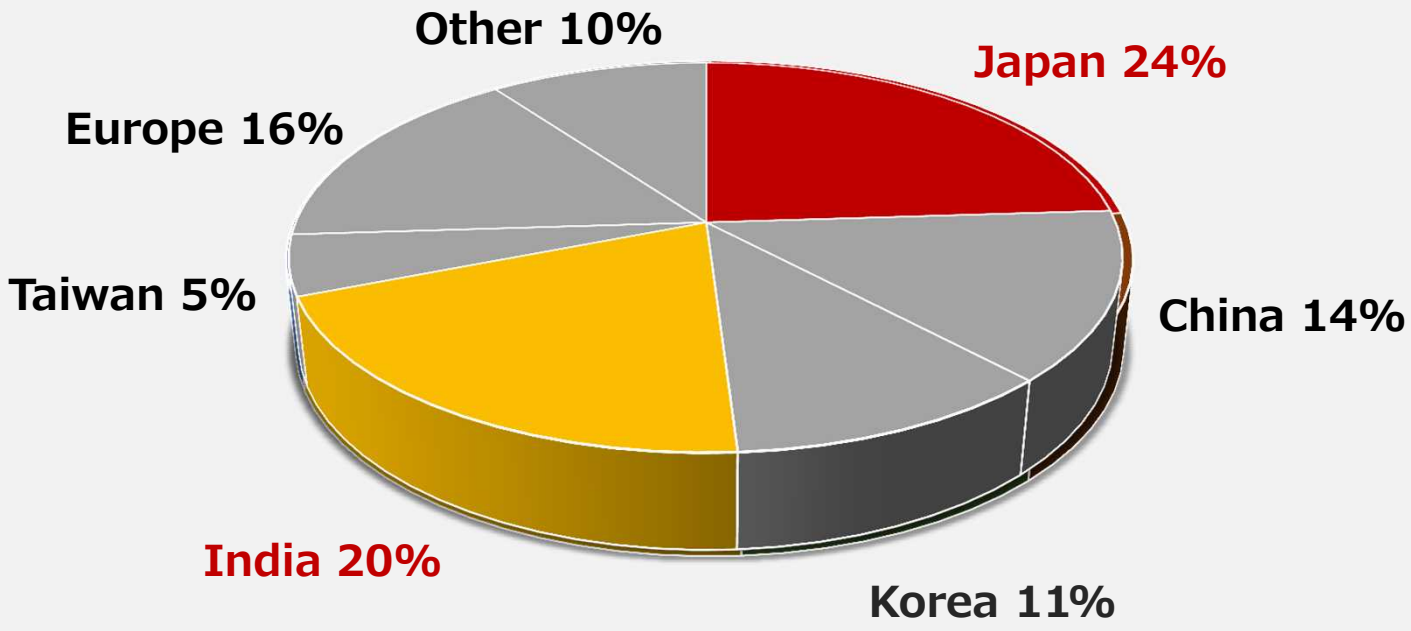
PMDA International Strategic Plan 2015

- **Expediting the global utilization of the Japanese Pharmacopoeia**
  - Further expedite harmonization of the JP, USP and EP through the activities of the PDG.
  - Contribute to improving quality of pharmaceuticals that are globally distributed, by proactively incorporating in the JP the concept of quality assurance based on cutting-edge science, and by promoting JP as one of the reference pharmacopoeia in other countries/regions.

3. Initiative of the cooperation with India

Initiative of the cooperation with India

India is the largest exporting country of the drug raw materials to Japan.



Further mutual understanding of JP is expected

To establish the conformity to JP, MAH and manufacturers are highly encouraged to understand the policies and details of JP.

JP provides the standardization and homogenization of quality for Japanese market.

Pharmaceuticals and Medical Devices Agency

Further mutual understanding between IP and JP is expected

To convergence the regulation for drug approval, basal concepts of the review and evaluation process of drugs referring the compendial standards should be shared.

Summary

- Considering globalization of drug supply chain and progress and diversification of quality control, there is a need to change the quality of Japanese Pharmacopoeia (JP) as well as the JP's position in the reviews of marketing applications.
- Keeping qualitative fulfillment, JP will proactively make international development.
- To convergence the regulation for drug approval, basal concepts of the review and evaluation process of drugs referring the JP should be shared with IP.

सत्यमेव जयते

Indian Pharmacopoeia

India – Japan Regulatory Symposium

18th May 2016, New Delhi

Dr. P. L. Sahu

Principal Scientific Officer,
Indian Pharmacopoeia Commission,
Ministry of Health and Family Welfare, Government of India

Overview

- Indian Pharmacopoeia Commission
- Indian Pharmacopoeia and NFI
- Indian Pharmacopoeia Reference Substances (IPRS)
- International Cooperation
- International Harmonization
- Skill Development Programs
- Way Ahead 2020

Overview

- Indian Pharmacopoeia Commission
- Indian Pharmacopoeia and NFI
- Indian Pharmacopoeia Reference Substances (IPRS)
- International Cooperation
- International Harmonization
- Skill Development Programs
- Way Ahead 2020

Indian Pharmacopoeia Commission

Sector-23, Raj Nagar,

Ghaziabad - 201002, Uttar Pradesh

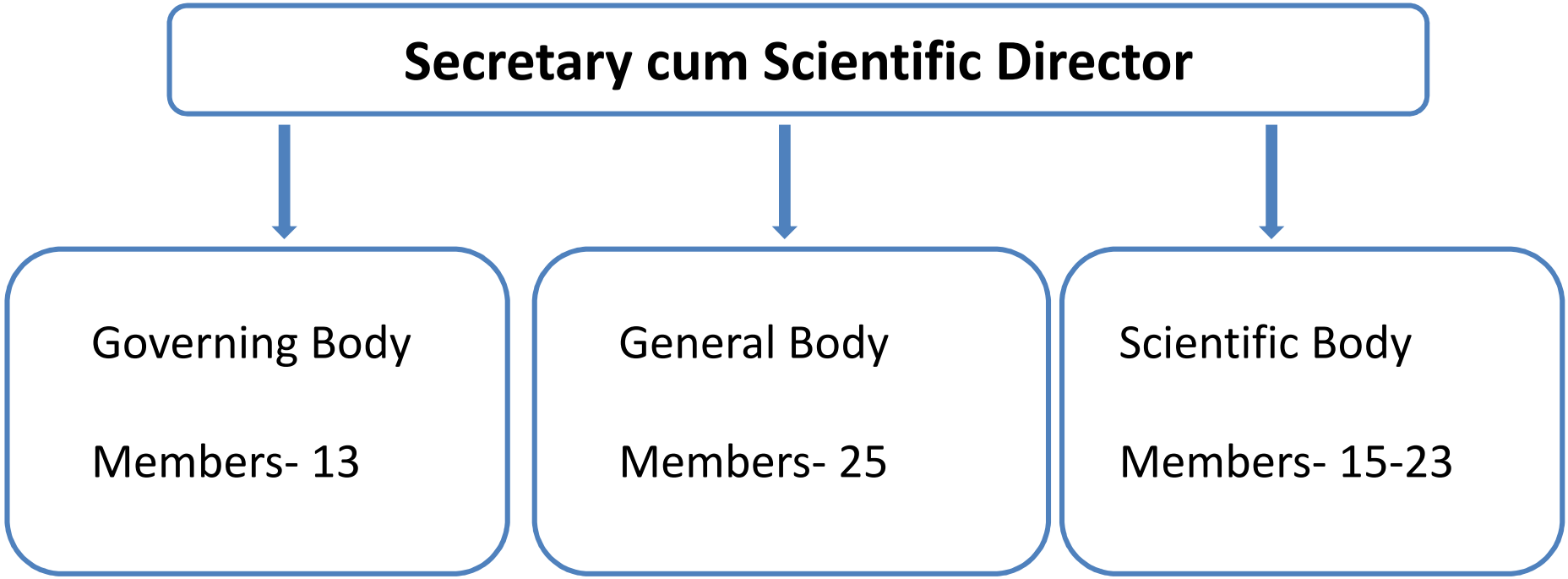
Introduction

- The Commission has become operational from 1st Jan., 2009 as an Autonomous Body, under administrative control of the Ministry of Health & Family Welfare, Government of India.

- The Indian Pharmacopoeia commission has a three-tier policy formulation and execution setup comprising of the **General Body, Governing body** and **Scientific Body** with experts drawn from various Science & Technology areas.

- The Secretary-cum-Scientific Director is the **Chief Scientific and Chief Executive Officer** and the Member Secretary of the all the three bodies of IPC.

Composition of Commission



Vision & Mission

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

Mission: To promote public health and animal 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.

Mandate

- To publish new edition and addendums of the Indian Pharmacopoeia.
- To publish the National Formulary of India.
- Certification and distribution of IP Reference Substances.
- National Coordination Centre (NCC) for running Pharmacovigilance Programme of India (PvPI)
- To establish working relations with other similarly placed institutions at National and International level.
- To organize educational programs, skill development and research activities.

Overview

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- International Harmonization
- Skill Developments Programs
- Way ahead 2020

Indian Pharmacopoeia

- Indian Pharmacopoeia plays a significant role by providing the Standards for Drugs and Pharmaceuticals.
- The Monographs of Drugs are official standards.
- Indian Pharmacopoeia (current edition, IP-2014) is a compilation of Monographs and other Standards that are being used in Pharma and Life Science industry as Standards.

Publication of Indian Pharmacopoeia

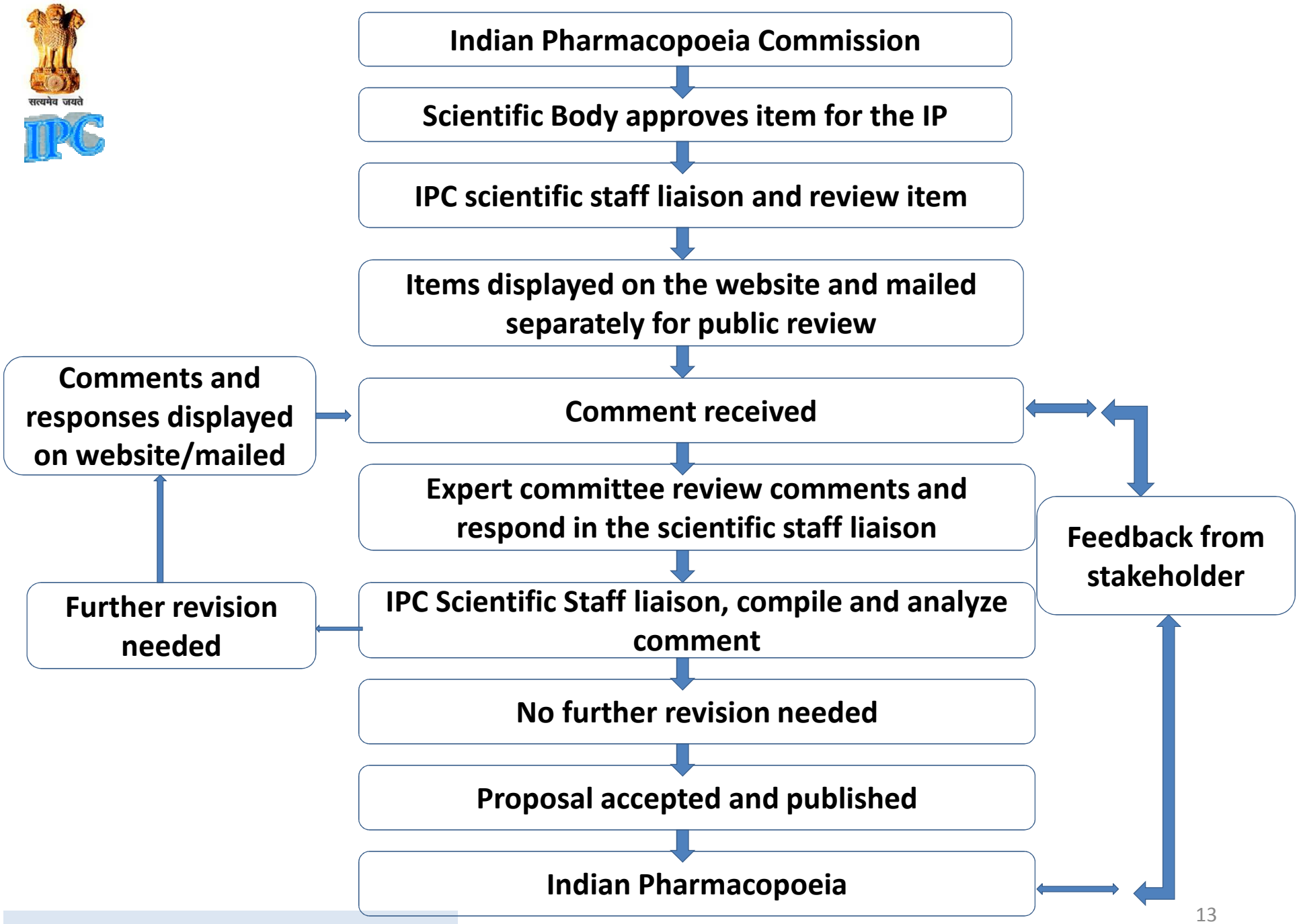
(By IP Committee)

Edition	Year
I	1955
Supplement	1960
II	1966
Supplement	1975
III	1985
Addendum	1989 & 1991
IV	1996
Addendum	2000
Vet Supplement	2000
Addendum	2002

(By IP Commission)

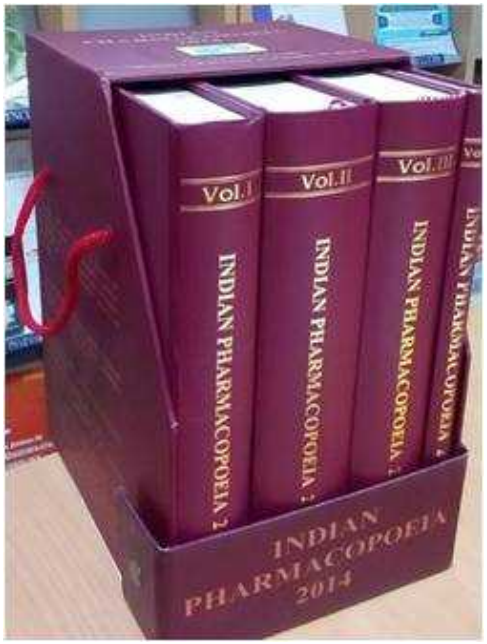
Edition	Year
Addendum	2005
V	2007
Addendum	2008
VI	2010
Addendum	2012
VII (New Edition)	2014
Addendum	2015
Addendum	2016
VIII	2018 (Under Preparation)

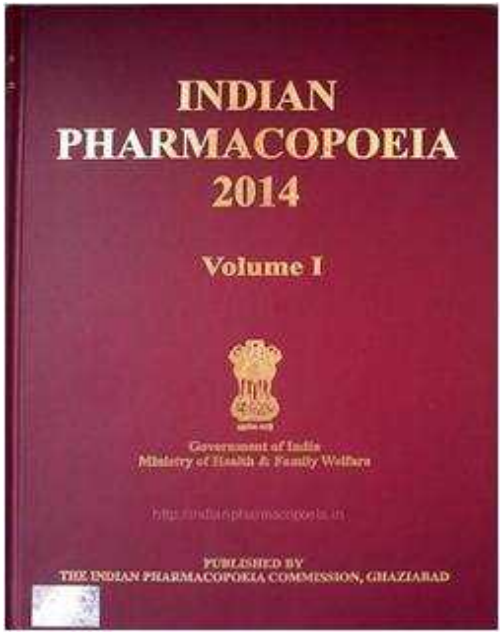
IP Monographs development


Indian Pharmacopoeia Commission
Scientific Body approves item for the IP
IPC scientific staff liaison and review item
Items displayed on the website and mailed separately for public review
Comments and responses displayed on website/mailed
Comment received
Feedback from stakeholder
Expert committee review comments and respond in the scientific staff liaison
Further revision needed
IPC Scientific Staff liaison, compile and analyze comment
No further revision needed
Proposal accepted and published
Indian Pharmacopoeia

LATEST EDITION : IP 2014

- During developing standards for IP 2014, tried to harmonize it with other Pharmacopoeias of the world without compromising with the quality of the products





IP-2014: Salient features

- 577 New Monographs added comprising of 134 API monographs, 161 Formulations monographs, 18 Excipients monographs, 43 NDS monographs, 10 Antibiotic monographs, 19 Anticancer monographs, 11 Antiviral monographs
- Also 31 Herbal monographs, 05 monographs on Vaccine & immunosera for human use, 06 monographs on Insulin products and 07 monographs on biotechnology products are included.
- 19 New General Chapters and about 200 New IR spectra's are also added
- **First time** 19 new Monographs on Radiopharmaceutical with one General Chapter on Radiopharmaceutical preparations included
- A **separate volume** of veterinary products is also introduced for easy access which include 143 monographs on veterinary products along with 16 General chapter

IP-2014: Salient features

- **Anticancer** monographs incorporated in IP are not available in other Pharmacopoeias.

S. No.	Anticancer drugs
1	Anastrazole Tablets
2	Bortezomib
3	Erlotinib Hydrochloride
4	Erlotinib Tablets
5	Gefitinib
6	Gefitinib tablets
7	Imatinib capsules

S. No	Anticancer drugs
8	Imatinib Tablets
9	Lapatinib Ditosylate
10	Lapatinib Tablets
11	Sorafenib Tablets
12	Sorafenib Tosylate
13	Topotecan Hydrochloride
14	Topotecan Injection

IP-2014: Salient features

- **Anti Tubercular** monographs incorporated in IP are not available in other Pharmacopoeia

Anti Retroviral monographs included in IP are not available in other Pharmacopoeia.

S. No.	Anti Tubercular drugs
1	Thiacetazone
2	Thiacetazone and Isoniazid Tablets
3	Prothionamide Tablets

S. No.	Anti Retroviral drugs
1	Nelfinavir Tablets
2	Stavudine & Lamivudine Tablets
3	Nelfinavir Mesylate
4	Nelfinavir Mesylate Oral Powder
5	Tenofovir & Emtricitabine Tablets
6	Tenofovir Disoproxil Fumarate
7	Tenofovir Disoproxil Fumarate Tablets

IP-2014: Salient features

- **Radiopharmaceutical** monographs included in IP are not present in other Pharmacopoeia

Biotechnology Product monographs incorporated in IP are not present in other Pharmacopoeia

S. No	Radiopharmaceutical Monographs
1	Technetium (^{99m}Tc) EC Injection.
2	Technetium (^{99m}Tc) Trodat- 1 Inj.
3	Technetium (^{99m}Tc) HYNIC TOC Inj.

S. No	Biotechnology Monographs
1	Biphasic Insulin Aspart Injection
2	Recombinant Streptokinase Bulk Solution
3	Recombinant Streptokinase for Injection
4	Filgrastim Injection

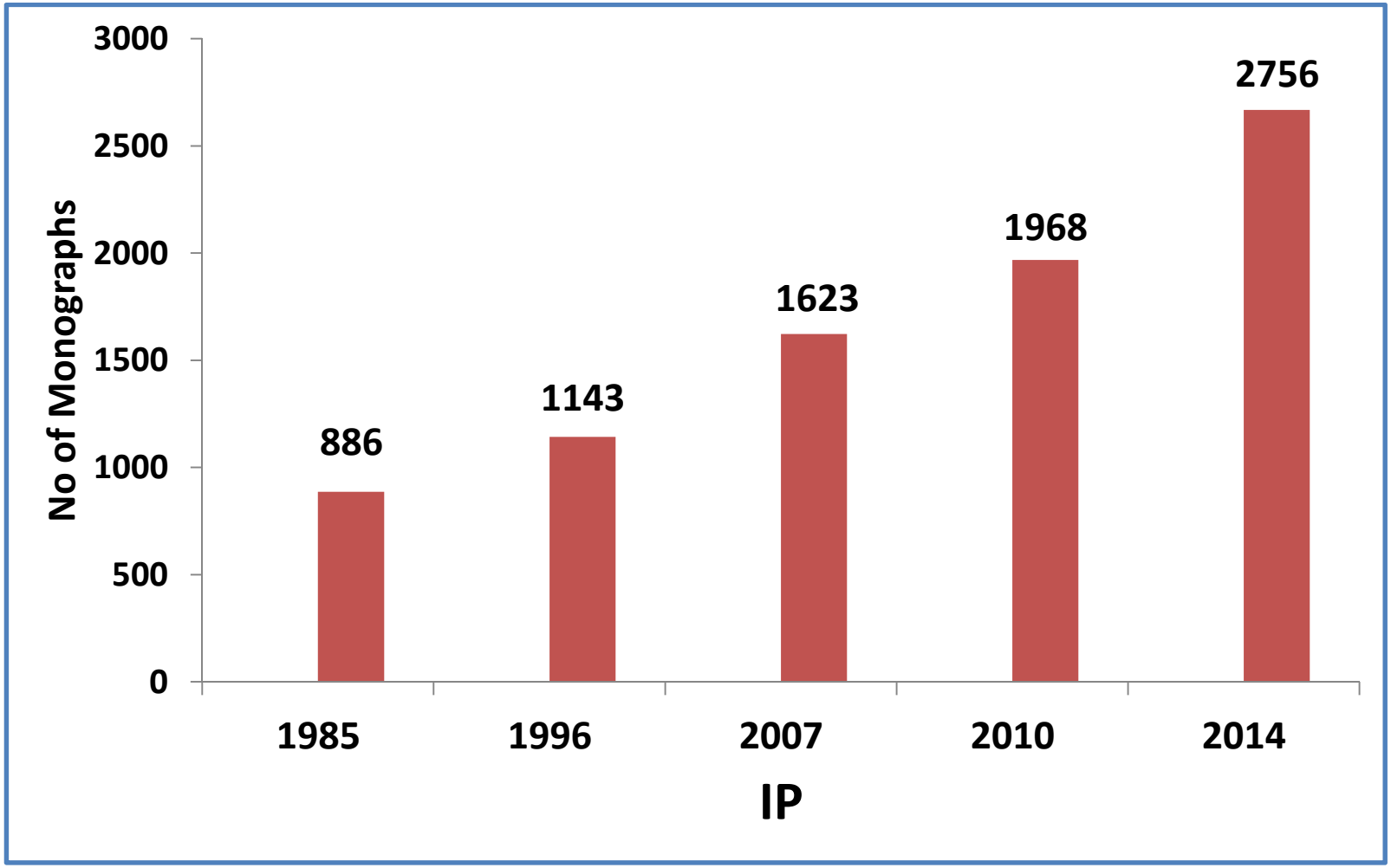
Release of IP-2014

IP-2014

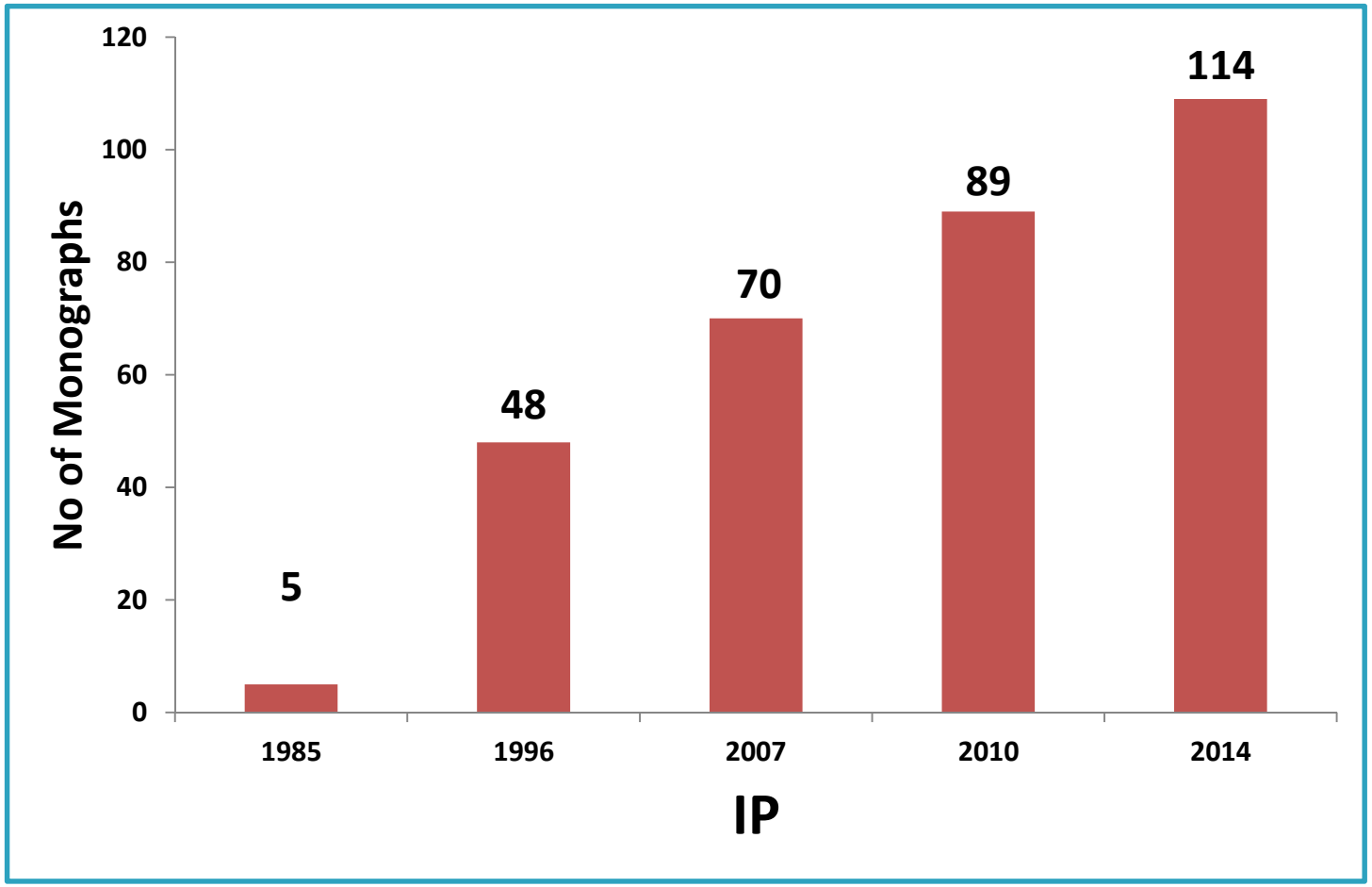
Release of IP Addendum-2015

Released on 28th Nov. 2014 by Sh. Lov Verma, Secretary, MoH & FW and Chairman, IPC at Nirman Bhawan, New Delhi.

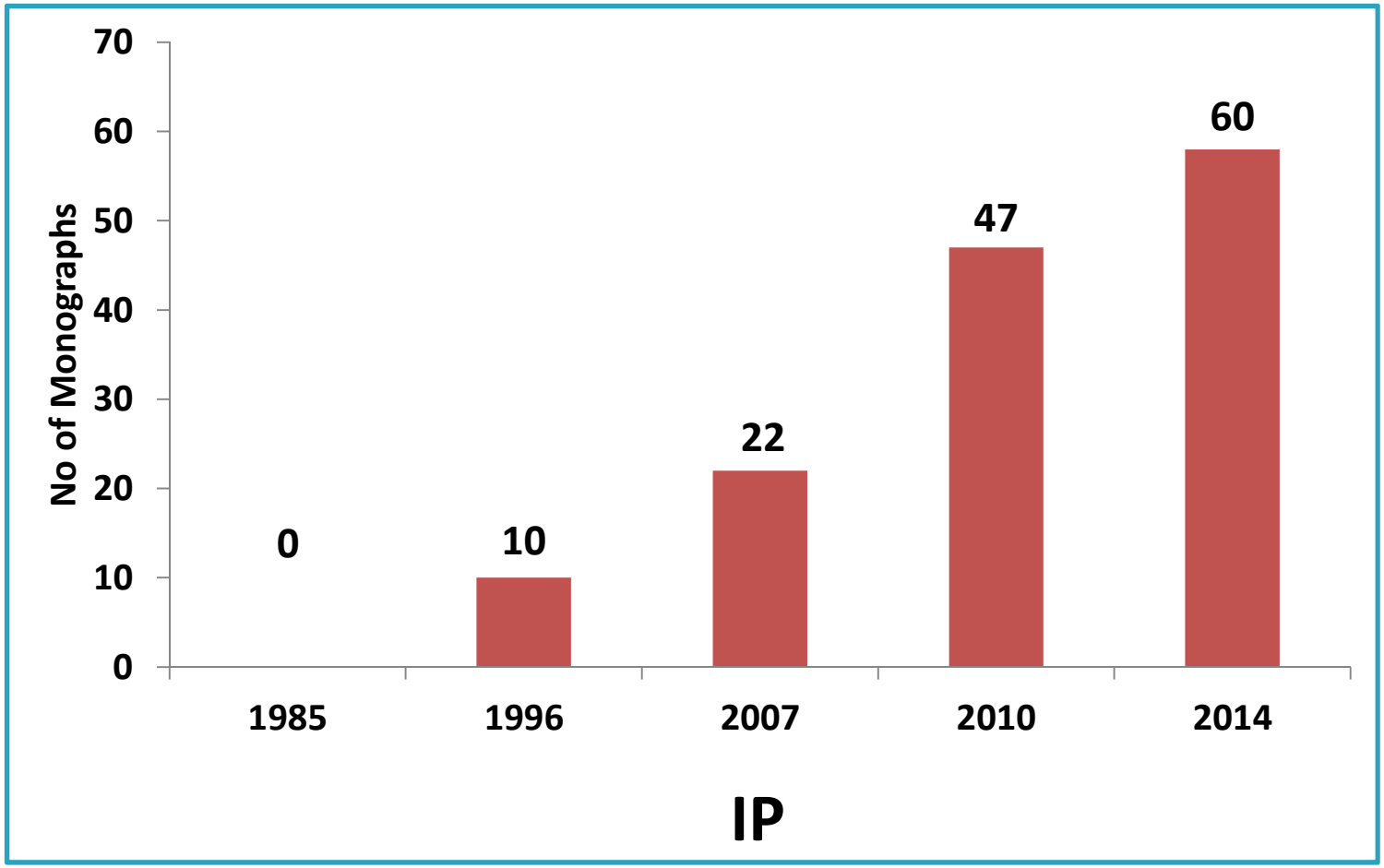
Monographs Developed



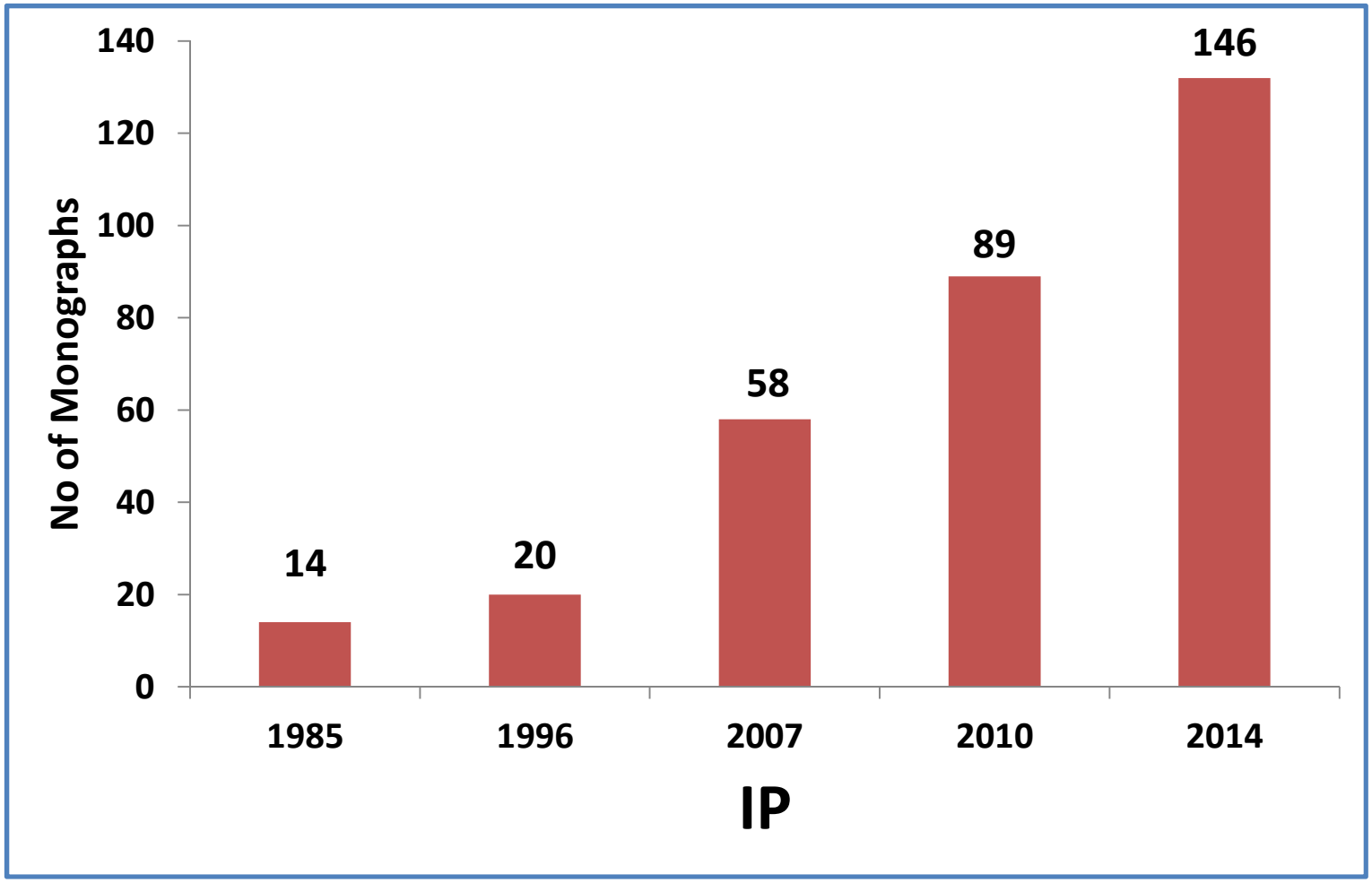
No. of Monograph for Anticancer



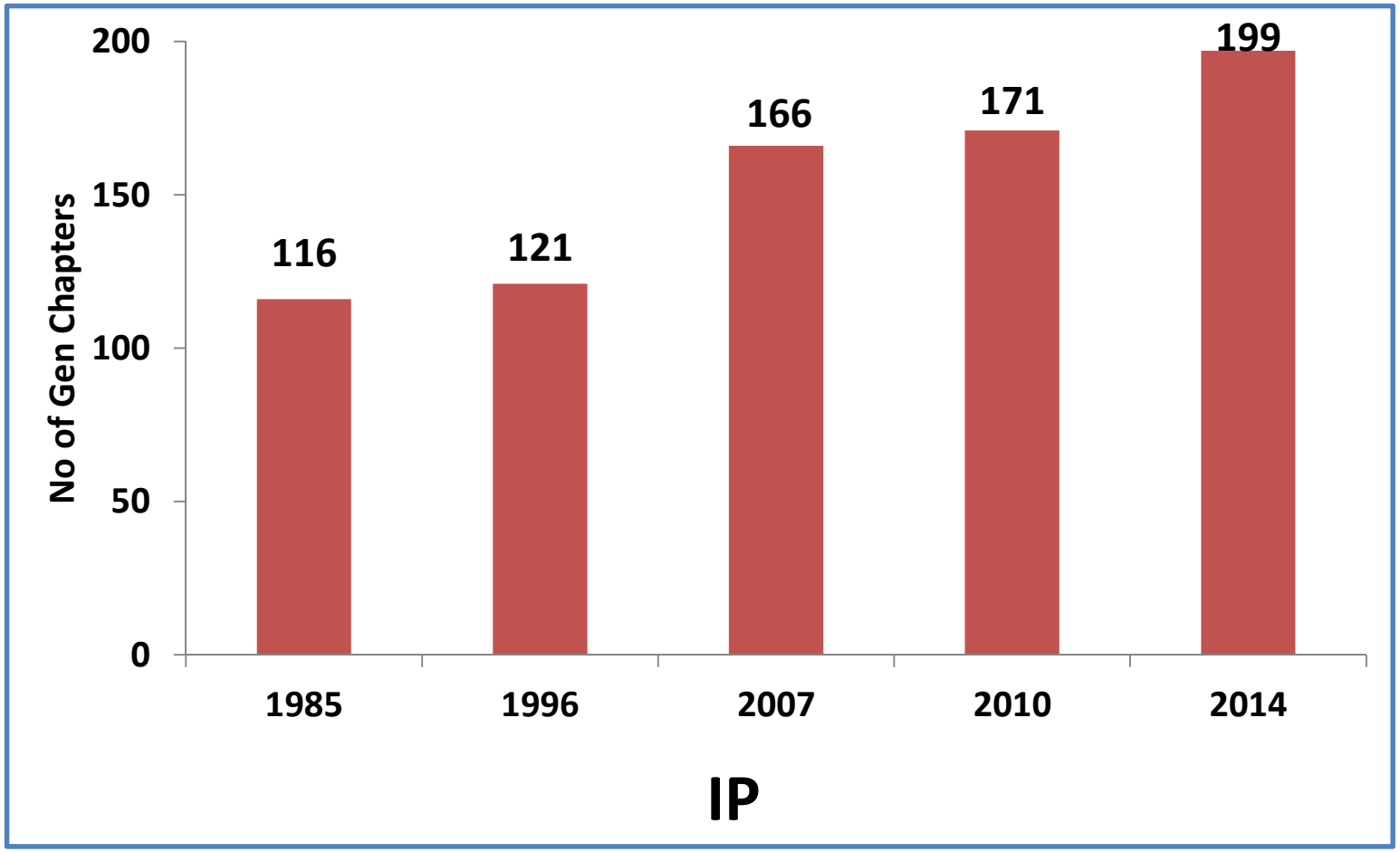
No. of Monographs for Antiretroviral



No. of Monograph for Herbal

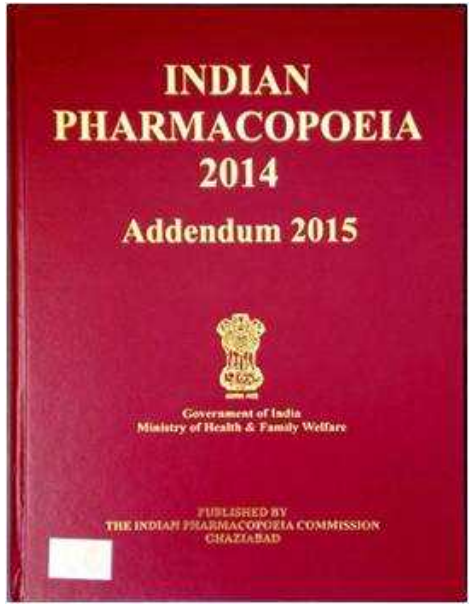


General Chapters



IP- Addendum-2015 to IP-2014

- 57 New Chemical monographs
- 13 New Herbal monographs
- 02 New Human Vaccines Monographs
- 10 Radiopharmaceutical Monographs
- 06 Revised monographs
- 29 Revised tests
- 20 New IR spectra



Addendum 2015 (Salient features)

- The Following monographs included in this addendum and not present in any other Pharmacopoeias.

S. No.	Monograph Name
1	Brimonidine Tartrate Eye Drops
2	Citicoline Prolonged release Tablet
3	Citicoline Sodium Tablets
4	Dutasteride Capsules

S. No.	Monograph Name
5	Eslicarbazepine Tablets
6	Illoperidone Tablets
7	Ketotifen Fumarate Tablets
8	Rabeprazole Injection
9	Tolterodine TartrateTablets

IP Addendum -2016

- 64 New Chemical Monographs
- 14 New Herbal Monographs
- 03 New Human Vaccines Monographs
- 03 Radiopharmaceutical Monographs
- 04 Biotechnology Products
- 01 Blood and Blood Products
- 18 New IR Spectra
- 12 TLC Chromatogram
- 20 HPLC Chromatograms

Addendum 2016 (Salient features)

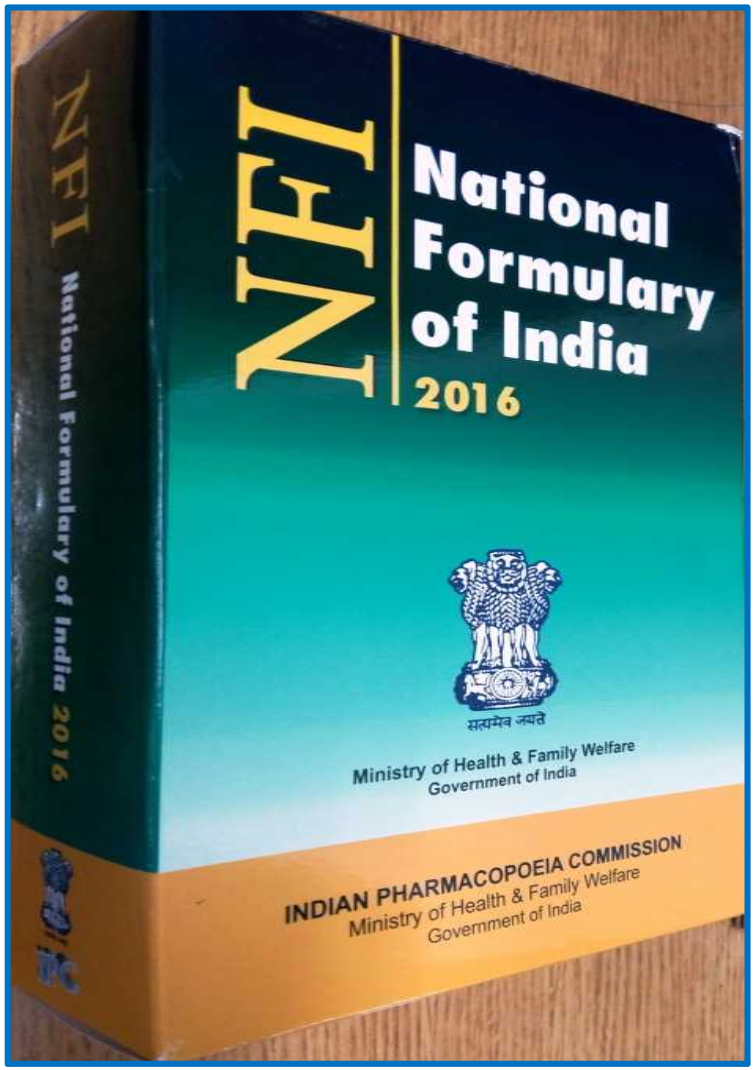
- The Following monographs incorporated in this addendum and not present in any other Pharmacopoeias.

S. No.	Monograph Name
1	Zolmitriptan Nasal Spray
2	Drotaverine Hydrochloride
3	Bendamustine Hydrochloride
4	Bendamustine Injection
5	Bortezomib Injection
6	Abiraterone Acetate
7	Pemetrexed disodium Injection

S. No.	Monograph Name
8	Teicoplanin Injection
9	Pirfenidone Tablets
10	Pirfenidone
11	Exemestane
12	Exemestane Tablets

Release of IP Addendum-2016 to IP-2014

National Formulary of India - 2016



National Formulary of India

- A guidance document to Medical Practitioners Pharmacist, Nurses, Medical and Pharmacy Students, other Healthcare Professionals and stakeholders in healthcare System.

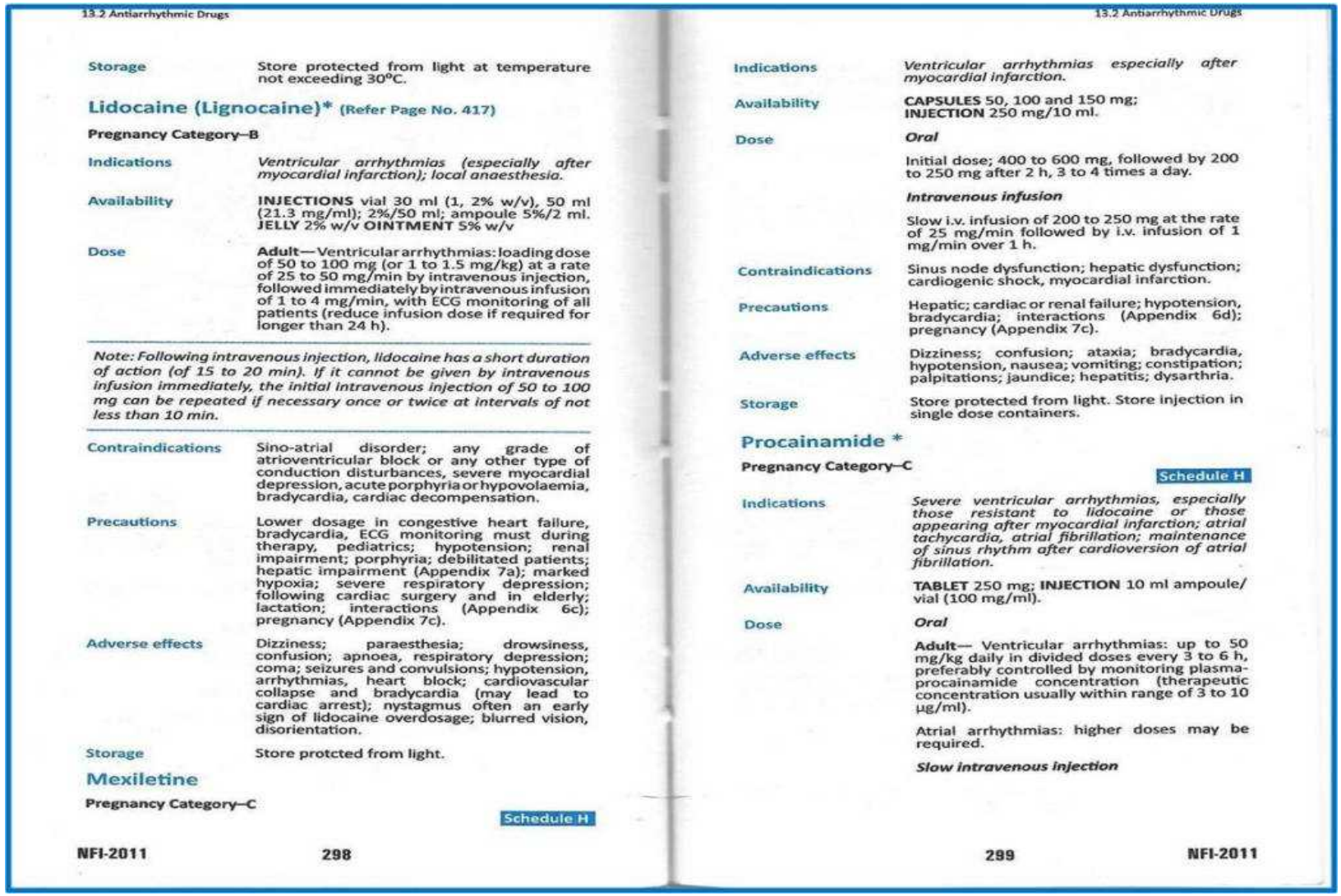
NFI- Special Features

- All drugs of **National List of Essential Medicines** (NLEM) 2011
- **New Chapters**:
  - Basics of medical emergencies
  - Drugs for oral health
  - Medicines banned in sports

NFI- Special Features

- Chapters 33
- Total drug monographs 521
- Fixed dose combinations (FDCs) 33
- Immunological 20
- Vitamins 12
- Unique, highly informative and useful Appendices 22

NFI- Monograph



Storage Store protected from light at temperature not exceeding 30°C.

Lidocaine (Lignocaine)* (Refer Page No. 417)

Pregnancy Category–B

Indications *Ventricular arrhythmias (especially after myocardial infarction); local anaesthesia.*

Availability **INJECTIONS** vial 30 ml (1, 2% w/v), 50 ml (21.3 mg/ml); 2%/50 ml; ampoule 5%/2 ml. **JELLY** 2% w/v **OINTMENT** 5% w/v

Dose **Adult**— Ventricular arrhythmias: loading dose of 50 to 100 mg (or 1 to 1.5 mg/kg) at a rate of 25 to 50 mg/min by intravenous injection, followed immediately by intravenous infusion of 1 to 4 mg/min, with ECG monitoring of all patients (reduce infusion dose if required for longer than 24 h).

Note: Following intravenous injection, lidocaine has a short duration of action (of 15 to 20 min). If it cannot be given by intravenous infusion immediately, the initial intravenous injection of 50 to 100 mg can be repeated if necessary once or twice at intervals of not less than 10 min.

Contraindications Sino-atrial disorder; any grade of atrioventricular block or any other type of conduction disturbances, severe myocardial depression, acute porphyria or hypovolaemia, bradycardia, cardiac decompensation.

Precautions Lower dosage in congestive heart failure, bradycardia, ECG monitoring must during therapy, pediatrics; hypotension; renal impairment; porphyria; debilitated patients; hepatic impairment (Appendix 7a); marked hypoxia; severe respiratory depression; following cardiac surgery and in elderly; lactation; interactions (Appendix 6c); pregnancy (Appendix 7c).

Adverse effects Dizziness; paraesthesia; drowsiness, confusion; apnoea, respiratory depression; coma; seizures and convulsions; hypotension, arrhythmias, heart block; cardiovascular collapse and bradycardia (may lead to cardiac arrest); nystagmus often an early sign of lidocaine overdosage; blurred vision, disorientation.

Storage Store protcted from light.

Mexiletine

Pregnancy Category–C

Schedule H

Indications *Ventricular arrhythmias especially after myocardial infarction.*

Availability **CAPSULES** 50, 100 and 150 mg; **INJECTION** 250 mg/10 ml.

Dose ***Oral***

Initial dose; 400 to 600 mg, followed by 200 to 250 mg after 2 h, 3 to 4 times a day.

Intravenous infusion

Slow i.v. infusion of 200 to 250 mg at the rate of 25 mg/min followed by i.v. infusion of 1 mg/min over 1 h.

Contraindications Sinus node dysfunction; hepatic dysfunction; cardiogenic shock, myocardial infarction.

Precautions Hepatic; cardiac or renal failure; hypotension, bradycardia; interactions (Appendix 6d); pregnancy (Appendix 7c).

Adverse effects Dizziness; confusion; ataxia; bradycardia, hypotension, nausea; vomiting; constipation; palpitations; jaundice; hepatitis; dysarthria.

Storage Store protected from light. Store injection in single dose containers.

Procainamide *

Pregnancy Category–C

Schedule H

Indications *Severe ventricular arrhythmias, especially those resistant to lidocaine or those appearing after myocardial infarction; atrial tachycardia, atrial fibrillation; maintenance of sinus rhythm after cardioversion of atrial fibrillation.*

Availability **TABLET** 250 mg; **INJECTION** 10 ml ampoule/ vial (100 mg/ml).

Dose ***Oral***

Adult— Ventricular arrhythmias: up to 50 mg/kg daily in divided doses every 3 to 6 h, preferably controlled by monitoring plasma-procainamide concentration (therapeutic concentration usually within range of 3 to 10 µg/ml).

Atrial arrhythmias: higher doses may be required.

Slow intravenous injection

NFI 2016 released by Hon'ble Health Minister at IPC on Nov 14th , 2015

Overview

- Indian Pharmacopoeia Commission
- Indian Pharmacopoeia and NFI
- Indian Pharmacopoeia Reference Substances (IPRS)
- International Cooperation
- International Harmonization
- Skill Developments Programs
- Way ahead 2020

Indian Pharmacopoeia References Substances (IPRS)

- A Reference Substances of the Indian Pharmacopoeia is only suitable for the intended use in the relevant monograph
- They are used by the regulatory agencies and Pharmaceutical manufactures to ensure identity, strength, quality and purity of the product as per official IP monograph

Process Flow of IPRS

Candidate material received

Preparation & approval of test protocol

Sampling as per designed protocol

Issuing of candidate material to concerned laboratory

Lab- 1 (IPL)

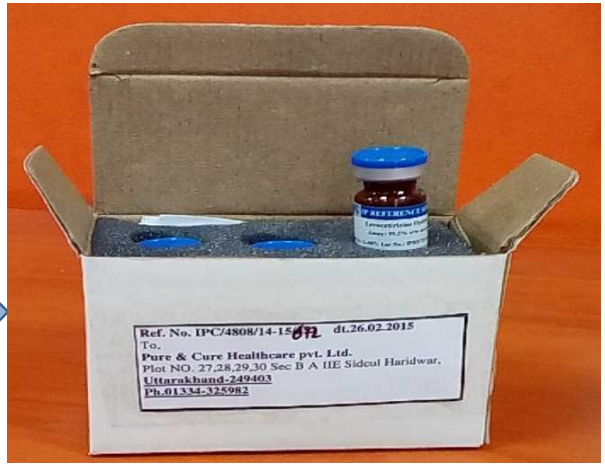
Lab- 2

Lab- 3

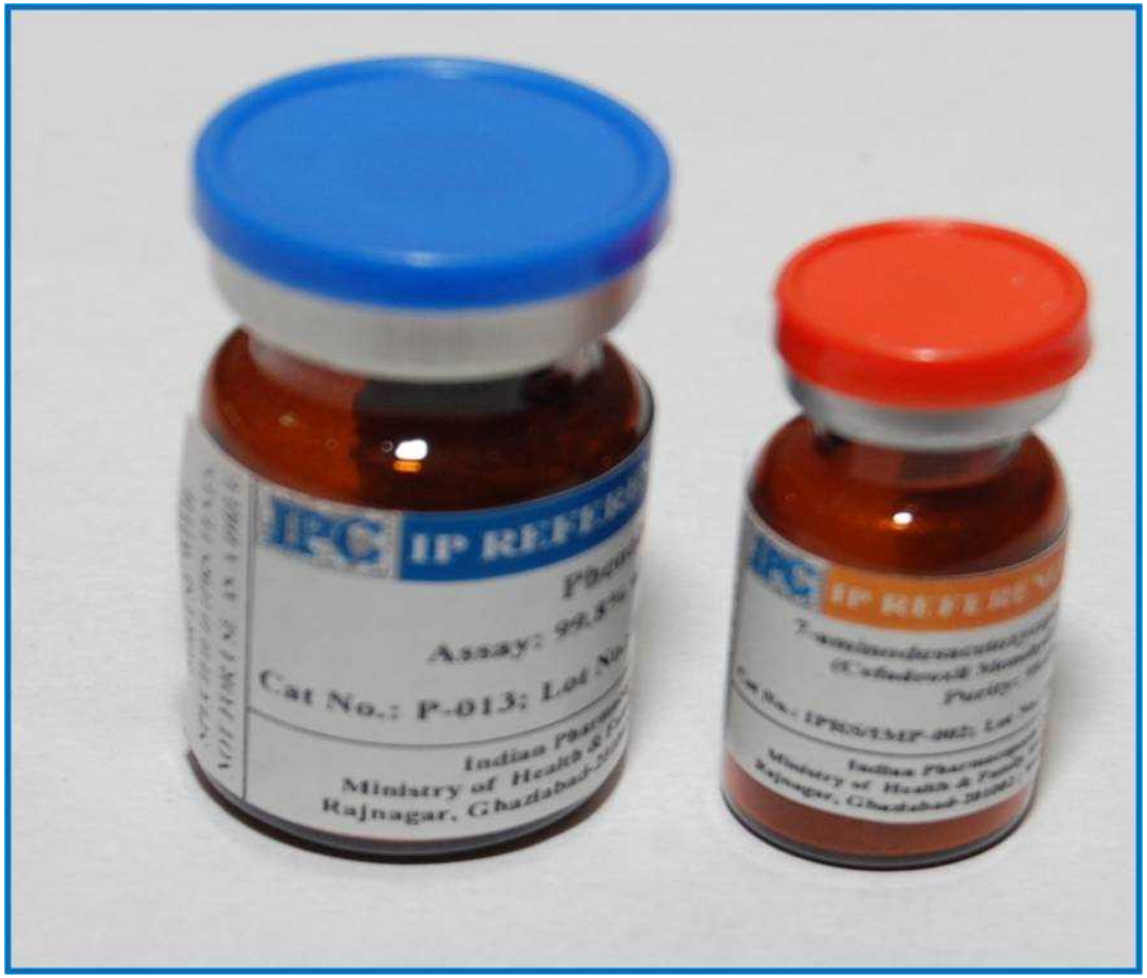
Data evaluation by Quality Control Laboratory Head

Review of data by Quality Assurance

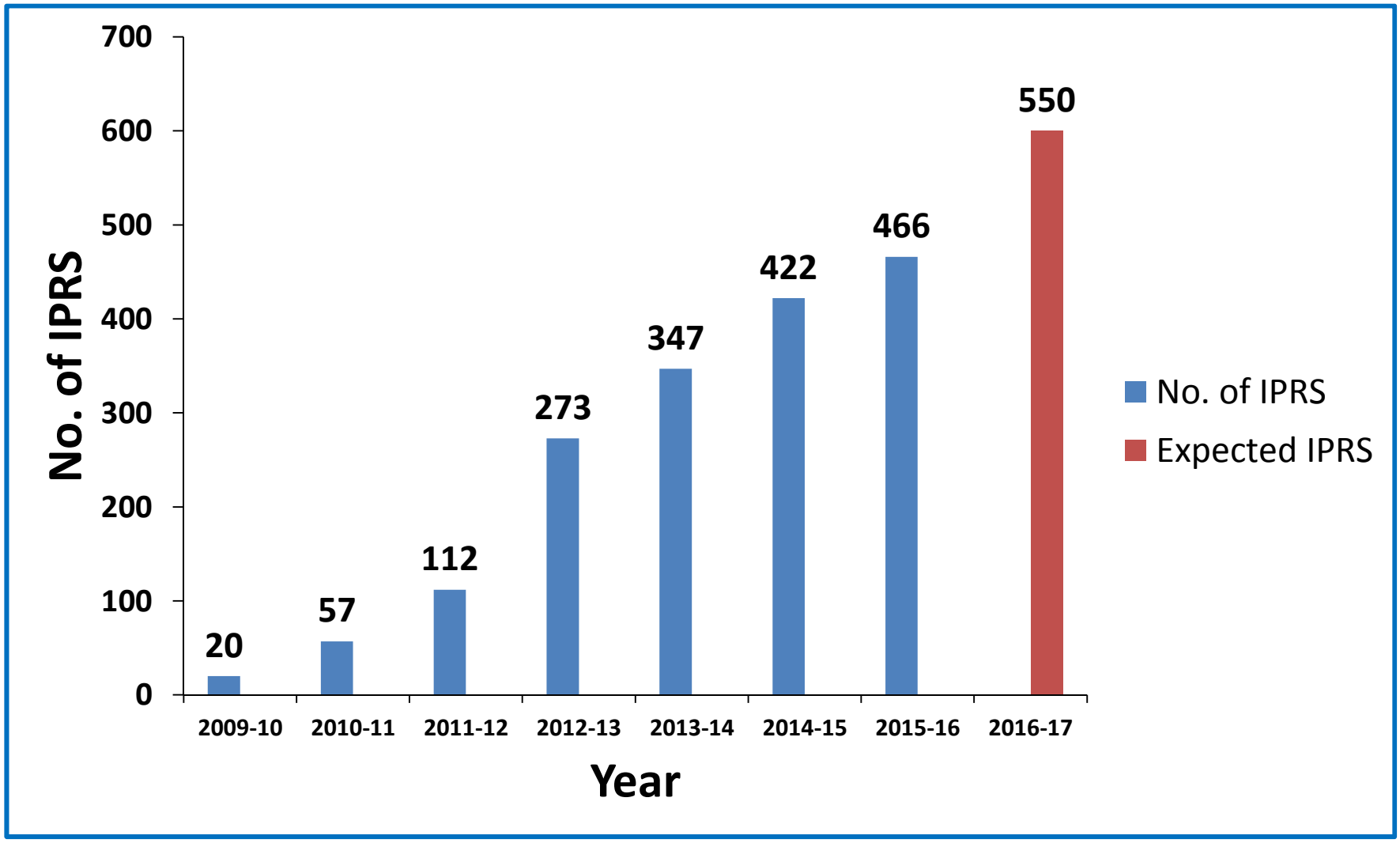
Final approval of Results of Analysis



IPRS & Impurity Standards



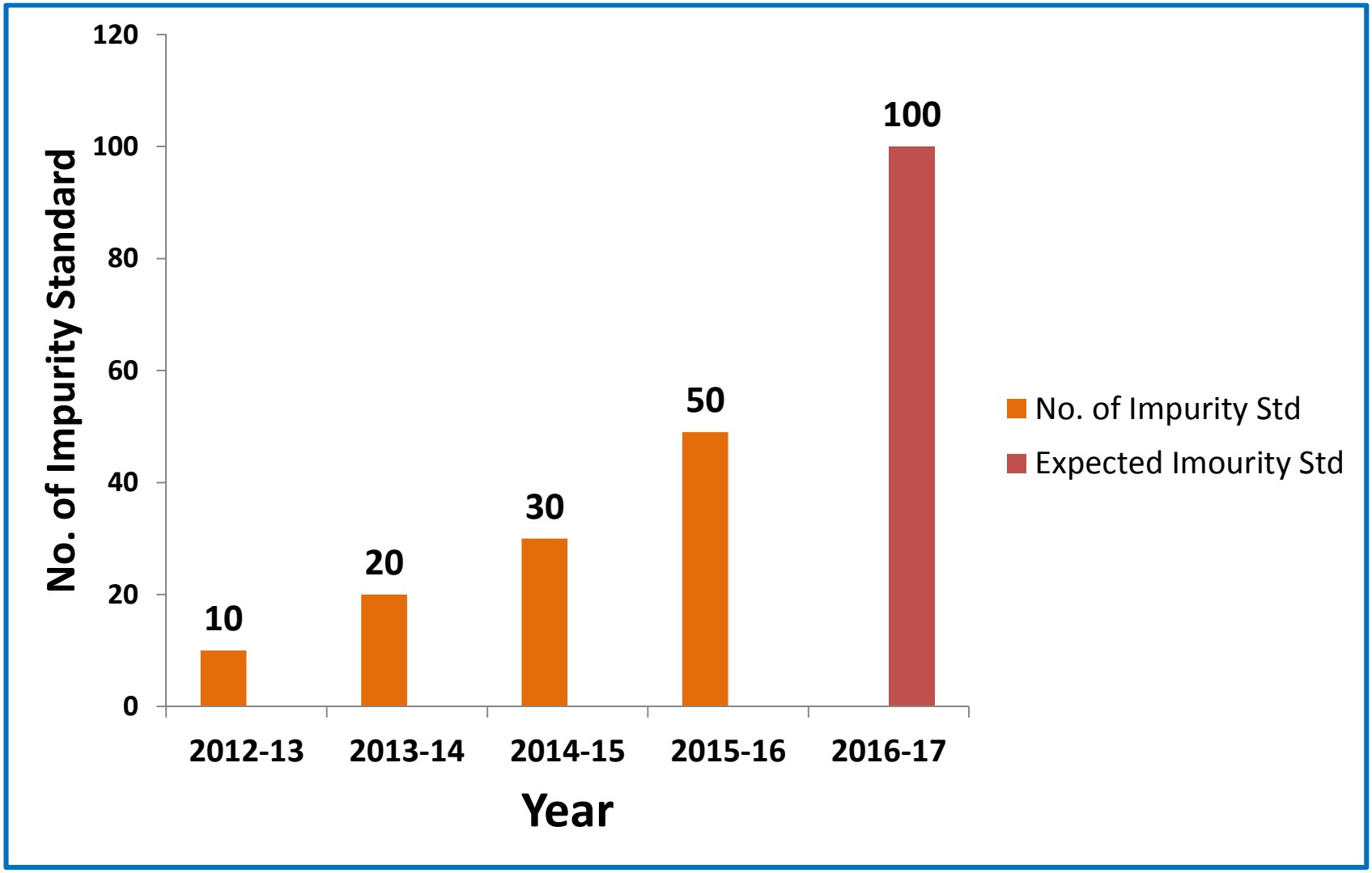
Availability of IPRS



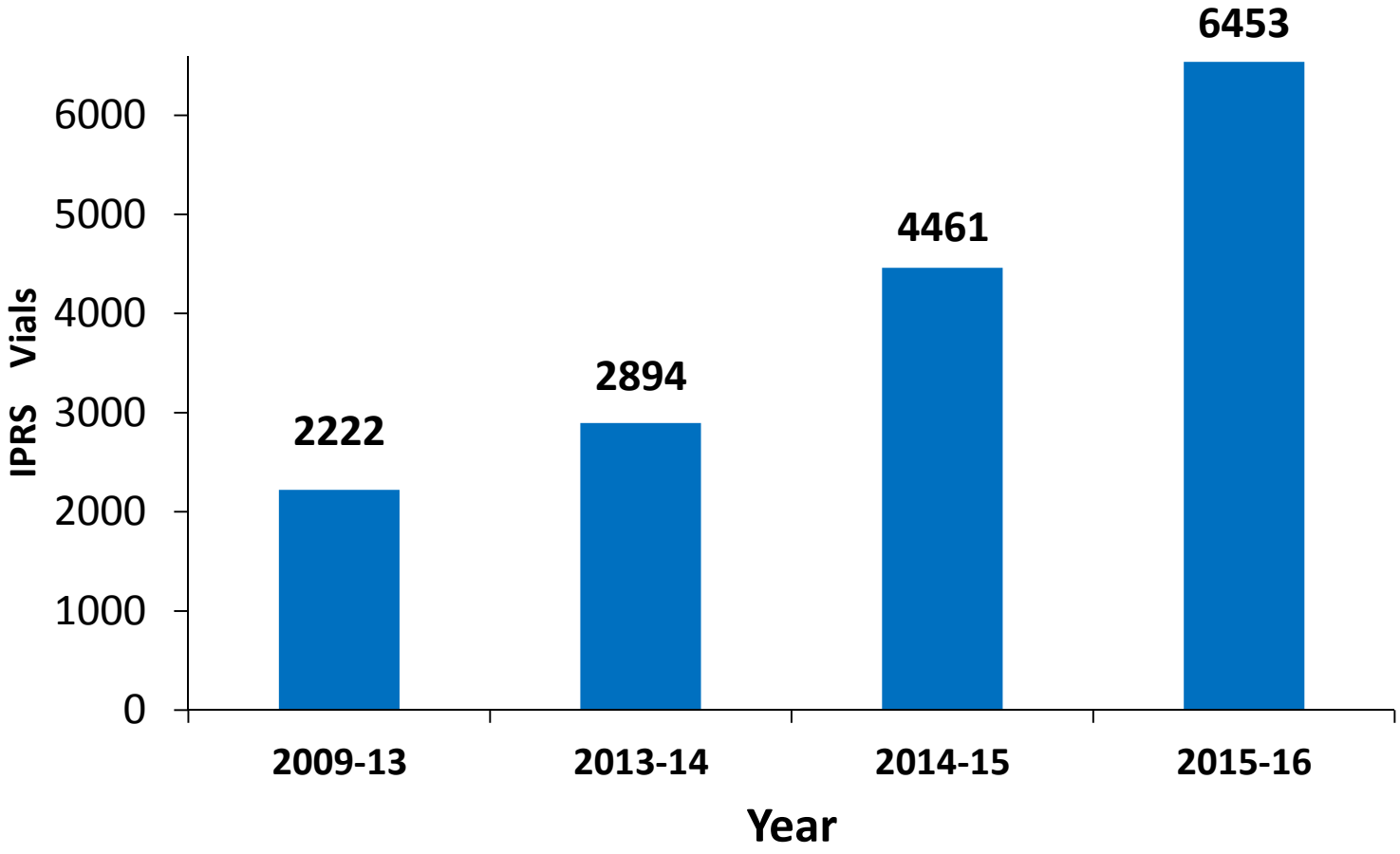
Launching of In-house Synthesized Impurity Standards

Launched on 3rd Dec. 2014 presence of Padmashree. Dr. Nitya Anand, Prof. B. Suresh, Prof. Lal Ji Singh and other SB Members & Sci. Staff. of IPC during 29th SB Meeting held in IPC.

Availability of Impurity Standards



Distribution of IPRS



Indian Pharmacopoeial Laboratory

- Indian Pharmacopeial Laboratory is fully equipped with modern Analytical Instruments

NMR (500 MHz)	Atomic absorption spectrometer
LC-MS/MS-QTOF	UV/Vis spectrophotometer
GC-MS Triple Quad	FT-IR Microscope spot light 200
GC-HS	TGA/DSC
CHNS-elemental analyzer	ICP-MS
Polarimeter	HPLCs , UPLCs
Ion chromatograph	Caulometric auto-titrator
Particle size analyzer	Dissolution test apparatus
Viscometer	Disintegration test apparatus
KF auto-titrator	

Instruments in IP Lab

IPRS Containerisation Machine

Indian Pharmacopoeial Laboratory

- **ISO Guide 34 : 2009** for “Reference Material Producer”
- **WHO** Pre-qualified for Quality Control Laboratory
- **ISO/IEC 17025:2005** Accredited for Chemical and Biological Analysis.

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International Cooperation

- World Health Organization (**WHO)**
- European Directorate for the Quality of Medicines **(EDQM)**
- **Japanese Pharmacopoeia (JP)**
- United States Pharmacopeia **(USP)**

International meeting of World Pharmacopoeias

- Active participation in World Pharmacopoeias Meetings for WHO Good Pharmacopoeia Practices (GPhP)
- Strengthening Global Pharmacopoeia Cooperation
- GPhP will enable transparency on development of Pharmacopoeial Standards

Second International Meeting of World Pharmacopoeias

18-19 April 2013, New Delhi, India

- Co-hosted by the **Indian Pharmacopoeia Commission** and **WHO**
- Discussion of DRAFT Good Pharmacopoeial Practices
- Stakeholders meeting: 19 April

2nd International Meeting of World Pharmacopoeias

International Meeting of World Pharmacopoeias

- 5th International Meeting of World Pharmacopoeias co-hosted by WHO & USP

  20-22 April, 2015 in Rockville, Maryland and Washington D.C.

- 6th International Meeting of World Pharmacopoeias co-hosted by Chinese Pharmacopoeia, China, 21-23 September, 2015

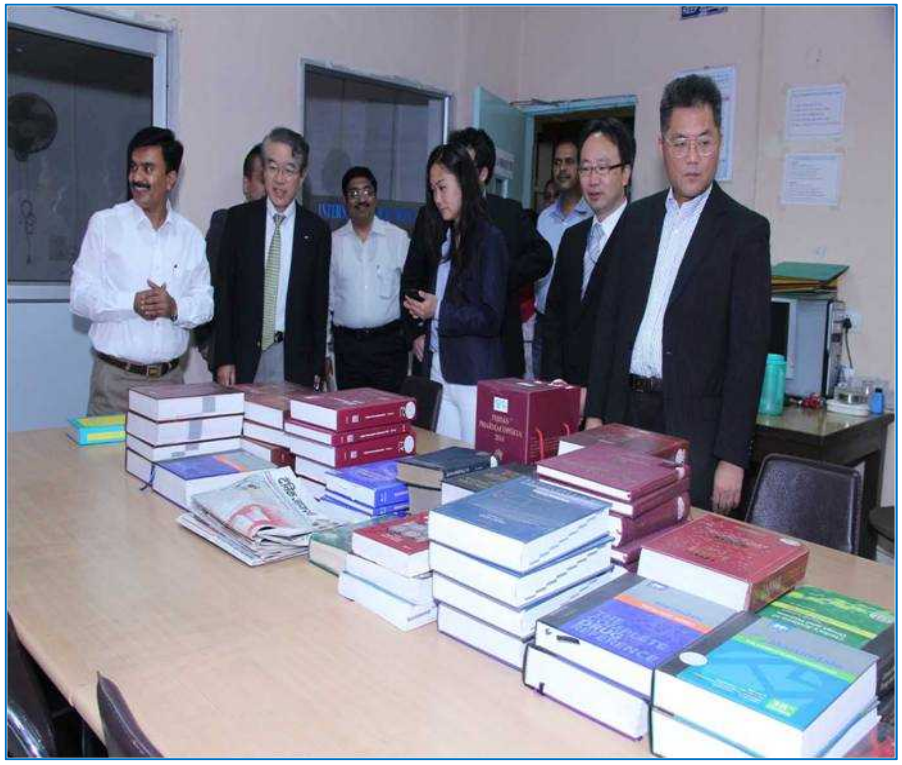
- 7th International Meeting of World Pharmacopoeias co-hosted by Japanese Pharmacopoea, Tokyo, Japan, Sept. 2016

6th International Meeting of World Pharmacopoeias

(**China-** Sept, 2015)

PMDA - IPC Meeting

- **PMDA (Japanese Pharmacopoeia) team visited IPC on 28th May 2015**



PMDA - IPC Meeting

Group photo of IPC and PMDA team

European Pharmacopoeia Observers- Meeting (Strasbourg, France - March, 2016)

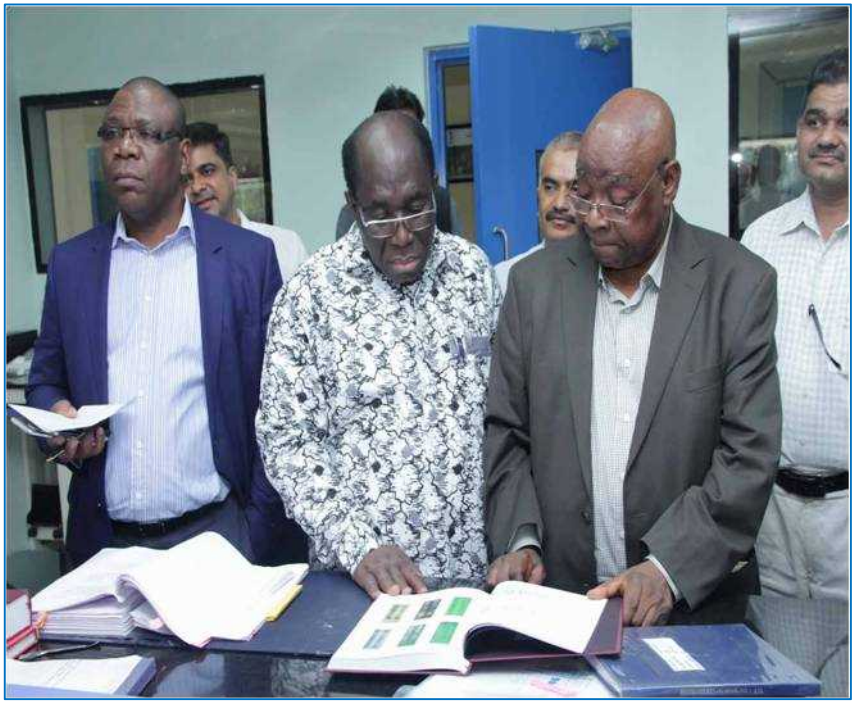
Skill Development Program for Overseas Professionals

2 Weeks Training Program for Medicine Control Laboratory Analysts from Mangolia to IPC Ghaziabad (16.11.2015 to 30.11.2015)

Skill Development Program for Overseas Professionals

High Level Ghana Delegation visited IPC on 25th April 2016

High Level Ghana Delegation visited IPC on 25th April 2016



International Cooperation

- Significant contribution in drafting Good Pharmacopoeial Practices, Chapters on Analytical Method Development, Validation & Herbal monographs

Overview

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International Harmonization

- Focusing to Harmonize General Chapters of IP with other World Pharmacopoeias
- Updating the monographs with new Science and Technology inputs
- Coordinating and contributing with WHO for Good Pharmacopoeial Practices for Chemical and Harbel Monographs
- Active participation in development of International Chemical Reference Standards organised by EDQM and WHO

Overview

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Skill Development

- IPC organizes skill development programs/ workshops for professional:
  - Analysts (Hands on training)
  - Drug Regulators
  - Research Students
  - Stakeholders

Skill Development

- Offers training for Analysts and Regulators from

  SAARC & ASEAN countries

- Offers support for Standards setting in Pharmaceuticals

Skill Development

S. No.	Participants	No. of Trainings /workshops		No. of Participants
1	Drug Analyst	Trainings	**5**	213
2	Drug Inspector	Trainings	**3**	113
3	Assistant Drug Controller	Training	**1**	14
4	Stakeholders	Workshop	**2**	395
5	Quality Analysts **(Mongolia)**	Technical Study Tour/Training	**1**	6
6	Government Analyst	NABL Training	**3**	83

Skill Development

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Way Ahead: 2020

- Targeting for 800 IPRS.
- Targeting 300 Impurity Standards
- Enhancing the scope of **Green** Analytical Chemistry.
- Establishing regional offices in Pharma-major Indian Cities like Ahmadabad , Mumbai, Hyderabad, Bangalore and Chennai etc.
- Establishing the State-of-the-art laboratory as Referral Laboratory for Analytical investigations.

Way Ahead: 2020

Advanced Level Research Center :

Hon'ble Health Minister Sh. J. P. Nadda laid the foundation stone of Advanced Level Research Center at IPC in presence of Gen. (Dr.) V. K. Singh, Minister of State, Dr. (Prof.) Jagdish Prasad DG & Dr. G. N. Singh

Way Ahead: 2020

- **To make functioning the Advanced Level Research Center by 2017**

Expectations form PMDA

- IPC offers Indian Pharmacopoeia as a trustworthy Reference Pharmacopoeia to PMDA and expects it to be utilize for ensuring the Quality of Pharmaceuticals in Japan.

Proposal for Cooperation Between IPC & PMDA

- Mutual cooperation for developing the Pharmaceutical Standards.
- Bilateral cooperation on skill development of Professionals including training for the trainers.
- Knowledge sharing for mutual benefit and opening new areas of collaboration.

- For any queries kindly visit us at

www.ipc.gov.in

❖

- or email at

ipclab@vsnl.net

Thank you !!

ありがとうございました