Pharmacopoeial Discussion Group (PDG) stakeholder event - The PDG is going global

Update on PDG

Moderator: Petra Doerr, EDQM, Council of Europe

Update on PDG

PDG overview, history and latest news

Dirk LEUTNER, EDQM, Council of Europe

PDG Overview and History

Latest News

Dirk LEUTNER

PDG stakeholder event

3 October 2024

Outline

- **PDG Overview and History**
- **PDG recent Strategic Reforms**
  - Pilot for Global Expansion with IPC as new PDG Member
  - Next Phase of PDG Expansion

- **Latest News:**
  Meeting Highlights PDG Annual Meeting 2024

Why do we need harmonization?

If each country/region has own pharmaceutical regulation without harmonisation….

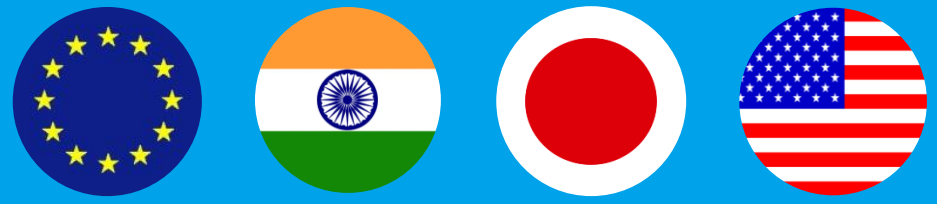
- Pharmaceutical products approved in one country/region that are sold in other countries/regions must meet the quality standards recognized in those countries/regions
- Must conduct similar redundant tests in each country/region, adding no value to the patient or public health

Pharmacopeial Harmonisation

→ can align test methods and specifications to a common quality standard

The Pharmacopeial Discussion Group (PDG)

- **Began as an informal group in 1989**; participants include USP, EP, IPC, and JP
  - ★ IPC joined as member in 2023
  - ★ WHO joined as observer in 2001
- Focuses on selected official, broad-impact General Chapters and excipient monographs
- Eliminates/minimises need to perform multiple tests and procedures and to comply with multiple acceptance criteria for the same article
- Detailed process, with specific stages and terminology
- One face-to-face meeting a year, with a video conference in the interim



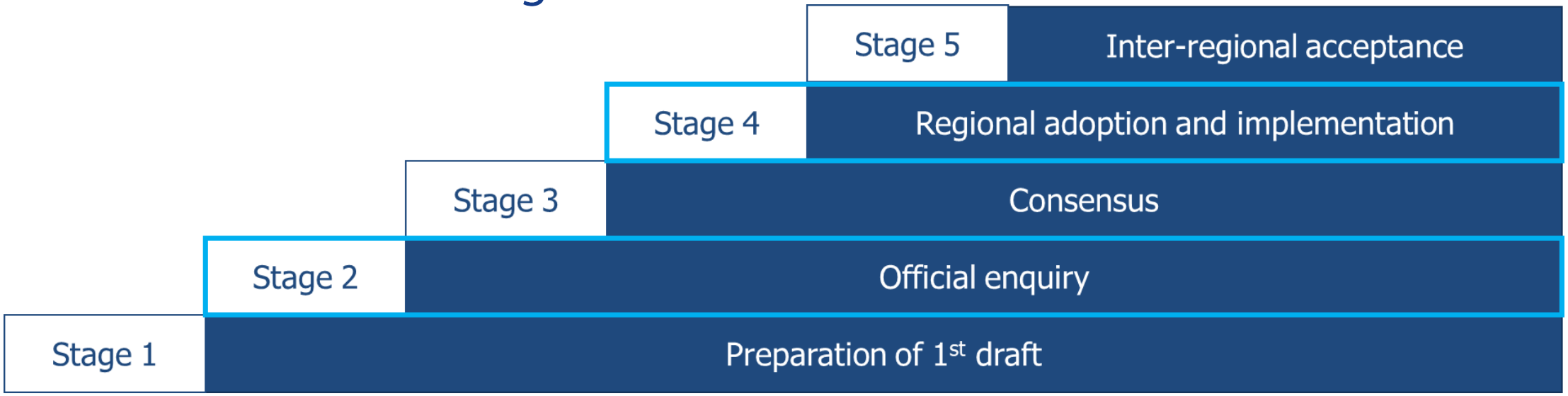
EP (EDQM) **IPC** **JP** (MHLW /PMDA) **USP**

PDG Mission

To harmonize pharmacopeial standards while maintaining a constant level of science with the shared goal of protecting public health.

PDG Harmonization Process

- PDG is an **informal body** but has a formal process
- **Fully embedded in local procedures**, e.g. through public consultation in each region



How PDG works for harmonisation?

Definition of Harmonisation:
A pharmacopeial general chapter or other pharmacopeial document is harmonized when a pharmaceutical substance or product tested by the harmonized procedure as published in PDG Pharmacopeias yields the same results, and the **same accept/reject decision** is reached.

- **Text does NOT have to be identical**
- Each Pharmacopeia can adapt the text to **local style**, and take into consideration of **local reference standards and reagents**

Harmonisation Process of PDG:

- Harmonisation occurs based on decisions of expert bodies of each pharmacopeia.
- PDG works transparently in many ways principally including public notice and comment procedures of each pharmacopeia.
- Each pharmacopoeia does not revise unilaterally after harmonization. When necessary, revision should be conducted according to the PDG Working Procedures.

PDG Policies and Working Procedure: https://www.usp.org/harmonized-standards/pdg

Harmonization by Attributes:
How PDG move forward

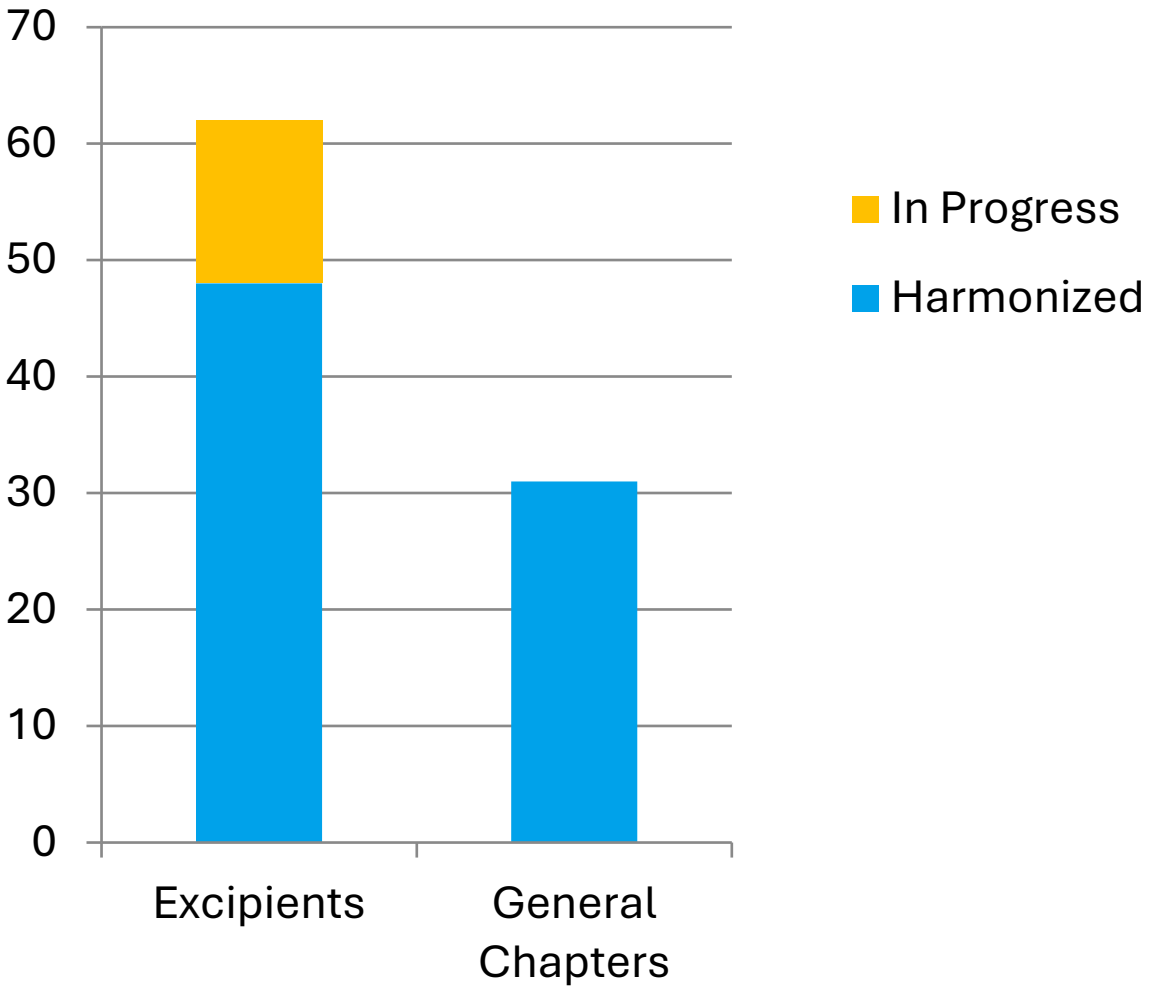
For the first 12 years of PDG, **zero** monographs or General Chapters were harmonised!

Harmonisation by Attribute was introduced as an acknowledgement that certain attributes simply cannot be harmonised because of:

- ★ (1) Differing **regulatory** or **legal** requirements
- ★ (2) **Non-harmonised** methodology for procedures
- ★ (3) Differences in **scientific** expert opinions

Acknowledgement that partial harmonisation is preferred to no harmonization!

PDG work plan – many success stories



All 31 General Chapters harmonised!

PDG work Program: General Chapters

General Methods Relevant to Q6A:

Q-01 Dissolution*3
Q-02 Disintegration*3
Q-03/04 Uniformity of Content/Mass
Q-05a Tests for Specified Microorganism
Q-05b Microbial Enumeration
Q-05c Limits for Non-sterile Products
Q-06 Bacterial Endotoxin
Q-07 Color (Instrumental Method)
Q-08 Extractable Volume*3
Q-09 Particulate Contamination*3
Q-10 Residue on Ignition
Q-11 Sterility Test

General Chapters:

G-01 Analytical Sieving*3
G-02 Bulk Density and Tapped Density
G-03 Conductivity
G-04 Gas Pycnometric Density of Solids
G-05 Powder Flow
G-06 Tablet Friability
G-07 Elemental Impurities*2
G-09 Optical Microscopy*3
G-10 Powder Fineness
G-11 Specific Surface Area
G-13 Laser Diffraction Measurement of Particle Size*3

General Chapters:

G-14 X-Ray Powder Diffraction
G-15 Water-solid Interaction
G-16 Thermal Analysis*3
G-20 Chromatography*1
G-21 Dynamic Light Scattering*1

Methods for Biotechnology Products:

B-01 Amino Acid Determination
B-02 Capillary Electrophoresis*3
B-03 Isoelectric Focusing
B-05 Peptide Mapping
B-06 Polyacrylamide Gel Electrophoresis

*1 : Signed-Off in 2021-2023
*2 : Recent Sign Off in 2024
*3 : Under revision

All 31 general chapters have now been harmonised!

PDG work Program: Excipients

E-01 Alcohols
E-02 Dehydrated Alcohol
E-03 Benzyl Alcohol
E-04 Calcium Disodium Edetate*3
E-05 Calcium Phosphate Dibasic
E-06 Calcium Phosphate Dibasic Anhydrous
E-07 Carmellose Calcium
E-08 Carmellose Sodium*2
E-09 Croscarmellose Sodium*3
E-10 Microcrystalline Cellulose
E-11 Cellulose, Powdered
E-13 Cellulose Acetate Phthalate
E-14 Citric Acid, Anhydrous
E-15 Citric Acid, Monohydrate
E-16 Crospovidone
E-17 Ethylcellulose
E-18 Hydroxyethylcellulose*3
E-19 Hydroxypropylcellulose
E-20 Hydroxypropylcellulose, Low Substituted
E-21 Hypromellose
E-22 Hypromellose Phthalate
E-23 Lactose, Anhydrous*3
E-24 Lactose, Monohydrate*3
E-25 Magnesium Stearate
E-26 Methylcellulose
E-27 Methyl Paraben
E-28 Petrolatum*1
E-29 Petrolatum, White*1
E-30 Polyethylene Glycol*2
E-31 Polysorbate 80*3
E-32 Povidone*3
E-36 Silicon Dioxide*2
E-37 Silicon Dioxide, Colloidal*2
E-38 Sodium Chloride
E-39 Sodium Starch Glycolate
E-40 Starch, Corn
E-41 Starch, Potato
E-42 Starch, Rice
E-43 Starch, Wheat
E-44 Stearic Acid
E-45 Sucrose*3
E-46 Talc *3
E-48 Ethyl Paraben
E-49 Propyl Paraben
E-50 Butyl Paraben
E-51 Glycerin*2
E-52 Carmellose
E-54 Copovidone*3
E-55 Gelatin
E-56 Sucrose
E-58 Mannitol
E-59 Propylene Glycol*2
E-60 Sodium Laurylsulfate
E-61 Starch, Pregelatinized*2
E-62 Sterile Water for Injection*2
E-64 Isomalt
E-65 Isostearyl Alcohol*2
E-66 Myristyl Myristate*2
E-68 Polysorbate 65*2
E-69 Calcium Silicate*2
E-70 Polysorbate 20*2
E-71 Purified Water*2

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*2 : Under discussion towards first harmonization
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48 of the 62 excipient monographs have now been harmonized

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- **Latest News:**
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Future of PDG: three strategic discussions

- The PDG is currently investigating and engaging in three strategic discussions designed to enhance the global reach and impact of international harmonisation of quality standards:
  - ★ **Engagement with Regulators**
  - ★ **Engaging Industry**
  - ★ **Engagement of other Pharmacopeias:** The PDG is working on ways to further improve interactions with other pharmacopoeias (e.g. Sharing PDG publications with IMWP, PDG membership expansion)

Global Expansion of PDG – Pilot Phase 2022 - 2023

- **2021** Landmark decision by PDG to **launch a pilot** for the first expansion of membership in 32 years.
- **Global Pharmacopeias** interested were **invited** to submit applications to evaluate against objective entry criteria
- 2022-2023 IPC became a **regular participant** in all PDG activities **for one year**
- October 2023: **IPC new 4th member**

October 3, 2023: A historical date for PDG!

Based on Evaluation by Established Members of PDG

- IPC met all objective criterial for participation in PDG activities
- PDG Performance maintained consistent level of quality during Pilot Period

New members will implement all finalised harmonised texts (31 general chapters and 48 excipient monographs)

October 2023-June 2024: **PDG discussed lessons learned and next steps**

PDG launched a new global membership expansion initiative

Newsroom

PDG announces global membership initiative

EDQM | STRASBOURG, FRANCE | 30/08/2024

The Pharmacopoeial Discussion Group (PDG) is excited to announce the launch of the next phase of its global expansion initiative aimed at increasing convergence of harmonised pharmacopoeial standards. This initiative will be the start of a process over the next couple of years to welcome additional pharmacopoeias as new members.

Pharmacopoeias interested in becoming members are encouraged to review the entry criteria, framework and reference information. They are required to submit a statement of intent to the PDG by 15 September 2024 and the formal application by 31 December 2024.

Founded in 1989, the PDG brings together pharmacopoeias to harmonise excipient monographs and selected general texts. Last year, the founding members – the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP) – welcomed the Indian Pharmacopoeia Commission (IPC) as the fourth member. The IPC joining the PDG marked the culmination of a pilot programme launched in 2022 which laid the groundwork for this global initiative.

The PDG has successfully harmonised and maintains 31 general chapters, including key analytical procedures such as chromatography, dissolution testing, sterility and microbiological examination. In addition, the PDG has harmonised 48 excipient monographs and has approximately 20 new texts in its pipeline (general chapters, excipients). The PDG remains committed to promoting the recognition of harmonised pharmacopoeial standards to achieve global convergence.

The PDG invites all interested world pharmacopoeias to visit the website for further information regarding the PDG and

- PDG sent an invitation to world pharmacopoeias in July 2024
- PDG press release announcing scheme published 30 August 2024
- Possible applicants were asked:
  - to submit application documents **by 31 December 2024.**

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Latest News: PDG annual meeting 2024

- **PDG expansion – opening up to other pharmacopoeias**
- **Update PDG working procedure**
- **ICH Q4B: subsequent maintenance of all annexes**
  - Interaction with 7 other pharmacopoeias and 17 regulatory ICH members
- **Exchanges and discussions on developments for important topics**
  - Nitrosamines
  - Bacterial Endotoxin Testing
  - Reflections on impact of developments for ICH Q6 revision

Latest News: PDG work programme 2024

- **Sign-Off of G-07 Elemental Impurities**
  - **Completion of elaboration of all 31 General Chapter**
- **Other sign-offs**
  - Corn Starch (revision 4)
  - Amino Acid Determination (correction)
  - Bulk density of Powders (correction)
- **First sign-offs by the Indian Pharmacopoeia Commission**

Thank You for Your Attention

Update on PDG

PDG & ICH Q4B maintenance

Kevin MOORE, US Pharmacopeia (USP)

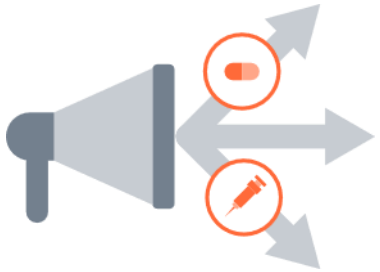
PDG Interaction with Other International Organizations

PDG Stakeholder Event
October 3, 2024
Strasbourg, FR

Outline

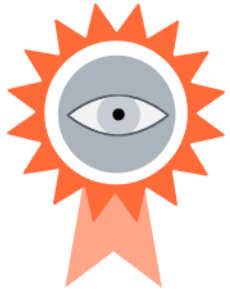
- Value of Pharmacopeial Collaboration and Harmonization
- Interaction with other Multilateral Organizations
  - International Council on Harmonisation (ICH)
  - International Meeting of World Pharmacopoeias (IMWP)

The Value of Effective Pharmacopeial Collaboration



PROMOTE

Access to Quality medicines leveraging global expertise



INCREASE

Value of public quality standards

FACILITATE

Global access to state of the industry technology

PRIORITIZE

Balance current paradigms and future trends

ENABLE

Global pharmaceutical trade

PDG and pharmacopeial challenges

- Public health is **global issue**
- **Burden and costs** for stakeholders of need to comply with parallel standards.
- **Changing regulatory landscape** with expanded ICH membership, but still reduced outreach of the PDG
- How can **resources** be **balanced** with **impact?**
- - PDG is expanding
- - PDG is looking for increased exchanges with all interested pharmacopoeias (Q4B, IMWP)

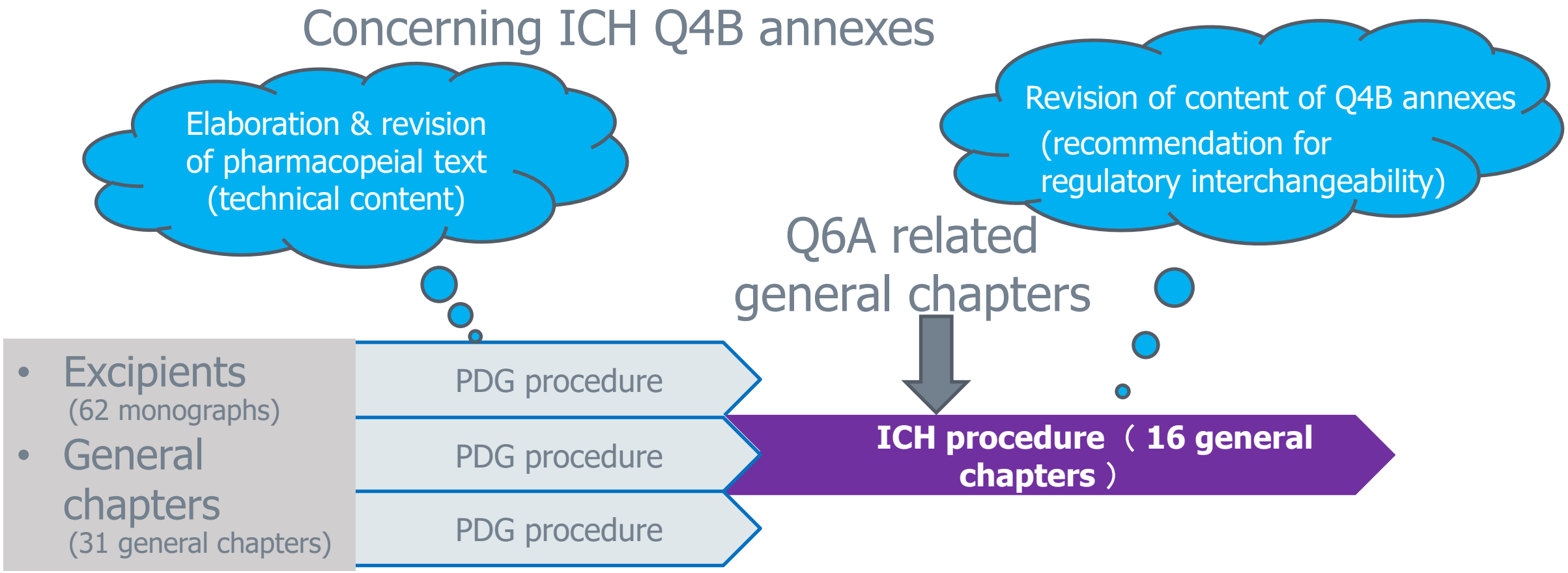
ICH Q4B Executive Summary

PDG (since 1989)		ICH Q4B (2003 – 2010)
Ph. Eur. (EDQM), JP (MHLW/PMDA), USP (USP), IP (IPC, since 2023)	Participant	Regulatory: EC, MHLW/PMDA, FDA Industry: EFPIA, JPMA, PhRMA
Harmonisation of Science (Analytical method, Acceptance Criteria)	Activity	Regulatory Harmonisation Regulatory Acceptance for use
31 general chapters, 62 monographs	Target	16 general chapters
Harmonised pharmacopoeial texts	Outcome	Guideline = Recommendation for regulatory use in the ICH regions

- **ICH Q4B annexes cover 16 harmonised pharmacopoeial general chapters** and were elaborated following an evaluation by ICH of the corresponding texts
- Once in agreement as **interchangeable**, the result was published as an annex to the ICH guideline
- ICH regulatory members are recommended to **accept references to all mentioned pharmacopoeias** in marketing authorisation dossier.

Clarification of scope of Q4B and its annexes

- **Declarations of Interchangeability by ICH regulatory members**
- **Relevant for pharmacopoeias from ICH regulatory members**



Why a new maintenance procedure?

- **ICH has grown**
- 4 ➔ 17 regulatory members
- 3 ➔ 10 involved pharmacopoeias
- **Pharmacopoeial texts have evolved**

ICH regulatory member	Pharmacopoeia
ANMAT, Argentina	Argentinian Pharmacopeia
EC, Europe	European Pharmacopoeia (Ph. Eur.)
FDA, United States	United States Pharmacopeia (USP)
PMDA/MHLW, Japan	Japanese Pharmacopoeia (JP)
Health Canada	-
Swissmedic, Switzerland	European Pharmacopoeia (Ph. Eur.)
ANVISA, Brazil	Brazilian Pharmacopoeia (FB)
COFEPRIS, Mexico	Mexican Pharmacopoeia (FEUM)
EDA, Egypt	Egyptian Pharmacopoeia
HSA, Singapore	-
JFDA, Jordan	-
MFDS, Republic of Korea	Korean Pharmacopoeia (KP)
MHRA, UK	European Pharmacopoeia (Ph. Eur.)
NMPA, China	Chinese Pharmacopoeia (ChP)
SFDA, Saudi Arabia	-
TFDA, Chinese Taipei	Taiwan Pharmacopoeia (TWP)
TITCK, Türkiye	European Pharmacopoeia (Ph. Eur.)

Maintenance of Q4B Annexes

Founding Regulatory Members: EC, Europe; FDA, United States; MHLW/PMDA, Japan;
Standing Regulatory Members: Health Canada, Canada*; Swissmedic, Switzerland**
* No active Ph. – ** member of the Ph. Eur.

Regulatory Members: ANVISA, Brazil; HSA, Singapore*; MFDS, Republic of Korea; NMPA, China; TITCK, Turkey**, TFDA, Chinese Taipei; MHRA, UK**, SFDA, Saudi Arabia*, COFEPRIS, Mexico; EDA, Egypt; ANMAT, Argentina; JFDA, Jordan*

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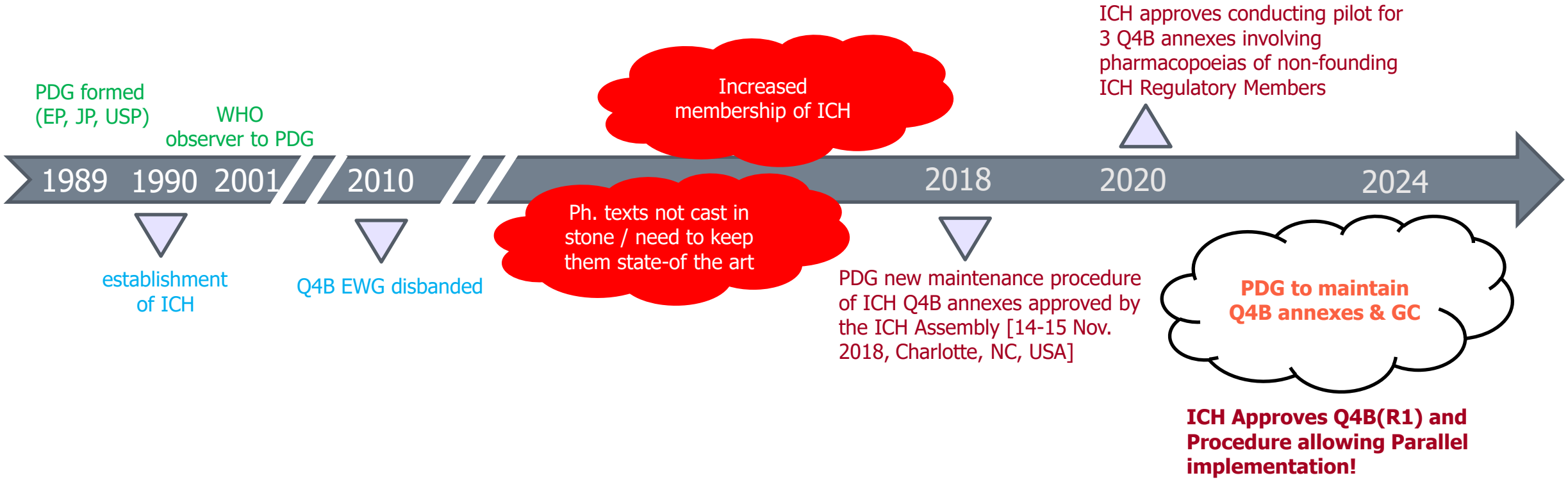


Next steps

- PDG will **update all 16 Q4B annexes subsequently** together with ICH
- maintenance will be triggered by

  1) revision of the PDG text

  2) new involved pharmacopoeia having harmonised its text
- This work aims for **regulatory interchangeability** of **16 important pharmacopoeial texts** between **10 pharmacopoeias involving all ICH regulatory members**

International Meeting of World Pharmacopoeias (IMWP)

- **Started in 2012**, meetings organised by WHO together with host
- **for all interested world pharmacopoeias**
- **Yearly face-to-face meetings** to exchange on on-going topics (meetings in 2021-2022 as videoconference); usually **15-30 representatives**
- Elaboration of **Good Pharmacopoeial Practices (GPhP)**
- "**pharmacopoeial alert system**" – nitrosamines and work on Favipiravir IMWP monograph
- **Next meeting 5-7 February 2025, New Delhi, India**

Goals for IMWP

Establish a common framework for pharmacopoeial standard-setting

Harmonize approaches and policies

Create a guiding set of principles for appropriate, design, development, maintenance, publishing and distribution of pharmacopoeial standards

Strengthen collaboration and exchange among pharmacopoeias

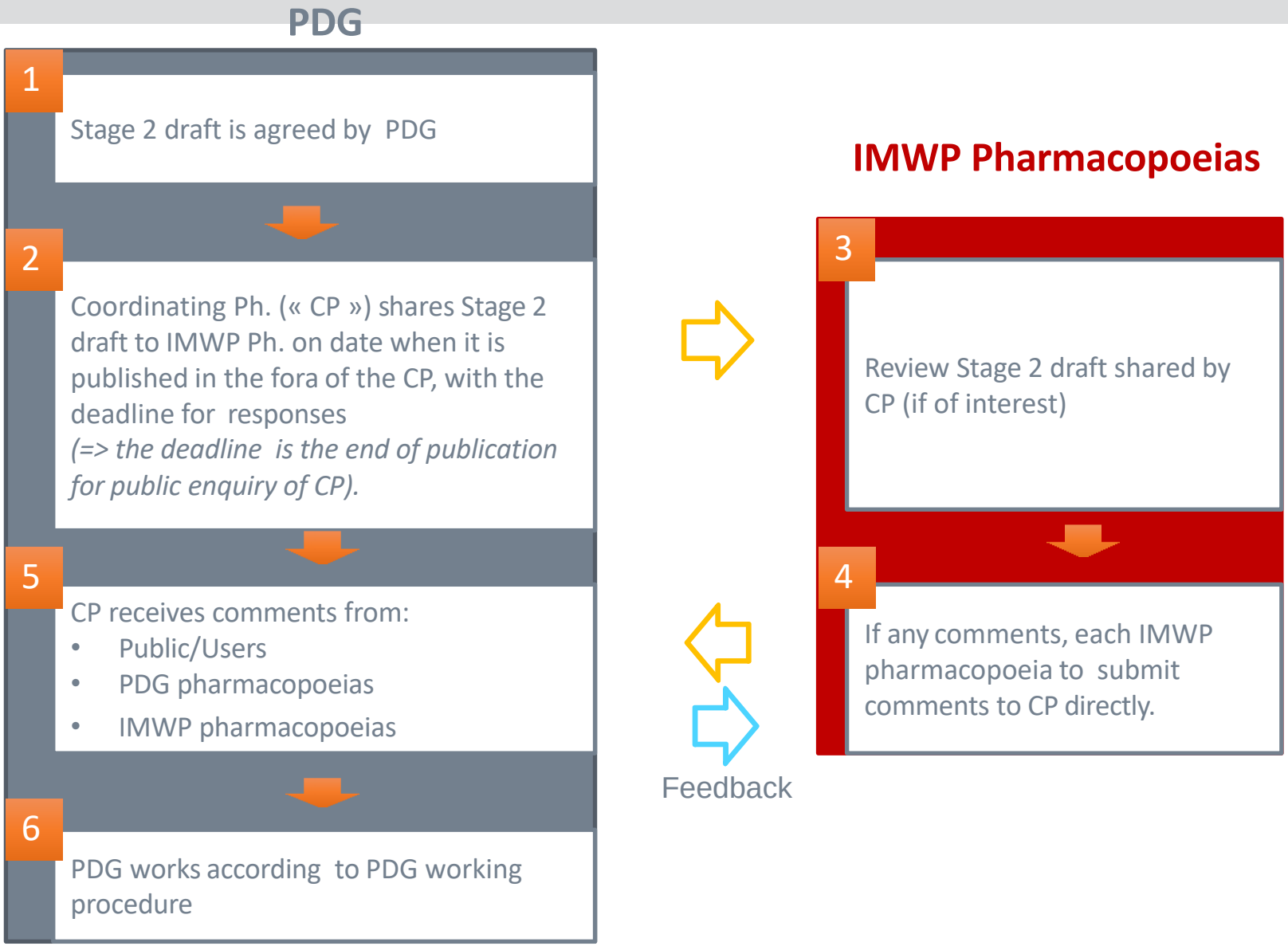
Reduce duplication of work and increase level of prospective convergence

IMWP as a venue

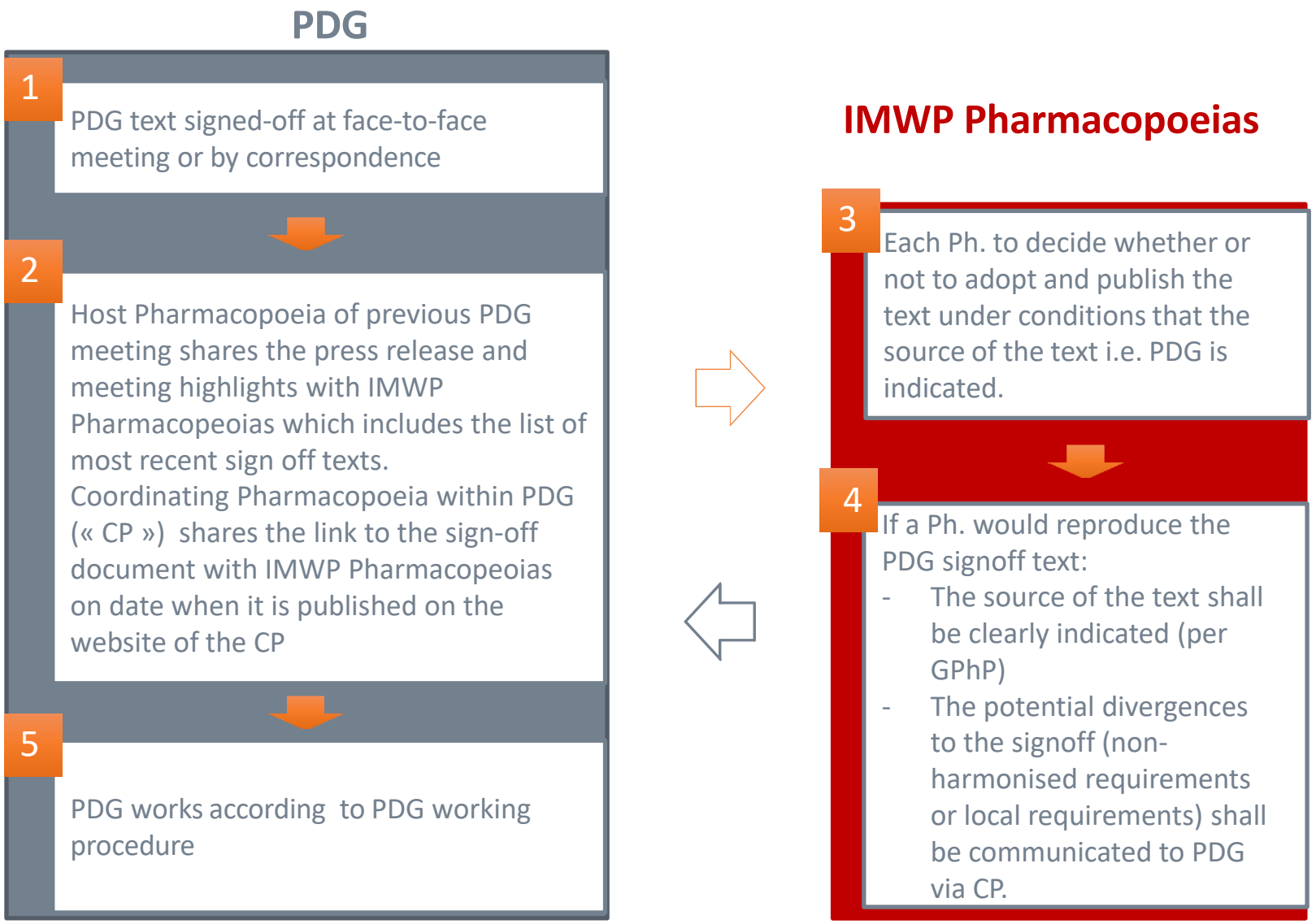
- **discussion forum** to
  - **get to know** peers
  - **build trust** among pharmacopoeias
  - **exchange information, knowledge and expertise**,
    e.g. to inform each other of recent challenges and share solutions found

- PDG committed to **support pharmacopoeial harmonisation** of quality standards by **liaising** with other world pharmacopoeias (e.g. via IMWP) and by **sharing PDG texts with all** IMWP ph. :
  - **for comments at public consultation** stage and
  - **after sign-off** for optional implementation following GPhP

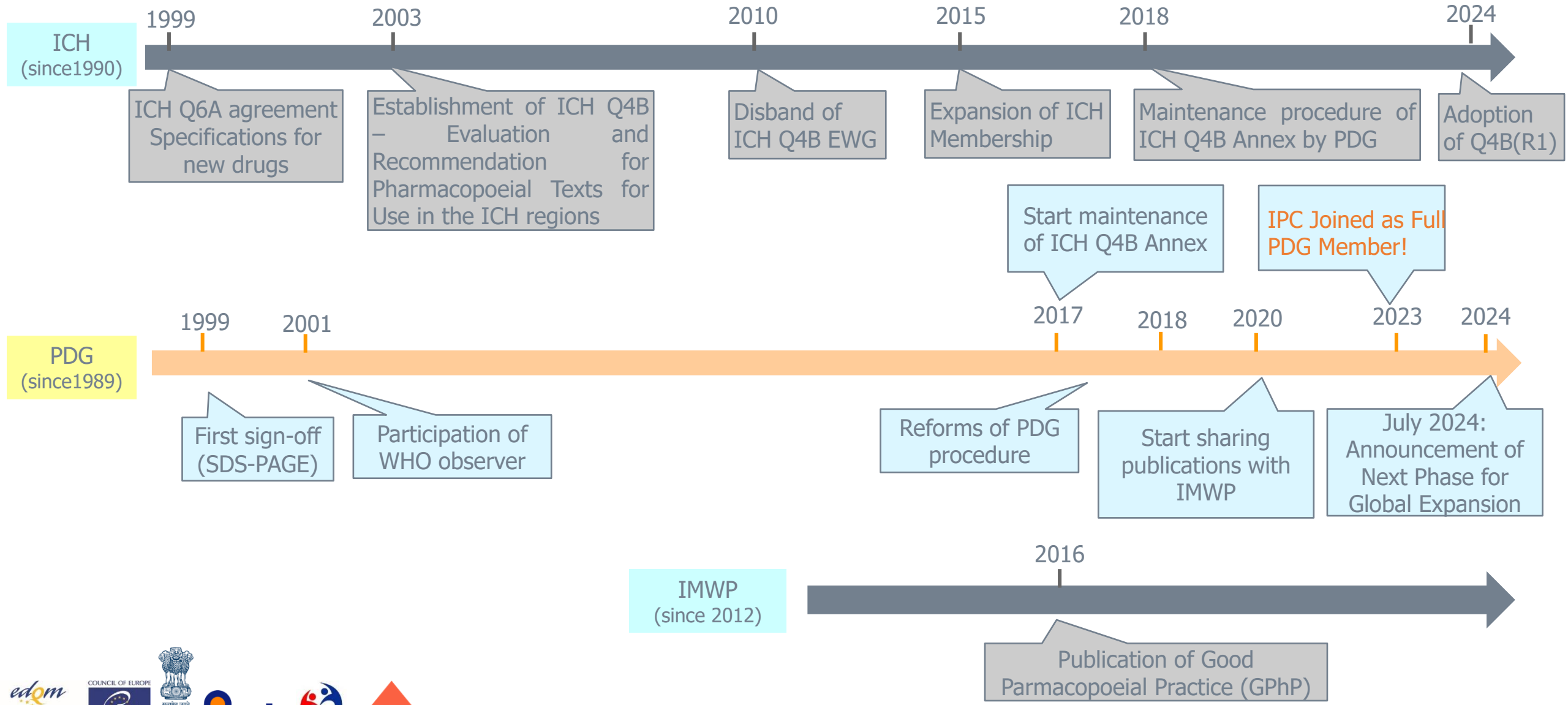
Interaction PDG-IMWP: PDG Stage 2 (Official Inquiry)



Interaction PDG-IMWP: Stage 4 (sign-off by PDG)



Summary: Timeline of Multilateral Collaborative Activities



Thank You for Your Attention

Update on PDG

PDG Expansion
Feedback on the pilot phase and future plans

Hikoichiro MAEGAWA, Japanese Pharmacopoeia (JP)

PDG expansion

feedback on pilot phase and future plans

October 3, 2024

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- PDG Performance maintained consistent level of quality during Pilot Period

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October 2023-June 2024: **PDG discussed lessons learned and next steps**

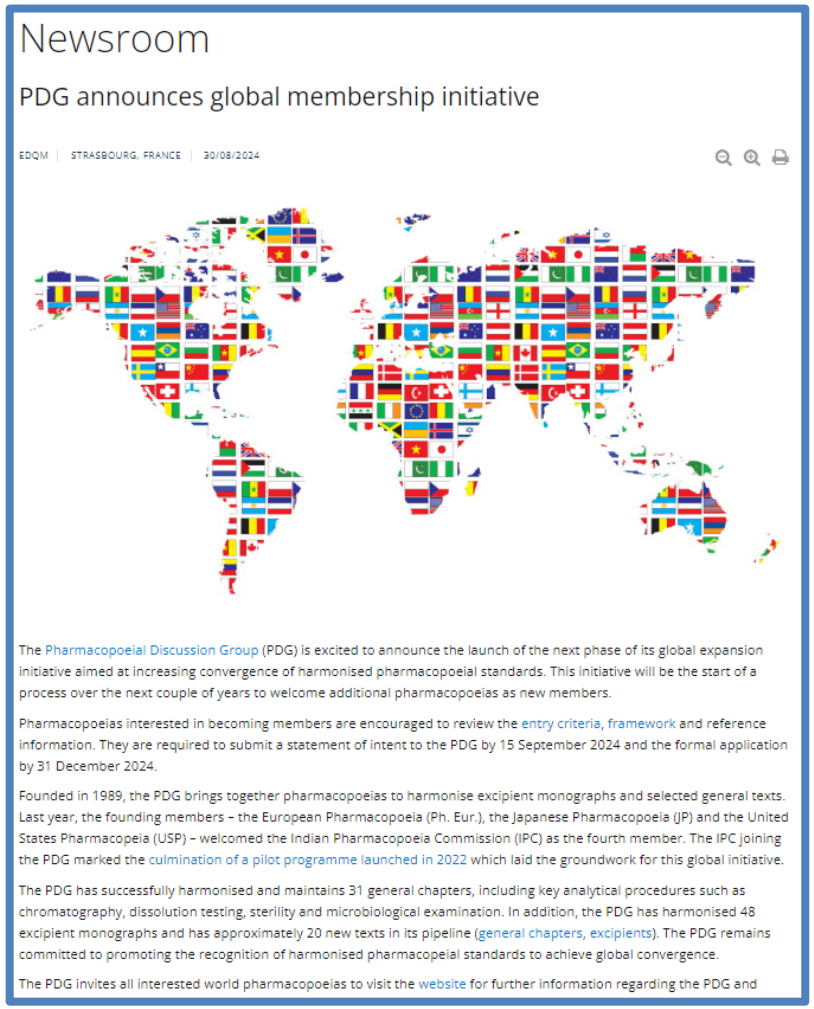
PDG discussed lessons learned and next steps

Feedback was taken into account to the next expansion model

- ✓ How PDG can modify the model to facilitate both future possible and current new members to learn about PDG activities?
- ✓ What additional information helps possible new members to consider joining PDG?
- ✓ Does PDG need to revise the work procedure?

etc…

PDG launched a new global membership expansion initiative



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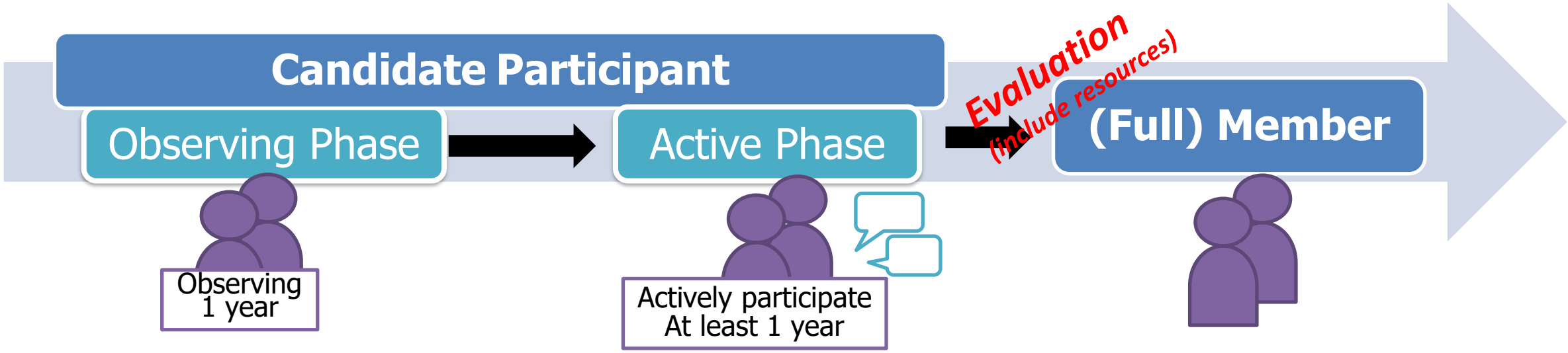
- PDG sent an invitation to world pharmacopoeias on 29 July 2024. Possible applicants were asked to:
  - Provide a statement of your intent to apply with your contact information **by 15 September 2024.**
  - Submit application documents **by 31 December 2024.**
- Press release was published on 30 August 2024.

Framework for Next Stage of PDG Expansion



- **Observe** PDG activities and all meetings (including technical meetings and subteam meetings)
- Comments or feedback allowed but not required
- Start implementing PDG harmonized texts
- Gain understanding of PDG's way of working from passive participation

- **Active participation** in PDG activities and all meetings (including technical meetings and subteam meetings
- Required to submit comments and feedback
- Continue implementing PDG harmonized texts
- Actively integrate into harmonization work

- **Full participation**
- Same status as existing members

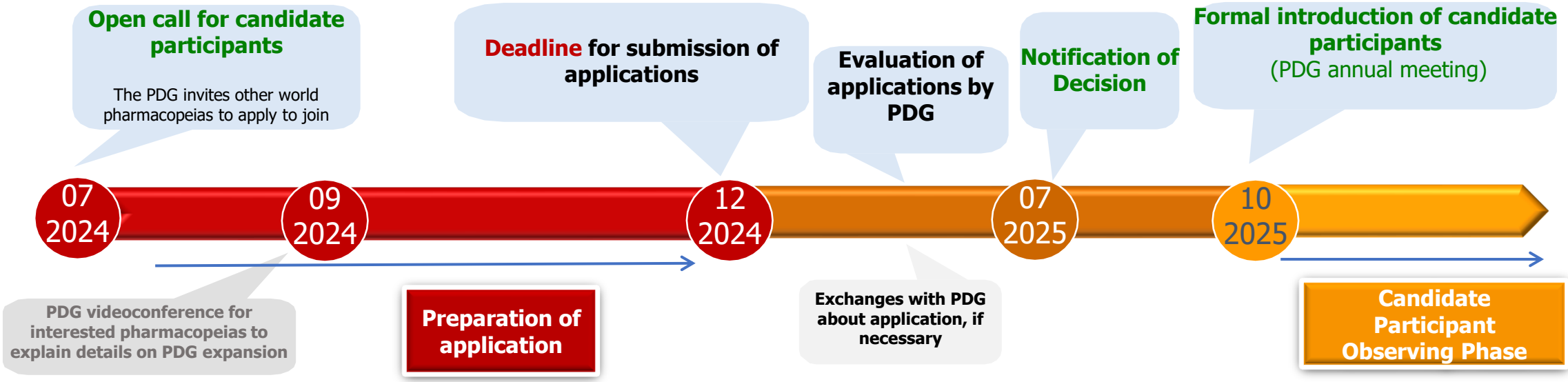
Entry Criteria for PDG Members

- Commitment to **implement complete PDG work plan,** no necessity to implement upfront but need to submit a plan of implementation following observing phase
- **Equivalent approaches and policies** to existing PDG members
  GPhP as basis with some enhanced principles and approaches
- **Application** of regulatory guidelines like **ICH Q2, Q3C and Q3D**
- **Appropriate publication cycle** for both public consultation and final texts
- **Regular updates** on implementation status
- **Active participation** in PDG activities
- **English version** of final published documents
  - minimum local harmonized text and related text (general notice, general methods, etc.)
- **Confidentiality policy** in place to secure data shared within the PDG, and policy transparently available to the PDG.
- Commitment to securing the **resources** required to engage in all PDG activities.
  - Note: For reference information, the average staff commitment among PDG pharmacopeias is around 3 full time equivalents, and independent expert commitment around 1-2 full time equivalents.

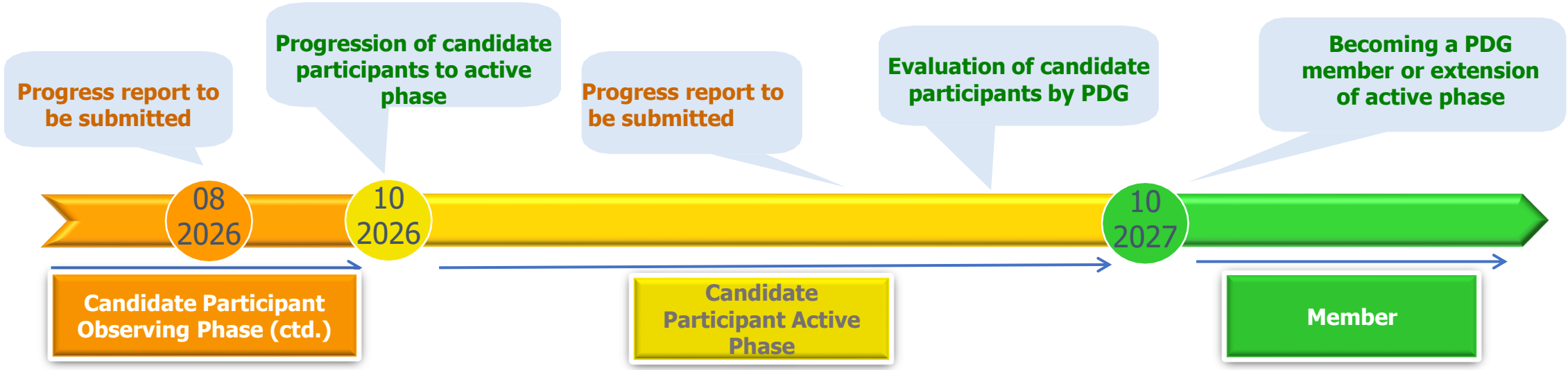
Evaluation of Candidate Participants

- Each candidate participant in the **Active** phase will be required to submit an updated progress report (following the entry criteria) and will be evaluated on the following:
  - **attendance** and **active participation** at meetings (especially monthly teleconferences, regular videoconferences, and annual face-to-face meeting)
  - **participation** in technical discussions (if the topic is on their implementation workplan); this includes the ability to find common solutions with the other PDG experts in order to make technical decisions
  - implementation of **Entry criteria**, especially follow-up of the implementation timetable
  - ability to meet deadlines
    - constructive support of PDG progress (especially not hindering progress on items), for example by timely replies (via email, letter, Sharepoint, etc.)
  - sufficiency of **resources**

Timeline: Application and introduction of candidate participants



Timeline: Candidate participants towards membership



Further Information

For further information, please check PDG press release!

- PDG Press release –published on 30 Aug, 2024
  URL: https://www.pmda.go.jp/files/000270356.pdf
  - Framework for Next Stage of PDG Expansion
    URL: https://www.pmda.go.jp/files/000270241.pdf
  - Entry criteria
    URL: https://www.pmda.go.jp/files/000270240.pdf
  - Reference information
    URL: https://www.pmda.go.jp/files/000270242.pdf

Thank you!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Update on PDG

IPC's perspective as a new PDG member

Shruti RASTOGI, Indian Pharmacopoeia Commission (IPC)

Indian Pharmacopoeia Commission (IPC) Perspective as new PDG member

Update on PDG

October 3, 2024

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India’s Role in Global Pharmaceutical Landscape

- Indian pharma industry is the 3rd largest by volume and 14th largest by value globally
- Total annual turnover (2021-22): ₹ Rs. 3,44,125 crore (USD 42.34 Bn)
- Export (2021-22): ₹1,74,955 crore (USD 23.5 Bn)
- India is one of the largest producers of generic medicines globally, with a significant contribution to affordable healthcare solutions worldwide.
- The inclusion of IPC in the PDG reflects recognition of India’s critical role in setting and maintaining global quality standards.
- IPC’s membership ensures that Indian standards are aligned with global expectations, enabling smoother international trade and fostering greater trust in Indian pharmaceutical products.

About Indian Pharmacopoeia Commission (IPC)

Establishment and Core Mission

- IPC was established on 1st January, 2009 with the primary objective of creating **set of standards** for drugs manufactured, sold, and consumed in India.
- Mission is to **promote public 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.

Role in Ensuring the Quality of Medicines in India

- IPC lays a crucial role in **setting specifications** by providing **scientifically validated methods** for testing the quality of drugs, ensuring they meet global safety and efficacy criteria.
- IPC also ensure that vital drugs remain available and affordable.

Focus on Modernization and Global Collaborations

Modernization through Digitalization

IPC is leveraging cutting-edge technologies like **digitalization and advanced analytical methods** to modernize the IP and improve operational efficiencies

Modernization through Revisions

The recent editions of the IP have introduced **revised standards** and testing methods to reflect the latest advancements in pharmaceutical science

Global Collaborations

IPC is actively aligning its standards with those of major international pharmacopoeias, including **the USP, the EP, and the JP**

IPC as a PDG Member

By becoming a new member of the PDG, IPC aims to strengthen India's role in the global harmonization of excipient monographs and general chapters

IPC’s Vision for Harmonization in the Global Pharmaceutical Landscape

Collaboration Opportunities

Collaborative discussions with Pharmacopoeias lead to the development of consensus standards and methods

Learning and Training

Gain insights into the latest developments in pharmacopoeial standards, testing methods, and quality control practices, which can enhance organization's capabilities

Access to Standards

IPC is actively involved in the development or revision of harmonized pharmacopoeial standards

Regulatory Compliance

Participation in PDG has helped IPC informed about global regulatory changes and requirements

IPC’s Entry in PDG

Dec, 2021

IPC gave intent to participate in pilot phase

April, 2022

Submitted application for PDG pilot for global expansion

Oct, 2023

PDG announced IPC as a PDG member

Feb, 2022

IPC participated in informational follow-up video conferencing

Oct, 2022

PDG agreed to start 1 year Pilot phase for expansion with IPC

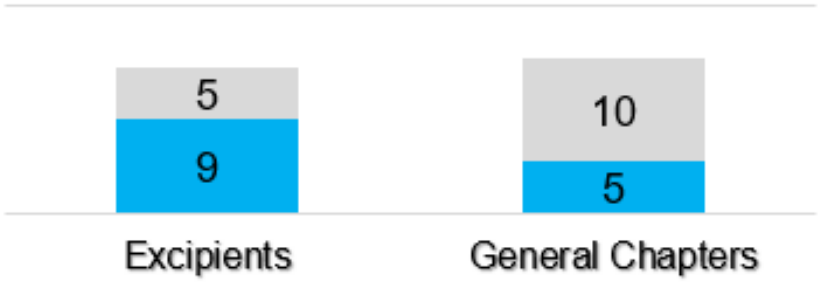
Contributions to Technical and Scientific Expertise

- IPC's inclusion in the PDG allows the organization to contribute in several areas of technical and scientific significance.
- IPC has participated in various subject expert teleconference (virtual):
  - G-07 Elemental Impurities (CP: USP): April 2023
  - E-32 Povidone and E-54 Copovidone (CP: USP): August 2023
  - E-62 Sterile Water for Injection (SWFI) in Containers (CP: USP): September 2023
  - Q-09 Particulate Contamination (CP: USP): November 2023
- IPC has Successfully sign-off 02 General chapters with PDG:
  - G-06 Tablet Friability
  - G-07 Elemental Impurities

IPC Harmonisation Progress

Excipients and General Chapters (Phase 1)

Excipients and General Chapters [in progress] (Phase 2)



Excipients and General Chapters [remaining] (Phase 3)

General Chapters Updates

Excipients Updates

IPC’s Future Impact on Global Standards

In conclusion, IPC’s entry into the PDG marks a **historic milestone** in the journey of Indian pharmacopoeial science. With its deep scientific expertise, global outlook, and commitment to innovation, IPC is set to play a pivotal role in shaping the future of **global pharmacopoeial standards**.

As a PDG member, IPC will:

- Enhance **global health** through harmonization.
- Promote **access to safe, affordable, and high-quality medicines**.
- Ensure that the voice of **emerging markets** is heard in the global standard-setting arena.

Thank You