World Health Organization

सत्यमेव जयते

IPC

Fifteenth International Meeting of World Pharmacopoeias

New Delhi, India | 6- 7 February 2025

Contents

Abbreviations

ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IPC	Indian Pharmacopoeia Commission
IMWP	International Meeting of World Pharmacopoeias
PDG	Pharmacopoeial Discussion Group

1. Introduction

The International Meeting of the World Pharmacopoeias (IMWP) is an annual event where world pharmacopoeias, including national, regional, and international pharmacopoeias, convene to share their experience and expertise. The goal of the meeting is to find ways of working together to synchronize efforts to improve public health outcomes.

The fifteenth IMWP, which was hosted by the Indian Pharmacopoeia Commission (IPC) in collaboration with the World Health Organization (WHO), was held in New Delhi, India, from 6–7 February 2025 (see Annex 1). A stakeholder event was held the day before, on 5 February 2025. In total, 38 participants, representing 14 pharmacopoeias, attended the meeting (see Annex 2). The European Pharmacopoeia represented on behalf of 28 pharmacopoeias within Europe.

2. General update on recommendations from the 14th IMWP

Outcomes of the fourteenth IMWP included an agreement to	
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1.	Survey world pharmacopoeias on what information to share during news updates.
2.	Draft a charter for IMWP that clearly sets out the mission, objectives, and tools of the IMWP.
3.	Create a programme of work to clarify expectations for communication and information sharing.
4.	Establish a set of principles on environmental sustainability and use them to develop an advocacy document to showcase the sustainability initiatives of world pharmacopoeias.
5.	Use the scientific priorities survey results to understand shared priorities and identify potential topics for collaboration.
6.	Keep IMWP monographs on favipiravir and favipiravir tablets open while stocks of reference substances last.
7.	PDG to consider ways to improve how it shares its work plan for developing new and revised texts.

2.1. Brazilian Pharmacopoeia

Ms Thaís Corrêa Rocha, Head of the Brazilian Pharmacopoeia, updated participants on significant advances since the last IMWP. The seventh edition of the Brazilian Pharmacopoeia had been published, featuring the introduction of the general monocyte

activation test method, a monograph for Cannabis sativa, and new monographs for oxygen and radiopharmaceuticals. Several other monographs had also been revised, and an English translation was underway. The third edition of the Homeopathic National Formulary had also been released.

Other activities included establishing new requirements for Brazilian nonproprietary names and publishing a guide to writing for the herbal medicines formulary. Work continued to establish new reference substances through analytical tests, update good pharmacopoeial practices guidance, including for herbal medicines, and developing a user guide for the Brazilian Pharmacopoeia.

Looking ahead, Ms Corrêa Rocha emphasized the continued importance of harmonization activities to align the Brazilian Pharmacopoeia with PDG texts, for example, on chromatography, and ICH guidelines, including Q4B, Q3C and Q3D. She noted that the Brazilian Pharmacopoeia was preparing to celebrate its centenary in 2026, with plans to hostthe eleventh Brazilian Pharmacopoeia Meeting and launch the eighth edition of the Brazilian Pharmacopoeia.

2.2. British Pharmacopoeia Commission

Mr Steve Hoare, Head of Standards and Regulatory Governance, Secretary & Scientific Director at the British Pharmacopoeia Commission, highlighted three key areas of work done by the British Pharmacopoeia over the past year.

- Continued expansion of non-mandatory guidance on advanced therapy medicinal products, in collaboration with stakeholders from the UK Catapult network, NHS, academia and industry;
- Development of non-mandatory guidance on analytical quality by design (AQbD).
- A sustainability programme to both reduce environmental impacts associated with the British Pharmacopoeia's laboratory and advocate for more sustainable quality control testing among its stakeholders.

Work to develop a new website for the British Pharmacopoeia was also ongoing. Mr Hoare stressed that the intention was not simply to provide the compendium as a digital book but to create a digital product that better met the needs of its users.

2.3. Pharmacopoeia of the Eurasian Economic Union

Dr Elena Kovaleva, Deputy Chairman of the Eurasian Economic Union (EAEU) Pharmacopoeial Committee, gave an overview of the EAEU Pharmacopoeia, which was a relatively young regional pharmacopoeia, established in 2017 to unify requirements for the quality, efficacy, and safety of medicinal products across EAEU Member States.[1]

[1] EAEU Member States include the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic, and the Russian Federation.

Three EAEU Member States already had their own pharmacopoeias. But Dr Kovaleva stressed that the EAEU Pharmacopoeia was binding for all EAEU Member States if a medicinal product was to be circulated in more than one EAEU country. It was governed by a Pharmacopoeial Committee comprising seven experts from each Member State, with standards elaborated through a structured process supported by a series of topic-specific expert working groups.

Dr Kovaleva identified three priorities for EAEU's standard-setting work done in the previous years:

- unifying pharmacopoeial language across EAEU Member States;
- harmonizing quality standards (general chapters) for tests, methods of analysis, dosage forms and medicinal product groups; and
- providing guidelines for developing monographs for chemical pharmaceutical substances, herbal medicinal products, and radiopharmaceuticals.

The EAEU Pharmacopoeia had approved and implemented three parts so far, covering general chapters and specific test methods, including those for veterinary medicine. Part 4 remained a work in progress, and would include general chapters on biological, herbal, and homeopathic medicines.

In response to questions, Dr Kovaleva clarified that the EAEU did not plan to have a unified regulatory authority. Currently, there is only the Pharmacopoeial Committee.

Manufacturers circulating medicinal products in only one EAEU Member State comply with the requirements of the relevant national pharmacopoeia.

2.4. European Pharmacopoeia

Dr Dirk Leutner, Head of Pharmaceutical Technology Division for the European Pharmacopeia Department at the European Directorate for the Quality of Medicines and Healthcare (EDQM), updated participants on key activities over the past year.

The European Pharmacopoeia had welcomed Egypt as an observer and celebrated its sixtieth anniversary. Key technical highlights included a new strategy for N-nitrosamine impurities, a general chapter on extractable elements in plastic materials for pharmaceutical use, and a cannabis flower monograph.

Significant advances had been made in implementing the 3Rs principles (replace, reduce, and refine) in the European Pharmacopoeia, by eliminating the rabbit pyrogen test and other animal tests for general safety. This aligned with the European Pharmacopoeia Commission's commitment to phasing out all animal testing by the start of 2026.

In the field of innovative therapies, a new general chapter on phage therapy was adopted in 2024 with ongoing work on bacteriophage potency determination. Guidance for gene therapies and mRNA vaccines was also adopted in 2024 and would be published soon.

Chapters on osmolality, elemental impurities, and powder characterization had also been updated.

Looking ahead, the European Pharmacopoeia's work programme included revisions and new chapters on various analytical procedures, quality aspects for data analysis, and liposomal preparations, among other things.

2.5. Indian Pharmacopoeia

Dr Pawan Kumar Saini, Senior Scientific Officer at the IPC, gave an overview of the commission's areas of responsibility and recent developments. The IPC oversaw publication of the Indian Pharmacopoeia and national formulary, developed reference substances, managed India's pharmacovigilance programme, carried out skills development activities and collaborated with national and international partners.

Dr Saini described how new and revised texts for the Indian Pharmacopoeia were developed; and gave an overview of the expert committees that support this process. The latest edition (2022), and its addendum 2024, covered 99% of medicines on India's List of Essential Medicines, and most medicines used in the country's national health system.

Dr Saini highlighted four areas of IPC's work in modernization and global collaboration:

- digitizing the Indian Pharmacopoeia and improving operational efficiencies;
- revising standards and testing methods to reflect advancements in pharmacopoeial science;
- aligning standards with major international pharmacopoeias; and
- strengthening India's role in harmonization as a new member of the PDG.

Looking ahead, Dr Saini said the next edition of the Indian Pharmacopoeia would be published in 2026, in print and online. It would include more than 100 new chemical monographs and dozens of new monographs for blood products, vaccines, biotech-derived therapeutic products, and veterinary vaccines. Some 12 general chapters and 13 excipient monographs would be harmonized to PDG texts, and, in line with ICH guidelines, elemental impurities tests would replace heavy metals tests.

2.6. International Pharmacopoeia

Dr Herbert Schmidt, Technical Officer, WHO, summarized the activities of *The International Pharmacopoeia*, which was the WHO's pharmacopoeia and focused on essential medicines. Every two years, *The International Pharmacopoeia* identified medicines on the WHO Model List of Essential Medicines that lacked public standards and prioritized the development of those missing monographs. The development process was open and transparent, allowing all stakeholders to comment on draft texts, and followed the principles of good pharmacopoeial practices.

The upcoming twelfth edition of *The International Pharmacopoeia*, set to be published in 2025, would include new and revised texts for 11 pharmaceutical substances, 12 dosage

forms, 3 methods of analysis, 2 supplementary information texts, and 1 general monograph on dosage forms. Dr Schmidt noted that with this edition, public standards would now be available for all WHO-recommended COVID-19 therapeutics as well as important HIV and contraceptive medicines.

Dr Schmidt reiterated *The International Pharmacopoeia's* commitment to support harmonization and convergence of pharmacopoeial standards, including by working with the PDG and aligning with ICH standards. *The International Pharmacopoeia* also promoted the use of physical standards established by other pharmacopoeias, such as the European Pharmacopoeia.

The International Pharmacopoeia established reference substances for use in physical and chemical tests, which were developed by EDQM but released by WHO's ECSPP. Dr Schmidt noted that access to suitable reference substances remained a challenge for many laboratories in LMICs Dr. Schmidt highlighted plans to revise WHO guidelines for establishing, maintaining, and distributing chemical reference substances to address these challenges.

2.7. Japanese Pharmacopoeia

Dr Hikoichiro Maegawa, Division Director of the Division of Pharmacopoeia and Standards for Drugs, Office of Review Management, explained the relationship between the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), and provided an update on the Japanese Pharmacopoeia.

In general, PMDA provides MHLW with the scientific basis for the MHLW to make final decisions on pharmaceuticals and medical devices. The Japanese Pharmacopoeia draft is prepared by the Division of Pharmacopoeia and Standards for Drugs and the JP Expert Committees established within PMDA. MHLW consults with the Pharmaceutical Affairs Council to review the draft; then, the Japanese Pharmacopoeia is finally notified.

The Japanese Pharmacopoeia had a major revision every five years, with the latest, eighteenth, edition published in 2021. Two supplements had been released since, with the latest one including a new general test for particle size measurement method in liquid by dynamic light scattering that was harmonized to PDG text. The latest supplement also updated and expanded the Japanese Pharmacopoeia's texts on balances, with new general information on: the concept of weighing in the Japanese Pharmacopoeia; calibration, inspection, and weight of a weighing instrument (balance); installation environment, basic handling method, and precautions for weighing of a balance.

Recent harmonization activities highlighted by Dr Maegawa included publication of the Japanese Pharmacopoeia in English, and Thailand's adoption of the compendium as a reference standard. Asked about the translation process, Dr Maegawa explained that the English version of each edition and supplement was produced by an outsourced company and reviewed by experts, with a lag of six months to a year behind the Japanese version.

2.8. Korean Pharmacopoeia

Dr Minkyeoung Kim, Scientific Officer of the Drug Research Division of the National Institute of Food and Drug Safety Evaluation, Republic of Korea, presented the priorities and recent updates of the Korean Pharmacopoeia, which included a free English version that was available online.

She explained that the Korean Pharmacopoeia was continuously updated based on stakeholder feedback collected through industry surveys, biennial forums, and the e-People online portal. She noted three priorities for revision: upgrading test methods, harmonizing standards, and introducing new content. One example of industry collaboration was the revision of seven monographs, such as diosmin tablets and choline alphoscerate, where methods were updated to meet international standards by removing heavy metal tests.

Indeed, replacing hazardous materials with green chemistry had been a key focus for the Korean Pharmacopoeia over the past year. Work was ongoing to ensure comprehensive control of elemental impurities by applying ICH Q3D guidelines, with plans to add this control to general considerations.

Other recent activities highlighted by Dr Kim included:

- developing public standards for essential medicines to help prevent drug shortages;
- establishing new general information for quality control of pharmaceutical packaging systems;
- creating a new test method for quality control of inhalers; and
- implementing alternatives to the rabbit pyrogen test.

Looking ahead, Dr Kim told participants that the Korean Pharmacopoeia planned to gradually reduce animal testing and expand its content to include new technologies and dosage forms, such as continuous manufacturing, synthetic peptide drugs, and nanoparticles.

In response to questions, Dr Kim confirmed that the Korean Pharmacopoeia had reference substances for verification.

2.9. Mexican Pharmacopoeia

Ms Daniela Monserrat Vázquez García, Internal Coordinator of Committees and International Affairs at the Comisión Permanente de la Farmacopea de los Estados Unidos Mexicanos, provided an overview of the Pharmacopoeia of the United Mexican States (FEUM), which was issued by the Mexican Ministry of Health and was available in Spanish, with an English version in progress. It was published both in print and online.

FEUM's standard-setting work covered various publications beyond the general Mexican Pharmacopoeia, including: Medical Devices Supplement, Herbal Mexican Pharmacopoeia, Homeopathic Mexican Pharmacopoeia, and a supplement for establishments involved in

the sale and distribution of medicines and health supplies. FEUM also produced 103 reference substances to support implementation of its standards and was expanding production with a new laboratory.

In 2024, new editions of the herbal and homeopathic pharmacopoeias had been launched online. Several more publications were planned for 2025, including new editions of the Mexican Pharmacopoeia, Medical Devices Supplement online version and Establishment's Supplement, as well as a Herbal Compendium of the Totonac People.

Ms Monserrat Vázquez García noted that key general animal-based tests, including the pyrogen test, would be eliminated from the new edition of the Mexican Pharmacopoeia, which would also include an annex on replacing in vivo methods with in vitro methods for vaccine quality control.

Ms Monserrat Vázquez García emphasized the importance of harmonization to FEUM, which continued to review and implement ICH guidelines and PDG texts. FEUM also participated as an observer in the European Pharmacopoeia Commission and the Expert Committee on Specifications for Pharmaceutical Preparations. FEUM also worked bilaterally with other world pharmacopoeias. For example, in 2025, it would co-host a scientific meeting with the United States Pharmacopoeia to discuss mutual interests and strengthen collaboration.

In response to a query from IMWP participants, Ms Monserrat Vázquez García confirmed that the Herbal Mexican Pharmacopoeia focused on local plants and herbal medicines produced in Mexico (rather than imports). FEUM did not produce herbal reference substances and had no plans to harmonize monographs for herbal medicines.

2.10. Russian Federation Pharmacopoeia

Mr Aleksei Iarutkin, Deputy Director of the Institute of Pharmacopoeia and Medicinal Products Standardisation at the Federal State Budgetary Institution "Scientific Centre for Expert Evaluation of Medicinal Products" of the Ministry of Health of the Russian Federation (FSBI "SCEEMP"), Moscow, Russian Federation, focused his update on presenting the national strategy for implementing the 3R principles in the Russian Pharmacopoeia.

He highlighted various ongoing activities:

- elaborating selective and precise *in vitro* alternatives, for example to evaluate histamine and depressor substances and the activity of herbal substances;
- deleting animal-based tests for abnormal toxicity, and histamine and depressor substances, from general monographs;
- updating monographs on vaccines to remove the abnormal toxicity test; and
- providing guidance and scientific consultations for manufacturers and stakeholders.

Mr Iarutkin reminded IMWP participants that all draft monographs for the Russian Pharmacopoeia were made available for comment for 30 days, through the online Russian

Pharmacopoeia Forum. The forum also provides access to the complete 15th edition of Russian Pharmacopoeia, as well as a structured interface for searching monographs by name, number, and content.

2.11. United States Pharmacopeia

Dr Kevin Moore, Senior Manager for Pharmacopeial Collaboration at the United States (US) Pharmacopeia, gave an overview of the US Pharmacopeia structure and recent developments. The US Pharmacopeia was governed by a convention that met every five years, with the next meeting scheduled for May in Rockville, USA.

The US Pharmacopeia's standard-setting work was carried out by more than 1 000 expert volunteers organized into committees across six broad topic areas. Their work was guided by a science quality framework, which would be refreshed as part of the US Pharmacopeia's 2025–2030 strategy.

Dr Moore outlined six new cycle mission commitments for 2025–2030.

- Enhance availability of essential medicines, with an ambitious goal to create 1 300 new monographs over the next ten years.
- Solve pervasive quality challenges in medicines, supplements and foods, including by addressing nitrosamines, mutagenic and other impurities.
- Strengthen the resilience of the global pharmaceutical supply chain.
- Expand access to quality—assured biologics.
- Advance quality through digital technologies, including by capturing monograph detail as structured data.
- Foster environmental sustainability, including by continuing to modernize monographs to eliminate non-specific and outdated test methods.

The US Pharmacopeia was committed to supporting innovation, developing guidance for new products and technologies, while also focusing on filling gaps in standards for the most-used medicines.

Dr Moore emphasized the importance of global collaboration, highlighting the US Pharmacopoeia's engagement in multilateral initiatives and bilateral collaborations with various countries and regions.

2.12. State Pharmacopoeia of the Republic of Uzbekistan

Mr Akmalkhodja Zaynidinov, Chief Specialist of State Pharmacopoeia Development Department gave an overview of the State Pharmacopoeia of the Republic of Uzbekistan, which was elaborated with the support of more than 200 experts. The State Pharmacopoeia was currently available in Uzbek and Russian, with an English version in development.

Mr Zaynidinov noted that through its Center for Pharmaceutical Product Safety, the Republic of Uzbekistan had become an official observer in the ICH and a member of the

International Pharmaceutical Regulators Programme. The center was now working to harmonize and implement ICH guidelines, including those for impurities (ICH Q3).

Mr Zaynidinov pointed to a range of other activities that were also planned for 2024–2029 to improve the regulatory system in the Republic of Uzbekistan, with potential impacts for the State Pharmacopoeia.

- Achieve WHO Maturity Level 3.
- Obtain an ISO 9001 certificate for the regulatory authority's quality management system.
- Obtain WHO prequalification for national quality control laboratories.
- Obtain PIC/S membership for GMP Inspection.
- Participate in WHO global initiatives to improve pharmaceutical manufacturing standards and pharmacovigilance.
- Apply ICH principles to ensure compliance with international standards.
- Digitize regulatory compliance requirements.
- Develop key performance indicators and a monitoring system.
- Develop a personnel management plan, including for continuous professional development.

3. Deep dive topic: impurities

Following the fourteenth IMWP's recommendation to use the scientific priorities survey results to understand shared priorities and identify potential topics for collaboration, the IMWP participants chose impurities for a focused knowledge exchange session. Various world pharmacopoeias shared their experiences in addressing impurities in their compendiums, in line with ICH Q3 guidelines. Their updates are detailed in the sections that follow.

In general, world pharmacopoeias had already aligned with ICH Q3A and Q3B on impurities in new drug substances and drug products. Alignment with ICH Q3C on residual solvents and ICH Q3D on elemental impurities remained in progress, complicated by technical, logistical and financial challenges. Participants noted the need for a grace period of around five years to allow stakeholders to prepare for changes, including learning new methods and procuring necessary instruments.

The ICH Q6 guideline was also identified as a key topic of interest with a brief update was provided on its development status (see Box 3.1).

Box 3.1. ICH Q6 update

Ms Vielle informed IMWP participants that the ICH had initiated efforts to update and modernize the ICH Q6 guideline, which covers specifications for new drug substances and products. This guideline was now under discussion, with expert working groups established to revise and unify the principles outlined in both Q6A (for chemical substances) and Q6B (for biotechnological/biological products).

Stakeholders would have the chance to provide comments on the draft guideline during the public consultation, which was the next stage phase of development.

3.1. Brazilian Pharmacopoeia

Ms Corrêa Rocha highlighted two areas where working groups had been convened to review the Brazilian Pharmacopoeia's general methods for impurities and update them in line with ICH Q3C and Q3D guidelines.

- **Residual solvents.** This review was still at an early stage of development, with the expert group comparing texts and noting similarities and differences.
- **Heavy metals.** This general method was already under revision, with agreement to rename it "Elemental Impurities" and harmonize it to ICH Q3D. To that end, the updated method would incorporate text on risk assessment and exclude the limit test for heavy metals.

In both cases, while the Brazilian Pharmacopoeia was working to align with ICH guidelines, it would still maintain some local requirements, especially around select detailed analytical procedures that had educational value.

Ms Corrêa Rocha noted that work to review and align with other ICH Q3 guidelines on impurities (Q3A, Q3B and Q3E) was being undertaken by the market authorization department in Anvisa, and so lay beyond the Brazilian Pharmacopoeia's current work plan.

3.2. British Pharmacopoeia

Mr Hoare told participants that the British Pharmacopoeia's approach to incorporating relevant ICH Q3 guidelines on impurities was fully aligned with the European Pharmacopoeia (see section 3.3). It had already aligned with requirements for new drug substances, residual solvents, and elemental impurities (including removing tests for heavy metals). It was preparing for the upcoming Q3E guideline on extractables and leachables. There was a slight divergence between Q3B requirements and degradation-only impurity control in new drug product monographs, although Mr Hoare stressed that this divergence did not exclude manufacturers or regulators from adopting ICH Q3B.

Mr Hoare told participants that the British Pharmacopoeia was also reviewing monographs to update outdated test methodologies and limits, replacing pass/fail limits with quantitative limits. He noted the British Pharmacopoeia took a similar approach to the US Pharmacopoeia with regards to flexible reporting (see section 3.8), stating thresholds based on the prescribed maximum daily dose in the British National Formulary.

3.3. European Pharmacopoeia

Dr Leutner emphasized the European Pharmacopoeia's continuous commitment to fully implementing ICH Q3 guidelines, applying them both prospectively and retrospectively unless otherwise decided by the EPC. He explained that these guidelines were implemented through general monographs, ensuring they applied to all products covered by those general monographs, not just those covered by individual monographs.

The European Pharmacopoeia controlled various impurities, including organic, inorganic, elemental, water and residual solvents, and genotoxic impurities. It provided reference substances for identifying and quantifying specified impurities and applied specific thresholds for unusually potent or toxic impurities. Manufacturers had to develop suitable tests for any new impurities that were not covered by individual monographs.

For medicinal product monographs, degradation products were controlled with higher thresholds than for active pharmaceutical ingredients. Impurities of synthesis were not controlled but were included in the transparency list if detected.

Dr Leutner reminded participants that all procedures in the European Pharmacopoeia were validated, so users did not have to validate them unless stated otherwise. But they did need to implement the methods, with guidance and examples provided in a dedicated chapter on implementation.

Looking ahead, the European Pharmacopoeia planned to monitor updates from ICH and make changes as and when needed. This included aligning with Q3E on extractables and leachables, with a focus on container materials. It would also continue working to align older monographs with ICH Q3A. Dr Leutner noted that the European Pharmacopoeia had not received any requests to shift towards flexible reporting thresholds.

3.4. Indian Pharmacopoeia

Dr Shruti Rastogi, Scientific Assistant at the IPC, summarized four areas of activity in IPC's approach to controlling impurities and aligning with ICH Q3 guidelines.

General chapters. These were being progressively updated to align with ICH Q3. A general chapter on impurities aligning with ICH Q3A and Q3B had already been developed and implemented (since July 2022).

Specific monographs. All new monographs would adopt IP general chapter 5.5 Impurities harmonised with ICH Q3 guidelines. Older ones were also being harmonized, a process that was progressing slowly.

Reference substances. IPC had developed 609 impurity reference substances.

Nitrosamines. IPC had issued guidance and introduced a general chapter on nitrosamines, which was referred to in sartan active pharmaceutical ingredient

monographs. Dr Rastogi stressed that the IPC expected stakeholders to adopt these guidelines for other drugs as well.

Dr Rastogi reiterated that the IPC remained committed to aligning with global pharmacopoeial standards and modernizing impurity testing methodologies. She said that, in line with ICH Q3, the next edition of the Indian Pharmacopoeia would delete heavy metals tests from individual monographs and replace them with general chapter "Elemental Impurities", and General monograph "Active Pharmaceutical ingredient".

3.5. International Pharmacopoeia

Dr Schmidt summarized *The International Pharmacopoeia's* approach to impurities, which was fully aligned with ICH Q3 guidelines (in part because ICH compliance was a prerequisite for WHO Prequalification). He highlighted the challenges in determining the maximum daily dose, especially for medicines that likely had off-label use.

Dr Schmidt also mentioned the challenges in detecting low levels of highly toxic impurities. *The International Pharmacopoeia* dealt with these with a general statement under manufacture requiring validation by the manufacturer to ensure toxic impurity was adequately controlled. This statement also served as a flag to regulators during dossier evaluation.

Asked about *The International Pharmacopoeia's* approach to tests for heavy metals, Dr Schmidt confirmed that the compendium still included these tests in its monographs, but a note in the corresponding general chapter made it clear that it was up to the regulatory authority to decide whether heavy metal tests should be used or ICH Q3D should be applied.

3.6. Japanese Pharmacopoeia

Dr Shoichi Sanuki, Technical Officer in the Division of Pharmacopoeia and Standards for Drugs at the Office of Review Management in PMDA, summarized the Japanese Pharmacopoeia's efforts to implement ICH Q3 guidelines. These had been implemented in different editions, with a recent focus on Q3D on elemental impurities. Considering the preparation period for manufacturers to transition to the new elemental impurities control, the Japanese Pharmacopoeia gradually implemented Q3D by transition from non-mandatory information to mandatory general test and the grace period was extended to three years, which is usually one and a half years.

Dr Sanuki highlighted some of the challenges to implementing ICH Q3D in Japan, such as the need for expensive analytical instruments and new risk assessments. Because of early implementation of Q3D in Europe and the US, global manufacturers can do early implementation, but sufficient preparation period was necessary for domestic manufacturers. In addition, extensive communication was needed to align expectations between drug marketing authorization holders and suppliers.

Looking ahead, 2.46 residual solvents on residual solvents would be revised to align with ICH Q3C (R9) and implemented in the nineteenth edition of the Japanese Pharmacopoeia in 2026. For nitrosamines, local manufacturers were required to conduct risk assessments and use control measures if necessary. Japan was also part of the PDG nitrosamine working group and monitoring regulatory activities.

3.7. Mexican Pharmacopoeia

Mr Juárez Sevilla focused his update on FEUM's efforts to address heavy metals requirements. He highlighted the introduction of two new methods: inductively coupled plasma optical emission spectroscopy (ICP-OES) and inductively coupled plasma mass spectrometry (ICP-MS). These methods would support the transition from traditional heavy metals testing to more advanced techniques, although challenges remained due to limited access to technology in Mexico. Updating the general method MGA 0561 would mark the start to incorporating these advanced methods for impurity determination into the Mexican Pharmacopoeia. Mr Juárez Sevilla stressed that any new elemental impurities methods used would be harmonized with PDG text and ICH Q3D guidelines.

Asked about residual solvents and nitrosamines, Mr Juárez Sevilla clarified that the Mexican Pharmacopoeia included general methods for both, although the one on nitrosamines needed updating. On the topic of extractables and leachables, Mr Juárez Sevilla noted that while there are no current monographs, FEUM's expert committee on primary packaging had included this topic in its 2025 work plan.

3.8. United States Pharmacopoeia

Dr Christian Zeine, Scientific Affairs Manager for the US Pharmacopoeia, summarized the US Pharmacopeia's approach to impurities, which he noted aligned with relevant ICH and FDA guidelines. Dr Zeine mentioned upcoming changes to general notices on organic impurities, which would become official in August 2025. He also highlighted various general chapters, including informational chapter <1086>, and specific monographs with acceptance criteria for both specified and unspecified impurities.

Dr Zeine explained the shift towards flexible reporting thresholds, and the two-tables approach to setting acceptance criteria for impurities that was introduced approximately 2.5 years ago to reduce confusion in monographs. He summarized the US Pharmacopeia's nitrosamines programme, which includes general chapter guidance as well as the Nitrosamine Exchange Community as a platform to encourage information sharing. He also pointed to US Pharmacopoeia resources for addressing other impurities, including elemental impurities, residual solvents, extractables and leachables, the latter including characterization of plastic components.

During the discussion, Dr Zeine addressed questions about the impact of upcoming ICH guidelines on extractables and leachables, noting that current USP chapters are aligned with Product Quality Research Institute recommendations. He also discussed the availability of relevant reference materials for impurities (Pharmaceutical Analytical

Impurities, PAIs), the product line being developed acknowledging the somewhat slow development of USP RS and the need for flexibility on additional materials. Regarding fixed-dose products with multiple active ingredients, he explained that limits on elemental impurities are applicable on the total amount of drug product rather than just the individual drug substances, ensuring comprehensive evaluation of all ingredients.

4. Charter for the IMWP

Mr Hoare led a session to review progress on IMWP's joint initiative to develop an IMWP charter or terms of reference, setting out the IMWP's mission, objectives, activities and tools. This initiative had been agreed at the fourteenth IMWP in 2023; and it was being led by the British Pharmacopoeia, with support from a working group of other world pharmacopoeias.

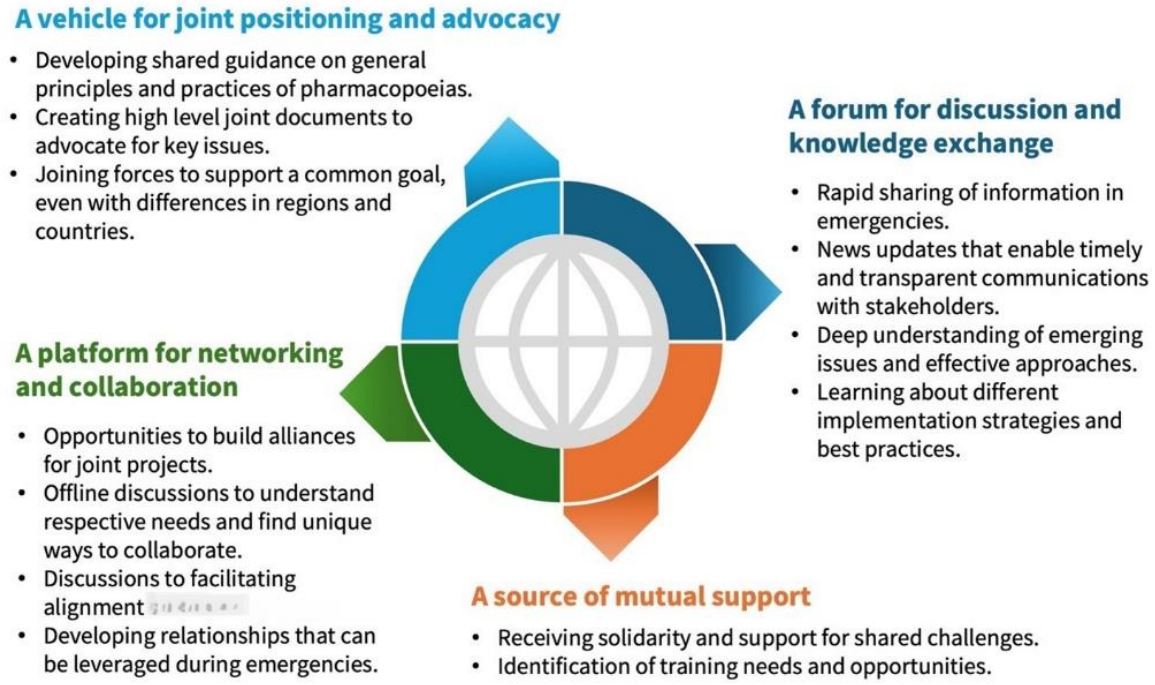
Mr Hoare summarized the work done so far. The working group had met several times since the last IMWP and had developed a draft terms of reference that had been circulated for comment to IMWP participants. A lot of feedback had been received, raising questions about the scope and content of the document.

Before discussing the draft document, world pharmacopoeias reflected on their reasons for participating in the IMWP and identified four key areas of added value (see Fig. 4.1).

World pharmacopoeias reviewed the proposed draft. Key points of discussion included:

- **Scope**. The scope for IMWP remained unchanged: to define IMWP's mission, goal and objectives. Several participants stressed that IMWP's role was to facilitate alignment among world pharmacopoeias, not to act as a harmonization body or duplicate PDG's efforts. They noted that not all pharmacopoeias were state actors, and the terms of reference should reflect that.
- **Communications.** World pharmacopoeias recognized the need to enhance their communication about IMWP to raise awareness and interest in its activities. They noted the importance of finding a mechanism to hear and consider the perspectives of pharmacopoeias not participating in IMWP as well as those of countries without a pharmacopoeia. Improving the dissemination of IMWP information through a better communication strategy was also highlighted.

Fig. 4.1. *Why pharmacopoeias value the IMWP.*



Action points

Action
• As lead for this project, British Pharmacopoeia, to circulate the developed draft document (subject to the amendments agreed at the meeting and any further minor editorial revisions required).
• World pharmacopoeias to take back the developed draft document to their stakeholders for adoption/ agreement and report back to IMWP.
• British Pharmacopoeia to receive comments and revise accordingly.
• British Pharmacopoeia to lead further rounds of revision if required.
• If agreed, use the document as the basis for framing the next (sixteenth) IMWP.
• European Pharmacopoeia, supported by the WHO Secretariat, to draft proposed text for the "meetings" section of the document.
• Include additions/revisions of the IMWP documents setting out the IMWP's mission, objectives, activities and tools as a standing agenda item on annual IMWP meetings.

5. Pharmacopoeial Discussion Group update

On behalf of the PDG, Dr Maegawa provided an update on key activities undertaken since the last IMWP.

PDG expansion

In October 2023, PDG expanded its membership for the first time in 34 years, welcoming IPC as a fourth member after a successful one-year pilot. The group was committed to preserving its achievements and was implementing a structured process for further expansion based on lessons learnt during the pilot. Dr Maegawa explained that joining the PDG would involve one year of observation only followed by at least one year of active participation before being considered for full membership.

The current round of applications had closed, with results to be announced. Dr Maegawa emphasized that the PDG would remain open to new members and would continue to regularly accept applications.

Maintenance of ICH Q4B annexes

The ICH Q4B annexes, comprising 16 topic-specific documents on the interchangeability of pharmacopoeial texts among ICH regions, had been maintained by the PDG since 2018. In 2023, a proof-of-concept pilot study had been done to involve non-founding ICH Regulatory Members in reviewing and revising three Q4B annexes.

Since then, the PDG had continued to work with ICH to update the Q4B annexes, using a phased approach that prioritized those annexes where PDG texts had evolved. Dr Maegawa informed participants that PDG and ICH could not commit to maintaining an annex for each individual pharmacopoeial update. This made it essential for world pharmacopoeias to work efficiently in the maintenance initiative and to respect all timelines.

Dr Maegawa noted that the deadline for reviewing Q4B annexes 6–8 had passed, and he thanked IMWP participants for all data shared. The deadlines for further annexes would be announced by PDG in due time.

Sharing of texts

The PDG remained committed to working with world pharmacopoeias to align standards, including by sharing information through the IMWP. PDG texts were shared both during development, at public consultation stage, and after development, for optional implementation.

One draft and eight final PDG texts had been shared since the fourteenth IMWP. The PDG had also had exchanges with world pharmacopoeias on various topics of shared interest, including endotoxin testing, nitrosamines and ICH Q6 guidelines.

PDG work programme

Dr Maegawa provided an overview of the PDG work programme, focusing on harmonization items under initial harmonisation or revision in addition to noting that all 31 general chapters, and 48 out of 62 excipient monographs, had been harmonized.

In response to a request from the fourteenth IMWP, PDG had considered ways to improve how it shared its plans for developing new and revised texts (see action points below).

Action points

- Share PDG work programme updates at IMWP meetings, including the annexes included in each phase of the ICH Q4B general maintenance.
- Indicate items added and the link to work programme in PDG's annual Meeting Highlights and send this to IMWP participants.
- Continue sharing Stage 2 drafts and Stage 4 harmonized texts with IMWP participants by email.

6. Promoting environmental sustainability

Dr Moore led a session to review progress on IMWP's joint initiative to agree a set of principles for environmental sustainability and develop a white paper or equivalent document compiling the sustainability initiatives of world pharmacopoeias to highlight best practices and possibilities. The work was being co-led by the IPC and US Pharmacopoeia, with support from a working group of other world pharmacopoeias.

Mr Richard Lew, Pharmacopoeial Collaboration Manager at the US Pharmacopoeia, summarized the work done so far. The working group had met several times since July 2024 and had aligned on three draft principles for environmental sustainability:

1. Minimize waste generation and contamination of the environment and reduce consumption of limited global resources.
    a. Reduce energy consumption and greenhouse gas emissions (carbon footprint).
    b. Minimize waste production related to use of hazardous materials, solvents, plastics, packaging, and other materials.
    c. Improve water stewardship, including through reduced water consumption and wastewater treatment.
2. Strengthen biodiversity conservation by reducing the need for and impact of animal testing.
3. Enhance protections of personnel against potential exposure to hazardous drugs and chemicals in industrial, laboratory, and pharmacy settings.

Based on these draft principles, the working group had created a draft scope statement for the white paper alongside a first draft, which had been circulated for comment to IMWP participants. A lot of feedback had been received, raising questions of scope and structure.

Before discussing these, the contributing pharmacopoeias were asked to share their perspectives on the purpose and objectives of the white paper. They identified five key reasons for developing a joint advocacy document:

- to showcase the good work being done already;
- to lead by example and inspire other pharmacopoeias to follow suit;
- to enable and encourage innovation in pharmacopoeias (and also in industry) by showing what is possible;
- to provide a practical tool that can help stakeholders understand the value of environmental sustainability and promote more sustainable methods; and
- to create dialogue and trigger feedback from stakeholders.

With these objectives in mind, IMWP participants revisited the scope of the environmental sustainability white paper to ensure it was still fit for purpose. Four key topics of discussion emerged.

- **Relevance.** IMWP participants agreed that the issue of environmental sustainability remained important, and the contents of the three principles listed above remained valid as key areas.
- **Voluntary nature.** IMWP participants emphasized the need to clarify that the white paper was not laying down mandatory requirements but simply showcasing examples of how pharmacopoeias can be helpful partners with stakeholders in this space. This would require a thorough review of the document's tone and content to ensure clear messaging about the voluntary nature of any measures presented in the document.
- **Implementation status.** While all IMWP participants may agree that environmental sustainability is an important topic, they noted that different countries were at different stages of implementing sustainability measures; and this should be reflected in the white paper.
- **Structure.** IMWP participants agreed that the proposed draft structure for the white paper would remain the same.

After discussion, IMWP participants agreed a revised scope for the environmental sustainability white paper and agreed a set of next steps (see action points below).

Action points

Action
• As co-leads of this project, US Pharmacopoeia and Indian Pharmacopoeia Commission to circulate the draft new scope and draft structure developed at the meeting for confirmation as a basis for continued discussion and drafting of white paper.
• Following confirmation, co-lead pharmacopoeias to do first edit of the current draft and circulate to the working group.
• Working group to comment on revised draft.
• All to suggest examples of sustainable practices to co-leads, as and where relevant.

- Co-leads to revise the draft based on working group feedback and share with all pharmacopoeias for comment.
- All IMWP participants to approve white paper.
- Working group to propose process for updating the white paper as a living document.

7. Future IMWPs

Participants discussed plans for the sixteenth IMWP. The Brazilian Pharmacopoeia kindly offered to host it as part of its centennial celebrations, and participants accepted. The meeting would likely be held May or June 2026 to maximize attendance by Brazilian stakeholders, including expert committee members.

Participants valued the in-depth discussion on impurities held at the fifteenth IMWP and agreed to keep deep-dive discussions as a standing agenda item. The topic would be identified using the scientific survey results. Participants agreed to also include communications and advocacy as an item on the next meeting agenda.

Finally, participants briefly discussed the seventeenth IMWP. EDQM kindly offered to host it and participants gratefully accepted.

Action points

- Brazilian Pharmacopoeia to confirm the timing for the sixteenth IMWP, and plan and host the meeting using a hybrid face-to-face and digital format.
- Include communications and promotion for discussion at the sixteenth IMWP.
- EDQM to host the seventeenth IMWP.

Annexes

Annex 1. Agenda

14th International Meeting of World Pharmacopoeias (IMWP)
Hybrid meeting. New Delhi, India 6–7 February 2025

Host: Indian Pharmacopoeia Commission (IPC).
Chairs: Dr Gaurav Pratap Singh Jaduan, IPC; Ms Cathie Vielle, EDQM.

1. Welcome remarks from Dr Gaurav Pratap Singh Jaduan, on behalf of IPC Secretary-cum-Scientific Director, Dr Rajeev Singh Raghuvanshi.

2. Introduction by Dr Luther Gwaza, WHO Secretariat.

3. General update on recommendations from the fourteenth IMWP.

4. Brief update on news from participating pharmacopoeias.

5. Deep dive discussion on emerging topics.
    - Approach to impurities and alignment with ICH Q3 guidelines.
    - Update on ICH Q6 guidelines.

6. IMWP charter/ terms of reference.

7. Update from the Pharmacopoeial Discussion Group, including proposed interaction with world pharmacopoeias.

8. Principles to promote environmental sustainability.

9. Preparation of the fifteenth IMWP meeting report.

10. Preparation of the sixteenth and seventeenth IMWP.

11. Any other business and conclusions.

Annex 2. List of participants

A2.1. Pharmacopoeias[2]

Farmacopeia Brasileira
Agência Nacional de Vigilância Sanitária (ANVISA), Brasília, Brazil
- Ms Thaís Corrêa Rocha, Head of the Brazilian Pharmacopoeia
- Ms Riviane Matos Gonçalves, Health Regulation Specialist

British Pharmacopoeia Commission
British Pharmacopoeia Secretariat, Medicines and Healthcare products Regulatory Agency (MHRA), London, United Kingdom of Great Britain and Northern Ireland
- Mr Steve Hoare, Head of Standards and Regulatory Governance, Secretary & Scientific Director

Chinese Pharmacopoeia Commission
Beijing, China
Ms Hanzhen Wang, Principal Pharmacist, Division for Integrated Management of ChP

Egyptian Pharmacopoeia
Egyptian Drug Authority, Cairo, Egypt
- Professor Marwa Hassan, Proofreading Group Team Leader
- Professor Nahla Ismael, Technical Assessment and Evaluation Team Leader
- Dr Lobna Sallam, Executive Office Director
- Dr Lamia Anwar Hassan, Pharmacopoeia coordinator

European Pharmacopoeia[3] [4]

[2] Unable to attend: Farmacopoea Argentina, Austrian Pharmacopoeia, Belarus Pharmacopoeia, Belgian Pharmacopoeia Commission, Chinese Pharmacopeia Commission, Croatian Pharmacopoeia Commission, Czech Republic Pharmacopoeia Commission, Danish Pharmacopoeia Commission, Finnish Medicines Agency, French Pharmacopoeia, German Pharmacopoeia Commission, Greek Pharmacopoeia Commission, Hungarian Pharmacopoeia Commission, Icelandic Pharmacopoeia, Indonesian Pharmacopoeia Commission, Irish Pharmacopoeia, Italian Pharmacopoeia Secretariat, Lithuania Pharmacopoeia Commission, Montenegro Pharmacopoeia, North Macedonia, Norwegian Pharmacopoeia, Polish Pharmacopoeia Commission, Portuguese Pharmacopoeia, Romanian Pharmacopoeia, Serbian Pharmacopoeia Authority, Slovakian Pharmacopoeia Commission, Slovenian Pharmacopoeia, Royal Spanish Pharmacopoeia, Swedish Pharmacopoeia Commission, Swiss Pharmacopoeia, Thai Pharmacopoeia, Turkish Pharmacopoeia.

[3] European Pharmacopoeia Members: Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine, United Kingdom, and the European Union.

[4] European Pharmacopoeia Observers: Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus*, Brazil, Canada, China, Egypt, Ethiopia, Georgia, Guinea, India, Israel, Japan, Kazakhstan, Kyrgyz Republic, Republic of Korea, Madagascar, Malaysia, Mexico, Morocco, Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, United States of America, Republic of Uzbekistan, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).

(European Directorate for the Quality of Medicines and HealthCare [EDQM]), Council of Europe, Strasbourg, France

- Dr Petra Doerr, Director
- Dr Dirk Leutner, Head of Pharmaceutical Technology Division, European Pharmacopoeia Department
- Ms Cathie Vielle, Head of the European Pharmacopoeia Department

Indian Pharmacopoeia Commission (Host)

Ministry of Health & Family Welfare, Government of India, Ghaziabad, India

- Dr Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director
- Dr Gaurav Pratap Singh Jaduan, Senior Principal Scientific Officer
- Dr Pawan Kumar Saini, Senior Scientific Officer
- Dr Shruti Rastogi, Scientific Assistant

Japanese Pharmacopoeia

National Institute of Health Sciences (NIHS) and Pharmaceuticals and Medical Devices Agency (PMDA), Tokyo, Japan

- Dr Yoshiro Saito, Deputy Director-General, NIHS
- Dr Hikoichiro Maegawa, Division Director, Division of Pharmacopoeia and Standards for Drugs, Office of Review Management, PMDA
- Dr Shoichi Sanuki, Technical Officer, Division of Pharmacopoeia and Standards for Drugs, Office of Review Management, PMDA

Korean Pharmacopoeia

National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety (MFDS), Chungbuk, Republic of Korea

- Dr JaYoung Kim, Deputy Director, Drug Research Division
- Dr Minkyeoung Kim, Scientific Officer, Drug Research Division
- Ms Minjung Lee, Translator, Pharmaceutical Policy Division
- Dr Kyunghun Son, Director, Drug Research Division

Mexican Pharmacopoeia

Comisión Permanente de la Farmacopea de los Estados Unidos Mexicanos, Cuauhtémoc, Mexico

- Ms Daniela Monserrat Vázquez García, Internal Coordinator of Committees and International Affairs
- Mr Ubaldo Juárez Sevilla, Executive Sub-Director of Pharmacopoeia

State Pharmacopoeia of the Russian Federation

Federal State Budgetary Institution "Scientific Centre for Expert Evaluation of Medicinal Products" of the Ministry of Health of the Russian Federation (FSBI "SCEEMP"), Moscow, Russian Federation

- Dr Valeriya Bagirova, Director of the Institute of Pharmacopoeia and Medicinal Products Standardisation
- Mr Aleksei Iarutkin, Deputy Director of the Institute of Pharmacopoeia and Medicinal Products Standardisation
- Dr Elena Kovaleva, Director of the Centre for Evaluation of Medicinal Products Quality

- Ms Elizaveta Botasheva, Chief Specialist of the International Cooperation Department

United States Pharmacopeia
Rockville, United States of America
- Mr Koustavayan Chowdhury, International Public Policy, Advocacy and Engagement Manager (USP India)
- Mr Richard Lew, Pharmacopeial Collaboration Manager
- Mr Kishor Mogulluru, Assistant Director, International Public Policy, Advocacy and Engagement (USP India)
- Dr Kevin Moore, Senior Manager, Pharmacopoeial Collaboration
- Mr Christian Zeine, Senior Scientific Affairs Manager (USP Switzerland)

State Pharmacopoeia of the Republic of Uzbekistan
State Institution "Center for Pharmaceutical Products Safety under the Ministry of Health of the Republic of Uzbekistan, Tashkent, Uzbekistan
- Mr Akmalkhodja Zaynidinov, Chief Specialist of the State Pharmacopoeia Development Department
- Dr Khabibulla Djalilov, Chief Editor of the State Pharmacopoeia of the Republic of Uzbekistan

Vietnamese Pharmacopoeia
National Institute for Control of Vaccines and Biologicals (NICVB) and National Institution of Drug Quality Control (NIDQC), Hanoi, Viet Nam
- Dr Van Ha Nguyen, Vice-Director
- Dr Thi Kieu Nguyen, Head of the Reference Standard Department

South-East Asian Regulatory Network (SEARN)
- Dr Md. Harun-Or-Rashid, Chair of SEARN Working Group 1 Quality, Deputy Chief, Head of Laboratory

WHO Country and Regional Offices

WHO India Country Office
- Dr Madhur Gupta, Technical Officer – Pharmaceuticals

WHO Regional Office for South-East Asia
- Dr Adrien Inoubli, Regional Adviser, Medical Quality Products & Regulation

WHO headquarters

Norms and Standards for Pharmaceuticals
- Dr Luther Gwaza, Team Lead
- Ms Sinéad Jones, Administrative Assistant
- Dr Sian Lewis, Report writer (Consultant)

The International Pharmacopoeia

- Dr Herbert Schmidt, Technical Officer

World Health Organization
20 Avenue Appia
1211 Geneva 27, Switzerland

https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/pharmacopoeia/IMWP

सत्यमेव जयते
IPC

World Health Organization