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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 fourteenth IMWP was co-hosted by the Pharmacopoeia of the United Mexican States (FEUM) and World Health Organization (WHO) in Mexico City, Mexico, from 8–9 November 2023, with a stakeholder event on 10 November 2023. The meeting was attended by 53 participants, representing 16 pharmacopoeia organizations. During the meeting, world pharmacopoeias shared their experience and information on news and work undertaken over the past year to support national and global public health. The meeting also reviewed the progress of ongoing joint projects and identified new areas for collaboration.

2. General update on recommendations from the 13th IMWP

Outcomes of the thirteenth IMWP included agreement to:

- continue working together to exchange information and knowledge that can help assure medicines quality;
- conduct a stakeholder consultation (through a survey and workshop) to gather feedback on IMWP COVID-19 activities to inform IMWP's future approach to public health emergencies and other crises;
- review internal collaboration and communication mechanisms to better support rapid communication and increased engagement of participating pharmacopoeias, including during crises;
- refresh the scientific priorities survey and use its results as a tool for understanding shared priorities and for identifying potential topics for collaboration; and
- use the results of the scientific priorities survey to identify a subgroup of world pharmacopoeias with a shared interest in herbal medicines, who could work together to develop a joint communication on the importance of quality control of herbal medicines during health emergencies.

3. News from world pharmacopoeias

3.1. Argentine Pharmacopoeia

Ms Melina Isabel Assalone of the Argentine Pharmacopoeia told participants that a second supplement to the current seventh edition of the Argentine Pharmacopoeia would be published before the end of 2024. It would include various new monographs and chapters on:

- quality by design applied to pharmaceutical product development;
- alternative methods to the use of animals for regulatory purposes; and
- nanotechnology in medicinal products.

The new supplement would incorporate texts from the regional MERCOSUR Pharmacopoeia and the latest guidelines from the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and PDG.

Other areas of work by the Argentine Pharmacopoeia included developing a new content update system; creating new limited-term working groups to address specific topics; and collaborating with other world pharmacopoeias through international forums such as IMWP.

3.2. Brazilian Pharmacopoeia

Mrs Riviane Matos Gonçalves from the Brazilian Pharmacopoeia told participants that the Brazilian Pharmacopoeia was working to: develop good pharmacopoeial practices (including for herbal medicines); monitor chemical reference substances; and develop guidance on Brazilian nonproprietary name rules and use of the Brazilian Pharmacopoeia. Work was also ongoing to harmonize pharmacopoeial texts with PDG texts and with the ICH Q4B annexes (see section 8) and Q3C and Q3D texts.

Several new texts were under development, including general methods for in vitro in vivo correlation, a monocyte activation test, and nitrosamines. New and revised monographs for various herbal medicines, radiopharmaceuticals and vaccines were also being developed.

A seventh edition of the Brazilian Pharmacopoeia, and a third edition of the Homeopathic National Formulary, would be published in 2024, to coincide with Anvisa's 25th anniversary.

Ms Gonçalves also informed participants of the upcoming tenth Brazilian Pharmacopoeia Meeting, which was scheduled for November 2023.

3.3. British Pharmacopoeia Commission

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

- expansion of some guidelines, with two new working parties established on advanced therapies and medicinal products (ATMP) and analytical quality by design (AQbD);
- support for new ways of working that impact positively on climate change, including developing sustainability toolkits and "signposting" guidelines;
- development of a new website (to be launched in 2024), which would respond to feedback received from stakeholders, improve transparency of the British Pharmacopoeia's work and give users more functionality; and
- establishment of new guidelines on emerging technologies, for example, by developing a microbiome toolkit in partnership with NIBSC.

Looking ahead, Mr Hoare informed participants that a new five-year strategy for the British Pharmacopoeia would be published in April 2024. He said it would include a strong emphasis on international collaboration and harmonization of standards.

3.4. European Pharmacopoeia

Ms Cathie Vielle from the European Directorate for the Quality of Medicines and HealthCare (EDQM) updated participants on three areas of activity over the past year.

New observers and working parties

Over the past year, two new observers had joined the European Pharmacopoeia Commission as official observers: Kyrgyz Republic (2023); and Ethiopia (2022).

Two new working parties had been created:

- EXS Working Party will identify and discuss how best to address the standard-setting process for excipients for pharmaceutical use in the European Pharmacopoeia.
- HTS Working Party will elaborate a general chapter for the European Pharmacopoeia on high throughput sequencing (HTS) methods to detect extraneous agents; and advise on the need to revise other European Pharmacopoeia texts.

A new working party had also been approved to establish rules and working methods for a European Drug Shortages Formulary, which would compile non-legally binding monographs to detail the preparation and quality control of unlicensed pharmaceutical preparations that could fill the gap left when licensed medicinal products are unavailable. The new formulary was one of several initiatives that had emerged from a review of lessons learnt during COVID-19 on what could be done to mitigate the effects of drug shortages, especially during public health emergencies.

Members for the working party for the European Drug Shortages Formulary had not yet been appointed; Ms Vielle reminded participants that membership for working parties was open to experts and members from all over the world, including non-European Pharmacopoeia Member States.

Technical decisions and adopted texts

Key technical decisions made by the European Pharmacopoeia Commission (EPC) since the last IMWP included:

- allowing the use of recombinant factor C to control bacterial endotoxins in water monographs;
- revising texts to keep up with veterinary vaccine developments;
- starting to elaborate three general texts on mRNA vaccines and components; and
- discussing alternatives to the rabbit pyrogen test at a global event co-hosted by EDQM and the European Partnership for Alternative Approaches to Animal Testing.

In 2023, the EPC also revised a general chapter on rubber closures and revised two major general monographs – Substances for pharmaceutical use (2034) and Pharmaceutical preparations (2619) – to align with the latest European regulatory requirements on N-nitrosamines. EDQM published a second edition of its herbal guide.

Ms Vielle reminded participants that more information about all EDQM's activities, including for the European Pharmacopoeia, could be found in EDQM's 2022 annual report.

Future priorities

Ms Vielle highlighted some of the European Pharmacopoeia priorities for 2023–2025, which included strengthening stakeholder engagement and international collaboration and modernizing ways of working. Technical priorities included elaborating texts and guidance

on topics such as alternatives to animal testing, impurities, herbal drugs, excipients, nanomedicines, and biologicals, among others.

3.5. Indian Pharmacopoeia Commission

Dr Pawan Kumar Saini, Senior Scientific Officer of the Indian Pharmacopoeia Commission (IPC), gave participants an overview of the commission's areas of responsibility, which included publication of the Indian Pharmacopoeia and National Formulary, and development of reference standards. The IPC was also custodian of India's pharmacovigilance programme, and carried out skills development activities and collaborations 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.

In July 2022, the ninth edition of the Indian Pharmacopoeia was published (implemented from 1 December 2022), with many new and updated monographs and general chapters. This latest edition included more than 3 000 monographs, mostly for formulations and active pharmaceutical ingredients. It also included general chapters on elemental impurities and nitrosamines.

Dr Saini informed participants that the Indian Pharmacopoeia was recognized in five countries: Afghanistan, Ghana, Mauritius, Nepal and Suriname. In 2023, it became an official member of the PDG (see section 8). It was now working on a three-phase plan (to 2028) to harmonize general chapters and excipients with PDG texts.

Dr Saini emphasized the collaborative nature of the Indian Pharmacopoeia's work, pointing to ongoing collaborations with other world pharmacopoeias, laboratories, universities and research organizations. The Indian Pharmacopoeia worked with these partners to develop reference standards, share specifications and support monograph development, and organize joint seminars and training.

Dr Saini encouraged IMWP participants to connect with the Indian Pharmacopoeia.

3.6. The International Pharmacopoeia

Dr Herbert Schmidt, Technical Officer, WHO, told participants that The International Pharmacopoeia focused on essential medicines with relevance to low- and middle-income (LMIC) countries.

Dr Schmidt said the latest (eleventh edition) of The International Pharmacopoeia had been published in 2023. It followed decisions taken by WHO's fifty-fifth and fifty-sixth Expert Committees on Specifications for Pharmaceutical Preparations (ECSPP) and included new and revised texts for: 16 monographs on pharmaceutical substances, 10 monographs on dosage forms, three methods of analysis and three general monographs on dosage forms. This included important monographs for WHO-recommended medicines for HIV, new medicines for COVID-19, and important long-term and emergency contraceptive medicines. Dr Schmidt noted that the eleventh edition had been aligned with other major pharmacopoeias as far as possible.

Since the last IMWP, The International Pharmacopoeia had continued to support the global COVID-19 response by establishing monographs on treatments recommended by WHO. Most recently this had included establishing active pharmaceutical ingredient and formulation monographs for molnupiravir and nirmatrelvir, which had been adopted by the fifty-seventh ECSPP in October 2023. Dr Schmidt drew attention to a scientific publication on The International Pharmacopoeia's response to the COVID-19 pandemic, which had been published in the *Journal of International Cooperation* in 2023.[1]

The International Pharmacopoeia had also responded to ongoing alerts to, and preventable deaths from, substandard and contaminated medicines, specifically cough syrups that had been contaminated with diethylene glycol (DEG) and ethylene glycol (EG). It had developed a tiered method for detecting DEG/EG that enabled less-resourced countries to quickly respond to medical product alerts and identify products that pose a high risk to patients. In the new approach, national quality control laboratories without access to a gas chromatograph would first screen samples for non-compliance using a semi-quantitative thin-layer chromatography method and then send any suspected contaminated products to a collaborating laboratory or regional centre for confirmation through gas chromatography.

Dr Schmidt reminded participants that The International Pharmacopoeia was open access. All users were free to use, share and copy text from it, provided they give due reference.

3.7. Japanese Pharmacopoeia

Dr Hikoichiro Maegawa, Division Director of the Division of Pharmacopoeia and Standards for Drugs, Office of Review Management, Pharmaceuticals and Medical Devices Agency (PMDA), told participants that the Japanese Pharmacopoeia undergoes a major revision every five years. The latest eighteenth edition was published in 2021. A first supplement to this edition was published in December 2022, with a focus on revising monographs related to the implementation of ICH Q3D guidelines.

A second supplement was scheduled for publication in June 2024. Focused on updating and expanding texts on balances, it would include revised general tests on measuring instruments and appliances. It would also include new general information on: the concept of weighing in the Japanese Pharmacopoeia; calibration, inspection and weight of a weighing instrument (balance); and installation environment, basic handling method and precautions for weighing of a balance.

The second supplement would also include a new test on particle size measurement method in liquid by dynamic light scattering. Other general tests that would be updated in the second supplement included those on thin-layer chromatography, residual solvents, determination of bulk densities and elemental impurities, among others. Several texts to provide new general information were also planned, for example, on the concept of flow cytometry, among others.

Looking to the future, Dr Maegawa said the next major revision of the Japanese Pharmacopoeia (nineteenth edition) was scheduled for publication in 2026. He said the basic

[1] Schmidt H, Sawyer J, Zribi K, van der Werf R. The International Pharmacopoeia: Focus, Processes, Response to COVID-19 and Collaboration with other Pharmacopoeias. Bulletin of the Scientific Centre for Expert Evaluation of Medicinal Products. Reg Res Med Eval. 2023;13(2):227–239. doi:10.30895/1991-2919-2023-455.

principles for preparing this edition had already been established. They were to: enrich monographs by prioritizing the inclusion of drugs that are important in healthcare, introduce the latest science and technology, promote internationalization in response to a globalizing drug market, facilitate smooth administration, and ensure transparency.

3.8. Korean Pharmacopoeia

Dr Minkyeoung Kim, Scientific Officer of the Drug Research Division of National Institute of Food and Drug Safety Evaluation, Republic of Korea, highlighted three key areas of progress for the Korean Pharmacopoeia.

Advancement in test methods

The Korean Pharmacopoeia had been modernized and improved to use more efficient and sensitive test methods (for example, moving from thin-layer chromatography to high-performance liquid chromatography; and moving from the use of packed columns to capillary columns).

Harmonization

Several texts had been revised to align with PDG texts, including 33 general monographs and information texts and 48 monographs of excipients. The Korean Pharmacopoeia had also made progress in harmonizing approaches for treating impurities, including 4-Aminophenol and N-nitrosamines, in various medicines.

New contents

In total, 25 new monographs had been added to the Korean Pharmacopoeia since the last IMWP. These included monographs on dapsone tablets and isoproterenol hydrochloride injection, among others.

3.9. Mexican Pharmacopoeia

Ms Loera Rosales updated participants on four key areas of work undertaken by FEUM since the last IMWP.

Publications

Over the past year, four key documents had been published:

- Supplement 13.1, with updates to 15 chapters of the Mexican Pharmacopoeia and 74 monographs of the Herbal Pharmacopoeia;
- Medical Devices Supplement 5.0, with 11 new general analysis methods, mostly on biocompatibility tests;
- Homeopathic Mexican Pharmacopoeia 4.0, with updates to 117 botanical names; and
- *Herbalism of the Yaqui Tribe*, published in the Yaqui language and Spanish, with 25 monographs intended to help preserve the traditional knowledge of herbal medicines among Mexico's indigenous peoples.

Two publications were planned for 2024, including a pharmacy supplement and the next (fourteenth) edition of the Mexican Pharmacopoeia.

Stakeholder events

The Pharmaceutical Attention Forum, which was co-hosted by FEUM and PAHO in June 2023, included discussions with diverse stakeholders (including associations, schools, academia and national authorities). It aimed to analyze the situation of pharmaceutical care in Mexico and establish a plan for addressing people's needs while promoting rational use of medicines.

The biennial Dissolution Forum aimed to engage stakeholders to inform the updating of pharmacopoeial texts by reviewing scientific and technological progress in dissolution methods and other related topics. The next Dissolution Forum was scheduled in October 2024.

Harmonization activities

In December 2022, FEUM and the US Pharmacopeia signed a memorandum of understanding to continue their cooperation, which included convening an annual scientific meeting to exchange knowledge and expertise. In 2023, FEUM also participated as an observer to sessions of the European Pharmacopoeia Commission and the ECSPP.

Reference substances

In 2023, FEUM replaced five reference substances and developed a new one (for chlorophenamine maleate). A further five reference substances were scheduled for replacement in 2024; and two new references would be developed (for pentoxifylline and bezafibrate).

3.10. State Pharmacopoeia of the Russian Federation

Mr Aleksei Iarutkin, Deputy Head of the Institute of Pharmacopoeia and Standardisation in the Area of Medicines Regulation at the Federal State Budgetary Institution "Scientific Centre for Expert Evaluation of Medicinal Products" (FSBI "SCEMP"), Moscow, Russian Federation, told participants that, like many other pharmacopoeias, the State Pharmacopoeia of the Russian Federation was updated every five years.

The latest (fifteenth) edition was published in July 2023, with a small supplement added in August 2023. It comprised:

- 322 general monographs, including 111 new monographs since the last edition, for example, on extemporaneous preparations and several radiopharmaceuticals; and
- 576 individual monographs, including 262 new texts since the last edition.

Mr Iarutkin outlined the process used to elaborate monographs, which was done with the support of expert committees and panels, and included public consultation through the websites of both the Ministry of Health website and the Russian Pharmacopoeia Forum (https://pharmacopoeia.regmed.ru). The Forum had been launched in 2023 to improve transparency of the development process.

Mr Iarutkin emphasized the importance of harmonization with other pharmacopoeias, telling participants that the State Pharmacopoeia of the Russian Federation followed the approach of other pharmacopoeias as much as possible, including the regional Eurasian Economic Union Pharmacopoeia and leading world pharmacopoeias.

Looking ahead, Mr Iarutkin highlighted two areas where new requirements were needed:

- compounding, including setting shelf-lives for extemporaneous preparations, and establishing requirements for excipients; and
- an expanded range of radiopharmaceuticals and herbal medicines.

3.11. State Pharmacopoeia of Ukraine

Dr Natalia Volovyk, Deputy Director for Quality at the Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines, provided a comprehensive overview of the centre's history, mission and main activities.

Dr Volovyk informed participants that the State Pharmacopoeia of Ukraine is the first national pharmacopoeia among post-Soviet countries. The first edition was published in 2001. This was followed by four supplements before the release of the second edition in three volumes in 2015. Since then, six supplements had been added to the second edition; the latest in 2023. Alongside updates in line with changes in the European Pharmacopoeia, it includes new national texts such as:

- an integral test for the verification of analytical systems and personnel qualification for the spectrophotometry method;
- a statistical power criterion;
- an evaluation of the total measurement uncertainty for assay procedures; and
- mesenchymal stem cells for human and veterinary use.

Dr Volovyk highlighted the advantageous timing of the State Pharmacopoeia of Ukraine's inception at the turn of the 21st century, which allowed for the integration of best practices from other pharmacopoeias and the latest advancements in analytical chemistry. It also helped meet the contemporary requirements of pharmaceutical manufacturers and regulatory authorities. As the State Pharmacopoeia was created, a theoretical foundation for the metrological system was established, paving the way for the concept of measurement uncertainty to be implemented in validation, the certification of reference standards, and the use of proficiency testing schemes. It also allowed for the development of target uncertainty requirements and standardized validation procedures for basic pharmacopoeial tests, along with criteria-setting based on target uncertainty for validation performance parameters.

Dr Volovyk noted the significant disruption to the activities of the State Pharmacopoeia of Ukraine caused by the Russian Federation's aggression against Ukraine. Work had continued nonetheless, and Dr Volovyk highlighted several areas where progress had been made over the past year.

Dr Volovyk emphasized the importance of international cooperation in the pharmacopoeia's work. She informed participants that Ukraine had been a member of the European Pharmacopoeia since 2013, and the Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines had been a voting member of the US Pharmacopeia Convention since 2010. In 2023, the organization had further strengthened its international ties by securing permission to incorporate texts from the German Pharmacopoeia and the German Homoeopathic

Pharmacopoeia; and by signing a new cooperation agreement with the UK Medicines and Healthcare products Regulatory Agency (following previous agreements in 2013 and 2017), to allow the use of texts from the British Pharmacopoeia.

Concluding her presentation, Dr Volovyk reiterated the collaborative nature of the State Pharmacopoeia of Ukraine, developed with inputs from various stakeholders, including scientific experts from the pharmaceutical industry, quality control laboratories, and academies. She encouraged other interested parties to engage with their work.

3.12. United States Pharmacopeia

Dr Gabriel Giancaspro, Distinguished Scientific Fellow at the United States (US) Pharmacopeia, gave an overview of the US Pharmacopeia Convention, which is governed by 460+ members in more than 40 countries around the world.

Dr Giancaspro described how the US Pharmacopeia's standard-setting work was carried out by a mix of staff and expert volunteers organized into expert committees that developed and set the standards; and expert panels that were convened to advise on specific topics or challenges. There were 29 expert committees in total, organized into six broad topic areas: biologics; small molecules; excipients; general chapters; healthcare quality and safety; and dietary supplements and herbal medicines and food ingredients.

Dr Giancaspro emphasized the US Pharmacopeia's commitment to go beyond the provision of standards to publish other information that could make an impact on public health; and he pointed to six key areas of work:

- providing additional resources to support agile responses to emerging public health issues, for example, by developing an infant formula guide and a toolkit to measure and control diethylene glycol and ethylene glycol contamination in cough medicines;
- supporting the COVID-19 response by updating vaccine handling and quality assessment toolkits;
- evolving and expanding priority standards and associated solutions, including a new dissolution performance verification standard and new approaches on nitrosamines;
- engaging stakeholders earlier in the standard development process, by introducing the concept of emerging standards (where a potential standard not yet under development is shared to help stimulate early discussion and stakeholder contributions before formal notice and comment);
- developing new standards on emerging modalities, including complex generics and excipients as well as biologics (especially mRNA vaccine quality and therapy vector design); and
- providing new guidance and standards on cannabis for medical use, including tool kits, a general chapter on quality considerations, information on impurities in synthesized delta-8 THC products, and a monograph for cannabis inflorescence.

Dr Giancaspro also informed participants of activities to improve diversity, equity, inclusion and belonging among the US Pharmacopoeia's expert volunteers.

3.13. State Pharmacopoeia of the Republic of Uzbekistan

Ms Nazrullaeva Khilola Said-Akhmedovna, Chief Specialist of State Pharmacopoeia Development Department at the State Pharmacopoeia of the Republic of Uzbekistan began by drawing participants' attention to the change in the name of her organization, which used to be called the SUE State Center for Expertise and Standardization of Medicines, Medical Devices and Medical Equipment; and was now called the State Institution Center for Pharmaceutical Products Safety.

In addition to developing and maintaining the State Pharmacopoeia of the Republic of Uzbekistan, this institution was responsible for developing regulatory legal documents in the field of medicines, medical devices and medical equipment, and regulatory documents in the field of technical regulation.

In 2018, the State Pharmacopoeia of the Republic of Uzbekistan was introduced as an observer to the European Pharmacopoeia. In 2019, an agreement was signed enabling the Republic of Uzbekistan to use text from the European Pharmacopoeia and adapt it to the Uzbek context. As a result of this agreement, in 2019, the first volume of the first edition of the State Pharmacopoeia of the Republic of Uzbekistan was published by the Ministry of Health. It included five chapters and 334 sections. A second volume published in 2021 contained three chapters and 55 sections.

In 2023, a similar agreement was signed, this time with the US Pharmacopeia Convention. At the same time, the State Pharmacopoeia of the Republic of Uzbekistan became an observer of the Eurasian Economic Union Pharmacopoeial Committee.

The third volume of the State Pharmacopoeia of the Republic of Uzbekistan was published in 2023. It contained six chapters and 442 sections, including new texts on vaccines for human use, immunosera for human use, radiopharmaceuticals, sutures for human use, herbal medicines and homoeopathic preparations.

Dr Said-Akhmedovna informed participants that the third volume was designed to:

- improve the quality of medicines and medical devices recommended for use to the level of international standards;
- stimulate the implementation of good practices among domestic pharmaceutical companies;
- increase the export potential of pharmaceutical products made by domestic pharmaceutical companies;
- raise the level of scientific research on the development of original medicines; and
- improve the quality of training and retraining of specialists dealing with the development, production and quality control of medicines and medical devices.

3.14. Vietnamese Pharmacopeia

Mrs Thi Thu Hang Luc, Head of Vietnamese Pharmacopoeia and Formulary Centre told participants that the latest (fifth) edition of the Vietnamese Pharmacopoeia had been published in 2017, in Vietnamese and English. The English version comprised 485 monographs for chemical substances and 385 monographs of their formulated preparations,

372 monographs for crude drugs and traditional medicines, 41 monographs for vaccines and biological products, and 228 general monographs.

In 2022, a supplement to this document was published (in Vietnamese only), including 190 new and updated monographs.

A new, sixth, edition of the Vietnamese Pharmacopoeia was expected to be published by the end of 2024. Dr Le told participants an estimated 150 new monographs would be added in this next edition, and 250 monographs would be updated. Priorities in developing the sixth edition were to:

- expand coverage of the most commonly used medicines in Viet Nam;
- review and update existing monographs;
- enhance content on traditional medicines; and
- establish herbal medicine references and reference substances extracted from herbal medicines.

3.15. Future news update

What would pharmacopoeias want to know about? What aspects of their own work would they want to share with others? And what type of information would they most want to know about other pharmacopoeias' work? Finding the answer to these questions could help inform the development of a template to shape the information that was shared during news updates and improve the efficiency of knowledge exchange and collaboration.

Action points

- Conduct a short survey of world pharmacopoeias to identify the type of information that should be shared during news updates; and, based on the results, develop a flexible template for providing future news updates.
  - This activity would be led by the US Pharmacopeia. Other pharmacopoeias were welcome to participate and any interested should contact the US Pharmacopeia.

4. Activities related to COVID-19

Participants noted that, at their last meeting, they had reflected on lessons learnt during these activities and identified options for leveraging those lessons to improve preparedness and response for future public health crises. At that meeting, they had agreed to conduct a stakeholder consultation, including a survey and a workshop, to gather feedback that can inform the IMWP's future approach during public health emergencies and other crises.

This action point had not been completed. Acknowledging that a significant amount of time had now passed since the COVID-19-related activities had been carried out, participants agreed that the window of opportunity for conducting a stakeholder survey and workshop on this topic had passed. They agreed that no further action on this topic would be taken.

5. Review of internal collaboration and communication mechanisms

IMWP members were also asked to share their opinions on current obstacles to engagement and proposals for improvement.

The survey was sent to all IMWP members; feedback was received from 14. Ms Garnier presented the answers received to each question of the survey. She reminded participants that a copy of the survey questions and all answers received was available through the IMWP SharePoint.

The subgroup conducting the review suggested that the survey results pointed to four high priority actions required to improve internal collaboration and communication among IMWP members:

1. Confirm and promote the importance of the contact point for interactions with the IMWP.
2. Clarify expectations of IMWP members, including during a crisis.
3. Draft a document to define the IMWP mission, objectives, activities, tools used, etc.
4. Clarify the expectations for communication and information sharing.

Other medium priority proposals for improving engagement recommended by the subgroup included to use lessons learnt and stakeholder insights to clarify the purpose and benefits of specific IMWP mechanisms – including the Pharmacopoeial alert system, monograph mapping dashboard, and IMWP monographs – and to develop clear instructions on how to use these mechanisms.

The session moderator, Mr Hoare, thanked the subgroup for an excellent job and noted the rich data that had been collected through the survey.

In response to a query from the floor, Ms Garnier clarified the process followed to establish the priority actions. The subgroup had reviewed and discussed all feedback received for each question in the survey and worked together to come up with the recommended priorities.

Participants noted that the response rate was good and could be considered representative; but they suggested that it would be useful to find out why more pharmacopoeias did not answer the survey. This would help understand barriers to participation. All pharmacopoeias who did not answer the survey were invited to provide feedback on barriers to participation. Participants suggested that gathering feedback from stakeholders and world pharmacopoeias would be important to inform most of the priority actions.

They suggested that the two were interconnected—if members could understand exactly what IMWP does, they would be better placed to know how to engage with it. Participants suggested that any efforts to articulate the scope of IMWP should clarify both what IMWP does as well as what it does not do.

After discussing the recommended priority actions, participants discussed how to proceed. They considered various approaches. Participants agreed that clarifying the IMWP's mission, objectives and activities (priority action 3) would help to inform all other priority actions; so the first step forward should be to draft a charter for IMWP that articulates these.

Participants noted that there was likely existing information that could be used as a starting point for drafting a charter; and that the survey results provided a rich source of data to inform the drafting group.

Action points

- Where possible, provide feedback on barriers to participation in the survey.
  - This activity would apply to all pharmacopoeias who did not respond to the survey on internal collaboration and communication mechanisms.

- Confirm focal point contact details to the WHO Secretariat.
  - This activity would be done by all IMWP members.

- Draft a charter for IMWP (priority action 3) that clearly sets out the mission, objectives, activities and tools of the IMWP.
  - This activity would be conducted by a subgroup led by the British Pharmacopoeia. Other participating pharmacopoeias would include the Brazilian Pharmacopoeia, the European Pharmacopoeia, the Japanese Pharmacopoeia, the Korean Pharmacopoeia, the Mexican Pharmacopoeia, the State Pharmacopoeia of Ukraine, and the US Pharmacopeia. Other pharmacopoeias may join the subgroup after discussion in their own organizations and would send expressions of interest to the British Pharmacopoeia.
  - After finalizing the charter, the same subgroup would propose a programme of work to address the remaining priority actions (to confirm and promote the importance of contact points; to clarify expectations of IMWP members; and to clarify expectations for communication and information sharing).

- Review existing IMWP documents and send any information that may be relevant to inform the charter to the subgroup.
  - This activity would be done by the WHO Secretariat.

6. Pharmacopoeial Discussion Group update

PDG expansion

In October 2023, PDG increased its membership for the first time in 34 years. Following a successful one-year pilot participation, the Indian Pharmacopoeia Commission had been welcomed as a fourth member of the group.

The group would now review lessons learnt from the one-year pilot for expansion and assess the operational impact of expanding the PDG membership. The results of this review would inform the PDG's future strategy, structure and organization; and could result in updated entry criteria for joining the PDG. Ms Vielle informed participants that a call for interest in participating in the PDG's expansion programme would be issued in Q2 of 2024.

ICH-Q4B annexes

Over the past year, the PDG continued to work to improve the maintenance process of ICH Q4B annexes by involving the pharmacopoeias of non-founding ICH Regulatory Members in a proof-of-concept project involving three annexes. The project involved pharmacopoeias from Brazil, People's Republic of China, Republic of Korea, Chinese Taipei, Egypt and Mexico in the Q4B process, with revised versions of the annexes agreed by June 2023.

The proof-of-concept phase of the project would end in November 2023, after which the revised ICH Q4B guideline and new standard operating procedure would come into effect. Non-PDG pharmacopoeias would have two options for implementation:

- a standard approach, in which they harmonize their own text with the PDG text and regulatory authorities accept reference to all pharmacopoeias found harmonized; or
- a parallel approach, in which the pharmacopoeia implements the PDG text alongside a local version and manufacturers must use the harmonized text for exported products but can use either version for local products.

Ms Vielle informed participants that the PDG would continue to work with the ICH to update all 16 ICH Q4B annexes, with maintenance work triggered by a revision of PDG text or the harmonization of text by a newly involved pharmacopoeia.

Sharing of texts

Six draft and 10 final PDG texts had been shared since the thirteenth IMWP.

Ms Vielle reminded participants of the PDG harmonization process, which was based on decisions of the pharmacopeias' expert bodies. All revisions were conducted according to the PDG working procedures, which include ensuring transparency by making certain that all texts go for public consultation.

Sometimes, full harmonization was not possible, for example, if there were differing legal requirements, non-harmonized methodologies or differences in scientific expert opinions. In these cases, the PDG used harmonization by attribute to acknowledge that partial harmonization is better than no harmonization at all.

Workplan

Ms Vielle also shared a brief overview of the PDG work programme, which included general chapters and excipient monographs. To date, 30 of the 31 general chapters and 48 of the 62 excipient monographs on the PDG work programme had been harmonized. She informed participants that additional exchanges were also ongoing on key topics, including endotoxin testing, N-nitrosamines, and improving the pharmaceutical environmental footprint.

Participants discussed several aspects of Ms Vielle's update, including details of the parallel approach to implementing ICH Q4B annexes and the challenges of retrospective harmonization. In response to a query from the floor, Ms Vielle told participants that the PDG had no current plans to introduce observers, because most requests to join PDG focused on membership.

They suggested that the process would be even more useful if the PDG could share its workplan for revising texts so that pharmacopoeias can align their own work plans and avoid duplication of effort. The PDG confirmed that it did already share its workplan but acknowledged that the ways in which it did this could be improved.

Action points

- PDG to consider ways to improve how it shares its workplan for developing new and revised texts.

7. What pharmacopoeias can do to promote sustainability

Participants noted that pharmacopeial standards impact the whole supply chain, which means pharmacopoeias have many opportunities to influence the environmental impact of not only their own operations but those of the pharmaceutical industry more broadly.

7.1. Experience from world pharmacopoeias

Argentine Pharmacopoeia

Ms Assalone gave a brief update on sustainability activities by the Argentine Pharmacopoeia, which included introducing a new general chapter on alternatives to the use of animals in the next supplement. A working group was also being established to reduce the use of hazardous chemicals, including mercury, in the pharmacopoeia.

Brazilian Pharmacopoeia

Mrs Riviane Matos Gonçalves provided an overview of the Brazilian Pharmacopoeia's strategic objective for 2021–2026 to become more sustainable and reduce the use of hazardous solvents and animal testing. To that end, the Brazilian Pharmacopoeia had a working group aiming to reduce the use of rabbits in pyrogenic tests and provide alternatives to animal-based endotoxin testing.

The Brazilian Pharmacopoeia was also working to reduce the use of hazardous chemicals in solubility tests. Benzene, chloroform, pyridine and carbon disulfide were all being phased out of the Brazilian Pharmacopoeia; and the use of n-hexane instead of petroleum ether was also being recommended.

In the field of herbal medicines, the Brazilian Pharmacopoeia was applying the principles of green chemistry to use solvents with reduced toxicity, and to reduce the quantity of material used in tests. An overall statement advising experts to try and avoid the use of toxic solvents was also included in the general guidance for developing monographs.

European Pharmacopoeia

Ms Vielle emphasized the importance of improving the pharmaceutical industry's environmental footprint to the European Pharmacopoeia, which had prioritized four key actions:

- avoid and reduce use of hazardous reagents (including hexane, chloroform and dioxane);
- reduce the amounts of solvent used in European Pharmacopoeia methods;
- avoid the use of mercury, mercury compounds and equipment with mercury (for example, thermometers) in European Pharmacopoeia tests; and
- develop and promote alternatives to animal testing in European Pharmacopoeia texts, such as, to implement the 3R principles (replace, reduce, refine).

Several European Union regulations further supported these key actions, including the existing regulations on fluorinated greenhouse gases and REACH regulation annex XIV (to replace di-(2-ethylhexyl) phthalate as a polyvinyl chloride plasticizer); as well as upcoming REACH regulation annex XV (to restrict polyfluorinated substances).

Ms Vielle told participants that reducing animal testing in particular was a very high priority, with a new strategy for pyrogenicity being implemented and a hope that, by 2025, the rabbit pyrogen test would have been completely deleted from the European Pharmacopoeia.

In addition to presenting the specific actions being taken by the European Pharmacopoeia, Ms Vielle highlighted some of the broader sustainability actions being taken by EDQM. These included reducing waste (in both chemicals used and packaging); reducing the impact of shipping reference standards (by grouping orders and re-using ice packs); and reducing the environmental footprint of its premises (by implementing a biodiversity charter, campaigning to reduce energy consumption and assessing the potential of installing rainwater tanks and solar panels).

The International Pharmacopoeia

Dr Schmidt shared The International Pharmacopoeia's approach to implementing green and sustainable chemistry and pharmacy.

Like other pharmacopoeias, The International Pharmacopoeia was eliminating the use of hazardous chemicals and reagents from its texts. It was doing this by avoiding their use in new monographs while simultaneously reviewing its existing compendial texts to introduce alternatives. For example, the obsolete use of mercury salts in non-aqueous titrations had been replaced in 32 monographs. The general chapters on general identification tests and colour of liquid had also been revised to avoid the use of hazardous chemicals.

In addition to eliminating hazardous chemicals, The International Pharmacopoeia was implementing the 3R principles to promote more humane animal research. For example, the innocuity test (or abnormal toxicity test), which uses guinea pigs and mice, had been suppressed; so too had the test for histamine-like substances.

In some cases, revisions were being made to reduce the use of non-sustainable materials. For example, a revision to the tests for diethylene glycol and ethylene glycol in liquid

preparations for oral use had been made to replace the non-renewable carrier gas helium with more sustainable alternatives (nitrogen and hydrogen).

Indian Pharmacopoeia Commission

Dr Saini informed participants of a pilot study to assess the use of hazardous chemicals in four pharmacopoeias (Indian Pharmacopoeia, US Pharmacopeia, British Pharmacopoeia and The International Pharmacopoeia). The study reviewed each pharmacopoeia to identify the prevalence of five hazardous chemicals: benzene, carbon tetrachloride, chlorobenzene, potassium cyanide, pyridine.

Dr Saini presented the results for each hazardous chemical, alongside recommendations on what action could be taken to eliminate its use wherever it was found. For example, in cases where one or more pharmacopoeia used the hazardous chemical but others did not, Dr Saini suggested pharmacopoeias could adopt the safer method; and, in cases where all of the pharmacopoeias used the hazardous chemical, he suggested they could work together to develop an alternative approach. Dr Saini noted that some hazardous chemicals were much more prevalent than others: for example, pyridine appeared in 37 different monographs and general chapters; chlorobenzene appeared in just three.

Dr Saini also informed participants of various initiatives that the Indian Pharmacopoeia Commission was doing to "go green and clean" in its own operations, including: installing and using rooftop solar power, recharging depleted groundwater levels, and cleaning and tree planting around its site, among other things.

Japanese Pharmacopoeia

Dr Shoichi Sanuki, Technical Officer, Division of Pharmacopoeia and Standards for Drugs, Office of Review Management, PMDA, summarized the Japanese Pharmacopoeia's approach to sustainability, which he said was embedded in its basic principles for development (see section 5.7).

As part of improving texts by introducing the latest science and technology (principle 2), the Japanese Pharmacopoeia was committed to revising general tests to promote clean analyses; and improve individual monographs by reducing the volume of samples, reagents, solutions and solvents for testing, and by using clean analysis.

Dr Sanuki highlighted a few examples of where this approach had been done in previous editions of the Japanese Pharmacopoeia. For example, in the seventeenth edition (second supplement), safer solvents had been introduced to 12 monographs; and in the eighteenth edition and its first supplement, hazardous reagents had been removed from 8 monographs. A further 21 monographs that still used hazardous reagents would be revised in and after the second supplement to the eighteenth edition.

Mexican Pharmacopoeia

Ms Daniela Monserrat Vázquez García, Internal Coordinator of Committees and International Affairs at FEUM, highlighted the Mexican Pharmacopoeia's approach to sustainability, which included:

- work to review monographs to identify solvents that can be eliminated or replaced;

- development of a 2024 workplan that focuses on adopting general analytical methods with less environmental impact (including a new general method on dissolution profiles or active substances); and
- implementation of the 3R principles in quality control and release testing of batches of biological products (vaccines).

Ms Vázquez García told participants that implementing the 3R principles was a particular priority that was not only expected to prevent animal suffering but also facilitate faster release of quality products at a lower cost. She said a new general monograph on the substitution of in vivo methods with in vitro methods for vaccine quality control had been developed. The individual monographs of all vaccines and other biologicals had also been revised to remove the abnormal toxicity test that relied on animal use. Other action being undertaken by the Mexican Pharmacopoeia to implement the 3R principles included plans to:

- review alternative methods to other tests that use animals in Mexican Pharmacopoeia monographs;
- jointly evaluate the scope for implementing the 3R principles with other FEUM Committees (on biotechnology, medical devices, etc);
- evaluate and follow up on recommendations from WHO's October 2023 ECSPP;
- participate in workshops and collaborative studies with other pharmacopoeias and organizations that already implement 3R principles; and
- harmonize requirements with other leading pharmacopoeias.

United States Pharmacopeia

Dr Giancaspro described the US Pharmacopeia's journey to reduce the pharmaceutical industry's environmental footprint, which began three decades ago, through the US Pharmacopeia Convention's 1995 resolution Environmental Concerns. He emphasized the value of two key mechanisms:

- modernization of US Pharmacopeia texts to reduce the use of hazardous and toxic substances and introduce new, more efficient and less wasteful testing methods; and
- harmonization with global pharmacopoeias to improve alignment with multilateral groups such as PDG and IMWP.

Dr Giancaspro showcased several examples of how these mechanisms had successfully reduced environmental footprints. For example, modernization and harmonization had reduced the use of carbon tetrachloride and benzene in US Pharmacopeia monographs by 96% and 80% respectively. These efforts had also helped protect animals. In collaboration with Sanofi, the US Pharmacopeia provided alternatives to rabbit assays in insulin testing, reducing animal use by an estimated 2 000 rabbits each year. Other examples of modernization for animal protection included introducing alternatives to oxytocin bioassays; and, most recently, alternatives to the horseshoe crab reagent for endotoxin testing.

In July 2021, the US Pharmacopeia began a new initiative to engage government authorities and international colleagues in an effort to improve the environmental impact of pharmaceutical manufacturing and quality testing across the supply chain. An early stakeholder roundtable in 2022 was followed by an open forum in February 2023 that was attended by more than 100 stakeholders from across the world. Some of the suggestions collected through these dialogues included, among others, enabling better use of: environmental monitoring technologies, green chemistry, inventories of past efforts, and recycled solvents.

7.2. Scope of sustainability efforts

Mr Hoare summarized the scope of sustainability efforts by world pharmacopoeias. He noted that it was clear from the experiences presented (see section 9.1) that IMWP members were already doing a lot to reduce environmental impacts and promote sustainability. He suggested these efforts could be divided into three categories.

1. **Monographs and methods:** directing experts to think about and minimize the environmental impact of the methods and materials (and their supply chains) used in monographs.
2. **Guidelines for stakeholders:** influencing industry practices through the advice given by pharmacopoeias in, for example, expert opinions, presentations at events, and written communications in media and social media.
3. **Pharmacopoeia operations:** taking action within pharmacopoeias' own operations and embedding requirements to assess environmental impacts within contracts with others.

Participants recognized that the actions each pharmacopoeia could take, especially with regards to its own operations, would be determined by various factors, such as how big the pharmacopoeia was. But they noted that even small actions would make a difference; and that everyone could and should contribute.

7.3. Next steps

Dr Moore moderated a discussion on next steps for IMWP.

Dr Giancaspro presented five principles based on the US Pharmacopeia's experience, that could be used to guide IMWP principles.

1. Reduce energy consumption and greenhouse gas emissions (carbon footprint).
2. Minimize waste production related to use of hazardous materials, solvents, plastics, packaging, and other materials.
3. Improve water stewardship, including through reduced water consumption and wastewater treatment.
4. Strengthen biodiversity conservation by reducing the need for and impact of animal testing.
5. Enhance protections of personnel against potential exposure to hazardous drugs and chemicals in industrial, laboratory, and pharmacy settings through development of guidelines and related educational efforts.

Participants discussed the five principles and suggested that they offered a good starting point but they would require some revision to tailor them to the IMWP priorities, for example by making hazardous chemicals more prominent, giving greater emphasis to the 3R principles, and incorporating herbal medicines under biodiversity conservation. They agreed to draw on all the experiences of IMWP members to refine the principles.

They proposed using the principles to inform a white paper or equivalent document that would:

- compile all the different efforts of world pharmacopoeias to show what is possible and highlight best practices; and
- point to what more IMWP members wanted to do.

Participants were clear that this advocacy document would focus on showcasing overall approaches and initiatives; they suggested that it could be complemented by later documents delving into details of specific topics or areas of interest.

Action points

- Develop a set of principles on sustainability for IMWP members to commit to.
  - This activity would be conducted by the existing sustainability subgroup, which is co-chaired by the Indian Pharmacopoeia Commission and the US Pharmacopeia. Other participants of the subgroup are the Brazilian Pharmacopoeia, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Korean Pharmacopoeia and Mexican Pharmacopoeia. Other pharmacopoeias were welcomed to join the subgroup and told they could do so by contacting the Indian Pharmacopoeia Commission or US Pharmacopeia.

- Use the agreed principles to develop an advocacy document, for example a white paper, to showcase the sustainability initiatives of world pharmacopoeias.
  - This activity would be a continuation of the activity above and would be conducted by the sustainability subgroup.

8. Results from the scientific priorities survey

The (original and) follow-up survey were designed to identify shared topics of interest for potential collaboration and action. In 2023, recipients were presented with the same 33 topics included in 2021 survey, as well as a new topic (environmental footprint), and asked to rate them on a five-point scale ranging from low to high priority. In total, 15 pharmacopoeias responded to the survey (compared with 16 last time).

Some of the same topics prioritized by IMWP in the last survey were again given high priority by world pharmacopoeias: standards harmonization, impurities (including organic impurities, elemental impurities, residual solvents and mutagenic impurities), and nitrosamines. Some topics had dropped off the high priority list, namely vaccines and complex products (including COVID-19 vaccines).

Two topics had emerged as new priorities by IMWP:

- new approaches to control impurities (including flexible and performance-based approaches to impurities measurement, and predicting the probability of impurities presence in active pharmaceutical ingredients and finished pharmaceutical products); and
- efforts to reduce environmental footprints (reducing the amount and toxicity of testing reagents that are harmful to human health, and the environment, including contributions to climate change).

Dr Moore emphasized that there were many other topics that were also highly rated by the survey and could provide a basis for establishing joint IMWP activities. Topics that were trending up compared with the last survey (i.e. up by 0.5 or more rating) included analytical procedure lifecycle and analytical quality by design (AQbD), and measurement and data

quality. Other topics that were given a high rating (4 or 5) by eight or more pharmacopoeias included:

- new performance tests (for equivalency testing, dissolution modelling and biorelevant dissolution testing);
- endotoxins and rapid sterility (how to determine the equivalency of results using new and traditional methods);
- therapeutic proteins and monoclonal antibodies; and
- performance verification and dissolution.

They further suggested that the results would provide useful data for the drafting subgroup working to define a charter for IMWP (see section 7).

Action points

- Use the results of the scientific priorities survey to identify shared interests and, where appropriate, collaborate bilaterally or multilaterally with other IMWP participants on separate projects towards a common objective.
  - All IMWP members would participate in this activity as and when they saw fit.

9. Update on the IMWP monograph

The monographs had both been published in August 2021, after being developed by the Japanese Pharmacopoeia with the support of other world pharmacopoeias. Since then, seven favipiravir reference substances had been sold. Recently the situation had changed. There had been no sales or inquiries for reference substances for more than half a year. COVID-19 was no longer a public health emergency of international concern; and the innovator had also ended development of favipiravir as a COVID-19 treatment medicine.

Dr Maegawa suggested that while the IMWP monographs likely contributed to the fight against falsified and substandard products during the pandemic, they may now have outlived its role. He noted that while favipiravir reference substances remained in stock, they would require updating in the future.

They agreed there were many reasons for this, including the fact that despite favipiravir's early promise, it was not, in the end, recommended by WHO as a COVID-19 treatment.

Participants suggested that it would be important to use lessons learned from the experience to improve their approach in future crises. They noted that manufacturers of other candidate COVID-19 medicines that were contacted did not want to participate in a new IMWP collaborative process because of the uncertainty of what would be expected and how much time it would take during a crisis situation. Participants suggested that more manufacturers might have been willing to participate if a clear criteria and process for developing an IMWP monograph had already been established.

Action points

- Keep the IMWP monographs on favipiravir and favipiravir tablets open; and continue to provide reference standards as long as stocks last.

- This activity would be led by the Japanese Pharmacopeia.

- Identify the criteria for triggering the development of a IMWP monograph in the future.
  - This activity would be conducted by the charter subgroup (see section 7), as part of its broader work to define IMWP objectives and activities.

10. The 15th IMWP

Participants discussed plans for their next meeting, the 15th IMWP.

Participants discussed the timing and format of the next meeting, noting that travel remained a significant challenge for some. They agreed that the 15th IMWP should ideally be held in a hybrid format (virtual and face-to-face).

Action points

- Confirm the timing for the next IMWP; and plan and host the meeting using a hybrid face-to-face and digital format.
  - This activity would be led by the Indian Pharmacopeia Commission.

Annexes

Annex A. List of participants

Opening guests

Dr Alejandro Svarch Pérez, Head of the Mexican Federal Commission for the Protection of Sanitary Risk (Cofepris), Ministry of Health, Mexico
Ms Miriam Jackeline Loera Rosales, Commissioner of Evidence and Risk Management, Cofepris, Ministry of Health, Mexico
Dr Armando de Negri Filho, Advisor on Health Services and Systems, Pan American Health Organization (PAHO)/World Health Organization (WHO)

Pharmacopoeias[2]

Farmacopoea Argentina
Instituto Nacional Medicamentos, Buenos Aires, Argentina
- Ms Celeste de Angelis, Technical Secretariat
- Ms Melina Isabel Assalone, Technical Secretariat

Farmacopeia Brasileira
Agência Nacional de Vigilância Sanitária (ANVISA), Brasília, Brazil
- Mrs Riviane Matos Gonçalves, Health Regulation Specialist
- Mrs Fernanda Smidt Lara Resende, Health Regulation Specialist
- Mrs Raquel Lima e Silva, 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
- Mr Michael Whaley, Head of BP and Labs Team 2.

Egyptian Pharmacopoeia
The Egyptian Drug Authority, Cairo, Egypt
- Dr Mohamed Abdallah, Head of Central Administration of Drug Control
- Dr Eman Mamdouh, Member of the General Administration of Public Relations and International Cooperation
- Dr Lobna Sallam, Egyptian Pharmacopoeia Preparation Group Team Leader

[2] Unable to attend: Austrian Pharmacopoeia, Belarus Pharmacopoeia, Belgian Pharmacopoeia Commission, Chinese Pharmacopoeia 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, Irish Pharmacopoeia, Italian Pharmacopoeia Secretariat, Lithuania Pharmacopoeia Commission, Montenegro Pharmacopoeia, 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, Turkish Pharmacopoeia.

European Pharmacopoeia[3] [4]

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

- Dr Petra Doerr, Director
- Ms Anne Garnier, Scientific Program Manager, European Pharmacopoeia Department
- Ms Cathie Vielle, Head of European Pharmacopoeia Department

Indian Pharmacopoeia Commission

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

- Dr Robin Kumar, Principal Scientific Officer
- Dr Pawan Kumar Saini, Senior Scientific Officer

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

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

- Dr Jieun Kim, Scientific Officer, Pharmaceutical Standardization Division
- Dr Minkyeoung Kim, Scientific Officer, Drug Research Division

Mexican Pharmacopoeia (Host)

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

- Ms María del Carmen Hernández Alonso, Manager of Committees Coordination
- Ms Daniela Monserrat Vázquez García, Internal Coordinator of Committees and International Affairs
- Mr Juan Carlos Gallegos Ortega, Manager of Editions and Publications
- Dr Angélica López Sotelo, Permanent Commission of FEUM member
- Mr Ubaldo Juárez Sevilla, Executive Sub-Director of Pharmacopoeia

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[3] European Pharmacopoeia Members: Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland, 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, the United States of America, Uzbekistan, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).

North Macedonia Pharmacopoeia

Agency of Medicines and Medical Devices, Skopje, North Macedonia

- Ms Eleonora Pandova, Head of Unit, Department for Assessment of Drug Documentation
- Mr Lirim Shabani, Director
- Mrs Marija Trajchuleski, Head of Sector for Evaluation of the Documentation for Marketing Authorization for Medicines and Medical Devices

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

- Mr Aleksei Iarutkin, Deputy Head of the Institute of Pharmacopoeia and Standardisation in the Area of Medicines Regulation

The State Pharmacopoeia of Ukraine

Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines, Kharkiv, Ukraine

- Dr Natalia Volovyk, Deputy Director for Quality

United States Pharmacopeia

Rockville, United States of America

- Mr Efren Elias, Government & Regulatory Affairs Director, Latin America
- Dr Gabriel Giancaspro, Distinguished Scientific Fellow, Documentary Standards & Compendia Policy
- Mr Guillermo Huerta, Scientific Affairs Manager
- Dr Kevin Moore, Senior Manager, Pharmacopeial Collaboration

State Pharmacopoeia of the Republic of Uzbekistan

State Institution Center for Pharmaceutical Products Safety, Ministry of Health of the Republic of Uzbekistan, Tashkent, Uzbekistan

- Mr Zaynidinov Akmalkhoja Oskarkhodzhayevich, Scientific Secretary of the Editorial Board
- Dr Djalilov Habibulla Karimovich, Chief Editor of the State Pharmacopoeia of the Republic of Uzbekistan
- Ms Nazrullaeva Khilola Said-Akhmedovna, Leading Specialist of the Pharmacopoeia Committee
- Dr Nuridullaeva Kamola Negmatilloevna, Chairwoman of the Pharmacopoeia Committee

Vietnamese Pharmacopoeia

Ministry of Health, Viet Nam

- Mrs Thi Thu Hang Luc, Health of Vietnamese Pharmacopoeia and Formulary Centre, NIDQC

WHO Regional Offices[5]

WHO Regional Office for Europe

- Ms Dorina Pirgari, Technical Office, Access to Medicines and Health Products

WHO Secretariat

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

[5] Unable to attend: WHO Regional Office for Africa, WHO Regional Office for the Americas, WHO Regional Office for the Eastern Mediterranean, WHO Regional Office for South-East Asia, WHO Regional Office for the Western Pacific

Annex B. Agenda

14th International Meeting of World Pharmacopoeias (IMWP)

Hybrid meeting Mexico City, Mexico 08-09 November 2023

Chairs and moderators: Ms Daniela Monserrat Vázquez García, FEUM; Mr Steve Hoare, British Pharmacopoeia; Mr Kevin Moore, US Pharmacopeia.

1. Welcome remarks from Dr Alejandro Svarch Pérez, Head of the Mexican Federal Commission for the Protection of Sanitary Risk (Cofepris) of the Health Ministry of Mexico.

2. Welcome remarks from Ms Miriam Jackeline Loera Rosales, Commissioner of Evidence and Risk Management, Cofepris.

3. Opening remarks from Dr Armando de Negri Filho, Advisor on Health Services and Systems, Pan American Health Organization (PAHO)/World Health Organization (WHO).

4. Introduction by Dr Luther Gwaza, WHO Secretariat.

5. General update on recommendations from the 13th IMWP.

6. Brief update on news from participating pharmacopoeias.

7. COVID-19-related activities:
   - Feedback from stakeholders on IMWP COVID-19 related activities.
   - IMWP future approach during public health emergencies.

8. Review of internal collaboration and communication mechanisms.

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

10. How to reduce the use of hazardous chemicals in pharmacopoeia monographs/methods.
    - Consideration of IMWP recommendations on implementation of the principles of the 3Rs of animal testing.

11. Future activity brainstorm:
    - Updated results from the scientific priorities survey.

12. Update on the IMWP monographs.

13. Preparation of the 14th IMWP Meeting Report.

14. Opportunities for reaching out, including preparations for upcoming stakeholders' meeting and press release or public statement.

15. Preparation of the 15th IMWP.

16. Any other business and conclusions.

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

World Health Organization