

13th International Meeting of World Pharmacopoeias

Virtual meeting | 27–29 September 2022

Background

Each pharmacopoeia in the world covers a different country or region, but all work to protect public health by creating and making available public standards that help ensure the quality of medicines. Every year, world pharmacopoeias – including national, regional and The International Pharmacopoeia – meet through the International Meeting of World Pharmacopoeias (IMWP) to share experience and expertise and find ways of working together to synchronize their efforts.

The 13th IMWP, which was co-hosted by the Pharmacopoeia of the United Mexican States (FEUM) and the World Health Organization (WHO), was held virtually from 27–29 September 2022. More than 38 participants, representing some 51 pharmacopoeial authorities, attended the meeting.

Welcome

Ms Miriam Jackeline Loera Rosales, Commissioner of Evidence and Risk Management of the Mexican Federal Commission for the Protection against Sanitary Risk, welcomed all participants to the 13th IMWP on behalf of Dr Alejandro Svarch, Federal Commissioner of the Protection of Sanitary Risk of the Health Secretary of Mexico.

In her opening remarks, Ms Loera Rosales recognized the immense value of pharmacopoeias to public health, saying that all health ministers rely on their regulatory authorities to make decisions that can restore the health of their populations, which in turn rely on the scientific knowledge generated and systematized by world pharmacopoeias.

Reflecting on the role of pharmacopoeias in supporting health emergency response, she praised the Mexican Pharmacopoeia for its work during the COVID-19 crisis to develop topical monographs in record time to support the national pandemic response. She also thanked the Mexican Pharmacopoeia for co-hosting the 13th IMWP and congratulated it on celebrating its 38th anniversary in September 2023.

Ms Loera Rosales noted that the IMWP had twice been forced to convene virtually due to the COVID-19 pandemic and re-issued an invitation to host the IMWP in Mexico City in 2023 if conditions allow.

Opening

Dr Clive Ondari, Director of WHO's Health Products Policy and Standards, provided opening remarks on behalf of WHO Director-General, Dr Tedros Ghebreyesus.

After welcoming all participants, Dr Ondari drew attention to the deep and far-reaching impacts of the COVID-19 pandemic on all societies and economies. He said these were shaping new, collaborative ways of working and thinking, including around the value and supply chains of medical products.

Dr Ondari praised the IMWP's contribution to the global collaborative effort through its pharmacopoeial alert system for COVID-19, which has been operational since March 2020. He emphasized the key role that this mechanism has had in enabling the availability and use

of public norms and standards for lifesaving essential medicines that ensure patients receive the quality therapeutics and vaccines they need.

Dr Ondari recommended world pharmacopoeias continue their collaborative efforts and integrate lessons learnt during the pandemic into routine use. He urged the IMWP to build on the global pharmacopoeial alert mechanism and to make supportive pharmacopoeial texts freely available to support the global public response to COVID-19.

Introduction

Dr Luther Gwaza, Team Lead of WHO's Norms and Standards for Pharmaceuticals (NSP) Team, gave a brief introduction to the meeting.

He told participants that world pharmacopoeias have a long history of working together to unify pharmacopoeial standards that dates back to 1874. This long-standing collaboration began as an effort to standardize terminology and specify dosages and composition of medicines. Dr Gwaza said standardization remained a key motivation behind the IMWP, whose goals include to:

- establish a common framework for pharmacopoeial standard-setting;
- harmonize approaches and policies;
- create a guiding set of principles for designing, developing, maintaining, publishing and disseminating pharmacopoeial standards;
- strengthen collaboration and exchange among pharmacopoeias; and
- reduce duplication of work and increase the level of prospective convergence.

Dr Gwaza reiterated the importance of the work of world pharmacopoeias to global health. This work contributes directly to all three goals of the WHO triple billion targets (one billion more people benefitting from universal health coverage; one billion more people better protected from health emergencies; one billion more people enjoying better health and well-being). The work of world pharmacopoeias is also fundamental to many of the Sustainable Development Goals.

Recap on outcomes from the 12th IMWP

To set the scene for the meeting, Dr Steve Estevão Cordeiro, Technical Officer, NSP, gave a recap on the outcomes from the 12th IMWP.

News from world pharmacopoeias

Each pharmacopoeia participating in the 13th IMWP gave a brief news update on achievements over the past year and planned activities for the year ahead.

Activities related to COVID-19

Dr Herbert Schmidt, Technical Officer, NSP, provided an overview of IMWP activities to support the global response to COVID-19, including outcomes from the monthly meetings of the IMWP pharmacopoeial alert system.

This system, which was originally established in 2018 to enable the timely exchange of information in case of crisis, proved invaluable to IMWP pharmacopoeias during the pandemic as a mechanism for rapidly sharing experience and expertise to support the COVID-19 response. Through the system, world pharmacopoeias:

- shared information on maintaining operations to develop and distribute standards during the pandemic;
- created an online dashboard mapping the availability of monographs for therapeutics in use (or in clinical trials) for COVID-19; and
- developed new standards for COVID-19 treatments, i.e. the monographs for favipiravir and favipiravir tablets.

Survey results

Dr Cathie Vielle, from the European Pharmacopoeia, presented the results of a survey on IMWP COVID-19-related activities. The survey was sent to world pharmacopoeias to identify lessons learnt from international pharmacopoeial collaboration during COVID-19, including what went well and what could have gone better.

Participants at the 13th IMWP pointed to IMWP's ability to move at pace during the pandemic as another major success. Just three months after COVID-19 was declared a public health emergency, the IMWP – through the pharmacopoeial alert system – had already started meeting to share learning and provide aligned solutions to the pandemic.

Participants discussed the survey results and reflected on lessons learnt during the pandemic.

Herbal supplements and medicines

Dr Daniela Monserrat Vázquez García, from FEUM, presented a proposal from the Mexican Pharmacopoeia to develop an advocacy tool on the importance of quality control for herbal medicines during public health crises, which could be used to increase awareness among health authorities, health care professionals and the general public.

Way forward

Participants discussed leveraging lessons learnt from COVID-19 to improve preparedness and response for future public health crises

Pharmacopoeial Discussion Group (PDG) update

On behalf of the PDG, Dr Hikoichiro Maegawa, Division Director of the Division of Pharmacopoeia and Standards for Drugs at PMDA in Japan, provided an update on four key activities undertaken since the last IMWP.

Future activity brainstorm

Mr Kevin Moore, Senior Manager of Pharmacopoeial Collaboration at the United States Pharmacopoeia, gave a recap of results from the 2021 IMWP Scientific Priorities Survey, some of which were also presented at the 12th IMWP.

This survey was designed to identify shared topics of interest for potential collaboration and action. Participants discussed the survey results and considered their continued value in

informing collaborative projects. They agreed that the survey results were extremely useful and agreed to use them as a tool for understanding shared priorities and for identifying potential topics and partners for bilateral or multilateral collaboration. These should be taken up separately by the relevant pharmacopoeias and, where appropriate, reported back to the IMWP.

Participants also recognized that science and technology is constantly evolving, and situations and priorities change from one year to the next, so it would be important to update the scientific priorities survey periodically. To this end, the IMWP agreed to refresh the scientific priorities survey in 2022.

Outreach opportunities

Participants discussed opportunities for outreach and stakeholder engagement. They emphasized the value of stakeholder meetings and looked forward to the stakeholder consultation (survey and workshop) on COVID-19-related activities.

The 14th IMWP

Participants discussed plans for their next meeting, the 14th IMWP. Participants agreed that the next meeting (14th IMWP) would take place in Mexico in 2023, conditions allowing and that the one after (15th IMWP) would take place in India in 2024.

Closing remarks

Dr Gwaza congratulated the world pharmacopoeias for a successful meeting and reconfirmed WHO's commitment to supporting them by continuing to serve as the IMWP Secretariat. He thanked all participants for their contributions and their high-quality discussions. He thanked the Mexican Pharmacopoeia for co-hosting the meeting; and all the meeting moderators for facilitating an efficient meeting. He closed the meeting.

Summary of outcomes

Participants of the 13th IMWP agreed to continue working together to exchange information and knowledge that can help assure medicines quality. Some of the key outcomes from the meeting are summarized below.

1. The IMWP shared experience and information on the latest news and activities undertaken by world pharmacopoeias over the past year to support national and global public health.
2. The IMWP acknowledged the value of IMWP COVID-19-related activities, including the global pharmacopoeial alert system, in supporting the timely sharing of experience and expertise for assuring quality medicines during public health emergencies.
3. The IMWP agreed to 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.

4. The IMWP agreed to review information-sharing mechanisms (for example, a shared web platform) to better support rapid communication and increased engagement of participating pharmacopoeias, including during public health emergencies and other crises.
5. The IMWP agreed to use the scientific priorities survey results to understand shared priorities and identify potential topics for bilateral or multilateral collaboration that can be taken up separately. It further agreed to refresh the scientific priorities survey (and to share results for information purposes during the stakeholder consultation).
6. The IMWP accepted the Mexican Pharmacopoeia's invitation to host the 14th IMWP in Mexico City in 2023 (conditions allowing) and agreed to make it a hybrid meeting.

Meeting Agenda

Moderators: Ubaldo Juarez Sevilla, FEUM; Rafael Hernández Medina, FEUM; Cathie Vielle, European Pharmacopoeia; Rajeev Raghuvanshi, Indian Pharmacopoeia Commission.

1. Welcome remarks from Dr Alejandro Svarch, Federal Commissioner of the Protection of Sanitary Risk of the Health Secretary of Mexico
2. Opening remarks from Dr Clive Ondari, Director, Health Products Policy and Standards, WHO.
3. Introduction by WHO Secretariat.
4. General update on recommendations from the 12th IMWP.
5. Brief update on news from participating pharmacopoeias (5–10 minutes each).
6. COVID-19-related activities:
 - Summary of IMWP COVID-19-related activities
 - Lessons learnt:
 - Survey results on IMWP COVID-19-related activities
 - Concept paper: *General methods and quality control, and control of herbal supplements and herbal medicines related to the COVID-19 pandemic*
 - Way forward
 - Communication on lessons learnt from COVID-19 on international collaboration
7. Update from the Pharmacopoeial Discussion Group, including proposed interaction with world pharmacopoeias.
8. Brainstorming on future list of activities:
 - Review of outcomes from IMWP Scientific Priorities survey.
9. Preparation of the 13th IMWP Meeting Report.
10. Opportunities for reaching out, including preparations for upcoming stakeholders' meeting and press release or public statement.
11. Preparation of the 14th IMWP.
12. Any other business and conclusions.

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>



**World Health
Organization**