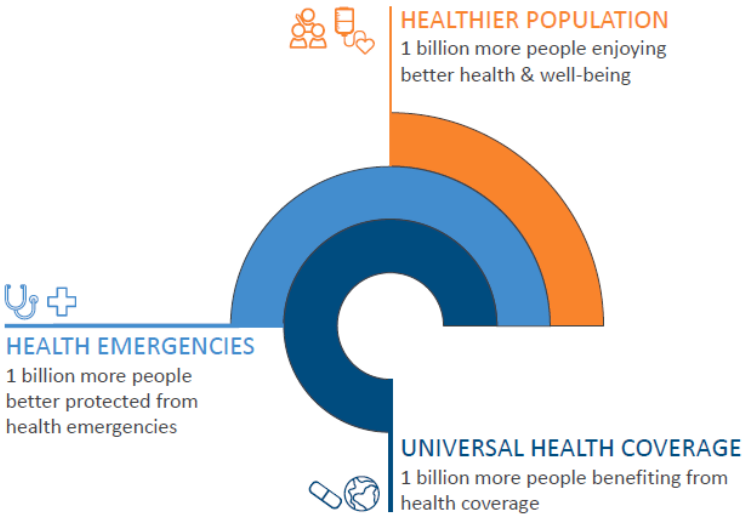
Background of the International Meeting of World Pharmacopoeias and feed-back from the 11th IMWP

Dr Sabine Kopp, Team Lead, Norms and Standards for Pharmaceuticals

World Health Organization (WHO)

GPW13

World Health Organization



3

SDG 3. Goal 3: Ensure healthy lives and promote well-being for all at all ages

World Health Organization

4

Access to and **availability** of **quality medical products**

5

Role of WHO in promoting quality

World Health Organization

- Promoting access to quality assured medical products is a key objective for WHO
- Underpinned by numerous WHA resolutions and a target in SDG 3, which speaks of access to quality assured medicines and health products and functioning regulatory systems
- WHO contributes to this objective through the setting of international norms and standards, regulatory system strengthening, efforts to combat substandard and falsified products, the prequalification programme and for providing an international platform

The International Pharmacopoeia - since 1947

- Is based on decision by **World Health Assembly**
- Contains analytical methods and specifications for
  - ✓ active pharmaceutical ingredients
  - ✓ finished pharmaceutical products
  - ✓ excipients
  - ✓ radiopharmaceuticals
- Focuses on **medicines**
  - ✓ Model List of Essential Medicines since 1975
  - ✓ Invitations to submit EOI for product evaluation to Prequalification, WHO/UN specific disease programmes

✓ Free online access **http://apps.who.int/phint/en/p/about/**

7

WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP)

Covers today* WHO's guidance for medicines quality assurance*:

- Development
- Production
- Quality Control, including *The International Pharmacopoeia*
- Quality related regulatory guidelines
- Inspection
- Distribution and supply

lifecycle of medicines

from development to delivery to the patient

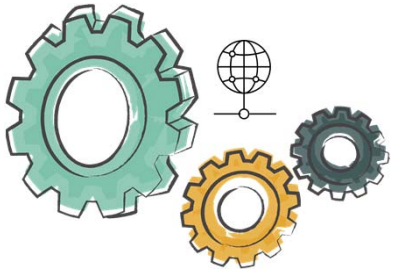
8

WHO's efforts towards convergence and reliance in quality control

- International Pharmacopoeia (Ph.Int.) based on international consultation process with focus on medicines of major public health impact globally
- Ph.Int. ready for use and implementation by WHO Member States (194)
- WHO signs MoUs and cooperation agreements with national and regional pharmacopoeias
- WHO actively collaborates with NRAs, national quality control laboratories, WHO Collaborating Centres and WHO Programmes
- WHO is observer in numerous inter- and intra-regional fora, including the Pharmacopoeial Discussion Group (PDG)
- WHO facilitates the International Meetings of World Pharmacopoeias

Trends towards convergence and reliance

International collaboration towards convergence among Pharmacopoeias include:



- Pharmacopoeial Discussion Group (PDG)
- MoUs between Pharmacopoeias
- Bilateral projects among Pharmacopoeias
- Fora and summits to discuss matters of joint interest
- International Meetings of World Pharmacopoeias

Trends towards convergence

1st *International Meeting of World Pharmacopoeias* – hosted by WHO, Geneva, Switzerland, 29 February–2 March 2012

11

Conclusions of First International meeting of world pharmacopoeias

- Main emerging suggestion: development of "Good Pharmacopoeial Practices" to favour prospective harmonization, procedure to be facilitated by WHO
- Formation of Initial drafting group during meeting, composed of: Argentina, Brazil, European Pharmacopoeia, India, Japan, Mexico, Russian Federation, Ukraine, United States Pharmacopeia, editorial assistance by the United Kingdom - process open to all pharmacopoeias
- Agreement to draft document under auspices of WHO Expert Committee on Specifications for Pharmaceutical Preparations

12

International Meeting of World Pharmacopoeias

1st *International Meeting of World Pharmacopoeias* (IMWP) – hosted by WHO, Geneva, 29 February–2 March 2012











13

11th International Meeting of World Pharmacopoeias

hosted by EDQM, Council of Europe,

18-19 February 2020

14

Who participates ?

Usually between 20-30 representatives from world pharmacopoeias

→ *representing usually 50 pharmacopoeias and pharmacopoeial authorities from the 56 listed **

→ *usually followed by special events organized by the host pharmacopoeia for* stakeholders and users

**Reference: Index of world pharmacopoeias and pharmacopoeial authorities*

15

What is the focus ?

- Opportunity for greater collaborative work
- Opportunity for sharing of information among world pharmacopoeias
- Development of good pharmacopoeial practices (GPhP)
- Address emerging pharmacopoeial issues

16

Link to regulators and users

- Outcome of meetings shared with users and stakeholders of pharmacopoeias, including regulators, quality control laboratories and manufacturers, usually stakeholders meetings follow the main pharmacopoeias meetings
- Discussion at International Conference of Drug Regulatory Authorities (ICDRA) meeting; public pre-ICDRAs
- Feedback to WHO Expert Committee on Specifications for Pharmaceutical Preparations

  → Impact on WHO activities

  → opportunity for impact on WHO Member States' activities

17

Outcome: Good pharmacopoeial practices (GPhP)

- Primary objective: "*to define approaches and policies in establishing pharmacopoeial standards with the ultimate goal of harmonization*"
- GPhP describe set of principles providing guidance for national and regional pharmacopoeial authorities to facilitate appropriate design, development and maintenance of pharmacopoeial standards
- Main GPhP adopted and published for pharmaceutical substances and FPPs, although principles may also apply to other products

(*Ref: WHO Technical Report Series (TRS), No. 996, 2016, Annex 1)*

http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex01.pdf?ua=1

18

BENEFITS OF GOOD PHARMACOPOEIAL PRACTICES

- *"GPhP is designed to facilitate collaboration among pharmacopoeias leading to possibilities for work sharing, prospective harmonization of standards and the recognition of published standards between NPAs and RPAs, increasing access to and availability of quality medicines."*
- *"In addition to the above, the establishment of GPhP may result in the following:*

– *strengthening of global pharmacopoeial cooperation;*

– *providing stakeholders with a better understanding of how pharmacopoeial standards are developed and maintained in a transparent manner;*

19

BENEFITS OF GOOD PHARMACOPOEIAL PRACTICES (2)

- *improving cooperation between NPAs/RPAs and stakeholders (e.g. regulators, industry) with a view to facilitating the global harmonization of pharmacopoeial standards, to reduce duplication of work."*

- *"Pharmacopoeial standards that are developed following GPhP can be relied upon for adequately validated analytical procedures and suitable reference standards in support of compliance determination. Adherence to GPhP can foster exchanges, work sharing and acceptance of monographs among pharmacopoeias. "*
- *"GPhP should ultimately enable harmonization of pharmacopoeial standards. "*

20

Implementation of good pharmacopoeial practices (GPhP)

World Health Organization

The International Pharmacopoeia: revised concepts and future perspectives (extract)

"*Implementation of the guidance on good pharmacopoeial practices and further collaboration with other pharmacopoeias are targeted, for example, through:*

■ *adoption or adaptation of existing standards (with due reference to the source of the text);*

■ *development of a new standard through coordinated consideration (prospective harmonization);*

■ *revision or creation of a standard between two or more pharmacopoeias (bilateral or multilateral harmonization), e.g. through a harmonization initiative of the PDG."*

(*Ref:* - WHO Technical Report Series (TRS), No. 996, 2016, Annex 1,

- WHO Technical Report Series (TRS), No. 1003, 2017, Annex 2*)*

21

Outcome of the 8th International Meeting of World Pharmacopoeias

World Health Organization

After a final round of consultation by all world pharmacopoeias, in addition to the main text:

- ❑ New GPhP text on compounding
- ❑ New GPhP text on herbal medicines

→ Included in report of the 52nd WHO Expert Committee on Specifications for Pharmaceutical Preparations (TRS 1010)

- ❑ Statement by *national, regional and international pharmacopoeias to emphasize important contribution public quality control standards can play in fighting AMR* (https://goo.gl/nxyj82)
- ❑ Review of survey on GPhP

22

Outcome of the 9th International Meeting of World Pharmacopoeias

- Decision to establish a new “pharmacopoeial alert system” to exchange information on issues detected with products covered by monographs that necessitate urgent action by a pharmacopoeia
- Review of outcome of a questionnaire on exchange of experience among national, regional and international pharmacopoeias, including identification of future challenges, possible “hot topics” and opportunities for joint activities
- Agreement to use annual IMWP as discussion forum to inform each other of recent challenges and share solutions found

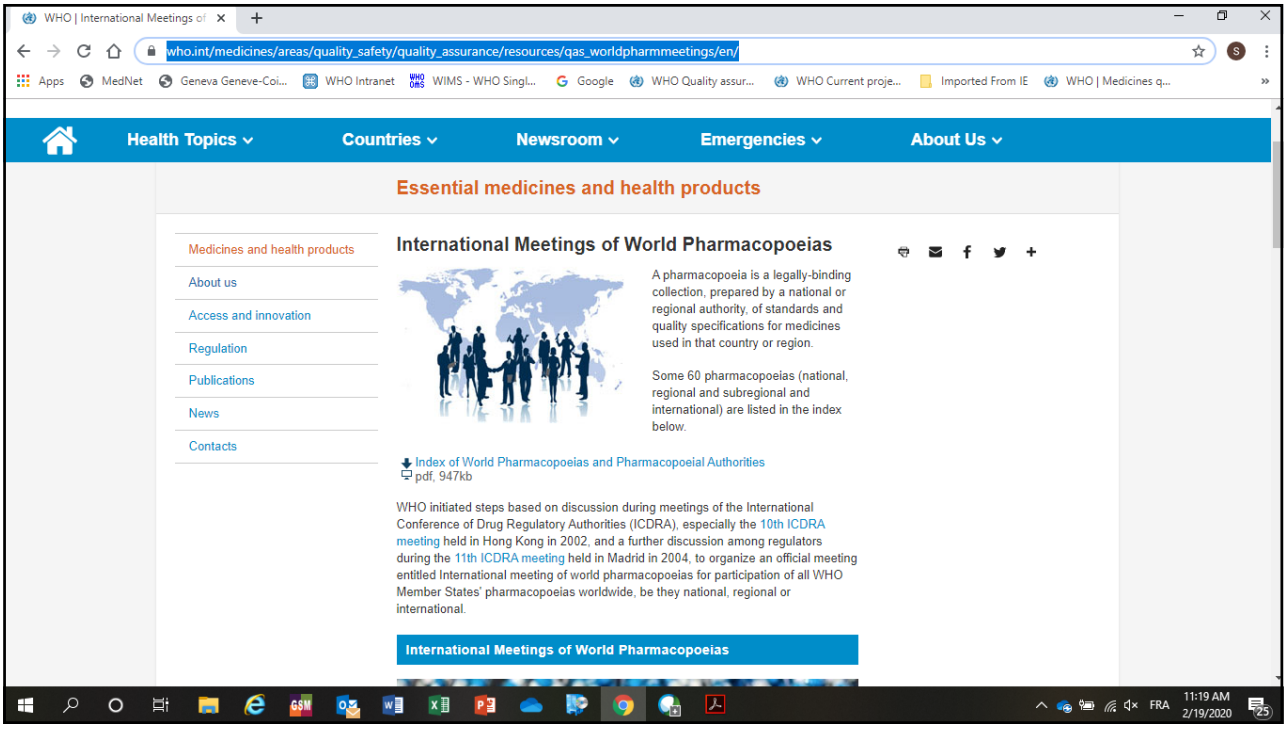
23

Outcome of the 9th International Meeting of World Pharmacopoeias

- IMWP flowchart model proposed to be used as basis for a model of collaboration, pharmacopoeias discussed model including the mechanism of working groups among the pharmacopoeias, details will be further worked on
- PDG proposed to formalize measures to increase transparency towards other pharmacopoeias
- Proposal to cross-link pharmacopoeial Reference Standards on the IMWP website

http://www.wpro.who.int/vietnam/mediacentre/features/international_meeting_of_world_pharmacopoeias/en/

24



Outcome of the 10th International Meeting of World Pharmacopoeias (IMWP)

World Health Organization

- Updates presented by participating pharmacopoeias and PDG
- Information on the challenges in case of «sartans» shared
- Models for future collaboration in the context of the IMWP finalized
- White paper on added value of pharmacopoeia standards for public health initiated
- Brainstorming on possible future projects
- News posted on WHO web site

https://www.who.int/medicines/areas/quality_safety/quality_assurance/resources/qas_worldpharmmeetings/en/

26

Outcome of the 11th International Meeting of World Pharmacopoeias (IMWP)

- Participants of 11th IMWP reiterated that meeting is a useful platform to exchange of information.
- Decision taken to increase frequency of interactions among the world pharmacopoeias: annual face to face meeting will be complemented by teleconference.
- Finalization of "*White paper on the value of pharmacopoeial standards for access to quality medicines*" with a plan for publication and communication.
- Agreement on interaction between PDG and IMWP and decision taken to start a 1 year pilot phase.
- Update on measures taken by the pharmacopoeias regarding the control of nitrosamine impurities in medicines.

27

WHO will...

World Health Organization

Continue its global activities serving WHO Member States, including:

- ❑ the development of international norms and standards for medicines quality assurance, *and*
- ❑ supporting initiatives towards convergence and future synergies, including among the world pharmacopoeias

In the focus: benefit for patients -
improved access to quality medicines worldwide

World Health Organization

A world where every child, man and woman has **access** to the quality essential medicines, vaccines and other health products they need to lead a healthy and productive life.

29

World Health Organization


Access to medicines
World Health Organization
Patient in focus