

Outcome of the 7th International Meeting of World Pharmacopoeias and its future prospects

15 September 2016

Tokyo, Japan



**World Health
Organization**

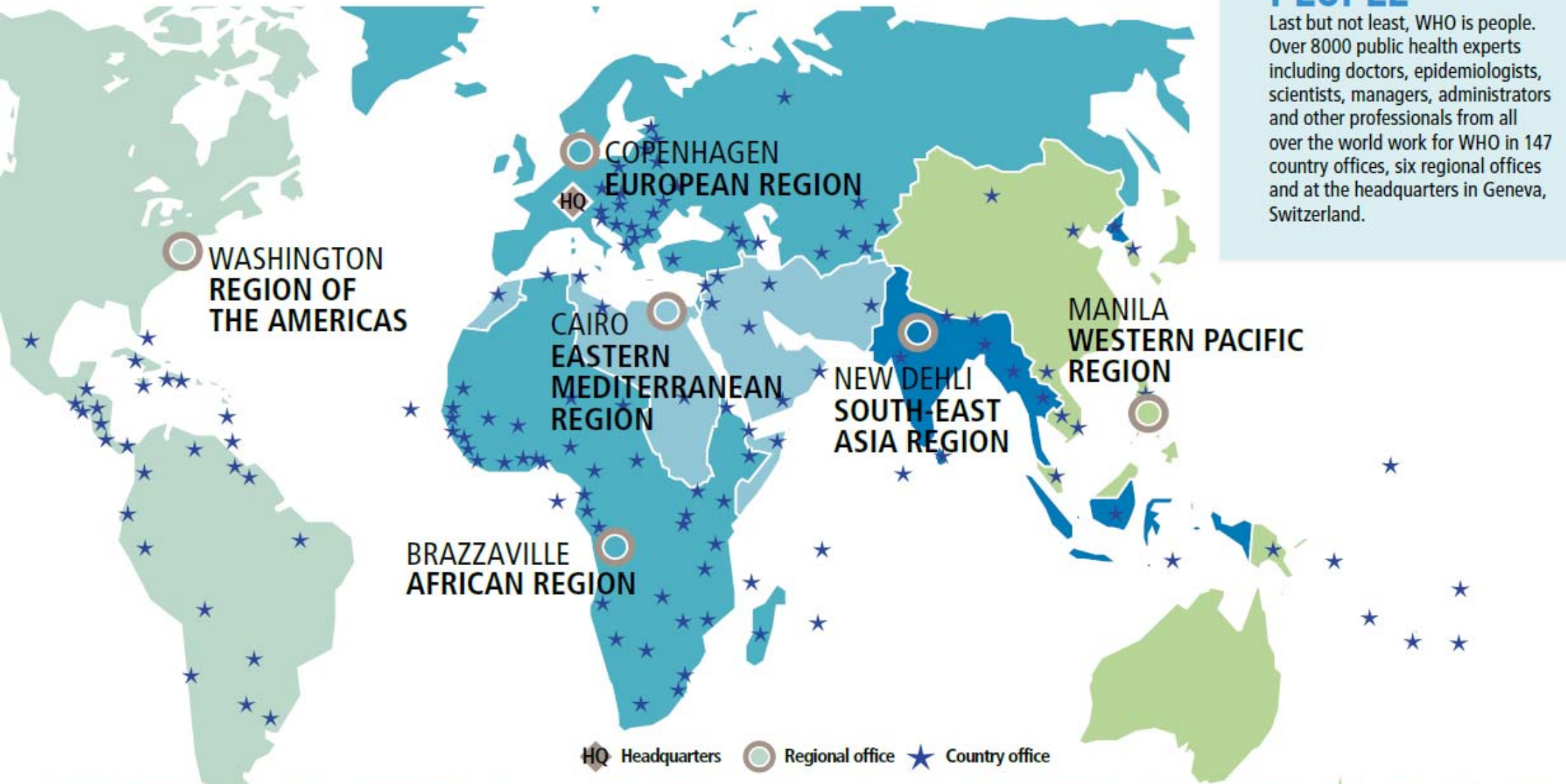
WHO at a glance

- 194 Member States
- Headquarters in Geneva
- 6 regional offices
- More than 150 country offices
- More than 7000 staff
- More than 700 institutions supporting
- WHO's work:
 - Close partnerships with UN agencies, donors, foundations, academia, nongovernmental organizations and the private sector



PEOPLE

Last but not least, WHO is people. Over 8000 public health experts including doctors, epidemiologists, scientists, managers, administrators and other professionals from all over the world work for WHO in 147 country offices, six regional offices and at the headquarters in Geneva, Switzerland.



HEALTH ORGANIZATION?

Governance of WHO

Governance takes place through the **World Health Assembly**, which is the supreme decision-making body; and the **Executive Board**, which gives effect to the decisions and policies of the Health Assembly.

The Organization is headed by

the **Director-General**,

appointed by the Health

Assembly on the nomination

of the Executive Board.

<http://www.who.int/about/governance/en/>



What does WHO ? Some examples ..

WHO - The Global Guardian of Public Health

Serves its Member States through, e.g.

- Providing means to communicate information, issue international alerts
- Developing global norms and standards
- Propose global measures, e.g. for supply chain integrity
- Suggest international tools and schemes
- Nomenclature and classifications



What does WHO ? Some examples..

WHO - The Global Guardian of Public Health

Serves its Member States upon request through, e.g.

- Enhancement of convergence among health authorities
- Providing a platform and enabling collaboration among national and regional health authorities
- Provision of assistance to improve capacity building
- Providing a global platform for exchange of information, e.g. International Conference of Drug Regulatory Authorities (ICDRA)



Pharmacopoeias: How WHO got involved..

1902 – 1925 Agreements establish a **Unified Pharmacopoeia**

1929 "Brussels Agreement" stipulates League of Nations should carry out related administrative function

1937 First meeting of "Technical Commission of Pharmaceutical Experts"

1947 Interim Commission of WHO takes over

1948 First World Health Assembly (WHA) approves *Expert Committee on Unification of Pharmacopoeia* to continue this work

1951 WHA renames the *Expert Committee on International Pharmacopoeia*
→ ***The International Pharmacopoeia*** published by WHO

Trends towards convergence

International Collaboration towards convergence, including among Pharmacopoeias:

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

Trends towards convergence

Within context of Regulatory Networks, e.g.

- International Conference of Drug Regulatory Authorities (ICDRA)
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- Pan American Network for Drug Regulatory Harmonization (*PANDRH*)

Trends towards convergence



- **1st *International Meeting of World Pharmacopoeias* – hosted by WHO, Geneva, Switzerland, 29 February–2 March 2012**
- **2nd *International Meeting of World Pharmacopoeias* – hosted by Indian Pharmacopoeia Commission, New Delhi, India, 18–19 April 2013**
- **3rd *International Meeting of World Pharmacopoeias* – hosted by Medicines and Healthcare products Regulatory Agency/British Pharmacopoeia Commission, London, United Kingdom, 10–11 April 2014**

Trends towards convergence



- **4th *International Meeting of World Pharmacopoeias* – hosted by Council of Europe/European Pharmacopoeia Commission, Strasbourg, France, 8–10 October 2014**
- **5th *International Meeting of World Pharmacopoeias* – hosted by United States Pharmacopeia, Rockville, USA, 20–22 April 2015**
- **6th *International Meeting of World Pharmacopoeias* – hosted by Chinese Pharmacopoeia Commission, Su Zhou, People's Republic of China, 21–23 September 2015**

Trends towards convergence

- **7th *International Meeting of World Pharmacopoeias* – hosted by Ministry of Health, Labour and Welfare / Pharmaceuticals and Medical Devices Agency /Japanese Pharmacopoeia in Tokyo, Japan, 13–14 September 2016**



Some impressions 1st meeting



Some impressions 1st meeting



Who participates ?

- Usually between 40-60 representatives from world pharmacopoeias, including Argentinian, Brazilian, British, Chinese, Czech, European (representing its 37 Member States and the European Union), Indian, Indonesian, International (WHO), Iranian, Japanese, Kazakh, Korean, Mexican, Russian, Spanish, Ukrainian, United States and Vietnamese pharmacopoeias → *representing about 50 pharmacopoeias and pharmacopoeial authorities worldwide*
- *Since 2nd meeting followed by special events organized by the host pharmacopoeia : stakeholders and users*

What is the focus ?

- Opportunity for greater collaborative work
- Opportunity for sharing of information between world pharmacopoeias
- Development of good pharmacopoeial practices (GPhP), in addition applying WHO's standard-setting processes and procedures
- Outcome presented to WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSP) → through ECSP also to WHO's 194 Member States

Purpose and scope of 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

(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)

Meeting agenda of 7th International meeting

- Review of feedback and comments received on additional chapters to GPhP as identified during the 6th international meeting of world pharmacopoeias on:
 - Compounded preparations
 - "Herbals"
 - Glossary
- Discussion on possible future supplements to GPhP and on new strategies /next steps to continue efforts towards convergence among pharmacopoeias

Outcome of the 7th International meeting

Roadmap with next steps and future actions for:

- 1. GPhP new supplements on Compounding and Herbal medicines + Glossary**
- 2. Identification of "hot topics" having potential public health impact**
- 3. Survey on impact and value of new GPhP**
- 4. Planning of next meeting(s)**

1. GPhP new supplements

- on **Compounding and Herbal medicines + Glossary**, planned actions and timeframe:
 - Drafting of additional paragraphs and circulation of updated version among the pharmacopoeias
 - Collation of feed-back
 - Review of comments during the 8th international meeting of world pharmacopoeias
 - Public consultation phase
 - Presentation of update to the WHO Expert Committee on Specifications for Pharmaceutical Preparations
 - Publication

Outcome of the 7th International meeting

2. Identification of "hot topics" having potential public health impact, planned actions and timeframe:

- Drafting of a proposal by current and future hosts
- Review by world pharmacopoeias for discussion during the 8th meeting

3. Survey on impact and value of GPhP, planned actions and timeframe:

- Drafting of survey questions and review by pharmacopoeias
- Mailing to stakeholders and users
- Data analysis and discussion during the 8th meeting

4. Planning of next meeting(s)

- **8th *International Meeting of World Pharmacopoeias*** – hosted by Agência Nacional de Vigilância Sanitária (ANVISA)/Brazilian Pharmacopoeia, *dates and site tbc*
- **9th *International Meeting of World Pharmacopoeias*** – hosted by NIDQ/Vietnamese Pharmacopoeia, *dates and site tbc*
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International future prospects

- *International Arena*: keep momentum, the global initiative, international forum to discuss challenges and future synergies to serve all pharmacopoeias and their users
- *WHO related*: input from stakeholders and collaboration with partners to define future strategies for WHO activities and recommendations to WHO Member States
- + *In the focus*: ... benefit for patients : improved access to quality medicines worldwide



ご清聴ありがとうございました

شكرا 谢谢

¡muchas gracias!

Thank You!

Merci beaucoup!

Спасибо

