Answers from *The International Pharmacopoeia (Ph. Int.)*
1. The International Pharmacopoeia (PhInt)
2. Pharmacopoeia referred to in national/regional legislations

The International Pharmacopoeia is "ready for use" by Member States

"The Ph.Int […] is intended to serve as source material for reference or adaptation by any WHO Member State wishing to establish pharmaceutical requirements. The pharmacopoeia, or any part of it, shall have legal status, whenever a national or regional authority expressly introduces it into appropriate legislation."

[Reference to World Health Assembly resolution WHA3.10, WHO Handbook of Resolutions and Decisions, Vol. 1, 1977, p. 127]
4. Publication of latest edition

Fourth Edition

Free access online
http://www.who.int/phi
5. Update frequency

The Ph.Int is based on the work and decisions of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

Annually

Adopted texts published on the web each year

Compilation made after WHO Expert Committee meetings
6. For which products does the pharmacopoeia provide specifications?

- Active Pharmaceutical Ingredients (APIs)
- Finished dosage forms
- General methods/texts

*Completed with:*

- General notices
- Supplementary information
- Infrared reference spectra
6. For which products does WHO provide specifications and standards?

- Biologicals through the WHO Expert Committee on Biological Standardization since 1947 for:
  - vaccines,
  - blood products and related biologicals.

- Herbal and complementary medicines, in collaboration with WHO Expert Committee on Specifications for Pharmaceutical Preparations:
  - Herbal materials, and
  - Medicinal Plants.
7. Number of texts included in the pharmacopoeia

- APIs/Excipients (441)
- FPPs (141)
- Radiopharmaceuticals (27)
- General monographs (9)
- General methods (73)
- Supplementary Information (14)
- IR spectra (154)
8. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

- During WHO Consultation process:
  - opportunity to comment drafts by all world pharmacopoeias
  - participation in meetings (consultations, Expert Committees)

- Special projects, examples of collaboration with:
  - African Pharmacopoeia
  - British Pharmacopoeia
  - Chinese Pharmacopoeia
  - Council of Europe/European Pharmacopoeia
  - International Chemical Reference Substances (ICRS)
  - Pharmacopoeial Discussion Group (PDG)
9. Publication of harmonized pharmacopoeial texts within the pharmacopoeia

In Collaboration with British Pharmacopoeia
- 3 texts adopted in 2010, 19 in the pipeline

In Collaboration with Pharmacopoeial Discussion Group (PDG, i.e. European Pharmacopoeia (Ph.Eur), Japanese Pharmacopoeia (JP) and United States Pharmacopeia (USP))
- 12 general methods adopted in 2011, more in the pipeline, for
  - Methods of analysis
  - Supplementary information
10. Interaction with stakeholders, including regulators

- National and regional regulatory authorities
- National and regional quality control laboratories
- National and regional institutions and institutes
- International organizations (UNAIDS, UNFPA, UNICEF, World Bank, WIPO, WTO, WCO, etc)
- International professional and other associations, NGOs (including consumer associations, MSF, industry: IFPMA-IGPA-WSMI, FIP, WMA, etc)
10. Interaction with stakeholders, including regulators

- Quality control laboratories (other than national/regional)
- Regional and inter-regional harmonization groups (ASEAN, GCC, ICH, PANDRH, SADC…)
- UN related organizations, such as Global Fund
- Manufacturers, worldwide, through their associations
- WHO Programmes, including INN, Prequalification, Regulatory Support, Safety, Traditional Medicines, Biologicals and Specific Disease Programmes
11. Strategy for the future

- Continue to fulfil the mandate of WHO given by its Member States;
- Respond to needs of WHO Member States;
- Respond to needs of quality control laboratories for post-marketing surveillance;
- Maintain the international applicability of the Ph.Int specifications;
- Provide standards for major public health needs, keeping the costs of analysis in mind.
World Health Assembly – some impressions
64th WHA: Some impressions

Floor of the Assembly

Dr Margaret Chan, WHO Director-General

Mr Bill Gates, Co-chair of the Bill & Melinda Gates Foundation

Her Excellency Sheikh Hasina, Prime Minister of Bangladesh

Dr Christos Patsalides, President of the Sixty-fourth World Health Assembly and Minister of Health of Cyprus, and

Dr Maria Teresa Valenzuela (Chile), Chair of Committee B.
Safe quality medicines