WHO Expert Committee on Specifications for Pharmaceutical Preparations

How does it work?

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Main points addressed

- Basis for Expert Committee
- WHO international guidelines, standards and norms in the area of quality assurance
- Implementation
Examples of WHO Expert Committees

- WHO Expert Committee on Specifications for Pharmaceutical Preparations
- WHO Expert Committee on the Selection and Use of Essential Medicines
- WHO Expert Committee on Drug Dependence
- WHO Expert Committee on Biological Standardization
- Joint FAO/WHO Expert Committee on Food Additives
- ....
Historical overview

→ **1874** Discussion on Unification of terminology and composition of drugs

→ **1902** First Conference organized by the Government of Belgium

→ **1906** Agreement on Unification of the Formulae of Potent Drugs ratified by 19 states

→ **1925** Brussels agreement (signed 1929)

→ League of Nations:

  “*international pharmacopoeia*”
Historical overview - 2 -

→ **1937** First meeting (experts from B, CH, DK, F, NL, UK, USA) - *League of Nations*

→ **1947** Interim Commission of WHO takes up health related work of League of Nations

→ **1948** First *World Health Assembly* established Expert Committee on Unification of Pharmacopoeia
Historical overview - 3 -

**WHO Expert Committee:**

→ **1951** named: Expert Committee on *International Pharmacopoeia*

→ **1959** named: Expert Committee on Specifications for Pharmaceutical Preparations --> *to date*
Historical overview - 4 -

WHO Expert Committee 1. in many activities!

→ 1. EC meeting held 13-17 October 1947

→ Report of 4th Expert Committee

→ 1. Technical Report (TRS 1) issued by WHO in January 1950!!

… Biological Committee → TRS 2!
What is a WHO Expert Committee?

- Official Advisory Body to Director-General of WHO
- Governed through rules and procedures (*Ref. WHO Manual*)

**Participation in Expert Committee (EC) meetings:**
- **Members** ("Experts") selected from WHO Expert Advisory Panels
- **Technical advisers**
- **Observers**: - *international organizations*,
  - *NGOs*,
  - *professional associations*...
How to become a "WHO Expert"?

- Official nomination process
- Upon proposal to WHO in consultation with:
  - Member State/national government (citizenship)
  - WHO Regional Office (in accordance with Member State)
  - WHO Headquarters
- First period of 4 years
- Possibility to renew
Outcome of the WHO Expert Committee?

- Report of the WHO Expert Committee:
  - Summarizes discussion
  - Gives recommendations to WHO + Member States
  - Includes newly adopted guidelines;
  - Is presented to WHO Governing Bodies for final comments, endorsement and implementation by Member States

→ constitutes WHO technical guidance
WHO's medicines quality assurance guidelines

Cover:
- Production
- Quality Control
- Quality related regulatory guidelines
- Inspection
- Distribution
- → from manufacture to delivery to patient
When does the WHO Expert Committee start development of a guideline/guidance?

- Based on recommendations by:
  - World Health Assembly resolutions (e.g. WHA 20.34, GMP - Good manufacturing practices)
  - Executive Board resolutions (e.g. EB37.R9 delegating certain functions of INN Programme to DG based on advice from Experts)
  - International Conference of Drug Regulatory Authorities (e.g. 10th + 11th ICDRA – FDC guidelines + Certification Scheme for pharmaceutical starting materials moving into international commerce)
  - Other WHO programmes and clusters (e.g. necessity for quality control specifications for specific medicines of major public health interest)
  - Expert Committee (e.g. revision of general methods included in The International Pharmacopoeia)
How does the WHO Expert Committee consultation process work?

- Step 1. Preliminary consultation and drafting
- Step 2. Draft guidelines
- Step 3. Circulation for comments
- Step 4. Revision process
- ........ (back to step 2 and 3 as often as needed)
How does the WHO Expert Committee consultation process work?

- → WHO Expert Committee (EC) meeting
  - → if guideline adopted, published in EC report as Annex
  - -> if not back to steps 2-4 (as on previous slide)

- → WHO Governing bodies
- → Recommendation to Member States for implementation
WHO Partners in the Expert Committee on Specifications for Pharmaceutical Preparations

- National and regional authorities
- 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)
- Members of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations
WHO Partners in the Expert Committee on Specifications for Pharmaceutical Preparations

- Specialists from all quality assurance related areas, including regulatory, university, industry
- WHO Collaborating Centres (official nomination process) – usually national quality control labs
- Pharmacopoeia Commissions and Secretariats, national institutions and institutes ..
- Regional and interregional groups (ICH...)
Advantages of WHO's Expert Committee standard-setting process

1. Guidelines and specifications validated internationally, through an independent scientific process, adoption by members of WHO Expert Advisory Panels

2. Collaboration with standard-setting organizations and parties, including regional and national pharmacopoeias

3. Networking and close collaboration with WHO Member States, Drug Regulatory Authorities, national medicines quality control laboratories
Advantages of WHO’s Expert Committee standard-setting process (2)

- 4. Links with other WHO activities
- 5. Reality check: Input from manufacturers (including international associations of research, generic and self-medication associations) around the world
- 6. Consideration of costs, e.g. keeping need for reference standards at a minimum
- 7. Service FREE FOR USE by all Member States
WHO Medicines Quality Assurance website:

http://www.who.int/medicines/areas/quality_safety/quality_assurance