World Health Organization

WHO Expert Committee on Specifications for Pharmaceutical Preparations

How does it work?

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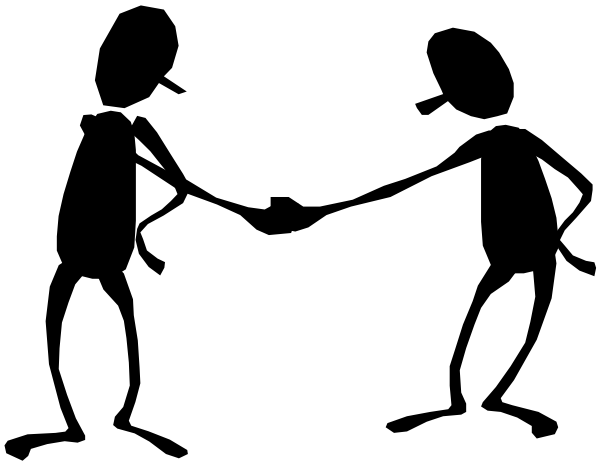
Main points addressed

- 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