WHO Expert Committee on Specifications for Pharmaceutical Preparations
Secretary: Dr Sabine Kopp
What is a WHO Expert Committee?

- Official Advisory Body to Director-General of WHO
- Established by World Health Assembly or Executive Board
- Governed through rules and procedures
- Participation in Expert Committee (EC) meetings:
  - **Members** ("Experts") selected from WHO Expert Advisory Panels
  - **Technical advisers**
  - **Observers**: - international organizations,
    - NGOs,
    - professional associations…
WHO Expert Committees rules and procedures → WHO Basic Documents

- **Constitution of WHO**
  - Expert Committees:
    - chapter V, article 18; chapter VIII, articles 38-40
    - *For normative function - pharmaceuticals:*
      - Chapter 2, article 2 (u): "to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products;"

ECSP covers today: WHO’s medicines quality assurance guidelines

Including:

- Development (new)
- Production
- Quality Control
- Quality related regulatory guidelines
- Inspection
- Distribution and supply

→ from development to delivery to patient
ECSPP adopts WHO guidance texts and guidelines in medicines quality assurance (without PhInt)

- **Total of:**

- **More than 70** CURRENT official WHO guidance texts and guidelines for medicines quality assurance, including

- **4** *(2 updates, 2 new published in 2013)*
4th Edition of Ph.Int. including Suppl. 1, 2 and 3

Number of monographs
- 439 on pharmaceutical substances
- 161 on specific dosage forms
- 9 general on dosage forms
- 60 texts on methods of analysis
- 27 monographs on radiopharmaceuticals.

and physical standards
- 236 International Chemical Reference Substances (ICRS)
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
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
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, ASEAN, etc)
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

  \( \rightarrow \) constitutes  WHO technical guidance
When does the ECSPP 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)
Additional steps for developments of specifications

To cover "practical" steps, such as:

- Provision of samples
- Laboratory studies and scientific research for suitability of test specifications
- *For details* full process adopted by the ECSPP → www.who.int/medicines/publications/pharmacopoeia/mono_dev
How does the WHO Expert Committee consultation process work? (2)

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

- -> WHO Governing bodies
- -> Recommendation to Member States and other parties for implementation
WHO Governing bodies …
47th WHO Expert Committee on Specifications for Pharmaceutical Preparations – presented in May 2013
CDROM Quality Assurance of Pharmaceuticals. 2013

- 73 current WHO guidelines and good practices on development, manufacture, inspection, distribution, quality control and related regulatory guidance for medicines

- 48 GXP training modules, including on GMP, inspection, laboratory practices, technology transfer
CDROM The International Pharmacopoeia 4th edition + Supplements 1, 2 and 3 (2013)

NEW:

- 48 new and revised monographs for APIs and specific dosage forms
- 2 general monographs
- 8 new and revised methods of analysis
- Additional Supplementary info
48th WHO Expert Committee on Specifications for Pharmaceutical Preparations (14-18 October 2013)

Adopted:

- *The International Pharmacopoeia* updating mechanism for the section on radiopharmaceuticals (Annex 1)
- WHO good manufacturing practices for pharmaceutical products: main principles (Annex 2)
- Model quality assurance system for procurement agencies, includes 16 Appendixes, with two newly revised ones (*Appendix 6 product questionnaire and Appendix 13 model inspection report*) (Annex 3)
48th WHO Expert Committee on Specifications for Pharmaceutical Preparations (14-18 October 2013)

- Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection (Annex 4)
- Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities (Annex 5)
- Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6)
48th WHO Expert Committee on Specifications for Pharmaceutical Preparations (14-18 October 2013)

Adopted for inclusion in *The International Pharmacopoeia*:

- For maternal, newborn, child and adolescent health medicines:
  - medroxyprogesterone acetate
  - medroxyprogesterone injection
- For antimalarial medicines:
  - chloroquine phosphate tablets
  - chloroquine sulfate tablets
  - chloroquine sulfate oral solution
Adopted for inclusion in *The International Pharmacopoeia*:

*For antiviral medicines:*
- aciclovir API
- aciclovir tablets
- aciclovir for injection

*For antituberculosis medicines:*
- streptomycin for injection
Adopted for inclusion in *The International Pharmacopoeia*:  
*For neglected tropical diseases:*
- albendazole chewable tablets
- niclosamide
- niclosamide tablets
- pentamidine isetionate
- pentamidine isetionate for injection
- sulfamethoxazole and trimethoprim intravenous infusion
- sulfamethoxazole and trimethoprim oral suspension
Adopted for inclusion in *The International Pharmacopoeia:*

*For other anti-infective medicines:*
- fluconazole

*For other medicines:*
- testosterone enantate

*General monographs for dosage forms and associated method texts:*
- General chapter 1.2.1: Melting temperature and Melting range (revision)
Adopted for inclusion in *The International Pharmacopoeia*:

For inclusion in the Supplementary information section:

- Chapter on dissolution testing of tablets and capsules
- Chapter on reference substances and reference spectra

The Committee endorsed the adoption of the International Chemical Reference Substances (ICRS) approved by the ICRS Board
Thank You!