World Health Organization
Standard-setting Activities
Impact on Global Health

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WHO Standard-setting Activities

Constitutional responsibility:

- to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products, as well as diagnostic procedures
WHO Standard-setting Activities
- Scope -

- WHO provides
  - **Written standards**: Guidelines & Recommendations
  - **Physical standards**: Biological and Chemical Reference Materials

- Both written and physical standards are established on the basis of global consultation and are used globally by regulators, national reference laboratories and manufacturers.
WHO Standards (written) Guidelines & Recommendations

- Define international technical specifications for the evaluation of quality and safety of products and processes
- Form the basis for national regulations when adopted by Member States
- Promote global harmonization to secure quality and safety of products
WHO standards (written)
- Examples -

Pharmaceuticals, Biologicals and *in vitro* diagnostic procedures

- Guidelines on Good Manufacturing Practices, quality control, guidance on products registration, evaluation of international reference materials or set of product specifications (e.g. International Pharmacopoeia)

- International Nonproprietary Names (INNs) to clearly identify each drug
WHO Standard-setting Activities
Physical standards

- Tools for comparison and evaluation of results between different analytical tests/assays worldwide
- Support harmonization of international regulations
- Facilitate development of diagnostic and therapeutic products
WHO Standards (physical) - Examples -

*In vitro* biological diagnostic procedures

- Guidelines and Reference Materials for Thromboplastins used in the control of oral anticoagulant therapy
- Guidelines and Reference Materials applied to the Diagnosis of Blood Coagulation Disorders
- Quality control of diagnostic tests used for detection of Hepatitis A, B and C, HIV, Parvovirus
- Study of Transmissible Spongiform Encephalopathies
- Other areas
WHO Standard-setting Instruments

- **Expert Advisory Panels**
  - members appointed by the Director-General in agreement with Regional Offices and national authorities
  - Membership from developing and developed countries

- **Expert Committees**
  - selected from Expert Advisory Panels
  - include developed and developing country experts
  - gender balance
  - temporary Advisors strengthen scientific advice
  - geographic representation
  - observers from industry

- **Other scientific and advisory groups**
WHO International Biological Reference Materials

- WHO has the leadership in the biological standardization field
- This involves international collaboration and coordination of specialized laboratory work, both in developed and developing countries
- Evaluation of international studies by the Expert Committee on Biological Standardization
WHO Standards - Accessability -

- Information published via the Technical Report Series, widely disseminated
- Reference materials held and distributed by the WHO Collaborating Centres for Biological Standards and WHO Collaborating Centre for International Chemical Reference Standards
- Catalogue of reference materials via Web
WHO Standard-setting Activities
Collaboration with partners

- WHO works in close collaboration with other standard-setting organizations

- Importance of having a common strategy for the development of standards
WHO Standard-setting process and future challenges

- Participation of developing countries in the standard-setting process
- Promote developing country compliance with international standards
- Assist developing countries in the implementation of international standards
World Health Organization

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Thank you for your attention