Policies on Drug Safety within WHO

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Quality Assurance and Safety: Medicines
Essential Drugs and Medicines Policy
World Health Organization
Topics

- History of WHO
- History of WHO Collaborating Centre for International Drug Monitoring alias the *Uppsala Monitoring Centre*
- Joint activities of WHO- UMC
- Future Challenges
History of WHO

1948 The World Health Organization, the United Nations specialized agency for health, was established on 7 April.

WHO’s objective is the attainment by all peoples of the highest possible level of health.

WHO’s Constitution states health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
Governance of WHO

WHO is governed by 192 Member States through the World Health Assembly.

The main tasks of the World Health Assembly are to approve the WHO programme and the budget for the following biennium and to decide major policy questions.
Secretariat of WHO

- The Secretariat is headed by the Director-General, who is nominated by the Executive Board and elected by Member States for a period of five years.

- WHO’s Secretariat is staffed by health professionals, other experts and support staff working at headquarters in Geneva, in the six regional offices and in countries.
Regional Offices of WHO

- AFRO situated in Brazzaville
- AMRO/PAHO situated in Washington DC
- EMRO situated in Cairo
- EURO situated in Copenhagen
- SEARO situated in New Delhi
- WPRO situated in Manila
WHO structure at HQ

- Director-General
  - Dr Gro Harlem Brundtland
- Communicable Diseases
- Noncommunicable Diseases and Mental Health
- Sustainable Development and Healthy Environments
- External Relations and Governing Bodies

- Link to Regional Directors
  - Family and Community Health
  - Health Technology and Pharmaceuticals
  - General Management

- Evidence and Information for Policy

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WHO Programme for International Drug Monitoring

WHO HQ

WHO Collaborating Centre, Uppsala

National Centres
History of UMC - 16th World Health Assembly 1963

Assembly Resolution - 16.36 Clinical and Pharmacological Evaluation of Drugs

INVITES Member States to arrange for a systematic collection of information on serious adverse drug reactions observed during the development of a drug and, in particular, after its release for general use.
Pilot project of ten countries

- Australia, Canada, Denmark, Germany, Ireland, Netherlands, New Zealand, Sweden, United Kingdom, USA
WHA23.13 International Monitoring of Adverse Reactions to Drugs

REQUESTS the Director-General to develop the activities of the project into a primary operational phase aimed at the establishment of an international system for monitoring adverse reactions with provision for alerting Member States in cases of urgency, in accordance with resolution WHA16.36, and to report to the World Health Assembly;
History of the Uppsala Monitoring Centre

WHO Programme for International Drug Monitoring
WHO’s Agreement with the Swedish Government

- 1978 An Agreement was signed with the Swedish Government stating that the operational activities of the WHO Programme for International Drug Monitoring should be based in Sweden.
- 2001 New Agreement was reached with Sweden
International Board for UMC since 2002

- New board based on agreement between Swedish Government and WHO
- Two new Board meetings
- First incorporated an open seminar
  - Attended also by representatives from other clusters/units (EIP, HTP/BCT) from WHO
Activities in Pharmaco-vigilance in WHO HQ

- Exchange of Information
- Policies, guidelines, normative activities
- Country support
- Collaboration with other organizations
Exchange of Information

- Four issues of the Pharmaceutical Newsletter
- Update of WHO Restricted List
- Ad hoc “Alerts”
- WHO Drug Information
- Pre-I CDRA Pharmacovigilance workshop
  ‘The Impact of Regulation on Drug Safety’
The WHO Programme for International Drug Monitoring is the only Organization with a mandate from ALL Member States to set global standards for safety of medicines.
Policies, Guidelines and Normative Activities

Guidelines

- The Importance of Pharmacovigilance (2002)
- Pharmacovigilance in public health - in preparation
- Safety monitoring of herbal medicines - in preparation jointly with TRM

Expert Advisory Panel - need for identified, but no solutions yet
Country Support

- Strengthen spontaneous reporting systems
- Establish active surveillance component in public health programmes
- Work with the WHO Collaborating Centre for International Drug Monitoring (the Uppsala Monitoring Centre)

Ongoing Regional projects:

- “Implementation and Development of Pharmacovigilance in Newly Independent States of Eastern Europe”, since 2000
- In all 8 participating countries National pharmacovigilance systems have been established
Partnerships with other organizations

- CIOMS
- Collaboration with ICH
  - ICD-ART vs MedDRA
  - Pharmacovigilance working groups
- Working with the Pharmaceutical Industry
- Working with Consumers
Partnerships with other organizations - CIOMS

- CIOMS I-V Series of books on adverse drug reactions
- CIOMS VI - Safety monitoring in Clinical Trials
- Pharmacogenetics
- MedDRA search categories
Partnerships with other organizations - ICH

- MedDRA MSSO Board observer
- New V Series on pharmacovigilance
  - Periodic Safety Update Reports
  - Clinical case management
  - Prospective Planning in Pharmacovigilance
55th World Health Assembly Resolution

Quality of Care - Patient Safety

... Recognizing the need to promote patient safety as a fundamental principle of all health systems,

1. URGES Member States:
(1) to pay the closest possible attention to the problem of patient safety;

(2) to establish and strengthen science-based systems, necessary for improving patients’ safety and the quality of health care, including the monitoring of drugs, medical equipment and technology.
Future challenges

• Renewed interest and mandate but will policies be followed by activities that make changes on the country level?
• Time to think and review existing activities to prepare for the future
• Do we need new approaches/methodologies?
• How to decrease the gaps?
Conclusion

WHO cannot work alone. All countries involved with the WHO programme must work together in order to improve the safe use of medicinal products.