WHO Programme for International Drug Monitoring

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Quality Assurance and Safety of Medicines
World Health Organization
In the sixties...
Forty+ years later......
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.
WHO Drug Monitoring Programme

Founding Members 1968

[Map showing regions covered by the WHO Drug Monitoring Programme]
96 Full Members and 28 Associate Members
WHO Programme for International Drug Monitoring

HQ-WHO + 6 Regional offices

Vaccines
HIV/AIDS
Malaria
Chagas
Others

National Centres

WHO Collaborating Centre, Uppsala
Advisory Committee on Safety of Medicinal Products (ACSoMP)

The Advisory Committee on Safety of Medicinal Products shall provide advice on pharmacovigilance policy and issues related to the safety and effectiveness of medicinal products

- to the relevant Assistant Director-General in WHO and through him/her
  - to the Collaborating Centre for International Drug Monitoring (the Uppsala Monitoring Centre), and
  - to the Member States of WHO.
Pharmacovigilance in WHO HQ

1. Exchange of Information
2. Policies, guidelines, normative activities
3. Country support
4. Collaborations
5. Resource mobilisation
1. Exchange of Information

- National Information Officers

- Publications (WHO Pharm Newsletter, Restricted Pharm List, Drug Information)
2. Policies, Guidelines and Normative Activities

Guidelines
- The Importance of Pharmacovigilance (2002)
- Policy perspectives on medicines (Pharmacovigilance) 2004
- Safety monitoring of herbal medicines
- Pharmacovigilance in Public Health
3. Country support

- Training courses on pharmacovigilance
- Address specific / stated needs: kava, ARVs, antimalarials...
- Annual Meeting of Pharmacovigilance Centres

10 courses offered in 2008
Over a 100 million people targeted for either diethylcarbamazine citrate (DEC) plus albendazole or ivermectin plus albendazole.
5. Resource Mobilisation

- Gates foundation
- European commission
- Global Fund
- Others
- Human resources: PvSF
WHO Collaborating Centre

the Uppsala Monitoring Centre

- Established as a foundation 1978
- Based on agreement Sweden - WHO
- International administrative board
- WHO Headquarters responsible for policy
- Self financing
Signal detection

Primary UMC task

- Identification of previously unknown drug reactions
What is a signal?

- A WHO signal is a hypothesis together with data and arguments. A signal is not only uncertain but also preliminary in nature: the situation may change substantially over time one way or another.
Flow of ADR reports

- WHO-ART MedDRA
- WHO Database VigiBase
- WHO Drug Dictionary
- VigiFlow
- E2B
- Intdis
- Own tools (home-built)
- VigiSearch VigiMine
- National Centre
Technical support

- Guidelines
  - Reporting format etc.

- Terminologies
  - WHO Adverse Reaction Terminology
  - WHO Drug Dictionary
    - ATC Classification

- Software development
  - VigiFlow
  - VigiSearch/VigiMine
Pharmacovigilance training

- Uppsala
  - 2 weeks
  - 25-40 participants
  - 12th course
    May 2009
- Regional courses with WHO
- National courses
Communication

- Internet website:  http://www.who-umc.org

- Vigimed mailing list

- Publications
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News & Issues

This issue covers regulatory and safety information on more than thirty medicines, both old and new products. Previous warnings have been reiterated, labels updated, products withdrawn or new adverse reaction reports have been recorded, as may be the case. The feature item includes recommendations from the fourth Meeting of the WHO Advisory Committee on Safety of Medicinal Products.

In the last issue we promised to include letters from you on items that we publish in our newsletters. We are happy to bring you one such letter on a feature article from 2005. By sharing this interesting exchange we hope that we can motivate you to take a more interactive interest. We look forward to receiving your comments on any items published in this newsletter.

Contents

- Regulatory matters
- Safety of medicines
- Feature
3 tiers-approach

1. As before
   (Spontaneous reporting)
   - Regional trainings

2. More than before
   (Active surveillance)
   - Tools
   - Handbooks
   - Nigeria, Tanzania, Ghana

3. As never before
   - Indicators
   - Consumers
   - Medication errors

Maintain as the cheapest, easiest, most sustainable method

Cohort event monitoring; ECDD; EML; DTC

Measure, support, optimise
New development areas in UMC

- Active surveillance support
  - Cohort Event Monitoring

- Patient safety focus including medication errors

- Improved reporting/analysis of vaccine reactions (AEFI)
  - Flu pandemic planning

- Integrate Chinese ADR database