Establishing a Pharmacovigilance Centre

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Decide about a Plan

- location
- organisation
- funding
- staffing
- reporting form + routines

- equipment
- promotion
- feed-back
- use of data
Affiliation

- drug regulatory authority
- university institution
- hospital department
- poison information or drug information centre
- association of professionals
Integrate systems needing similar competence and resources

- drug information
- poison information
- drug monitoring
Organisation

• Centralised

• Regional Centres
Countries with decentralised reporting system

17 of 70 member countries

✓ Argentina
✓ Brazil
✓ Canada
✓ China
✓ Cuba
✓ France
✓ Italy
✓ India
✓ the Netherlands
✓ Norway
✓ Poland
✓ Portugal
✓ Russia
✓ Spain
✓ Sweden
✓ Thailand
✓ United Kingdom
Support

- political
- economical

stable and on a long-term basis
Staff

- pharmaceutical competence
- medical competence
- secretarial assistance
- dedication
- education
  - formal training course
  - visit established centre
Centre facilities

- computer with printer
  - word processor
  - report recording system
- literature sources
- telephone, fax, e-mail
- photocopier
Routines

- who should report?
- what should be reported?
- voluntary or mandatory reporting?
- coding system
- method of causality assessment
Mandatory reporting for physicians

- Austria
- Bulgaria
- France
- Hungary
- Italy
- Morocco
- Norway
- Slovak Republic
- Spain
- Sweden
Methods to stimulate reporting by professionals

- Facilitate access to reporting forms
- Facilitate reporting
- Acknowledge receipt of report
- Feedback
- Publication in medical journals
- Participation in scientific conferences
Methods to stimulate reporting by professionals

• Include ADR monitoring in curricula
• Set up regional centres
• Engage drug/therapeutics committees
• Approach professional associations
• Support development of clinical pharmacology/pharmacy
Methods to stimulate reporting by patients

• Approach patient associations
• Publication in lay press
• Include in patient drug information advice to report to doctor
• Telephone medicines information service
Highest reporting rates

- More than 200 reports/ million inhabitants
  - Australia
  - Denmark
  - Cuba
  - Ireland
  - the Netherlands
  - New Zealand
  - Norway
  - Sweden
  - United Kingdom
  - USA
Use of data

• method of signal identification
• establishment of advisory committee
• feed-back routines
  – individual response
  – adverse reactions newsletter
  – web site
• educational activities
Use of data (2)

- National Centre
  - follow-up cases
  - preliminary case assessment
  - recording
  - carry out actions

- Advisory Committee
  - final case assessment
  - promote reporting
  - analyse problems
  - propose actions
Relationships to consider

- drug regulatory authority
- pharmaceutical companies
- journalists
- academic institutions
- professional associations
- pharmacovigilance centres in other countries
- consumer and patient organisations