WORLD HEALTH ORGANIZATION

Drug Safety Pharmacovigilance

AIDE MEMOIRE

For a national strategy for safe drugs and their appropriate use.

During last decades it has been demonstrated that medicine related morbidity and mortality is one of the major health problems.

It has been estimated that adverse drug reactions are the 4th to 6th largest cause for mortality in some countries. The percentage of hospital admissions due to such reactions is 10-20%. There is a concomitant high economic impact on health care services. Some countries spend up to15-20% of their healthcare budget on drug-related problems.

Medicine induced morbidity and mortality can be substantially reduced through an integrated strategy for drug safety monitoring which includes:

- Establishment of the national pharmacovigilance service.
- Education and training of health care professionals on benefit/risk assessment and rational use of drugs.
- Behaviour change amongst patients and healthcare workers to decrease unnecessary and irrational use of drugs.

A well-organized drug safety management - pharmacovigilance service is a prerequisite for the early detection of the risks of drugs, prevention of adverse drug reactions (ADR) and aiding health professionals and patients to make the best benefit/risk assessment for safe and effective pharmacotherapy.

Pharmacovigilance plays a major role in pharmacotherapy decision-making, be it individual, regional, national or international.

Words of advice

- **Secure government commitment and support for the national pharmacovigilance programme.**
- **Establish a National Centre for Pharmacovigilance as a separate unit with responsibility and authority, an adequate budget and trained staff.**
- **Develop a national policy and action plan.**
- **Provide information on drug safety to healthcare professionals and consumers.**
- **Educate and train healthcare providers on rational use of drugs and pharmacotherapy monitoring.**
- **Monitor the impact of activities on the safety of pharmacotherapy.**

☑ Checklist

Pharmacovigilance service

- ❑ Government commitment and support
- ❑ Legislation/regulation
- ❑ National pharmacovigilance policy/plan
- ❑ National Pharmacovigilance Centre with responsibility and authority
- ❑ Adequate resources for pharmacovigilance activities
- ❑ National system of drug registration and quality control
- ❑ National system of postmarketing surveillance including requirements for pharmaceutical companies in relation to continuous benefit/ risk assessment and periodic safety update reporting

National policy on the safe and appropriate (rational) use of drugs

- ❑ Undergraduate and continuing education on rational use of drugs
- ❑ Assessment of pharmaco-therapy practices
- ❑ Promotion of rational use of drugs
- ❑ Preparing and distribution of educational and informational materials
- ❑ Monitoring and evaluation of activities

Key elements

National policy on pharmacovigilance

It is the responsibility of governments to ensure the provision of good quality, safe and effective drugs and their appropriate use.

The achievement of these goals requires the establishment of a national drug regulatory agency and a special centre for ADR study, and maintenance of their activities. Multidisciplinary collaboration involving different departments of the Ministry of Health and other stakeholders, such as pharmaceutical industry, universities, non-governmental organizations and professional associations for education on rational use of drugs and pharmacotherapy monitoring is of great importance.

Important activities include:

- Establishment of national pharmacovigilance systems, including national pharmacovigilance centres (and if appropriate regional centres)
- Development of necessary legislation/regulation for drug monitoring
- Development of national policy and plans of action (including costing, budgeting and financing)
- Undergraduate and continuing education of healthcare providers on safe and effective pharmacotherapy
- Continuously providing information on ADR to professionals and consumers
- Monitoring of the impact through process indicators and outcome

Develop national guidelines and regulations and implement them into clinical practice

A national strategy should be developed that ensures that pharmacovigilance services at all levels adhere to national and international regulations and standards.

- National regulations and guidelines for drug monitoring should be approved and implemented in the country.
- Guidelines on ADR control and reporting and case-report forms should be available to all healthcare professionals.
- Make contact with the health authorities and with local, regional or national institutions and groups, working in clinical medicine, pharmacology and toxicology outlining the importance of pharmacovigilance and its purposes.
- Produce printed materials to inform health professionals about definitions, aims and methods of the pharmacovigilance.
- An adequate number of trained staff should be available in hospitals or regions in accordance with their needs.
- Organize meetings in hospitals, academia and professional associations, explaining the principles and demands of pharmacovigilance and the importance of reporting.

Set up a Pharmacovigilance Centre(s) and maintain its activities

(See the WHO Guidelines for setting up and running a Pharmacovigilance Centre)*

- Create the ADR centre: staff, accommodation, telephone, word processor, database management capability, bibliography etc.
- Ensure the education of pharmaco-vigilance staff with regard to:
  - data collection and verification
  - interpreting and coding of adverse reaction descriptions
  - coding of drugs
  - case causality assessment
  - signal detection
  - risk management
- Establish a database (administrative system for the storage and retrieval of data).
- Promote the importance of reporting adverse drug reactions through medical journals, other professional publications, and communications activities.
- Conduct research on specific drug related problems including pharmaco-epidemiological studies.
- Provide information on drug safety to healthcare providers and consumers.
- Maintain contacts with international institutions working in pharmacovigilance, e.g., the WHO Department of Essential Drugs and Medicines Policy (Quality Assurance and Safety: Medicines) and the

* WHO Collaborating Centre for International Drug Monitoring (The Uppsala Monitoring Centre), www.who-umc.org Tel: (46-18) 656 060, Fax: (46-18) 656 080.

Quality Assurance & Safety: Medicines
Essential Drugs and Medicines Policy, World Health Organization
20 Avenue Appia, CH-1211, Geneva 27, Switzerland
Fax: +(41 22) 791 4730, E-mail: couperm@who.int