EMEA/CPMP WORKING GROUP WITH PATIENTS' ORGANISATIONS

8 May 2003

PHARMACOVIGILANCE

Scope of Pharmacovigilance

→ Directive 2001/83/EEC, Article 102

Surveillance of authorised medicinal products by collecting and evaluating

information on

- adverse drug reactions under normal conditions of use
- misuse and abuse which may have an impact on the evaluation of benefit and risks
- consumption of medicinal products
- other useful information

Goal of Pharmacovigilance

= Detection, evaluation, understanding and prevention
of adverse drug reactions
and optimisation of benefit-risk balance
at patient and population level

Definition of Adverse Drug Reaction

Abbreviation: ADR

= A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for restoration, correction or modification of physiological function

Tasks of Pharmacovigilance

- Collection, validation and storage of ADR case reports
- Collection of other clinical, non-clinical, epidemiological and drug utilisation data
- Data management
- Data transmission between stakeholders
- Identification of signals of potential safety issues
- Data assessment, risk quantification and benefit-risk assessment
- Regulatory action optimising the benefit-risk balance
- Risk management tools
- Communication of safety-related information
- Outcome evaluation

Stakeholders of Pharmacovigilance

- Patients, parents/carer and general public
- Healthcare professionals, healthcare institutions and healthcare system
- Patients' personal care providers and social contacts
- Marketing authorisation holders and pharmaceutical industry
- Research organisations, e.g. universities, hospitals, companies
- Competent authorities
- Other public health authorities and public institutions
- Medical, scientific and lay media

Involvement of Patients in Pharmacovilgilance

Data Collection

»Patient as supplier«

- Awareness
- Contact physician, pharmacist, community/school nurse or hospital in case of suspected adverse drug reaction
  → Treatment / ADR management
  → Reporting of ADR case

Involvement of Patients in Pharmacovilgilance

Communication

»Patient as costumer«

- Package Leaflet (PLs, in line with SPCs)
- Summaries of Product Characteristics (SPCs, terms of marketing authorisation)
- European Public Assessment Reports on centrally authorised products (EPARs)
- Position Statements on (potential) safety issues
- CPMP Press Releases

Working Together with Patients' Organisations

→ Specifying patients' roles, needs and expectations in the field of drug safety and pharmacovigilance

→ Maintaining and developing ways to meet these needs and expectations

→ Exploring ways of stakeholder roles and co-operation when performing the various pharmacovigilance tasks