

Pharmacovigilance for Patients & Consumers

WHAT IS PHARMACOVIGILANCE?

Pharmacovigilance is the process of evaluating and improving the safety of medicines. It plays an essential role in the early detection of drug-induced harm. Every medicine is tested on a relatively small number of people before it is approved for use by the wider population, where previously undetected reactions can emerge. Each patient is a unique medicines user with a distinctive lifestyle and circumstances. Medicines that cause serious adverse drug reactions (ADRs) need to be re-evaluated or removed from the market to protect public health.

It is important to improve pharmacovigilance in Europe, particularly in light of the harm caused by the use of medicines. Evidence suggests that adverse drug reactions are increasing and a series of public health disasters (from thalidomide in the 1960s to rofecoxib (Vioxx[®]) in the early 2000s) have reminded us how crucial pharmacovigilance is to the safety of patients and consumers of medicines.

WHAT ARE ADVERSE DRUG REACTIONS?

Adverse drug effects (ADRS) are unintended and usually harmful reactions to medicines. The European Commission Impact Assessment estimates that 5% of all hospital admissions are due to ADRs. In addition, 5% of all hospital patients suffer from an ADR, and ADRs are the fifth most common cause of hospital death. It is estimated that ADRs cause 197,000 deaths per year in the European Union with a cost of 79 billion EUR.

DIRECT PATIENT REPORTING OF ADRS

Patients and consumers are in the best position to provide details of their personal experience of suffering from the medicine's side effect.

While physician reporting is valuable, physicians may feel responsible or guilty for prescribing the medicine, or they may not include certain aspects in the report that they believe to be irrelevant.

Direct patient reporting is a rich data collection mechanism, providing comprehensive details about the medicine's impact on the quality of life of the patient.

IMPACT OF THE PHARMACOVIGILANCE DIRECTIVE PROPOSAL

In spite of several recent public health disasters, the pharmacovigilance directive proposals could destabilise the entire European system by promoting measures that:

- Institute risk management systems in place of post-authorisation evaluation of all medicines. Risk management systems needlessly risk patient safety and privacy;
- Transfer pharmacovigilance activities from public to industry-funded units, relegating the Member States' pharmacovigilance systems to the level of service providers for pharmaceutical companies;
- Collect pharmacovigilance data at the supra-national level and store it in an electronic "mega-database"-Eudravigilance. This could deprive local pharmacovigilance experts access to information that is crucial to the in-depth analysis of adverse event reports and could further dilute the data;
- Perpetuate the lack of transparency of pharmacovigilance data under the pretext of the 'commercial confidentiality' of the information. When the information concerned includes valuable accounts of drug safety, its disclosure is in the public interest.

HOW TO STRENGTHEN THE PHARMACOVIGILANCE DIRECTIVE TO IMPROVE THE SAFETY OF EUROPEAN CITIZENS

The priorities of the Pharmacovigilance Directive must be shifted to:

- require that medicines must demonstrate their therapeutic advance relative to existing treatments in order to obtain marketing authorisation, thereby protecting patients;
- guarantee public funding of the European, national and regional pharmacovigilance systems to promote the effectiveness and impartiality of their work;
- develop the intellectual independence of health authorities from pharmaceutical industry, through stricter control of conflicts of interest and by limiting the influence of the biased International Conference on Harmonisation (ICH) standards;
- redefine the Pharmacovigilance Risk Assessment Advisory Committee (PRAAC) as a European pharmacovigilance committee, with the authority to make proposals directly to the European Commission on: changes to summaries of product characteristics (SPCs) and patient leaflets; or the market withdrawal of medicines with an unfavourable harm-benefit balance;
- organise public Europe-wide collection of high quality adverse event reports (i.e. via a database such as Eudravigilance), where data would be entered exclusively by the pharmacovigilance systems of Member States in order to benefit from their expertise. The data must be made available, in an accessible format, to all European citizens;
- make health authorities accountable for the effective use of European pharmacovigilance data (improving feedback to reporters, faster decision-making on measures to protect citizens etc.);
- increase the transparency of all pharmacovigilance activities.

