



EU Commission's proposals on pharmacovigilance dismantle the entire system

Executive summary

In December 2008, the European Commission published a proposed Regulation and Directive concerning pharmacovigilance.

In spite of recent public health disasters, several of the proposed measures will weaken rather than strengthen the European pharmacovigilance system:

- rather than stepping up the post-authorisation evaluation of all drugs by reinforcing independent national and regional pharmacovigilance systems, an **increased use of "risk management systems"** is proposed. Experience reveals that the latter often act as an excuse for dangerous cutbacks in the evaluations performed prior to licensing;
- **end of the requirement for public funding of pharmacovigilance activities**, relegating the Member States' pharmacovigilance systems to the level of service providers for pharmaceutical companies, while pharmaceutical companies have a vested interest in delaying the disclosure of pharmacovigilance data;
- **tightening of the pharmaceutical companies' stranglehold on the collection, analysis and interpretation of data**, bypassing the Member States' public pharmacovigilance systems, depriving society of their expertise and risking their demise in the medium term;
- **setting up a European Pharmacovigilance Risk Assessment Advisory Committee (PRAAC) with no authority or autonomy, nor the adequate means to act effectively;**
- **providing for the dilution of pharmacovigilance data**, which will be stored directly in an electronic "mega-database" - Eudravigilance - depriving independent experts from local pharmacovigilance systems of information that is crucial to the in-depth analysis of adverse event reports;
- **maintaining the lack of transparency surrounding pharmacovigilance data** (for example, no access to periodic safety update reports (PSURs)), on the pretext of its "commercially confidentiality", whereas, in fact, these are scientific data on adverse effects suffered by patients/consumers and a matter of public interest.

To improve the safety of European citizens, the priorities must be:

- to protect patients from exposure to the adverse effects of drugs that provide no therapeutic advance, by **requiring**

that the therapeutic advance of a drug relative to existing treatments be demonstrated in order to obtain marketing authorisation;

- to **guarantee public funding** for the European pharmacovigilance Committee and the national and regional pharmacovigilance systems of Member States, in order to allow them, in full independency, to fulfil their responsibility in terms of population protection. The effectiveness of their work will lead to more timely decisions (i.e. strengthened monitoring or market withdrawal of medicines found to have an unfavourable risk-benefit balance), and consequently important savings (i.e. reduction of the numbers of hospital admissions, days of sick leave, and medical consultations caused by adverse reactions due to medicines);
- to **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;
- to **redefine the PRAAC as a European pharmacovigilance committee, which would be an instrument for cooperation between the pharmacovigilance systems of Member States**, with the authority to propose directly to the European Commission: changes to summaries of product characteristics (SPCs) and patient leaflets; or the market withdrawal of medicines with unfavourable risk-benefit balance;
- to **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 a usable format, to all European citizens;
- to **make health authorities accountable for the effective use of European pharmacovigilance data** (improving feedback to reporters, faster decision-making on measures to protect their citizens, etc.);
- to **increase the transparency** of pharmacovigilance activities.

As long as they are profoundly amended, the EU Commission proposals on pharmacovigilance can be refocused to defend the public interest.