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Pharmacovigilance in Europe: some progress, but a missed opportunity

On 29 November 2010 the Council of the European Union approved the new European pharmacovigilance regulation and directive. Below are some points contained in a joint press release by Prescrire and its partners in a campaign to improve the originally dangerous proposals.

The European Commission's original proposals were greatly improved. Thanks to the mobilisation of civil society and the numerous amendments adopted by the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI), improvements included:
– making clear that risk management systems must not be used as a pretext for granting premature marketing authorisations;
– giving patients in all Member States the right to report adverse drug reactions;
– having patients report adverse drug reactions to health authorities, rather than to pharmaceutical companies;
– granting public access to the agendas and detailed minutes of meetings of European Medicines Agency (EMA) committees.

However, Member States will no longer be required to provide public funding for pharmacovigilance systems, which will jeopardise the independence of pharmacovigilance systems.

A missed opportunity. If patient safety is to be truly strengthened in the EU, the following actions would be required:
– regulatory authorities should only grant authorisation for drugs that have been shown to provide a tangible therapeutic advantage for patients;
– a system should be set up to strongly encourage health professionals to systematically report the adverse effects they observe;
– drug regulatory authorities should be made more independent.

Dangerous medicines should not be allowed to continue harming patients and the proliferation of pharmacovigilance scandals (Vioxx°, Accomplia°, Avandia°, Mediator° etc.) must be stopped. We therefore call on the European Commission to rapidly propose more ambitious measures in order to reinforce patient safety.

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