

## For Immediate Release

### **The European Patients' Forum welcomes new rules on Pharmacovigilance that will enable patients and health professionals to work more effectively together for improved medication safety**

Brussels, Belgium, September 22, 2010 - The European Parliament adopted today in a plenary session, a legislative proposal to strengthen the European pharmacovigilance system and reduce adverse effects of medicines. The proposal amends the existing EU framework on pharmacovigilance provided in Regulation (EC) No 726/2004 and Directive 2001/83/EC. The new legislation is expected to enter into force by the end of 2010 or early 2011, and must be put into effect in Member States within 18 months of its publication in the EU Official Journal.

The European Patients' Forum (EPF) welcomes the new legislation, which will strengthen the pharmacovigilance system and make it more transparent, enhancing the confidence of patients, health professionals and regulators in the system. The EU Eudravigilance database will be the single repository of adverse reaction reports, and will be made accessible for patients and the general public. The new framework also strengthens patients' involvement, including provisions for direct patient reporting of suspected adverse reactions.

EPF particularly welcomes the possibility for patients to report suspected adverse events directly to national competent bodies. Patients have a unique knowledge and experience of the effects of the medicinal products they take, which should be used more effectively. EPF last week organised a seminar on the topic at the European Parliament, jointly with PGEU, the Pharmaceutical Group of the European Union, to highlight the importance collaboration between patients and pharmacists in medicines safety. The event was sponsored by **Mrs Linda McAvan MEP**, the Rapporteur on the legislative proposal, whose contribution was invaluable in ensuring the new rules take into account the views of the patient community.

Responding to the new legislative proposal, **EPF President Anders Olauson** says that "direct patient reporting and a wider access to safety data are necessary as they contribute to patients' empowerment and greater patient safety. These efforts should be seen as integral to the wider EU debate on patient empowerment and health literacy, with the aim of enhancing the safety and quality of care for all patients across the European Union."

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*For more information on EPF's position on the Pharmacovigilance legislative proposal, please consult [EPF website](#). EPF is a not-for-profit, independent organisation and umbrella representative body for patients' organisations throughout Europe. Representing the EU patient community we advocate for patient-centred equitable healthcare, and the accessibility and quality of that healthcare in Europe.*