



Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

## Statement

### EU citizens get a voice in pharmacovigilance

30 September 2010 – The monitoring of medicines safety in the Europe Union (EU) took a step forward following last week's approval by Parliament of the amendments to EU legislation on Pharmacovigilance. One notable and positive outcome is the legal provision that will enable patients and consumers to directly report their adverse reactions to medicines.

Direct and spontaneous patient reporting strengthens pharmacovigilance by generating additional data on the adverse effects of medicines, thereby speeding up the acquisition of knowledge about the safety profile a new medicine. It also signals the advancement of greater citizen participation in decisions that affect our health.

The value of DPR (Direct patient reporting of adverse events) is that it is often more detailed than the indirect reports submitted by health professionals, and unlike reports from clinicians, patient reports can tell the full story about how an adverse effect impacts on people's lives. Whilst DPR systems were already in place in some EU countries, this new provision paves the way for the establishment of DPR systems in all EU Member States.

What we do not yet know is how direct patient reporting will be implemented. We have the legislation, but now EU citizens need to be made aware that the system exists and governments need to ensure that the systems in place are accessible and user-friendly.

Aside from DPR, the amendments to EU legislation on Pharmacovigilance also increased the transparency of some European Medicines Agency activities by establishing public hearings; and by enabling broader participation and input from stakeholders, including independent experts and researchers, when reviewing the benefit/harm balance of medicines.

However, the legislative changes did not bring only good news. There was no commitment to public funding of European, national and regional pharmacovigilance systems, which would support the impartiality of their work. In addition, the amendments also failed to address the issue of therapeutic advance, which would require that new medicines must demonstrate their therapeutic advance relative to existing treatments in order to obtain marketing authorisation.

Nonetheless, HAI Europe welcomes the changes on direct patient reporting and transparency, and we hope to see swift and effective action from EU Member States so that citizens can play their part in ensuring medicines safety in the Europe.

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