

Direct Patient Reporting of Adverse Drug Reactions

The European Parliament is now discussing changes to the legislation on pharmacovigilance systems, which Member States will then adopt to harmonize national adverse events systems. An important change to the current law foresees the inclusion of direct patient reporting (DPR) of adverse events.

We here provide background information for policy development on pharmacovigilance in the European Union, particularly for the proposal to allow citizens themselves to report adverse drug reactions (ADRs). The project was commissioned from HAI Europe.

Direct and spontaneous patient reporting offers added value for pharmacovigilance in that it can speed up the acquisition of knowledge about adverse effects. Patient reports are more direct and often more detailed and explicit than indirect reports through health professionals. Unlike reports from clinicians, they often describe how the adverse effects affect people's lives.

Spontaneous direct reporting also has important benefits beyond pharmacovigilance: it supports and allows for greater patient participation. This fits doctors' expectations - that patients agree to drug regimens and take the medicines. In the process the patient learns how to manage her or his medicines and to communicate more effectively with health professionals. Lastly, public health estimates of disease burden in populations do not consider the effects on people's everyday lives, and they should.

For these reasons direct patient reporting should be encouraged and routinely incorporated in pharmacovigilance activities.

We investigated the current state of direct reporting of ADRs by:

- a. interviewing people concerned with ADR reporting (working in regulatory agencies or other organisations in 15 countries) about their experiences and attitudes.
- b. reviewing published work on direct reporting of ADRs by patients/consumers and related matters.

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