

ADR Reporting by the General Public: Lessons Learnt from the Dutch and Swedish Systems

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Consumer reporting of adverse drug reactions (ADRs) has existed in several countries for decades, but throughout Europe the role of consumers as a source of information on ADRs has not been fully accepted until recently. In Europe, The Netherlands and Sweden were among the first countries to implement consumer reporting well before it was mandated by law throughout the EU. Consumer reporting is an integral part of the spontaneous reporting systems in both The Netherlands and Sweden, with yearly numbers of reports constantly increasing. Consumer reporting forms and handling procedures are essentially the same as for healthcare professional reporting; the message in the reports, not the type of messenger, is what is of importance. Studies have established the significant contribution of consumer reporting to ADR signal detection. Combining all reports regardless of reporter type is recommended since it yields the largest critical mass of reports for signal detection. Examples of signals where consumer reports have been of crucial importance for signal detection are electric shock-like sensations associated with the use of duloxetine, and persistent sexual dysfunction after discontinuation of selective serotonin reuptake inhibitors. An example of consumer reporting significantly strengthening a detected signal is Pandemrix (influenza H1N1 vaccine)-induced narcolepsy. Raising public awareness of ADR reporting is important, but time- and resource-consuming. The minimum effort taken should be to passively inform consumers, e.g. via stakeholders' homepages and via drug product information leaflets. Another possibility of reaching out to this target group could be through co-operation with other (nongovernment) organizations. Information from consumer reports may give a new perspective on ADRs via the consumers' unfiltered experiences. Consumers' views may change the way the benefit-harm balance of drugs is perceived and assessed today, and, being the ultimate users of drugs, consumers could have a relevant influence in the regulatory decision-making processes for drugs. All stakeholders in pharmacovigilance should embrace this new valuable source of information.

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