

EDITORIALS

Drug safety: reporting systems for the general public

WHO's latest guidance is relevant to developed and developing countries

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Harms from drugs are an important cause of morbidity, mortality, and extra costs to healthcare.¹ Such costs are high in developed countries—the average treatment costs of a single adverse drug reaction in Germany were recently estimated to be €2250 (£1766; \$2762).² The costs to healthcare delivery in developing countries could be even greater, because real harm to even a few patients can destroy the credibility and success of an important public health programme. Public concern about adverse effects of drugs can spread rapidly and is difficult to refute in the absence of good data.^{3,4} The latest guidance on monitoring the safety of drugs from the World Health Organization focuses on planning and implementing adverse drug reaction systems for the general public and will probably make an important contribution to pharmacovigilance strategies.⁵

Spontaneous reporting systems remain a core element of pharmacovigilance—the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug related problem. But is the WHO report relevant to countries with an existing consumer reporting scheme (Australia, Canada, Denmark, Netherlands, Sweden, United Kingdom, and United States) or only to those who are yet to establish one? The answer, it seems, is yes.

The value of consumer reporting as an integral part of pharmacovigilance has not always been recognised. It took some powerful examples of important observations by lay users to change perceptions of users' potential to contribute valuable information on drug safety. These include lipodystrophy associated with certain anti-HIV drugs and debilitating effects associated with selective serotonin reuptake inhibitors, particularly on withdrawal.^{6,7}

A review conducted on the 40th anniversary of the UK's Yellow Card scheme in 2004 concluded that it should be opened up to consumer reporting, despite the worry that this might make it more difficult to detect "real" signals of drug safety concerns because of the additional "noise."⁸ Subsequently, an analysis of 26 129 reports made by patients and health professionals, of which 20% were made by patients, showed that more signals were detected when reports of suspected adverse reactions from both consumers and health professionals were collated. Moreover, patients' descriptions of suspected adverse reactions were more detailed than those of health professionals and were

more likely to explain the effect of the reaction on the patient's life.⁹

For countries that are yet to introduce consumer reporting of adverse drug reactions, the new guidance issued by WHO provides comprehensive advice on which questions need to be considered and which stakeholder organisations should be involved. As a step by step guide to implementing a well organised and effective consumer reporting system, it is applicable to developing countries and developed countries that lack the systems for consumers to report drug reactions. In this regard, its publication is particularly opportune for European Union countries, which are now required to accept consumer reports by new EU-wide legislation that came into force in July 2012.^{10,11}

The WHO guidance is also relevant to countries whose existing systems need to be improved or strengthened. In advising that there should be no restrictions to the drug related harms that consumers can report it is in tune with the extended scope of an adverse drug reaction as defined in the new EU legislation. This definition now includes harms associated with medication error, off-label use, unlicensed use, and misuse. As the WHO guidance clearly states, all reports are welcome and useful.

In addition, at this time of increasing concern about counterfeit drugs entering the supply chain, reports from patients can help identify such drugs. For example, a patient on olanzapine, who had taken to polishing his tablets, reported that the colour in the coating was rubbing off. When the drug's ineffectiveness was also deduced this led directly to identification and action on a major counterfeit operation.

Importantly, the WHO guideline recognises the role of the medicines regulator to evaluate new drug safety signals and take prompt and proportionate regulatory action to minimise risk. However, the guideline envisages the regulatory function as quite distinct from safety monitoring. In developed countries, pharmacovigilance is generally closely aligned with or integrated in regulatory agencies that are responsible for monitoring the benefit-risk balance throughout a drug's lifetime in clinical use. In countries with no legal base for pharmacovigilance, public health protection is limited by the inability of regulatory authorities to enforce the responsibilities of drug companies for post-marketing safety activities.¹² In particular, the companies'

responsibilities for surveillance of the safety of donated drugs must be clarified.

Notwithstanding these qualifiers, the WHO guidance has general relevance and goes a long way to setting standards for consumer reporting of adverse reactions so that its potential to contribute useful information on drug safety can be maximised. The report's timing in terms of influencing new and evolving pharmacovigilance systems could not be better. Even well established consumer reporting schemes—such as the UK's Yellow Card—evolve over time, and with international data exchange a suspected adverse reaction reported via a local system could help to prevent harms from a drug worldwide.

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