

## Focus on Patient Yellow Card Reporting

### Strengthening Patient reporting

This edition of *re:Action* concentrates on the reporting of adverse drug reactions by patients. The MHRA, supported by our unit in the West Midlands region, are raising public awareness of the Yellow Card scheme in a publicity campaign running from 18<sup>th</sup> of February to the 31<sup>st</sup> of March 2008. A copy of the poster to be displayed in pharmacies is shown below.



Patients can report on-line using a simple form (<http://www.yellowcard.co.uk>) or using Yellow Card forms (available from our centre). Community pharmacies are an important part of this campaign, and MHRA are making printed support materials available in the form of posters and credit card-sized patient information leaflets.

Pharmacists have an important role in the advising patients on the use of the medicines they dispense. In

addition, pharmacists may detect ADRs during Medication Usage Reviews. They are therefore well placed to advise patients about ADRs and how such ADRs can be reported. The MHRA is encouraging patients to speak to their pharmacists and/or to pick up an information leaflet from their pharmacy. Remember, patients may be more familiar with the term side effects, rather than adverse drug reaction.

### Why patient reports?

In 2004, an Independent Review of the Yellow Card scheme recommended that direct patient reporting should be introduced. The MHRA hopes that collecting patients' views on ADRs will help improve the safety of medicines. Patients' qualitative experiences will be valuable.

### What should be reported?

The MHRA are asking patients to report:

- Side effects not mentioned in the patient information leaflet
- Side effects bad enough to interfere with day to day life

Suspected side effects should be reported even if the patient or pharmacist is not sure that the drug caused the reaction. Side effects to prescribed medicines, OTC medicines, herbal preparations, and medicines bought over the internet can be reported. As well as side effects experienced directly by members of the public, they can also report side effects in those they are caring for (such as the children or the elderly), or at the request of another person who has experienced a side effect.

### What's the evidence?

A number of studies have shown that patients, including older patients, can recognise ADRs similar to those found by healthcare professionals. Patients are also willing to participate in such schemes. Patient reporting of ADRs to OTC medicines or

herbal preparations may also find reactions not noted by general practitioners.

A study performed in Holland compared patient reports of ADRs to paroxetine to similar report from healthcare professionals (Egberts, 1996). New ADRs were spotted by both groups, but patients found new ADRs eight months before healthcare professionals.

Qualitative examination of patient reports has shown that they were rich in terms of their description of the nature, severity, and significance of reactions (Medawar, 2003/2004).

An MHRA evaluation of the first 6 months of patient reporting showed that there was no difference in the proportion of serious ADRs reported, compared with reports from healthcare professionals. Patients focused on well established drugs, rather than new black triangle drugs (Ekins-Daukes, 2006). A MHRA patient reporting group considered that international experience suggested new ADRs had been discovered (Blenkinsopp A, 2006).

Professor Robin Ferner, the medical director of YCC West Midlands in Birmingham said: *“Modern medicines bring great benefits to patients, but unfortunately they can sometimes cause adverse effects that can occasionally be serious. We need to know as much as possible about adverse effects if they do occur, so we can protect others from them. Patients can now make a vital contribution by reporting adverse effects directly through the Yellow Card scheme. Community pharmacists are experts in helping patients understand the importance of their medicines and the ways that patients can report*

*adverse effects. Their support will be very helpful in ensuring the safety of the medicines that patients take.”*

## References

Blenkinsopp A, Wilkie P, Wang M, Routledge PA. Patient reporting of suspected adverse drug reactions: a review of published literature and international experience. *British Journal of Clinical Pharmacology* 2006;**63**(2):148-156

Egberts TCG, Smulders M, de Koning FHP, Meyboom HB, Leufkens HGM. Can adverse drug reactions be detected earlier? A comparison of reports by patients and professionals. *British Medical Journal* 1996;**313**:530-531.

Ekins-Daukes S, Irvine D, Wise L, Fiddes S. The Yellow Card Scheme: Evaluation of Patient Reporting of Suspected Adverse Drug Reactions. *Pharmacoepidemiology and Drug Safety* 2006;**15**(S105).

Medawar C, Herxheimer A. A comparison of adverse drug reaction reports from professionals and users, relating to risk of dependence and suicidal behaviour with paroxetine. *International Journal of Risk and Safety in Medicine* 2003/2004;**16**:5-19

## Sharing our expertise

Do you need a speaker for an educational event, or a lunchtime meeting? Our centre is keen to promote the Yellow Card scheme, and can provide training on adverse drug reactions, the Yellow Card scheme, and related subject areas - such as medical error.

If you would like to discuss this with us, please ring 0121 507 5672 or email [yccwm@swbh.nhs.uk](mailto:yccwm@swbh.nhs.uk).

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## The Yellow Card Centre West Midlands

**We encourage the reporting of Yellow Card reports for all suspected adverse reactions to new (▼) drugs, vaccines and unlicensed herbal remedies, all suspected reactions to all drugs in children, and all serious or unusual reactions to well-established drugs.**

**You do not have to be certain that a drug caused a reaction in order to report.**

Please send reports to: Medicines and Healthcare Products Regulatory Agency, CHM, Freepost, London, SW8 5BR. No stamp is needed. If you would like a supply of pre-addressed and reply-paid yellow cards, please contact us:

**Phone:** 0121 5075672 **Email:** [yccwm@swbh.nhs.uk](mailto:yccwm@swbh.nhs.uk)

**Address:** Yellow Card Centre West Midlands, City Hospital, Dudley Road, Birmingham, B18 7QH.

**If you would like to receive this bulletin by email contact:** [yccwm@swbh.nhs.uk](mailto:yccwm@swbh.nhs.uk)

Please send any comments to:

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