

# NHS

### **Adverse Drug Reaction (ADR) Reporting by Patients**

### Key points

- For patient Yellow Card reporting to be successful, members of the public must be made aware that they are able to report. Community pharmacists are well placed to promote this message.
- · Patients only require a suspicion that a medicine has caused the reaction to report.
- Patients should be encouraged to report all suspected serious side effects that were bad enough to interfere with everyday activities and all suspected reactions not listed in the Patient information leaflet for a medicine.
- Patients need not worry that a healthcare professional may have reported the same reaction.
- The MHRA need everyone healthcare professionals and patients to tell them about possible side effects they or someone they care for experiences via the Yellow Card Scheme.

### **Background**

Patient reporting of suspected ADRs to the Yellow Card Scheme began as a pilot scheme of the Medicines and Healthcare products Regulatory Agency (MHRA) in 2005. Since then patients have joined healthcare professionals as established reporters to the Yellow Card Scheme.

Reports from healthcare professionals are vital in gaining clinical information and perspective on suspected ADRs. However, patient reporting of ADRs complements healthcare professional reporting in a number of ways, as described below:

- 1. Patients report directly, cutting out the 'middle man'. That is, for a healthcare professional to consider a Yellow Card report, they must first be informed of a side effect that the patient is experiencing. After discussion with the patient the healthcare professional will then decide if the side effect warrants reporting. If they do decide to report they must then report without changing the meaning of the patient's concerns.
- Patients tend to report ADRs earlier than their healthcare professional(s), which is particularly important for serious ADRs that require prompt action from the MHRA.
- 3. Patients provide a more detailed description of side effect(s) and how it affects their quality of life; this is often not provided in reports from healthcare professionals.

For these reasons the MHRA wish to increase patient awareness of this important advancement in the monitoring of the safety of medicines in the UK.

All community pharmacists should be aware, however, that patient reporting is in addition to healthcare professionals' reporting. Therefore the MHRA request that you continue to report ADRs via the Yellow Card as per these criteria:

- All suspected ADRs for new medicines (i.e. those carrying the black triangle (▼) symbol) for which the safety profile in routine clinical use requires further definition.
- All serious suspected ADRs for established medicines and vaccines. The MHRA lists serious reactions as those that are fatal, life-threatening, disabling or incapacitating, result in or prolong hospitalisation, and/ or are medically significant.
- 3. All reactions occurring in children.

### **ADR versus Side Effect**

The MHRA define an ADR as 'an unwanted or harmful reaction experienced following the administration of a medicine or combination of medicines under normal conditions of use and which is suspected to be related to the medicine'. While a side effect implies some pharmacological basis for the reaction, which may include beneficial effects of a medicine.

Patients may describe their experiences with medicines using different terms compared to healthcare professionals. For instance the term side effect is used synonymously with ADR by most and is likely to be the term most widely used by patients. It is important to be open to the use of lay definitions in use in your discussions with patients.

## What can a community pharmacist do to help?

For patient Yellow Card reporting to be successful patients need to be aware that they are able to report. As one of the most accessible of the healthcare professionals, community pharmacists are well placed to inform patients about the Yellow Card Scheme. Pharmacists have a professional responsibility to advise patients on the reporting of any suspected side effects associated with their medicines including over the counter (OTC) medicines and herbal products.

The advice you can offer patients includes helping to think about whether a possible side effect could be due to a patient's medicine; whether the possible side effect meets the MHRA criteria for reporting; and what details to include on the report.

### Who can report via the patient Yellow Card?

Anyone can report a possible side effect via the patient Yellow Card. These include those side effects that an individual suspects that they, or a child for whom they are responsible (i.e. as the parent or legal guardian), may have had.

In addition, people can report ADRs on behalf of someone else, such as:

- their spouse/partner
- their adult offspring
- someone who they look after

As long as the person who had the ADR has agreed to this.

Sometimes it is difficult to tell whether a possible side effect is due to a medicine. Patients do not have to be certain a medicine caused a side effect – if they reasonably suspect that this is the case then they should be encouraged to complete a Yellow Card report. Patients should not worry that a healthcare professional may also have reported the reaction; the MHRA can identify duplicate reports.

### What should patients report

The MHRA ask patients to follow the guidance listed in **Table 1**.

Table 1 – Types of ADRs for patients to report.

Unknown side effect	All suspected side effects that are not mentioned in the patient information leaflet.
Serious side effect	All suspected serious side effects that were bad enough to interfere with everyday activities.

It is important to note that the MHRA is interested in reports for all prescription and OTC medicines, as well as herbal preparations (licensed or unlicensed). Many herbal remedies are still unlicensed and are purchased from outlets other than pharmacies, including Ayurvedic and Traditional Chinese Medicines. The MHRA would ask you to consider this possibility when patients seek advice on potential side effects. Also it is always worthwhile to consider interactions between herbal preparations (i.e. drug/food, drug/disease and drug/drug) and other medicines, which can possibly lead to side effects.

### Areas of special interest

The MHRA is particularly interested in hearing about any side effects occurring in children, the elderly, and other vulnerable groups (e.g. patients who are pregnant, nursing mothers, or those who have a history of allergies). Community pharmacists could encourage patients and carers to make these reports.

### Completion of patient Yellow Card reports

Paper Yellow Cards for use by patients have been supplied to all community pharmacists for this promotional campaign. Additional Yellow Cards can be downloaded or submitted electronically from the MHRA website www.yellowcard.gov.uk

There are four required pieces of information required from patients when they complete a Yellow Card. These items can be seen in **Table 2**.

Patients can be encouraged to complete as much of the Yellow Card report they can before sending to the MHRA, however, patients should be reassured that the lack of any particular piece of information should not prevent reporting. Some patients may appreciate help in the completion of Yellow Cards.

#### Action once received

The MHRA will acknowledge each Yellow Card report submitted, and will send the patient a copy of their report for their records. In some cases they may contact the patient requesting additional details regarding the report. This will then aid them in investigating the possible side effect, and taking any necessary action to minimise the risks to other patients taking the same medicine(s).

#### **Additional information**

Additional information on Yellow Card reporting for healthcare professionals and patients can be found at www.mhra.gov.uk



Table 2 – Information to include on a patient Yellow Card Report.

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Suspected medicine(s)	The name of the suspected medicine(s) must be provided.
	Further information could include formulation; route of administration; dosage; where medicine was obtained from; dates of when medicine was started and stopped; and indication.
	For herbal products, additional useful information (if available) could include the ingredient(s); source or supplier; batch number; and the use to which the remedy was being put.
Suspected reaction(s)	The name and/or a description of the reaction(s) must be provided.
	Further information (e.g. any treatment given, together with the dates the reaction started and stopped, and how bad the reaction was; the outcome of the suspected side effect) is useful but not essential.
Patient details	One of the following pieces of information must be provided:
	Patient's initials, sex or age at the time of the reaction.
Reporter details	Name and full address of the reporter, so that the report can be acknowledged and contact made for further information, if necessary. Patients should be advised that their personal data are confidential and will be kept secure; and would not be passed to anyone outside the MHRA with their permission.

Please note this information is desirable but patients should not worry if they do not have all this information.

This information sheet was produced on behalf of the MHRA by YCC Scotland, January 2008.