The MHRA and the Commission on Human Medicines (CHM) run the UK’s spontaneous adverse drug reaction (ADR) reporting scheme - called the Yellow Card Scheme. This receives reports of suspected ADRs from healthcare professionals and patients.

**What is an ADR?**

An adverse drug reaction is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs under normal conditions of use and is suspected to be related to the medicine.

<table>
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<tr>
<th>How common are ADRs?</th>
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<td>ADRs are common. A study of hospital admissions in the UK(^1) found that:</td>
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<td>6.5% of admissions were related to ADRs</td>
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<td>Projected annual cost to the NHS is £466 million</td>
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<td>Over 2% patients admitted with an ADR died, suggesting an overall fatality rate from ADRs within the population of 0.15%</td>
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<td>72% of ADRs were definitely or possibly avoidable</td>
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**Background**

The Yellow Card scheme relies on professionals such as you to voluntarily report ADRs. It acts as an early warning system for the identification of previously unrecognised reactions and enables us to identify risk factors, outcome of the ADR and other factors that may affect clinical management.

The value of the scheme has been demonstrated many times and it has helped to identify many safety issues. For example Yellow Cards about liver toxicity with black cohosh resulted in improved safety warnings. The continued success of the scheme depends on the vigilance of UK healthcare professionals and your willingness to report suspect ADRs. Every report can make a difference.

**What do I report?**

Please report all suspected ADRs to drugs. We are particularly interested in receiving reports of:

- ADRs to new drugs i.e. drugs marked with an inverted black triangle (▼). The [Intensive monitoring list](#) gives details of all black triangle drugs and is updated monthly
- Reactions to over-the-counter (OTC) and herbal medicines
- Serious reaction to all prescription medicines (including unlicensed use or drug, see also box below)

**Serious reactions are those which are:**

- Fatal
- Life-threatening
- Disabling
- Incapacitating
- Results in, or prolongs, hospitalisation

We are also keen to receive Yellow Cards on:

- Adverse drug reactions in children
- Adverse drug reactions in the elderly
- Delayed drug effects
- Pregnancy and [congenital abnormalities](#)

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<th>HIV medicines</th>
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<td>Causality does not need to be established. You only need to have suspicion that a reaction is related to a drug.</td>
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**How do I report?**

The easiest way to report is using the electronic Yellow Card at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk). It is quick and easy, and you do not have to worry about finding a post-box. You can register on the site and the Yellow Card can be saved at any time. The website gives full instructions on how to complete the Yellow Card.

Alternatively Yellow Cards are also available:

- By [downloading a Yellow Card](#) to print out
- By writing to: MHRA, CHM Freepost, London SW8 5BR
- By emailing [pharmacovigilance@mhra.gsi.gov.uk](mailto:pharmacovigilance@mhra.gsi.gov.uk)
- From the [British National Formulary](#) (BNF).
- From the [ABPI Medicines Compendium](#).
- From the [MIMS Companion](#).

**What information do I include?**

Please include four critical pieces of information on the report:

1. **Patient details**
   - Basic information about the patient is vital in assessing reports and obtaining further information. Please provide at least one of the following:
     - Patient sex, age at the time of the reaction and weight if known.
     - Patient’s initials and local identifier which can identify the patient to you.
   - This does not breach [confidentiality](#) agreements between you and your patient.

2. **Suspect drug(s)**
   - Name of the drug(s) suspected to have caused the reaction. Include daily dose, dose frequency/schedule, start and stop dates and route of administration.

3. **Suspect reaction(s)**
   - Describe the suspected reaction(s), including a diagnosis if relevant. Include when the reaction occurred, seriousness, any treatment given and outcome.

   If the reaction has already been reported (e.g. by another healthcare professional or the patient) but you have additional information to report, please submit a Yellow Card as we can detect duplicate reports.

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Reporting Adverse Drug Reactions with the Yellow Card Scheme -
A Guide for Pharmacists

4. Reporter details

This field must be completed in all cases. Please include your name and full address. This is so we can acknowledge receipt of the report, and follow up your report for further information if necessary.

Any additional information

We would be grateful for any additional information that you think might be relevant to the reaction:

- Other drugs taken in the last three months prior to the reaction, including OTC and herbal medicines
- Any information on rechallenges with the suspect drug(s)
- Relevant medical history, including allergies
- Relevant test results
- For congenital abnormalities please state all other drugs taken during the pregnancy and the date of the last menstrual period

If the patient was not taking any other drugs, or if no other information is available on the case, please indicate this.

Any information you provide helps us to interpret the case and evaluate safety issues. Please provide as much relevant information as is readily available because this will reduce the need for follow-up, but do not delay reporting just because some details are not known.

Reporting by patients

Patients are welcome to directly report suspected ADRs to us through the Yellow Card Scheme.

As a pharmacist, you are well placed to inform patients of the Yellow Card Scheme. We ask you to encourage patients to report all possible side effects that were bad enough to interfere with everyday activities, and all possible reactions not listed in the patient information leaflet included with their medicine. This is reflected in the pharmacist’s professional responsibility to advise patients on the reporting of any suspected side effects associated with their medicines, including OTC and herbal products.

Patients can report online at www.yellowcard.gov.uk or on a Yellow Card form which can be found at pharmacies. Alternatively they can call the Yellow Card hotline on 0808 100 3352.

Reporting by pharmacists is key

The MHRA and the Royal Pharmaceutical Society believe that pharmacists have an important role to play in the Yellow Card Scheme, both by raising awareness of patient reporting, and by continuing to identify and report ADRs through the scheme.

A better understanding of reactions allows us to give advice on how medicines can be used more safely. If you suspect that a reaction experienced by a patient is associated with a medicine being taken, then you should report. Please do not be put off from reporting just because you are uncertain about cause and effect.

Complete a Yellow Card if you have a suspicion that a drug has caused an adverse reaction. Remember - if you are in any doubt please report.

DON'T DELAY REPORT TODAY!