the yellow card scheme

epilepsy society factsheet 36

The Yellow Card Scheme is for reporting previously unknown side effects of drugs. It is also a scheme for reporting 'breakthrough seizures' due to switching between different versions of your medication. It is a form you fill in and send to the MHRA.

As with any drug, anti-epileptic drugs (AEDs) can cause side effects in some people. Side effects vary from one AED to another. Most side effects for an AED will be listed in the patient information leaflet (PIL) which comes with the AED. However, some rare or previously unknown side effects will not be listed, and should be reported via the Yellow Card Scheme.

what is the MHRA?

The MHRA is the Medicines and Healthcare products Regulatory Agency. The MHRA licenses drugs to be used in the UK. It also monitors the effectiveness and safety (called 'pharmacovigilance') of all medicines once they are licensed and being used. Part of this includes monitoring the side effects of drugs, and identifying any problems which may not already be known about. If you complete a Yellow Card it will be sent to the MHRA.

what are side effects?

Side effects are symptoms cause by medical treatment. They are sometimes called 'adverse effects' or 'adverse drug reactions'. Side effects are often unwanted or unpleasant, but some may be positive (such as causing sleepiness if you find it hard to sleep).

For the Yellow Card Scheme, breakthrough seizures are also considered a 'side effect' of medication.

what are breakthrough seizures?

'Breakthrough seizures' is a term used to describe seizures that happen when someone's epilepsy has otherwise been well controlled. This means people who stop having seizures but then unexpectedly have another seizure. There are many possible causes for breakthrough seizures such as missing medication. However, only breakthrough seizures related to switching between different versions of your AEDs should be reported to the MHRA.

what else should I report?

Alongside reporting side effects, the Yellow Card Scheme can be used to report any effects from switching between different versions of an AED, such as breakthrough seizures or more frequent seizures.

For some AEDs there are several different versions of the same drug available. This might include a branded drug (the original version of the drug) and other generic versions (with the same active ingredient as the original version). Alternative versions might be different in size, shape or colour, but they all have the same active ingredient (the chemical part of a drug that works in the body to control or treat a condition or disease). Although all versions of a drug have to have the same amount of active ingredient as the original version, there can be differences in some of the other ingredients (such as colours and binding agents). For some people these changes might affect how well the drug works to control their seizures.

See our factsheet *generic and branded AEDs*.

If you have had your AEDs switched from one version to another, and you experience any of the following, you can report this through the Yellow Card Scheme:

- a breakthrough seizure;
- seizures different from those you normally have;
- more or worse seizures; or
- worse side effects.

why should I report this?

The MHRA is collecting evidence about whether switching between different versions of AEDs can affect seizures. By reporting any changes in your seizures through the Yellow Card Scheme, you are helping to show the impact of switching AEDs. This will help the MHRA to understand the risks around switching AEDs, and inform what guidance they give to healthcare professionals (including specialists, GPs and pharmacists) about prescribing and dispensing AEDs.

For more on the MHRA guidance visit: epilepsysociety.org.uk/mhra-guidance-antiepileptic-drugs

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drug development and side effects

When new drugs are developed, part of the process is 'clinical trials' to test the drug for safety (that it doesn't cause illness), effectiveness (how well it works for the condition it is designed to treat) and whether it causes any common or predictable side effects.

During development, drugs are tested on people. Firstly they are tested on healthy volunteers (without the disease or condition the drug is being developed for) to give information about how the drug distributes in the body, and the likely doses needed. They are then tested in people with the relevant disease or condition to test their effectiveness on that disease or condition. Some groups of people are not included in these trials: children, people aged 60 or over, and pregnant women, so the effect in these groups is not known at this stage.

Any side effects seen are recorded during these trials. Once licensed, drugs can be prescribed and used.

Visit epilepsysociety.org.uk/aeddevelopment for more about how drugs are developed.

Aren't all side effects of a drug already known?

Any side effects that become known when drugs are developed are recorded, and listed in the patient information leaflet that comes with every prescription of medicines. These side effects are listed according to how often they happen (how many people are likely to experience the side effect).

They are listed as:

- very common – affects at least 1 in 10 people;
- common – affects 1 in 100 to 1 in 10 people;
- occasional – affects 1 in 1,000 to 1 in 100 people;
- rare – affects less than 1 in 1,000 people;
- very rare – affects less than 1 in 10,000 people; and
- extremely rare – affects less than 1 in 100,000 people.

Some side effects only become known after a drug is used in the population (after it is licensed and starts to get prescribed to a larger number of people). This might be because the side effects only happen after a drug is used for a long time (long-term or 'chronic' side effects), or they become known after a greater number of people have started to use the drug. Also, some side effects are unique to the person experiencing them and so cannot be predicted.

more about the yellow card scheme

How do I get a Yellow Card?

You can get a Yellow Card from your GP surgery, pharmacist, hospital or NHS drop-in centre, or by calling the yellow card hotline on 0808 100 3352. You can also download the form, or complete it online, or report side effects via the yellow card app.

Visit yellowcard.mhra.gov.uk

What information will I need to include?

When you report a side effect, you will be asked about:

- the side effect;
- the person who had the side effect;
- the medicines which may have caused the side effect;
- your doctor (optional); and
- you - the person making the report.

What happens once I report it?

The doctors, pharmacists and scientists at the MHRA look into each Yellow Card report. They compare it with other information on the medicine (from the development trials) to check if it is a previously unknown side effect, and consider how it affects the safety of the medicine. They might also be able to issue relevant warnings and safety advice about taking the medicine.

The MHRA is also looking at data around reporting of breakthrough seizures to see how this might affect the way AEDs are prescribed and dispensed.

further information

www.yellowcard.mhra.gov.uk – information from the MHRA on the Yellow Card Scheme.

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