

Resource

Reporting side effects

The Medicines and Healthcare products Regulatory Authority (MHRA) has launched an app for patients and healthcare professionals to report the side effects of medicines via the Yellow Card Scheme. Side effects can also be reported through the scheme online or by phone.

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All medicines can occasionally cause unwanted side effects. Many side effects are mild, but some can be serious and even life-threatening. Occasionally, they can appear after a person has stopped taking medicine. Some side effects, especially those associated with newer drugs, may not be recognised until many people have been taking medicine for a long time. That's why it is important for people to report suspected side effects, especially if these are severe.

The Yellow Card Scheme collects information on suspected side effects from all types of medicines. These include prescription medicines or vaccines, medicines you can buy without a prescription, herbal and complementary remedies. Yellow Card reports are sent to the MHRA, the government

agency responsible for ensuring that medicines and medical devices work and are acceptably safe.

The new app supplements the existing website and is the only app that allows the reporting of side effects directly to the MHRA. The app is free to download on iOS and android. Key features of the app include:

- A convenient, paperless way to submit a report of a side effect of a drug
- The ability to create a 'watch list' of medications to receive official news and alerts. This means patients can keep an eye on any emerging safety concerns with their own medicines and promptly seek advice from a GP or pharmacist should they occur.
- The facility to view the numbers of Yellow Cards submitted for a particular medicine
- The power to view and submit updates to previously submitted Yellow Cards (for instance if the side effect has got worse or improved or gone away on stopping a medicine)

So what should I report?

It is especially useful for the MHRA to know about side effects that:

- are not mentioned in the patient information leaflet supplied with the medicine
- cause problems severe enough to interfere with everyday activities
- occur when taking more than one medicine, since these could be caused by drug interactions.

"Sometimes, it is difficult to tell whether a symptom is a side effect of your medicine, or something else," said Sarah Smith, Senior Pharmacist Pharmacovigilance at Yellow Card Centre Northern and Yorkshire. "Even if you are not sure, please make a Yellow Card report if you think a medicine might have caused a side effect. Additional information such as what the medicine was used for, the dose, details of any other medicines that may have been taken and any relevant medical history can help us better understand the background to a report."

Side effects can also be reported by:

- Using the online Yellow Card at <https://yellowcard.mhra.gov.uk/>
- Picking up a patient Yellow Card form from a pharmacy or GP surgery
- Calling the Yellow Card hotline on 0800 731 6789 (weekdays 9 am- 5 pm).

What will happen after a report is made?

All reports are handled in strict confidence. If reported via the app, you will receive an immediate acknowledgement of your report. If reported via other means an email or letter will be sent to you. The information is added to the MHRA database, so that the reports can be analysed for emerging drug safety signals, and evaluated together with information from clinical trials and other medical literature.

If a new side effect is identified, it is carefully considered in the context of the overall side effect profile for the medicine, and how that compares with other medicines used to treat the same condition.

Sarah Smith added: “If a new side effect is found, the MHRA will review the way that the medicine can be used, and the warnings given to people taking it. In some cases, the medication may even be withdrawn from market. We want to ensure that medicines are used in a way that minimises risk while maximising patient benefit. The information that you provide can ultimately improve the safe use of medicines.”

If you are worried about a suspected side effect, contact a doctor or pharmacist, or call NHS 111 in England and Wales or NHS24 in Scotland also on 111. The MHRA cannot provide medical advice in individual cases.

For more information on Yellow Card reporting visit <https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/>

Medicines in rheumatoid arthritis

We believe it is essential that people living with RA understand why certain medicines are used, when they are used and how they work to manage the condition.

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