

## Members Of The Public To Be Encouraged By Pharmacists To Report Suspected Side Effects Of Medicines, UK

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Medicines and Healthcare products Regulatory Agency (MHRA) is launching a six-week campaign to get community pharmacists to mention the Yellow Card (YC) Scheme when they talk to their customers about their medicines. During this week, pharmacists will receive an information pack containing updated Yellow Card reporting forms, information leaflets, and a new poster for display in the pharmacy. The Yellow Card reporting forms have been made simpler and easier to use than previous versions and an updated online system at <http://www.yellowcard.gov.uk> will make it quicker and easier to report suspected side effects of medicines to the MHRA.

Dr June Raine, Director of Vigilance and Risk Management of Medicines at the MHRA said, "We are keen to let people know that whilst their medicines have important benefits, they may also have unwanted side effects. If you suspect that you have had a side effect to your medicine, please tell us about it via the Yellow Card Scheme. Please speak to your local pharmacist if you need help to do this, as they can provide expert help and support. Please pick up and fill out our improved reporting form or go online and tell us about your experiences there. By providing this information, not only are we able to gain better insights into the safety of medicines, but you can directly become involved in medicines regulation."

Shelley Flanagan, a member of the public who suffered side effects from antibiotics after being treated for pneumonia said, "I would encourage anyone who believes they have had a side effect to a medicine to fill out a Yellow Card like I did, or report online. I think it's important to discuss the medicines you are taking with your pharmacist or doctor so that you understand what you are taking and why."

### Notes

1. Yellow Card reports are used to identify side effects and other issues with medicines which might not have been known before. If a new side effect is found, the MHRA will review the way that the medicine can be used, and the warnings that are given to people using it. The value of the YC Scheme has been demonstrated many times and it has helped to identify numerous important safety issues. It flagged up that Warfarin can interact with cranberry juice by lessening its benefits, and in 2001 Yellow Card reports identified that the smoking cessation medicine Zyban can cause seizures.
2. The MHRA typically receives around 20,000 Yellow Card reports of suspected side effects annually. It is encouraging to note that in recent years, Yellow Cards submitted by pharmacists have accounted for around 15-16% of all reports received. However, reporting by community pharmacists has not taken off in the way expected. In 2000, the first full year of community pharmacist reporting, they sent in just over 400 Yellow Cards - and this figure has remained fairly constant since then at around 300-500 reports per year. In contrast, the number of reports from hospital pharmacists has doubled (1300-1500 reports per year in recent years, compared with around 700 reports in 1998). Almost 7,000 patient reports have been received, this represents about 10% of the totality of reporting at a consistent level of over 200 reports per month.
3. For over 40 years, the Yellow Card Scheme has been the cornerstone of medicines safety monitoring in the UK. Since the Yellow Card scheme was set up, over 500,000 reports of suspected side effects (known as adverse drug reactions) have been completed.
4. The Yellow Card Scheme was set up in 1964 following the Thalidomide tragedy to provide a system for early detection of emerging drug safety hazards, and the routine monitoring for all medicines in clinical use. Reports of suspected side effects are also received from pharmaceutical companies, who have a legal obligation to report suspected serious side effects to the MHRA.
5. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone - the public and healthcare professionals as well as the industry - to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action.

<http://www.mhra.gov.uk>

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