Milestone 1 million Yellow Card report for suspected side effects in #MedSafetyWeek

Press release

The Yellow Card scheme is the UK's system for reporting suspected side effects to medicines and adverse events with medical devices run by the Medicines and Healthcare products Regulatory Agency (MHRA).

- Major milestone – 1 million Yellow Card reports since scheme started over 50 years ago
- Reporting suspected side effects helps to make medicines safer for everyone
- MHRA launches #MedSafetyWeek to further encourage people to report

The MHRA received its one millionth Yellow Card. This major milestone coincides with the launch of the 5th annual #MedSafetyWeek (2-8 November), which highlights the value of the Yellow Card scheme to the nation's health, and the importance of reporting suspected side effects from medicines. The MHRA has seen an increased rate of Yellow Card reports and would like to continue to encourage more reporting this #MedSafetyWeek.

Reporting helps to identify new side effects, as well as unexpected and serious safety problems. It also adds to existing information about known effects. By reporting, patients and the public can help the safe use of medicines for everyone. It helps the MHRA to take action, through effective regulation.

One recent positive change to medicines information for users involves a woman in the UK who has helped identify a newly recognised side effect from a blood pressure medication. While pregnant, Liz noticed some unusual side effects when taking her medicine and reported it to the MHRA using the Yellow Card scheme.

> Shortly after taking each dosage, I would feel an extreme burning

> sensation in my nipples which intensified over a period of about 20 minutes. It was agonising.
>
> At first, I didn’t make the link between the tablets and the pain – I presumed it was just a pregnancy side effect. My doctor and other healthcare professionals weren’t aware of it as a reported side effect for my medication.
>
> I decided to report my symptoms to Yellow Card because, however rare, I wanted to make sure anyone else experiencing it wouldn’t feel alone.
>
> MHRA investigated my report alongside other reporting and clinical data and found that nipple pain was a symptom of Raynaud’s phenomenon, a known side effect of this particular medicine.
>
> They worked with the manufacturers to improve the patient safety information – and the medicine now includes nipple pain as a possible side effect of Raynaud’s phenomenon.
>
> It didn’t take much time to do and I’m glad that anyone else experiencing this problem will now understand its probable cause. It’s good to know I’ve been able to make a difference.

Liz recovered from the side effect she experienced.

Minister for Innovation Lord Bethell said:

> Everyone should have access to safe and effective medicines, without fear of unexpected side effects, and the news of the MHRA receiving their one millionth Yellow Card is a testament to how important this scheme truly is.
>
> I urge everyone to report any side effects or other major concerns with their medicines through this vital scheme and ensure we all play our part in keeping the British public safe.

Mick Foy, Head of Pharmacovigilance Strategy of MHRA’s Vigilance and Risk

Management of Medicines Division, said:

> Patient safety is our number one priority.
>
> We want this campaign to encourage everyone to report suspected side effects from medicines and make more people aware of our Yellow Card scheme. This important milestone shows that every report counts and contributes to improving the safety of medicines for all patients.

Ends

Notes to Editor

1. The MHRA, who run the Yellow Card scheme, are responsible for protecting and improving the health of millions of people every day through the effective regulation of all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

2. Anyone can use the Yellow Card scheme to report suspected side effects of medicines, incidents involving medical devices, defective, fake medical products and safety concerns for e-cigarettes or their refill containers (e-liquids). Reports can be made on the Yellow Card website, via the mobile app from the Google Play Store or Apple App Store, via freephone (0800 731 6789, 9am to 5pm Monday to Friday) or by reporting an issue to their healthcare team who can file a report on their behalf. Patients are also advised to contact a healthcare professional if they are worried about their health. Yellow Card reporting for suspected side effects is also integrated into some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank and Ulysses).

3. The Yellow Card scheme is an early warning system for detecting medicines and patient safety issues. Many suspected side effects reported to spontaneous reporting systems, such as the Yellow Card scheme in the UK, are expected and listed in the product information. Data over a longer period and a larger database allows regulators to assess and look for patient safety trends and conduct robust signal detection. Thereby enhancing the detection of new, rare reactions, interactions, medication errors where harm occurs, reactions associated with long term use of a medicine and to gain more information about the safe use of medicines e.g. in vulnerable populations. The Yellow Card scheme has identified many new safety issues that were unknown before being reported via a Yellow Card.

4. National medicines regulatory authorities from 73 countries across the globe and their stakeholders will be taking part in this international campaign led by Uppsala Monitoring Centre (UMC), a World Health Organisation (WHO) Collaborating Centre for International Drug Monitoring. The campaign is supported by members of the Heads of Medicines Agencies (HMA) and the International Coalition of Medicines Regulatory Authorities (ICMRA). The #MedSafetyWeek 2020 project team consists of representatives from the following medicines regulators working collaboratively: the Medicines and Healthcare products Regulatory Agency (UK), the Food and Drugs Authority (Ghana), Pharmacy and Poisons Board (Kenya), Health Sciences Authority (Singapore), and the State Institute for Drug Control (Slovakia).

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