Medicines & Healthcare products Regulatory Agency

Drug Safety Update

Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

Volume 18 Issue 4 November 2024

Contents

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicines and medical devices work and are acceptably safe.

The Commission on Human Medicines gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.

NICE accredited
www.nice.org.uk/accreditation

NICE has accredited the process used by the MHRA to produce Drug Safety Update guidance. More information on accreditation can be viewed on the NICE website.

To subscribe to monthly email alerts of Drug Safety Update see: https://www.gov.uk/drug-safety-update

This month, we highlight that 4 – 10 November 2024 is MedSafetyWeek. The theme for this campaign is ‘preventing side effects’, focusing on the importance of using healthcare products in the right way to prevent harm and reporting suspected adverse drug reactions to medicines and suspected adverse incidents with medical devices.

We ask healthcare professionals to support the campaign and talk to their patients and colleagues about side effects and how to report suspected safety concerns to the Yellow Card scheme.

Finally, we provide a summary of recent letters and notifications sent to healthcare professionals about medicines and medical devices.

If you have been forwarded this issue of the Drug Safety Update, you can subscribe directly via our website.

MedSafetyWeek November 2024: your Yellow Card report helps prevent future harm to others and improves patient safety

The ninth annual #MedSafetyWeek social media campaign is taking place 4 to 10 November 2024. The theme for this campaign is 'preventing side effects', focusing on the importance of using healthcare products in the right way to prevent harm and reporting suspected adverse drug reactions (ADRs) to medicines and suspected adverse incidents with medical devices.

We ask healthcare professionals to support the campaign and talk to their patients and colleagues about side effects and how to report suspected safety concerns to the Yellow Card scheme.

What healthcare professionals can do to support MedSafetyWeek – 4 to 10 November 2024:

- follow the MHRA social media channels and show your support for this year's MedSafetyWeek by reposting, commenting, liking and sharing material with your social media contacts using #MHRAyellowcard, #MedSafetyWeek, #ReportSideEffects and #patientsafety
- we ask that you report suspected ADRs (side effects) to medicines to the Yellow Card scheme or via the Yellow Card app (download from the Apple App Store or Google Play Store)
- please also report ADRs where harm occurs due to adverse incidents with medical devices (including software, apps and artificial intelligence), safety concerns about e-cigarettes and their refill containers (e-liquids), adverse reactions to herbal or homeopathic medicines and defective, low-quality or falsified (fake) healthcare products
- adverse drug reactions where harm occurs as a result of a medication error are reportable as a Yellow Card or through the local risk management systems into the Learn from Patient Safety Events (LFPSE) service. If reported to the LFPSE, these will be shared with the MHRA. If the LFPSE is not available and harm occurs, please report using a Yellow Card
- to ensure the use of medicines in the right way to prevent harm, we remind you to discuss with your patients:
    - the importance of taking the right medicine, at the right time, in the right way and at the right dose and of carefully following instructions for use of medical devices
    - the importance of reading the Patient Information Leaflet that comes with a medicine or vaccine
    - what to do if patients experience problems with a healthcare product, such as contacting a healthcare professional and self-reporting to the Yellow Card scheme. For patients using continuous glucose monitors or insulin pumps for diabetes management, highlight our available guidance on reporting to the Yellow Card scheme
- please do talk to your colleagues about staying vigilant for suspected adverse reactions to medicines or vaccines, especially new, serious or rare reactions, those that may have a delayed onset or any medication interactions. Emphasise the importance of reporting these to the Yellow Card scheme

About MedSafetyWeek

MedSafetyWeek, an annual event, forms part of international efforts to raise awareness about the importance of reporting suspected adverse reactions to national medicines regulatory authorities, such as the MHRA. This year, regulators from 94 countries and 107 organisations will take part across the globe.

The theme for 2024's campaign is 'preventing side effects', aligning with the third World Health Organisation (WHO) Global Patient Safety Challenge: Medication Without Harm.[1] Preventable ADRs contribute significantly to an increasing burden on patients and healthcare services with associated admissions contributing to morbidity and mortality.[2] Epidemiological studies have consistently shown that between one third and a half of all ADRs may be potentially preventable.[3]

Anticipating and managing ADRs is key to reducing this burden and protecting patients from avoidable harm. Importantly, Yellow Card reports help to identify previously unknown ADRs and provide new safety knowledge to inform risk minimisation measures. Every report counts to strengthen healthcare product vigilance.

Before using healthcare products, it is good practice to follow the adapted WHO guidance Know, Check, Inform, and Ask:

- Know: the healthcare product
- Check you have the right: patient, medicine, route, dose, time
- Inform: your patient about the healthcare product, discuss potential side effects and what to do if they experience any; this includes reporting any suspected problems using the Yellow Card scheme
- Ask: your patient if they understand

More information about the global MedSafetyWeek campaign is available on the Uppsala Monitoring Centre's website.

About Yellow Card reports

The Yellow Card scheme helps us to monitor the safety of healthcare products once they are on the market. Reporting to the scheme allows the MHRA to identify new adverse effects and gain more information about known adverse effects. By completing a Yellow Card report, you help contribute to the safe use of healthcare products for patients.

We ask that you report suspected ADRs to a medicine or vaccine directly to the Yellow Card scheme as soon as they arise. Please also report adverse incidents to medical devices on a Yellow Card; if you are in Scotland or Northern Ireland report via your local reporting systems. More information on reporting potential problems with medical devices is available.

It is particularly important that all suspected adverse reactions involving Black Triangle (▼) medicines are reported. Yellow Card reports can also be made for

products such as blood factors and immunoglobulin products. Read more about the different types of Yellow Card reports.

The Yellow Card scheme has helped to identify numerous safety issues, many of which were not previously linked to a particular healthcare product until Yellow Card reports were received by the MHRA. Read our case studies describing how Yellow Card reports have contributed to patient safety

We need your help with the Yellow Card Biobank study

The Yellow Card Biobank is a collaboration between the MHRA and Genomics England. The goal is to improve understanding of how patients' genetic makeup may increase their risk of experiencing adverse reactions from prescribed medications. We are looking for patients who have experienced specific side effects when taking allopurinol or direct oral anticoagulants (DOACs) to join the study, before mid-January 2025.

Side effects covered in this pilot study are:

- severe bleeding events with a DOAC - apixaban, dabigatran, edoxaban, rivaroxaban – see Drug Safety Update for a reminder on this risk
- rare severe skin reactions with allopurinol, including Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome

If you have any questions on the Biobank study, please email Yellowcardbiobank@mhra.gov.uk

Resources for healthcare professionals

More information and resources, such as accredited e-learning modules and materials to help raise awareness locally, are available on the Yellow Card website. Links to new materials to download and print for local promotion and social media are available on the MedSafetyWeek campaign page.

Please speak to your local Medication Safety Officer (MSO) or one of our six Yellow Card centres if you are able to help support the campaign locally and help raise awareness. You can also discuss with your local Medical Device Safety Officer (MDSO) how you can help support the reporting of adverse incidents with medical devices.

Please encourage your colleagues to sign up to receive alerts for Drug Safety Update and other safety information from the MHRA about medicines and medical devices – these messages are also available through the Yellow Card app (download from the Apple App Store or Google Play Store).

For queries or more information, please contact info@mhra.gov.uk

Article citation: MHRA Safety Update volume 18, issue 4: November 2024: 1

References

1. https://www.who.int/initiatives/medication-without-harm. Accessed October 2024.
2. Osanlou R and others. Adverse drug reactions, multimorbidity and polypharmacy: a prospective analysis of 1 month of medical admissions. BMJ Open 2022: volume 12, page e055551
3. Coleman, J.J. and Pontefract, S.K. Adverse drug reactions. Clinical Medicine 2016: volume 16, pages 481 to 485

Letters and medicine recalls sent to healthcare professionals in October 2024

A summary of recent letters and notifications sent to healthcare professionals about medicines and medical devices.

Letters

In October 2024, the following letters were sent or provided to relevant healthcare professionals:

- Medroxyprogesterone acetate: Risk of meningioma and measures to minimise this risk
- Idacio ▼ 40 mg solution for injection in pre-filled pen (adalimumab) & Idacio 40 mg solution for injection in pre-filled syringe (adalimumab) - PLGB 08828/0321 and 0322: Temporary Supply of Swedish/Finnish labelled stock
- Glatiramer acetate: Anaphylactic reactions may occur months to years after treatment initiation
- Infanrix hexa [diphtheria, tetanus, pertussis (acellular), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b]: Packaging issue potentially impacting the sterility of needle softpacks of 2 batches of Infanrix hexa for Northern Ireland (batch A21CE437A and A21CE376A).
- PyzchivaTM▼ (ustekinumab) 90 mg solution for injection in pre-filled syringe Interim Supply of Nordics Stock (Homecare company)
- PyzchivaTM▼ (ustekinumab) 130 mg concentrate for solution for infusion Interim Supply of Nordics Stock (Wholesaler)
- Fampyra 10mg Prolonged Release Tablets (fampiridine): Interim Supply of Belgium Stock to Mitigate Supply Disruption

Medicine Recalls and Notifications

In October 2024, recalls and notifications for medicines were issued on:

Class 2 Medicines Recall: Bristol Laboratories Ltd, Phenobarbital Bristol Labs 15mg Tablets, EL(24)A/50. Issued 23 October 2024. Bristol Laboratories Ltd. are recalling one batch of Phenobarbital Bristol Labs 15mg Tablets as a precautionary measure due to the potential of contamination of small metallic particles within the tablets.

Class 2 Medicines Recall: Tillomed Laboratories Limited, Labetalol 200mg Tablets, EL(24)A/52. Issued 29 October 2024. Tillomed Laboratories Limited is recalling one batch of Labetalol 200mg Tablets as a precautionary measure due to potential mix-up at the manufacturing site. A limited number of Labetalol 200mg Tablets (Batch Number 240537) cartons may contain a blister strip of Vera-Til SR 240mg Tablets, (verapamil), PL 11311/0078 (Batch Number 240750) with the blister strips of Labetalol 200mg Tablets.

Updated 31 October 2024. This recall notification has been updated to include the correct description for Labetalol 200mg Tablets. Tillomed Laboratories Limited erroneously provided incorrect information pertaining the description and have ensured that all other information is correct.

Class 3 Medicines Recall: Glenmark Pharmaceuticals Europe Ltd Cyanocobalamin 50 mcg Tablets, EL(24)A/46. Issued 3 October 2024. Glenmark Pharmaceuticals Europe Ltd is recalling the affected batches as a precautionary measure due to out of specification results for unknown impurities during routine stability testing and additional re-testing.

Updated 24 October 2024. This recall notification has been updated to include the correct batch information for Cyanocobalamin 50 mcg Tablets, batch 17231510A. Glenmark Pharmaceuticals Europe Ltd erroneously provided incorrect information pertaining the expiry date of batch 17231510A and have ensured that all other batch information is correct.

Class 3 Medicines Recall: Viatris UK Healthcare Ltd, Trandolapril 2mg and 4mg capsules, EL(24)A/47. Issued 7 October 2024. Generics (UK) Ltd T/A Mylan UK is recalling specific batches of trandolapril after re-testing showed out of specification results. The listed batches in this notification are being recalled as a precautionary measure after testing showed variability of the Trandolapril content.

Class 4 Medicines Defect Information: Sandoz Ltd., Rosuvastatin 20mg, 40mg Tablets, EL(24)A/45. Issued 1 October 2024. Sandoz Ltd. has informed the MHRA that there is missing safety information in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) for Rosuvastatin 20mg and 40mg Tablets.

Class 4 Medicines Defect Information: Sandoz Ltd., Linezolid 600 mg film-coated tablets, EL(24)A/48. Issued 10 October 2024. Sandoz Ltd. has informed the MHRA that there is missing safety information in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) for Linezolid 600 mg film-coated tablets.

Class 4 Medicines Defect Information: Kent Pharma UK, Paracetamol 500mg Effervescent Tablets, EL(24)A/49. Issued 21 October 2024. Kent Pharma UK has identified an error in the Patient Information Leaflet (PIL) for Paracetamol 500mg Effervescent Tablets. The PIL incorrectly states that the maximum daily dose contains 438mg of sodium, whereas this is the sodium content for a single dose. The maximum daily dose is in fact 3504mg of sodium.

Class 4 Medicines Defect Information: Kent Pharma UK, Parasolve (Paracetamol) 500mg effervescent tablets, EL(24)A/51. Issued 28 October 2024. Kent Pharma UK has identified an error in the Patient Information Leaflet (PIL) for Paracetamol 500mg Effervescent Tablets. This notification is in addition to EL 24(A)/49 and provides further information in relation to the impacted product mentioned in this notification.

Article citation: MHRA Safety Update volume 18, issue 4: November 2024: 2