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

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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.

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This month we are calling for healthcare professionals to contribute to our Yellow Card Biobank study to explore whether there is a genetic basis of side effects associated with direct-acting oral anticoagulants (DOACs) and allopurinol. If a patient under your care has experienced one of the side effects included in the pilot phase of the study, please report without delay to the Yellow Card scheme, providing as much information as possible.

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

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

Yellow Card Biobank: call to contribute to study of genetic links to side effects

Support this initiative to explore whether there is a genetic basis of side effects associated with direct-acting oral anticoagulants (DOACs) and allopurinol.

About the Biobank

The Yellow Card Biobank is a collaboration between the MHRA and Genomics England. The goal is to improve understanding of how a patient's genetic makeup may increase their risk of experiencing harmful side effects to medicines.

Adverse drug reactions, or side effects, continue to be a significant burden on the NHS and account for one in 6 hospital admissions.[1] The Yellow Card Biobank forms part of a long-term vision for more personalised medicine approaches. By collecting biological samples from patients who have experienced suspected side effects, the Yellow Card Biobank aims to create a rich resource of genetic information that could help researchers to determine whether a suspected side effect was caused by a specific genetic trait. Ultimately it is hoped this would support the development of pharmacogenetic testing strategies.

If a patient under your care has experienced one of the side effects included in the pilot phase of the study, please report without delay to the Yellow Card scheme, providing as much information as possible.

Study details

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

Once reported, the MHRA may contact you directly to discuss the case further and may ask you to contact the patient on our behalf to ask if they will participate in the Yellow Card Biobank study. The patient will be able to choose whether or not to take part. Having consented to participate the patient may then be asked to provide a blood sample for genetic analysis.

If you have already submitted a Yellow Card report in the past relating to either of the 2 study topics, we may also contact you directly in the coming months to discuss the case further.

Patients who report directly to Yellow Card will also be contacted to be included in the study.

How the biobank works

The MHRA will be responsible for patient recruitment and sample collection. Genomics England will work alongside the MHRA to sequence and analyse genomes from

patients and add this genomic data to the National Genomic Research Library, a secure national database of de-identified genomic and health data. In addition, Genomics England's secure research environment will enable approved researchers to access the data.

All the information collected about you and patients through Yellow Card Biobank will be de-identified before researchers see it. Details of our privacy policy can be found in the Biobank Privacy Policy**.**

If you have any questions about the biobank, you can email Yellowcardbiobank@mhra.gov.uk or call 0203 080 6600 (lines are open Monday-Friday, 9am-12pm excluding bank holidays. Calls are charged at the standard rate). For general queries or more information, contact info@mhra.gov.uk

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References

1. Osanlou R and colleagues. 'Adverse drug reactions, multimorbidity and polypharmacy: a prospective analysis of 1 month of medical admissions.' BMJ Open 2022; volume 12, article e055551. 4 Jul. 2022, doi:10.1136/bmjopen-2021-055551

Letters and medicine recalls sent to healthcare professionals in July 2024

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

Letters

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

- Abecma ▼, Breyanzi ▼, Carvykti ▼, Kymriah ▼, Tecartus ▼ and Yescarta ▼ (CD19- or BCMA-directed CAR T-cell therapies): risk of secondary malignancy of T-cell origin
- Talzenna 0.25mg capsules, hard (talzoparib): Interim Supply of Northern Ireland Stock to Mitigate Supply Disruption
- Lagevrio® (molnupiravir) 200 mg hard capsules – Extended Use Beyond Labelled Expiry Date.
- ZEJULA (niraparib) 100mg film-coated tablets: Repack of specific batches with the contemporaneous Patient Information Leaflet
- Privigen (human normal immunoglobulin (IVIg)) 10% 50 mL: flakes reported in some batches of finished product.

Medicine Recalls and Notifications

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

Class 3 Medicines Recall: Accord Healthcare Ltd, Atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg Hard Capsules, EL(24)A/25. Issued 2 July 2024. Accord Healthcare Ltd is recalling various batches after retesting showed out of specification results. The tabled batches are being recalled as a precautionary measure after testing showed variability of the capsule contents beyond permitted levels.

Class 2 Medicines Recall: Kent Pharma UK, Itraconazole 10mg/ml Oral Solution, EL(24)A/26. Issued 4 July 2024. Kent Pharma UK is recalling various batches of Itraconazole 10mg/ml Oral Solution as a precautionary measure due to out of specification in the appearance of the solution, particularly the presence of suspended particles or clusters of crystals.

Class 4 Medicines Defect Information: Chelonia Healthcare Limited, Propantheline Tablets 15mg (Genesis Pharmaceuticals livery), EL(24)A/27. Issued 9 July 2024. Chelonia Healthcare Limited has informed the MHRA that an error relating to the product description was identified in the Patient Information Leaflet (PIL) for the batches listed in this notification. In the PIL supplied, the product is described as being “pale pink in colour”, whereas the tablet is actually orange in colour.

Class 2 Medicines Recall: Sun Pharma UK Limited, Gemcitabine PPF 1800mg/180mL Infusion; Gemcitabine PPF 1600mg/160mL Infusion; Irinotecan PPF 360mg/240mL Infusion, EL(24)A/28. Issued 15 July 2024. Sun Pharma UK Ltd is recalling certain batches as a precautionary measure due to a small number of leaks found intermittently in the infusion bags.

Class 2 Medicines Recall: Sun Pharma UK Limited, Pemetrexed 1000MG/100ML (10mg/ml) & 1100MG/100ML (11mg/ml) Infusion Bag, EL(24)A/29. Issued 16 July 2024. Sun Pharmaceutical Industries Europe B.V. is recalling the listed batches as a precautionary measure due to visible particulate matter during stability testing.

Class 2 Medicines Recall: Glaxo Wellcome UK Limited (trading as GlaxoSmithKline UK), Flolan 1.5 mg Powder and Solvent for Solution for Infusion, EL(24)A/30. Issued 22 July 2024. Glaxo Wellcome UK Ltd (GSK) has informed the MHRA that vials of Flolan 1.5 mg Powder and Solvent for Solution for Infusion, batch number AB8M may have been damaged during the packaging process.

Class 4 Medicines Defect Information: Fresenius Kabi Limited, Hartmann's Solution for Injection BP as Steriflex No. 11 or freeflex, EL(24)A/31. Issued 24 July 2024. Fresenius Kabi Limited has informed the MHRA of a labelling error on the packaging of Hartmann's solution for Injection BP as Steriflex No.11 or freeflex. The calcium content in the active ingredient section of the infusion bag label is incorrectly stated as '12 mmol/500 mL'; this should state '1 mmol/500 mL'.

Class 4 Medicines Defect Information: Aspen Pharma Trading Limited, Co-trimoxazole 80mg/400mg per 5ml adult suspension, EL (24)A/32. Issued 25 July 2024. Aspen Pharma Trading Limited has informed the MHRA that an error has been found in the Patient Information Leaflet. In one section, the PIL states '4001mg sulfamethoxazole' instead of '400 mg sulfamethoxazole'.

Class 3 Medicines Recall: Glenmark Pharmaceuticals Europe Ltd, Atomoxetine 10mg, 18mg, 25mg, 10mg, 40mg, 60mg, 80mg & 100mg Hard Capsules, EL(24)A/33. Issued 30 July 2024. Glenmark Pharmaceuticals Europe Ltd is recalling various batches after retesting showed out of specification results.

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