



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 16 Issue 3 October 2022

Contents

MedSafetyWeek November 2022: Every Yellow Card report helps to improve patient safety	page 2
COVID-19 vaccines and medicines: updates for October 2022	page 5
Letters and medicine recalls sent to healthcare professionals in September 2022	page 6

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 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](https://www.nice.org.uk/accreditation).

To subscribe to monthly email alerts of Drug Safety Update see: <https://www.gov.uk/government/organizations/medicines-and-healthcare-products-regulatory-agency/email-signup>

This month, we ask healthcare professionals to support our annual #MedSafetyWeek social media campaign, which will take place 7 to 13 November 2022. This year's focus is the importance of reporting suspected adverse reactions to medicines and vaccines. We are also encouraging the reporting of suspected problems with medical devices or other healthcare products to the Yellow Card scheme.

Show your support for this year's campaign on social media and by discussing with your patients and colleagues how they can report suspected problems to the Yellow Card scheme.

Next, on page 5 we summarise recent advice relating to COVID-19 vaccines and medicines published since the September 2022 issue of Drug Safety Update. And on page 6, we include recent letters, recalls, and notifications sent to healthcare professionals about medicines and medical devices.

On page 8, we ask healthcare professionals to contribute their views on how we should communicate with them in our [public consultation](#).

MedSafetyWeek November 2022: Every Yellow Card report helps to improve patient safety

The seventh annual #MedSafetyWeek social media campaign will take place 7 to 13 November 2022 and this year's focus is the importance of reporting suspected adverse reactions to medicines and vaccines. We are also encouraging the reporting of suspected problems with medical devices or other healthcare products to the Yellow Card scheme.

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

What healthcare professionals can do to support MedSafetyWeek – 7 to 13 November 2022:

- follow the MHRA on its social media channels and show your support for this year's MedSafetyWeek by retweeting, commenting, liking, and sharing material with your social media contacts using #MHRAYellowcard, #MedSafetyWeek, #ReportSideEffects, and #patientsafety
- don't delay in reporting suspected adverse drug reactions (side effects) to the [Yellow Card scheme](#) or via the Yellow Card app (download from the [Apple App Store](#) or [Google Play Store](#)) – only a suspicion is needed to report a suspected reaction to us
- you can also use the Yellow Card scheme to report a suspected defective or fake medicine, adverse reactions to herbal or homeopathic medicines, and any problems with medical devices (including software, apps and artificial intelligence) and e-cigarettes including their refill containers (e-liquids)
- for suspected adverse reactions associated with COVID-19 vaccines and medicines, as well as suspected incidents with medical devices and test kits, report directly to the [Coronavirus Yellow Card reporting site](#) or use the Yellow Card app
- 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 they experience problems with a healthcare product, such as contacting a healthcare professional and reporting to the Yellow Card scheme
- talk to your colleagues about being vigilant for suspected adverse reactions with medicines or vaccines, especially new, serious or rare reactions or those that may have a delayed onset, and the importance of reporting them to the Yellow Card scheme

About MedSafetyWeek

The annual MedSafetyWeek 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 81 countries will take part.

The theme for 2022's campaign is "how patients and healthcare professionals make safety work". More information on MedSafetyWeek is available on the [Uppsala Monitoring Centre's website](#).

This MedSafetyWeek, we ask that you report suspected adverse drug reactions to a medicine or vaccine directly to the Yellow Card scheme as soon as they arise. Do not wait or rely on someone else to report concerns. Only a suspicion is needed to submit a Yellow Card, so, if in doubt, please complete a report.

Adverse incidents associated with a medical device can be reported through the Yellow Card scheme and [local reporting systems](#). Report incidents with any instrument or appliance (including software), used alone or in combination, which is intended by the manufacturer to be used for the diagnosis, prevention, treatment or alleviation of a medical condition. Potential problems with medical devices can also be [reported](#).

In addition, Yellow Card reports can also be made for other healthcare products in the UK, such as blood factors and immunoglobulin products, herbal or homeopathic medicines, and e-cigarettes including their refill containers (e-liquids).

Safety monitoring systems protect public health

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 can help contribute to the safe use of healthcare products for patients and contribute to the safety information of a product and how it is used.

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. You can read some of our [case studies where Yellow Card reports have contributed to patient safety](#).

There are some medicines for which it is very important that healthcare professionals, patients, and carers report all suspected adverse drug reactions to these products. The [Commission on Human Medicines \(CHM\)](#) and the MHRA intensively monitor the safety of all products with a [Black Triangle symbol](#) (▼).

What to include on a Yellow Card?

We take every report seriously and encourage everyone to report any suspicions of adverse effects to medicines and other healthcare products. Further guidance is available on [how to complete a report](#).

When submitting a Yellow Card, please provide as much information as possible, including product brand name, batch number (for vaccines and biological products), medical history, concomitant medications, treatment dates, onset timing, and duration.

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](#).

Healthcare professionals should also speak to their local Medication Safety Officer or Yellow Card Centre 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.

You should also 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](#)).

Article citation: Drug Safety Update volume 16, issue 3: October 2022: 1.

COVID-19 vaccines and medicines: updates for October 2022

Information relating to COVID-19 vaccines and medicines that has been published since the September 2022 issue of Drug Safety Update, up to 21 October 2022.

Summaries of Yellow Card reporting

We continue to publish the summaries of the [Yellow Card reporting for the COVID-19 vaccines](#) being used in the UK. The report summarises information received via the Yellow Card scheme and includes other data such as usage of COVID-19 vaccines and relevant epidemiological data. The report is updated regularly to include other safety investigations carried out by the MHRA under the [COVID-19 Vaccine Surveillance Strategy](#).

Other recent MHRA updates on Coronavirus vaccines and medicines:

We have also recently:

- updated the shelf life and storage instructions for Spikevax (COVID-19 Vaccine Moderna) in the [Summary of Product Characteristics](#) (sections 6.3 and 6.4) and the [Patient Information Leaflet](#) to allow the vaccine to be stored to the range of –50°C to –15°C

See [guidance on COVID-19 for all our latest information](#), including after publication of this article. We previously included summaries of latest COVID-19 information, including in the [July 2022](#), [August 2022](#), and [September 2022](#) issues of Drug Safety Update.

Reporting Yellow Cards

Report suspected side effects to medicines, vaccines and medical device and test kit incidents used in coronavirus (COVID-19) testing and treatment using:

- the dedicated [Coronavirus Yellow Card reporting site](#)
- the Yellow Card app (download from the [Apple App store](#) or [Google Play store](#))

For products under additional monitoring (▼) such as the COVID-19 vaccines, you should report all suspected adverse side effects. This will allow the MHRA to identify new safety information for these products. When reporting please provide as much information as possible, including information about medical history, any concomitant medications, onset timing, and treatment dates, and for vaccines, the product brand name and batch number.

You may be contacted following submission of a Yellow Card report so that we can gather additional relevant information for the assessment of the report. These contributions form an important part of our understanding of suspected side effects. If you have been forwarded this article, subscribe directly to Drug Safety Update via our [website](#).

Article citation: Drug Safety Update volume 16, issue 3: October 2022: 2.

Letters and medicine recalls sent to healthcare professionals in September 2022

National Patient Safety Alert and recall of Targocid 200mg powder for solution for injection/infusion or oral solution

On 21 October 2022, we issued a [National Patient Safety Alert](#) to support the recall of 2 batches of the antibiotic Targocid (teicoplanin) 200mg powder for solution for injection/infusion or oral solution (batches 0J25D1 and 0J25D2; expiry 30/04/2023). This is due to out of specification results obtained for bacterial endotoxins, which has been confirmed through testing of retained samples.

This issue was observed following a medical adverse event, which reported that 4 patients experienced high grade of fever approximately 3 hours post-administration of vials from the impacted batches. Due to the out of specification results observed, there is a potential life threatening or serious risk to patient health.

Follow the advice in the [National Patient Safety Alert](#) and [Class 1 Medicines Recall](#) to stop use of these batches immediately and return to the manufacturer.

In the event the affected batches have been administered to patients, appropriate clinical assessment should be performed, in addition to close monitoring for any adverse reaction.

Although most use is in hospitals, it may have been prescribed to take at home. Identify any potential patients who may be taking it at home and ensure they stop use. GPs and other prescribers are asked to ensure that a new prescription is available for the patient when they return their medicine to the pharmacy.

All suspected adverse events should also be reported via the MHRA's [Yellow Card scheme](#) immediately. For more information, please see the [National Patient Safety Alert](#) page.

Letters

In September 2022, the following letters were sent or provided to relevant healthcare professionals:

- [Rixathon ▼ \(rituximab\): Temporary supply of Rixathon 500mg vials in foreign packaging](#)
- [Streptokinase 250,000 IU and 1,500,000 IU vials for injection: supply of non-serialised packs](#)
- [Tukysa ▼ 50 mg and 150mg film-coated tablets: interim supply of French or German/Austrian stock](#)
- [Spikevax ▼ bivalent Original/Omicron BA.1 COVID-19 mRNA Vaccine \(nucleoside modified\) \(elasomeran/imelasomeran\): Temporary supply of product with different product name, carton and multidose vial labels](#)

Medicine Recalls and Notifications

In September 2022, recalls and notifications for medicines were issued on:

[Class 4 Medicines Defect Information: Quadrant Pharmaceuticals Limited, Bezalip Mono 400mg Tablets, EL \(22\)A/38](#). Issued 12 September 2022. Batches of Bezalip Mono (bezafibrate) 400mg tablets have been identified to contain Patient Information Leaflets (PIL) omitting safety information on possible side effects of Stevens Johnson syndrome and toxic epidermal necrolysis. Healthcare professionals are advised to discuss the missing information with patients and provide a copy of the updated PIL, where possible.

[Class 4 Medicines Defect Information: Rosemont Pharmaceuticals Ltd, Atorvastatin 4mg/ml Oral Suspension & Sildenafil 10mg/ml Oral Suspension, EL \(22\)A/39](#). Issued 13 September 2022. Batches of Atorvastatin 4mg/ml Oral Suspension and Sildenafil 10mg/ml Oral Suspension have been identified with incorrect expiry dates stamped on the base of the bottle. The correct expiry dates (as stated in the table) are printed on the bottle label and on the outer carton. Healthcare professionals should follow the expiry date printed on the bottle label and the outer carton, and advise patients of the issue when dispensing these products.

[Class 2 Medicines Recall: Novartis Pharmaceuticals UK, Sandimmun Oral Solution, EL\(22\)A/40](#). Issued 20 September 2022. A batch of Sandimmun (ciclosporin) Oral Solution is being recalled as a precautionary measure due to ciclosporin crystals in the solution. Stop supplying the batch immediately, quarantine all remaining stock and return to supplier.

Medical Device Safety Information

In September 2022, a MHRA Device Safety Information page was published on:

[Haemodialysis and haemofiltration machines: Actions to take following pressure-related alarms to avoid unintentional alteration of alarm limits DSI/2022/004](#). Issued 21 September 2022. Venous and arterial pressure limits may be altered unintentionally following acknowledgement of the alarm in some haemodialysis and haemofiltration machines. The MHRA is aware of serious events, including some with a fatal outcome, where following an alarm the lower pressure limits suggested by the machine were too low. If the underlying cause of the alarm is not addressed, the machine may not re-alarm to alert the user to an ongoing problem. Actions and advice for heads of renal units and renal nursing staff are available in the device safety information page.

For all of the latest safety notices from the MHRA on drugs and medical devices, see [Alerts and recalls for drugs and medical devices](#).

Consultation on how MHRA communicates with healthcare professionals

The MHRA is reviewing its approach to engagement with healthcare professionals to improve the safety of medicines and medical devices.

The MHRA has [launched a consultation](#) to enable healthcare professionals across the UK to have their say on how they wish to receive vital safety information, how they'd like to be engaged, and to feedback on the Yellow Card safety reporting system.

The consultation will close at 11:45pm on 18 January 2023. Please see the [consultation page](#) for more information.

Article citation: Drug Safety Update volume 16, issue 3: October 2022: 3.