Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

October 2025

Summary of the latest safety advice for medicines and medical device users

Contents

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Isotretinoin – updates to prescribing guidance and survey of services

Access the full article

Specialisms: *Dermatology, Dispensing GP practices, General practice, Pharmacy, Psychiatry*

Overview of Measures

The Medicines and Healthcare products Regulatory Agency (MHRA) has reviewed the impact of the implementation of the recommendations advised by the Commission on Human Medicines (CHM) who were informed by its Isotretinoin Expert Working Group (IEWG) and Isotretinoin Implementation Advisory Expert Working Group (IIAEWG) in 2023.

The CHM has endorsed changes to the isotretinoin prescribing guidance of the IIAEWG and an addendum to the IIAEWG report has been published to amend and clarify previous advice, regarding follow-up consultations, pregnancy testing and sexual function monitoring.

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In addition, the CHM agreed an effective approach is required to monitor the adherence to risk minimisation measures going forward, whilst supporting patient access to treatment across all age groups. As such, the MHRA seeks to undertake a survey of services where isotretinoin is prescribed to support its safe prescribing.

Both NHS and private services which prescribe isotretinoin for the treatment of acne will be asked to complete a baseline survey by 16 November 2025. This data will be used to inform the CHM recommendations on the regulatory requirements of isotretinoin, whilst supporting patient access to treatment across all age groups. It will also provide baseline information to monitor adherence to risk minimisation measures, to ensure the continuation of safe prescribing.

Action and Advice for Healthcare Professionals:

Survey

- Clinical Service Leads for any service or clinic (NHS or private) that prescribes isotretinoin for the treatment of acne need to complete a baseline survey for their service by 16 November 2025. There should only be one survey response per service provider
- the MHRA will hold this data securely and provide a summary to the CHM in an anonymised format to support the development of a new approach to monitor the adherence to risk minimisation measures while minimising any impact on patient access to treatment across all age groups. It will also provide baseline information for comparison with future monitoring of adherence to risk minimisation materials, to ensure the continuation of safe prescribing
- the link to the survey will be sent directly to organisations through various routes, if you or your service have not received this link and you believe that you need to complete the survey, please contact info@mhra.gov.uk

Changes to isotretinoin prescribing advice

- from today, updates to the IIAEWG guidance have also been published as an Addendum to the original report (see background of main article for further information) which advise that:
    - follow-up consultations do not necessarily need to be in person (face to face) and could be remote if appropriate, however the first appointment should be in person
    - medically supervised pregnancy testing may be performed remotely with appropriate oversight to ensure tests are performed correctly and safely
    - patients should be asked about sexual function at follow up appointments, although by the third appointment, this may be brief
- new clinical guidance on these topics is available from the British Association of Dermatologists website (please see links in background section of main article)

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BD BodyComm™ version 3.3 software used for BodyGuard infusion pumps, BodyGuard-T and T34 syringe drivers: Important steps to manage transition to Windows 11 (DSI/2025/006)

Access the full article

Specialisms: *Electro-biomedical engineering personnel (EBME departments), medical physics, care home staff, critical care, general practice, haematology & oncology, obstetrics & gynaecology, paediatrics, pharmacy, anaesthesia, Community Nursing, palliative care and specialist palliative care; medical device and equipment managers*

Device Details:

BD BodyComm™ software
Software version 3.3

Post-publication update for 28 October 2025: the cables will be available for customer use shortly. The manufacturer will issue supporting customer communication.

Summary

The BodyComm software is used for the servicing and set up of the Bodyguard pumps, Bodyguard-T and T34 syringe drivers. These pumps are used for pain management and other infusion therapies. From 14 October 2025 Windows 10 has no longer been supported by Microsoft. An updated cable is therefore required to connect the pumps to BodyComm software, due to the transition to Windows 11. However, the cables are not available yet. This will need effective management to mitigate potential impact to patient treatment.

Advice for Clinical Engineers, EBME staff, Medical Device Managers and MDSOs:

BD have issued a customer letter advising that all impacted customers should take effective action to allow for continuous use of the BD BodyComm 3.3 software.

1. Identify whether your site uses the BodyComm software for configuration or servicing of BodyGuard pumps, or for BodyGuard-T and T34 syringe drivers (see device details section).
2. If you do have the BodyComm software, ensure the following is in place:
   - A plan to manage service and maintenance of pumps and syringe drivers, which are due for servicing during October 2025 and November 2025 to allow sufficient time to receive the new USB-to-serial cable (OKT00037) for use with Windows 11.
   - Consider updating the service schedule of BodyGuard pumps and BodyGuardT/T34 syringe drivers to complete servicing prior to Windows 11 updates in your department **or;**
   - as an alternative, in collaboration with your IT department, consider retaining access to a Windows 10 PC to ensure continued servicing and setup of BodyGuard pumps, BodyGuard-T and T34 syringe drivers. This PC will not need a live internet connection for BodyComm to be used, but will require the old USB-to-serial 197-100X cable for connection
   - Should either of the above options not be possible, manual servicing and operation of pumps and syringe drivers remains possible, but is more time consuming.
3. In the event of usage disruption consider if alternative pump options can be used for patients treated in hospital to ease the pressure on the usage of BodyGuard pumps and BodyGuard-T and T34 syringe drivers.
4. BD will contact you once their new USB to Serial communication cable (product code: OKT00037) for use with Windows 11 and associated instructions for use are ready for release. Once received, ensure the new cable is used as per BD guidance and replace the old communication cable.
5. Ensure that the correct cable is used at all times, as the old and new cable are not interchangeable.

Please note, no update is required to the infusion pumps themselves (BodyGuard infusion pumps, BodyGuard-T and T34 syringe drivers)

#MedSafetyWeek (3-9 November 2025): A call to action to improve patient safety

Access the full article

Specialisms: *All*

Summary

The annual **#MedSafetyWeek** campaign takes place from **3 to 9 November 2025**. This year's campaign theme is '**we can all help make medicines safer**.'

Anyone can report, either for yourself or someone else, with everyone benefiting each time we do. This aligns with the World Health Organization (WHO) 'Patients for patient safety' programme.

In the UK, we are focusing on highlighting the importance of reporting suspected problems from all healthcare products to the Yellow Card scheme, no matter who you are. We are seeking your support to raise awareness of the scheme and the importance of reporting.

You can report suspected adverse drug reactions to any medicine (including blood products, vaccines and herbal/homeopathic medicines), as well as from other healthcare products including medical device incidents, defective and falsified (fake) products, and safety concerns with e-cigarettes/vapes and their refill containers (e-liquids).

This year we're celebrating 10 years of #MedSafetyWeek and working together with regulators from 117 countries and 131 organisations participating across the globe in the campaign.

Calling all Healthcare Professionals to support #MedSafetyWeek 2025:

- follow MHRA social media channels and share campaign content using hashtags #MHRAYellowCard, #MedSafetyWeek, #ReportSideEffects, and #patientsafety to increase the awareness of reporting
- use campaign materials and other resources available on the Yellow Card website to raise awareness locally, including a digital poster for screens and for patient waiting areas

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- report suspected adverse reactions to medicines and other healthcare products to the Yellow Card scheme or via the Yellow Card app, encourage your colleagues to do the same
- inform patients about potential risks of healthcare products and what to do if they experience any side effects; this includes encouraging them to self-report using the Yellow Card scheme and the importance of reporting to improve patient safety

Background

Healthcare professionals play a vital role in identifying and reporting suspected problems with healthcare products. Reporting is considered the cornerstone of effective safety monitoring. Yellow Card reports help identify new adverse effects and gain more information about known adverse effects to prevent future harm to others.

Resources and Further Information

- Visit the Yellow Card #MedSafetyWeek campaign page and download the materials for use
- See the Yellow Card website for more information and resources including e-learning modules, promotional materials, and reporting guidance
- Contact your local Yellow Card Centre, Medication Safety Officer (MSO) or Medical Device Safety Officer (MDSO) for support and wider opportunities
- Read the Yellow Card scheme guidance for healthcare professionals and the public on gov.uk
- Reporting makes a big difference – share our case studies where Yellow Card reports have directly contributed to improving patient safety
- Sign up to receive our MHRA safety alerts (see below additional information section), or find guidance on our website about the different types of alerts we issue
- Find more information and resources about the global #MedSafetyWeek campaign which is available on the Uppsala Monitoring Centre's website

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Letters, medicines recalls and device notifications sent to healthcare professionals in October 2025

Direct Healthcare Professional Communications

We received notification that the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals in October 2025:

- Fucithalmic 1% w/w Viscous Eye Drops/ Fusidic acid 1% w/w Viscous Eye Drops - Interim supply of Spanish stock to mitigate supply disruption

Medicine Recalls and Notifications

In October 2025, recalls and notifications for medicines were issued on:

Class 2 Medicines Recall: Baxter Healthcare Limited, Compound Sodium Lactate Solution for Infusion BP (Hartmann's Solution for infusion) in Viaflo 1000ml, EL(25)A/46. Issued 28 October 2025.

Baxter Healthcare is recalling one batch of Compound Sodium Lactate (Hartmann's Solution) 1000mL. This is due to a packaging error where some cartons labelled as Hartmann's Solution may contain Ringer's Solution 1000mL.

Class 3 Medicines Recall: Accord Healthcare Ltd, Ipratropium Bromide 500 microgram / 2ml Nebuliser Solution, EL(25)A/45. Issued 23 October 2025.

Accord Healthcare Ltd is recalling a batch of Ipratropium Bromide 500 microgram/2ml Nebuliser Solution after a foil pouch was found to contain ampoules with incorrect labels intended for the Korean market. The incorrectly labelled ampoules are the same product and contain the same active ingredient but have Korean language labels and different batch details.

Class 4 Medicines Defect Notification: Relonchem Ltd, Various Products, EL(25)A/44. Issued 23 October 2025.

Relonchem Ltd has informed the MHRA that duplicate GTIN numbers have been assigned to certain Losartan potassium/Hydrochlorothiazide coated tablets in error and a duplicate EAN number has been assigned to certain Risperidone tablets in error.

Medical Device Field Safety Notices

Find recently published Field Safety Notices

Report suspected drug reactions and device incidents on a Yellow Card

Please continue to report suspected adverse drug reactions and device incidents. Your report will help us safeguard public health.

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates and particularly if a side effect continued or started after treatment was stopped.

Report a medicine

Healthcare professionals should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store
- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

Reporting for medical devices

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures

Reporting for Patients

Report a medicine or medical device

Patients should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store

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News Roundup

Reminder of the risk of incorrect dosing when switching between different drug formulations

There is an ongoing risk of medication errors when switching between different formulations of medications such as posaconazole, including between tablets and oral suspension. Switching from oral suspension to tablets can lead to overdosing and serious adverse drug reactions, whereas switching from tablets to oral suspension can lead to underdosing and lack of efficacy.

Since publishing a Drug Safety Update in 2016, the MHRA is aware of further reports of medication errors involving switching between different posaconazole preparations.

A new formulation of posaconazole (Noxafil), gastro-resistant powder and solvent for oral suspension (PFS), has been approved for use in children 2 years of age and older.

Similar medication errors can occur when switching between oral formulations of other antifungal medicines, for example, fusidic acid or itraconazole.

Healthcare professionals are reminded to always check the Summary of Product Characteristics (SmPC) for any warnings, particularly when switching between medications. They are also advised to use caution when prescribing, dispensing and administering medications, particularly medicines that are available in different formulations. It is recommended that dosage form is specified on each prescription.

Patient safety essay writing competition 2025 for medical students and foundation doctors now open

Entries are now open for the MHRA patient safety essay competition 2025. Medical students and foundation doctors are invited to explore how genetic differences can affect responses to medicines, and how the MHRA Yellow Card scheme – the UK system for reporting suspected side effects – could better capture this information. This competition offers a unique platform for future clinicians to influence national thinking on medicine safety and pharmacovigilance. Entrants are being asked to submit an essay on a related topic.

For more details on how to enter and prizes, please see link above and share with your networks. Entries need to be received by 5pm GMT, Monday 15 December 2025.

Side effects from drug interactions to be predicted by AI before reaching patients

The Medicines and Healthcare products Regulatory Agency (MHRA) leads three new government-backed projects using AI-driven approaches to make medicines safer and bring treatments to patients more quickly.

A new study will use artificial intelligence (AI) and NHS data to predict side effects from drug combinations before they reach patients. These projects are set to modernise how

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medicines and medical technologies are tested and approved – ensuring faster access for patients, while maintaining the highest safety standards.

The goal is a reliable tool that doctors can use to better understand how combinations of medicines affect people in real life, improving how treatments are prescribed together so patients get the safest and most effective care, tailored to them, more quickly. For more information access the full article.

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