Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

July 2025

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

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Abrysvo▼ (Pfizer RSV vaccine) and Arexvy▼ (GSK RSV vaccine): be alert to a small risk of Guillain-Barré syndrome following vaccination in older adults

Access the full article

Specialisms: *Anaesthesia and intensive care, General practice, Neurology, Obstetrics, gynaecology and fertility, Pregnancy, Respiratory disease and allergy*

Summary

There is a small increase in the risk of Guillain-Barré syndrome following vaccination with Abrysvo (Pfizer respiratory syncytial virus (RSV) vaccine) and Arexvy (GSK RSV vaccine) in adults aged 60 years and older. Healthcare professionals should advise all recipients of Abrysvo and Arexvy that they should be alert to signs and symptoms of Guillain-Barré syndrome and, if they occur, to seek immediate medical attention as it requires urgent treatment in hospital.

There is currently no evidence of an increased risk of Guillain-Barré syndrome in pregnant women following vaccination with Abrysvo, the only RSV vaccine approved for use during pregnancy. The Commission on Human Medicines (CHM) advise that the benefits of vaccination against RSV outweigh the small increased risk of developing Guillain-Barré syndrome in older adults.

Key Advice for Healthcare Professionals:

- there is a small increase in the risk of Guillain-Barré syndrome following vaccination with Abrysvo and Arexvy in adults (aged 60 years and older). Currently, there is no evidence of an increased risk of Guillain-Barré syndrome in pregnant women following vaccination with Abrysvo, the only RSV vaccine approved for use during pregnancy
- be attentive to signs and symptoms of Guillain-Barré syndrome in all recipients of Abrysvo and Arexvy to ensure early and correct diagnosis, initiate adequate supportive care and treatment, and rule out other causes
- early medical care can reduce severity and improve outcomes

- report suspected adverse drug reactions associated with Abrysvo and Arexvy on a Yellow Card

Key Advice for Healthcare Professionals to Provide to Patients:

- the RSV vaccine helps protect against respiratory syncytial virus (RSV), a virus which can make older adults and babies seriously ill. RSV can cause a type of chest infection called bronchiolitis in babies which can cause breathing problems and may need to be treated in hospital. RSV can also cause a serious lung infection (pneumonia) in older adults requiring hospital care in some cases
- the Pfizer RSV vaccine Abrysvo is currently offered in NHS vaccination programmes against RSV to adults aged 75-79 years old and to pregnant women to help protect babies after they are born
- the GSK RSV vaccine Arexvy is not currently available on the NHS but may be available privately for use in individuals aged 60 years and older, or those aged 50–59 years who are at increased risk of RSV disease; Arexvy should not be given to pregnant individuals.
- rare or very rare cases of Guillain-Barré syndrome have been reported in older adults who have received the Abrysvo or Arexvy RSV vaccines respectively. Currently, there is no evidence that the Abrysvo RSV vaccine increases the risk of Guillain-Barré syndrome in pregnant women
- Guillain-Barré syndrome is a serious nerve condition. It usually affects your arms and legs first before you get symptoms in other parts of your body
- you might feel tingling, numbness or pins and needles in your feet and hands first. This is usually followed by muscle weakness and difficulty moving your joints.
- other symptoms can include:
    - tingling, numbness or pins and needles in your feet and hands
    - muscle weakness and difficulty moving your joints
    - sharp, shooting pain (nerve pain), often in your legs or back
    - problems breathing
    - problems with your face, such as drooping face muscles or trouble swallowing or speaking
    - problems with your eyes, such as double vision
- some people’s symptoms become so severe that they are not able to move their legs, arms and face (paralysis)
- urgent hospital treatment is required to help prevent the symptoms progressing and improve recovery, however the effects of Guillain-Barré syndrome may sometimes be long-lasting
- seek immediate medical attention if you notice signs of Guillain-Barré syndrome
- report suspected side effects associated with the RSV vaccine on a Yellow Card

Aurum pre-filled syringes - phased introduction of new 10ml CONNECT syringe barrel: Importance of selecting compatible needle-free connectors to minimise the risk of syringe blockage (DSI/2025/002)

Access the full article

Specialisms: *Anaesthetics and intensive care, Critical care, General surgery, Theatre practitioners, Emergency medicine, Ambulance service/paramedics, Hospital pharmacies*

Device Details:

Aurum pre-filled syringes
Needle free connectors

Summary

The use of incompatible needle-free connectors (NFCs) with Aurum pre-filled syringes (PFSs) has led to adverse incidents in emergency situations. Attaching an incompatible NFC can block the syringe and prevent delivery of emergency medicine.

A new 10ml barrel design for the Aurum pre-filled syringes, the Aurum CONNECT, will be compatible with a wider range of NFCs to minimise the occurrence of these adverse incidents.

Introduction of the CONNECT syringe to the market has commenced in a phased manner in early July 2025, starting with Adrenaline 1:10,000 PFS. This will be followed by the phased rollout of the 10ml CONNECT barrel for the Amiodarone and Calcium Chloride PFS products.

Importantly, all NFCs compatible with the established syringe design remain compatible with the CONNECT syringe design. However, due to the wider range of NFCs compatible with the CONNECT PFS, the reverse is not applicable. Therefore, during the transition period, until March 2028, there remains a risk of inadvertently using an incorrect NFC.

NFCs compatible with both designs of the Aurum pre-filled syringes will eliminate the risk of NFC incompatibility during the transition period. Healthcare professionals should refer to the list of compatible NFCs under the product information listings below. This can also be viewed by using the below QR code:

- Adrenaline (Epinephrine) Injection 1:10,000
- Amiodarone
- Calcium Chloride
- Naloxone Hydrochloride

Key Advice for Healthcare Professionals

- refer to the list of compatible needle-free connectors (NFCs) under the product information listings (see summary section) to identify NFCs compatible with both, the established PFS and the new CONNECT Aurum PFS.
- ensure that the specification of NFCs integral to vascular access devices are checked for compatibility before procuring or putting into use in areas where Aurum pre-filled syringes may be used
- consider displaying a list of compatible NFCs for use with Aurum pre-filled syringes in clinical areas containing the emergency drug boxes and resuscitation training rooms - see additional information section
- for the currently established syringe barrel only, certain specified NFCs can be used with appropriate adaptors (see summary section above) in case compatible NFCs cannot be procured. Completion of a risk assessment as per local clinical protocol is recommended in these cases, ensuring that adaptor, NFC and pre-filled syringe are stored together (for example, emergency trolleys or kits)

Key Advice for Healthcare Professionals to Provide to Patients:

- There is no related advice for healthcare professionals to provide to patients

Trinity Biotech Premier Hb9210™ HbA1c Analyser: Risk of Positive Bias and Updates to Instructions for Use (IFU), including use as a diagnostic aid in diabetes mellitus (DSI/2025/003)

Access the full article

Specialisms: *Endocrinology, Diabetology and metabolism, General Practice, Pathology and Metabolism*

This DSI has been sent to relevant organisations only.

Device Details:

The Trinity Biotech Premier Hb9210 HbA1c analyser is a High Pressure Liquid Chromatography based laboratory system intended for the quantitative measurement of haemoglobin A1c (HbA1c) in human capillary and venous whole blood, used for the monitoring of long-term glycaemic control in individuals with diabetes mellitus

Summary

The MHRA has received reports describing a positive bias in HbA1c results delivered by the Trinity Biotech Premier Hb9210 HbA1c analyser, which has resulted in patients being incorrectly diagnosed as pre-diabetic or diabetic. The MHRA is working closely with the manufacturer, Trinity Biotech, to resolve this. In addition, Trinity Biotech, has committed to updating the Intended Use statement in the Instructions for Use (IFU), to include the use of the analyser as a diagnostic aide, and to provide further clarity regarding the frequency of preventative maintenance required to ensure the consistent performance of the analyser.

Key Advice for Healthcare Professionals:

- the Trinity Biotech Premier Hb9210 HbA1c analyser Intended use statement in the IFU will be updated to state that results from the analyser can be used as an aid to the diagnosis for diabetes mellitus
- where HbA1c measurements are taken, ensure that you are familiar with the information presented in the recent Field Safety Notices (FSNs), issued by the manufacturer, and the Operator's Manual, to use the analyser accurately
- if you are using the Trinity Biotech Premier Hb9210 HbA1c Analyser and notice a change in the performance of the analyser that falls outside the manufacturer's expected tolerance, please report the details to Trinity Biotech and the MHRA
- it is advised to closely monitor performance with independent Quality Control material, and to consider appropriate corrective action if significant changes in performance are detected
- consider whether recalling and retesting is required for any patients newly diagnosed as diabetic between April 2024 to the present

Key Advice for Healthcare Professionals to Provide to Patients:

- to seek medical attention immediately if adversely affected following any changes to medication, such as hypoglycaemia (shaking/trembling, sweating, confusion, loss of consciousness) or hyperglycaemia (excessive thirst, blurred vision recurrent infections)

Updated guidance on the management of the recalled Endologix Nellix EndoVascular Aneurysm Sealing System (DSI/2025/004)

Access the full article

Specialisms: *Radiology and imaging, Vascular and cardiac surgery*

Device Details:

Endologix Nellix EndoVascular Aneurysm Sealing (EVAS) System

Summary

Following a review, the MHRA provides an update to previous guidance on the management of patients treated with the recalled Endologix Nellix EndoVascular Aneurysm Sealing (EVAS) System to reflect revised recommendations. All implanted patients in the UK with this device should be identified and appropriate action taken.

Key Advice for Healthcare Professionals:

- previous MHRA advice regarding management of implanted patients with these devices has now been superseded
- healthcare professionals should identify, assess and treat patients with these devices in line with the updated recommendations from the European Society for Vascular Surgery (ESVS) Abdominal Aortic Aneurysm Clinical Practice Guidelines
- refer to the ESVS guidelines for comprehensive steps for patient management, in summary you should:
    - identify all patients with an implanted Nellix device at your centre
    - inform patients regarding the high mid- and long-term failure rates of EVAS and explain potential problems that may occur
    - enrol patients in enhanced surveillance, for those deemed necessary

- for patients with a failing Nellix implant, early elective explantation is recommended as the preferred treatment in surgically fit patients

Key Advice for Healthcare Professionals to Provide to Patients:

- if you are implanted with one of these devices you will be contacted by your treatment centre. They will discuss the risks associated with your device and the options available to you depending on your circumstances
- if you experience any symptoms such as pain, numbness, or weakness in the legs back, chest or abdomen, dizziness, fainting, or rapid heartbeat, please seek urgent medical attention

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

Direct Healthcare Professional Communications

In July 2025, the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals:

- The Aurum range of 10ml Pre-filled syringes - New 10ml CONNECT syringe barrel
- Vitamin B and C Intravenous High Potency, Concentrate for Solution for Infusion 5mL x 6 ampoule pairs (PL 35533/0195): Potential ampoule damages in unopened cartons
- Trodelvy▼ (sacituzumab govitecan) - Update to Summary of Product Characteristics (SmPC) regarding primary prophylaxis with granulocyte colony-stimulating factor (G-CSF) in patients at increased risk of febrile neutropenia
- IXCHIQ powder and solvent for solution for injection - Chikungunya vaccine (live) temporary restriction in use for those over 65 years Sent to relevant stakeholders in June 2025
- Zentiva Bosutinib 500 mg film coated tablets PL 17780/1300 – interim supply of Spanish stock to mitigate supply disruption. Sent to relevant stakeholders in June 2025
- Palforzia®▼ [Defatted powder of Arachis hypogaea L., semen (peanuts)], German stock to be supplied to the United Kingdom (UK) to mitigate supply disruption. Sent to relevant stakeholders in May 2025

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Medicine Recalls and Notifications

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

Class 2 Medicines Recall: ChloraPrep 1mL Clear Sterile Solution/Applicator, Becton Dickinson UK Ltd, EL(25)A/36. Issued 28 July 2025

Becton Dickinson UK Ltd has informed the MHRA that some units exhibit an open seal on the packaging of the applicator. This is linked to the Class 2 Medicines Notification EL(25)A/22. This defect could increase the risk of the applicator device being contaminated with pathogens.

Class 2 Medicines Recall: Flutiform 250 micrograms / 10 micrograms per actuation pressurised inhalation, suspension, CD Pharma Ltd, EL(25)A/35. Issued 24 July 2025

CD Pharma Ltd have notified the MHRA of an error on the outer carton of the product for the batches listed in this notification. While the total active content statement is correct, the delivered dose content statement is incorrect. The other details on the carton are correct.

Class 2 Medicines Recall: Zaditen 0.25 mg/ml, eye drops, solution, Laboratoires Théa EL(25)A/34. Issued 7 July 2025

Laboratoires Théa trading as Thea Pharmaceuticals Limited have notified the MHRA of an out of specification event related to environmental monitoring during manufacturing, which may increase the risk of microbial contamination of the medicinal product.

Class 2 Medicines Recall: Depo-Medrone 80 mg in 2 mL, Maxearn Limited EL(25)A/29. Issued 25 June 2025

A batch of Depo-Medrone has been released to the market with an error. The vial over label incorrectly states that the total vial content is 40 mg in 1 mL, when the correct total vial content is 80mg in 2 mL (with a concentration of 40mg/ml of methylprednisolone acetate).

Class 3 Medicines Recall: Omeprazole 20 mg/15 ml Oral Solution, Glenmark Pharmaceuticals Europe Ltd, EL(25)A/30. Issued 30 June 2025

Glenmark Pharmaceuticals Europe Ltd is recalling a specific batch of Omeprazole Oral Solution as a precautionary measure due to an investigation following a customer complaint indicating precipitation and discoloration of the product in the bottles.

Class 3 Medicines Recall: Tamoxifen 20mg Film-Coated Tablets, Wockhardt UK Ltd, EL(25)A/31. Issued 30 June 2025

Wockhardt UK Limited is recalling a batch as a precautionary measure following the identification of a dissolution failure during stability testing.

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Class 3 Medicines Recall: Kimmtrak 200 micrograms/mL concentrate for solution for infusion, Immunocore Limited, EL(25)A/28. Issued 25 June 2025
Immunocore Limited is recalling the batches listed below as a precautionary measure. The recall is due to a decrease in potency identified during stability testing. All other stability test results remain within specification.

Class 4 Medicines Defect Notification: Olmesartan medoxomil 10mg film-coated tablets, Jubilant Pharmaceuticals NV, EL(25)A/37. Issued 31 July 2025
Jubilant Pharmaceuticals NV has informed the MHRA that the Patient Information leaflet (PIL) in the cartons for the batches listed in this notification include an outdated PIL.

Class 4 Medicines Defect Notification: Simvastatin 10mg Tablet, Crescent Pharma Ltd, EL(25)A/33. Issued 3 July 2025
Crescent Pharma Limited has informed the MHRA of an error with the European Article Number (EAN) barcode on the cartons of a batch of simvastatin 10 mg Tablets distributed by Alliance Healthcare UK.

Class 4 Medicines Defect Notification: Erythromycin Stearate BP 250mg Tablets, Amdipharm UK Ltd, EL(25)A/32. Issued 1 July 2025
Amdipharm UK Ltd has informed MHRA that the Patient information leaflet (PIL) in the cartons for the batch listed in this notification includes a now superseded PIL.

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.

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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

News Roundup

Patients should be advised not to use non-sterile alcohol-free skin cleansing wipes for the treatment of wounds or cleaning of intravascular devices

The UK Health Security Agency (UKHSA) is investigating an outbreak of Burkholderia stabilis involving individuals across the UK. Following testing, Burkholderia spp has been recovered from certain non-sterile alcohol-free skin cleansing wipes, including those used for wound care and included in first aid kits. They have issued a National Patient Safety Alert which reminds health professionals to follow relevant guidance and advise patients accordingly regarding intravascular device care and treatment of wounds or broken skin. For the full set of actions please refer to the alert.

Passy Muir speaking valve (PMV) – reminder of safe management after incident reports

The MHRA has become aware of reports where healthcare professionals inflated the tracheostomy cuff while a Passy Muir speaking valve (PMV) was in situ. This has resulted in airway obstruction, respiratory distress and increased risk of aspiration. As outlined

within the instructions for use (IFU), the tracheostomy cuff must be completely deflated prior to PMV placement to allow for safe airway management.

The PMV is supplied with a warning label which alerts staff of the presence of the valve within the breathing circuit. It provides instructions to the healthcare professional to deflate the tracheostomy cuff before connecting the speaking valve to the patient. Healthcare professionals must ensure that all patients fitted with a PMV have the provided warning label attached to the pilot balloon. The observation and monitoring requirements of patients with PMV in place are outlined within the IFU. Healthcare providers must ensure that all relevant staff members have received appropriate training for speaking valve management prior to use.

Yellow Card Biobank has launched a new topic recruiting patients experiencing acute pancreatitis while taking GLP-1 RAs

The Yellow Card Biobank, a collaboration between MHRA and Genomics England, is calling on all healthcare professionals to report Yellow Cards on behalf of patients who experience acute pancreatitis whilst taking glucagon-like peptide-1 receptor agonists (GLP-1 medicines).

When completing a Yellow Card please provide as much information about the side effect as possible and agree for the Yellow Card Biobank to get in touch. We are not contacting patients who may have had gallstone-induced pancreatitis, chronic pancreatitis or hereditary pancreatitis.

When a Yellow Card report of GLP-1s and acute pancreatitis is received, and the HCP has agreed to be contacted, the Biobank team will get in touch with them to ask for help inviting the patient to take part in the study.

Patients who sign up will be sent an at home saliva collection kit and their DNA will be extracted and analysed to explore whether some people are at a higher risk of acute pancreatitis when taking these medicines, due to their genetic makeup.

If you are interested in finding out more please get in touch with the team via Yellowcardbiobank@mhra.gov.uk.

Publication of fluoroquinolone antibiotics Public Assessment Report (PAR)

The MHRA has now published a Public Assessment Report (PAR) on our previous review of fluoroquinolone antibiotics. This report looks at the safety data we reviewed and the expert advice we received from the Commission on Human Medicines (CHM) about how to manage risks. We shared the outcome of this review in a Drug Safety Update in January 2024. The PAR presents the evidence we had at the time of the review. It is not intended to offer clinical advice. The MHRA will continue to monitor the safety of fluoroquinolone antibiotics.

Have your say: Views on the UK medicines and medical device regulation

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The MHRA, in collaboration with the Department of Health and Social Care (DHSC), is conducting a statutory review of the UK's regulatory framework for human medicines and medical devices, under the Medicines and Medical Devices Act 2021.

As part of this review, we've launched a survey to gather insights from stakeholders across the sector. We're keen to hear your experiences and views on how the current legislation is working in practice and kindly ask you to share specific examples where possible and circulate across your networks. The deadline for the survey is 19 September 2025. Access the survey online

For queries, contact us at Partnerships@mhra.gov.uk with "MMD Act Review" in the subject line.

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For any enquiries, please contact info@mhra.gov.uk

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