Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

9 May 2023

Dear Healthcare Professional,

DRUG ALERT CLASS 1 DRUG ALERT 23 2023 – CLASS 1 MEDICINES RECALL – ACTION NOW INCLUDING OUT OF HOURS – NatPSA 2023/004/MHRA – PHARMASWISS CESKA REPUBLIKA S.R.O AND DISTRIBUTOR BAUSCH & LOMB UK LTD – EMERADE 500 & 300 MCG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

Please see drug alert, National Patient Safety alert and letter for patients for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

St Andrew's House, Regent Road, Edinburgh EH1 3DG
www.gov.scot

Medicines & Healthcare products Regulatory Agency

M E D I C I N E S R E C A L L

CLASS 1 MEDICINES RECALL

Action Now – including out of hours
Patient/Pharmacy/Wholesaler Level Recall

Date: 09 May 2023 NatPSA/2023/004/MHRA Our Ref: MDR 020-05/23

Dear Healthcare Professional,

Pharmaswiss Česka republika s.r.o. and distributor Bausch & Lomb UK Limited

Emerade 500 micrograms solution for injection in pre-filled syringe	**PL 33616/0015**
SNOMED Code 23420111000001107	
Emerade 300 micrograms solution for injection in pre-filled syringe	**PL 33616/0014**
SNOMED Code 23415811000001102	

Active Pharmaceutical Ingredients: adrenaline (as tartrate)

Brief description of the problem
Pharmaswiss Česka republika s.r.o. and distributor Bausch & Lomb UK Limited is recalling all unexpired batches of Emerade 500 micrograms and Emerade 300 micrograms adrenaline auto-injectors (also referred to as pens) from patients. This is due to an issue identified during an ISO 11608 Design Assessment study where some auto-injectors failed to deliver the product or activated prematurely.

Specifically, the 1-metre free-fall (vertical orientation) pre-conditioning resulted in damage to internal components of the auto-injector, leading either to failure to deliver the product or premature activation. This damage was not visibly apparent following the pre-conditioning but was evident only on subsequent functional testing. It is unclear what impact this has on auto-injectors in clinical use, however as a precautionary measure and owing to the inability to identify this issue before the auto-injectors are used, the auto-injectors are being recalled.

The MHRA, in conjunction with the Department of Health & Social Care (DHSC) has established that there are sufficient supplies of alternative auto-injectors to allow for a recall at patient level. Pharmaswiss Česka republika s.r.o. and distributor Bausch & Lomb UK Limited has confirmed that future production of Emerade 500 micrograms and Emerade 300 micrograms auto-injectors is on hold. Therefore, no further supplies will be available, and patients will need to be switched to an appropriate alternative.

Healthcare professionals should inform patients, or carers of patients, who carry Emerade 300 or 500 microgram auto-injector pens to obtain a prescription for and be supplied with an alternative brand. They should then be informed to return their Emerade 300 or 500 microgram pens to their local pharmacy.

At the point of prescribing and dispensing, it is vital that patients and carers receive training to ensure they are completely familiar with how their new device works. This is because each brand of adrenaline auto-injector works differently. **Patients should continue to carry two devices at all times** in case they need to administer a second dose of adrenaline before the arrival of the emergency services (see links to training material below).

Alternative brands of adrenaline auto-injectors (EpiPen and Jext) are available in a maximum strength of 300 micrograms. **There is evidence to suggest that a single EpiPen (300 micrograms) or Jext (300 micrograms) pen will be a suitable replacement for a single Emerade 500 micrograms pen**. This is based on recently available results from two studies (including one by the manufacturer of Emerade) which compared blood levels of adrenaline following injection of Emerade 500 micrograms pens with those following EpiPen 300 micrograms or Jext 300 micrograms pens. Patients must continue to always carry two adrenaline pens at all times. Prescribers are to follow dosage guidance in individual Summary of Product Characteristics (SmPC).

Further information is available in the recent Public Assessment Report: Recommendations to support the effective and safe use of adrenaline auto-injectors accessible via the link below. This report provides a combined summary of the conclusions and recommendations of the Commission on Human Medicines' Adrenaline Auto-injector Expert Working Group to support the effective and safe use of Adrenaline Auto-injectors.
https://www.gov.uk/government/publications/public-assessment-report-recommendations-to-support-the-effective-and-safe-use-of-adrenaline-auto-injectors

Advice for all healthcare professionals

General Practitioners (GPs) and Pharmacy Teams should send the attached letter "Advice for patients who have been prescribed an Emerade 500 micrograms or Emerade 300 micrograms auto-injectors", to all patients and carers who have been prescribed Emerade 500 micrograms or Emerade 300 micrograms auto-injectors.

All healthcare professionals in primary, secondary or specialist healthcare services who prescribe, supply (dispense) or administer adrenaline auto-injectors, or who advise patients and their carers, should note the advice and take appropriate action, as required.

The below actions should be initiated by General Practitioners (GPs) and Pharmacy Teams immediately:

- stop supplying the impacted products immediately. Quarantine all remaining stock and return it to your supplier/MAH using your supplier's approved process

- identify patients who have been supplied with Emerade 500 micrograms and Emerade 300 micrograms auto-injectors and ensure that they are reviewed by their prescriber to determine whether their adrenaline auto-injector prescription is still appropriate and in line with existing guidance

- immediately inform patients and carers to request a new prescription to replace each Emerade 500 micrograms and Emerade 300 micrograms auto-injector with an adrenaline pen in an alternative brand. Epipen 300 or Jext 300 are appropriate alternatives to Emerade 500 micrograms. Dosing recommendations are available in the Summary of Product Characteristics (SmPC) and should be followed (see links below)

- inform patients to return Emerade 500 micrograms and Emerade 300 micrograms auto-injectors to any pharmacy after they have obtained a total of two equivalent strength adrenaline auto-injectors in an alternative brand;
    - Pharmacies that receive Emerade 500 micrograms and Emerade 300 micrograms auto-injectors from patients should quarantine the pens and return them to the supplier using the supplier's approved process

- Inform patients:
    - that they should carry two in-date adrenaline auto-injectors with them at all times in case they need to administer a second dose of adrenaline before the arrival of the emergency services
    - that they need to receive training, so they are confident in being able to use any new devices (see further information in the attached document)
    - of the signs of anaphylaxis and the actions they should take immediately (see Management of Anaphylaxis in the alert for further advice)

- be aware that this recall also applies to Emerade 500 micrograms and Emerade 300 micrograms auto-injectors that are in emergency anaphylaxis kits held by healthcare professionals, such as dental surgery kits etc.

- stock adrenaline ampoules, as opposed to auto-injectors, when renewing the adrenaline in anaphylaxis kits (ensuring dosing charts, needles and syringes are included). See further information below

- be aware that this recall also applies to Emerade 500 micrograms and Emerade 300 micrograms auto-injectors that are currently held by schools. See further information below

Prescribers should issue no more than two adrenaline auto-injectors per patient (of any brand or strength) unless:

- schools require separate pens to be kept on the school premises (e.g., in a medical room) in which case, prescribers may need to consider issuing more than two but no more than four pens per child (of any brand or strength). See further information on the use of pens in schools below
- patients rarely need more than two adrenaline pens prescribed (for example, a prior severe reaction resistant to treatment with adrenaline), where the prescriber may issue additional pens

Different brands of adrenaline pens work differently. Patients and carers should be told of these important differences.

- Healthcare professionals – doctors, nurses and pharmacists – should, where possible, ensure that they provide training to patients and carers in the correct use of the new pen. Instructions for use can be found in the SmPC (prescriber's information) and in the Patient Information Leaflets (PILs) that are supplied with the different pens and on the respective manufacturers' websites where training videos are available. Training pens that do not contain adrenaline can also be obtained free of charge from the manufacturers. Healthcare professionals and patients are strongly recommended to obtain these to assist with training. The trainer pens can be used repeatedly, allowing patients to practice regularly with them so they are prepared for use in an emergency.

- The following links provide training materials for the different devices:

  EpiPen
  - EpiPen® devices: http://www.EpiPen.co.uk/patients/EpiPenr-user-guide
  - EpiPen® 0.15mg: https://www.medicines.org.uk/emc/product/4290/rmms
  - EpiPen® 0.3mg: https://www.medicines.org.uk/emc/product/4289/rmms

  Jext
  - Jext® devices: https://jext.co.uk/
  - Jext® 150 Training Video: https://www.medicines.org.uk/emc/product/5747/rmms
  - Jext® 300 Training Video: https://www.medicines.org.uk/emc/product/5748/rmms

Emergency Use Adrenaline Auto-injectors in the Healthcare setting: Adrenaline pens that are currently held by healthcare professionals, i.e., in emergency anaphylaxis kits, dental kits etc. are subject to the recall.

- Advice from DHSC is that healthcare professionals providing services where anaphylaxis treatment may be required should be competent to administer intramuscular adrenaline from ampoules with a syringe and needle. These services should use adrenaline from ampoules in preference to adrenaline auto-injectors. This is to preserve supplies of adrenaline pens for patients to self-administer, during the ongoing global fragile supply situation for all adrenaline auto-injectors.

- Therefore, when re-stocking adrenaline in anaphylaxis kits, all staff are alerted to stock these with ampoules (together with dosing charts for use of intramuscular adrenaline to treat anaphylaxis, needles and syringes) and not adrenaline pens (of any brand).

- The Green Book and Resuscitation Council guidance provides additional advice to healthcare professionals on the use of adrenaline in response to anaphylaxis.

Guidance on the use of adrenaline auto-injectors in schools:

For more information on the use of adrenaline auto-injectors in schools, see the link below:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/645476/Adrenaline_auto_injectors_in_schools.pdf

- Children at risk of anaphylaxis should have their prescribed adrenaline auto-injectors at school for use in an emergency.
- Depending on their level of understanding and competence, children and particularly teenagers should carry their adrenaline pens with them at all times or the pens should be quickly and easily accessible at all times. If the adrenaline auto-injectors are not carried by the pupil, then they should be kept in a central place in a box marked clearly with the pupil's name but NOT locked in a cupboard or an office where access is restricted.

Advice for patients

The MHRA is aware of a safety issue, potentially impacting all Emerade 500 micrograms and Emerade 300 micrograms auto-injectors (also referred to as pens). The issue may mean that pens fail to activate and deliver adrenaline if they have been dropped. Premature activation was also detected in one Emerade pen after it had been dropped, meaning that the adrenaline solution may be released prior to administration. As a precautionary measure and due to the inability to identify this error before the auto-injector is used, the autoinjectors are being recalled.

If you have been given an Emerade pen, continue to use it as instructed. If your first Emerade pen does not activate despite firm pressure, immediately use your second pen. Always carry two adrenaline pens with you and use them if you need to.

Your GP/doctor, pharmacist, or other healthcare professional will contact you to make sure you get a new prescription for an alternative product. Once you have a replacement, you should return your Emerade auto-injectors to any pharmacy. You can contact your healthcare professional directly if you are worried.

What to do if you suspect anaphylaxis

All patients should be made aware of the signs and symptoms of anaphylaxis and that at the first onset of any signs or symptoms of anaphylaxis, they or a carer/bystander should:

What to do if you suspect anaphylaxis

- administer an adrenaline auto-injector device without delay, even if there is doubt whether it is anaphylaxis
- call an ambulance (999) immediately after giving the injection and say this is an emergency case of anaphylaxis
- if you are not already lying down, then do so
- administer a second auto-injector 5 minutes after the initial dose, if no improvement is seen or if the patient deteriorates after an initial improvement
- patients should be advised to use a second adrenaline auto-injector immediately if the first adrenaline autoinjector pen fails to activate despite pressing firmly against the thigh (pictorial guidance on whether an Emerade pen has activated or not is given below)
- make further attempts to activate a failed adrenaline autoinjector pen while waiting for the ambulance if the patient is not improving, even if one pen has worked, as this may suggest a need for a second or more doses. The purpose of adrenaline pens is to start treatment for anaphylaxis that is continued by the emergency services.

For further information please refer to the MHRA's Adrenaline Auto-Injectors (AAIs) safety campaign - GOV.UK (www.gov.uk)

We encourage patients and carers to read this fact sheet with advice on the use of adrenaline auto-injectors. The risk of device mishandling or device failure exists with all adrenaline auto-injectors and is something that patients and carers should be aware of.

The chance of a successful outcome is increased if adrenaline is administered promptly at the first signs of anaphylaxis. Even with an apparently successful response to adrenaline auto-injector administration, patients may relapse some hours later, which underlines the importance of the emergency services always being called.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.
When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Further Information

For stock enquiries, please contact Bausch & Lomb Customer Services, Tel: 020 8781 2991
Email: Pharma_CS@bausch.com
For medical information enquiries please contact the Medical Information Team, Email: medinfo.europe@bauschhealth.com

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk

Medicines & Healthcare products Regulatory Agency

Advice for patients who have been prescribed an Emerade 500 micrograms or Emerade 300 micrograms auto-injector. Reference: NatPSA/2023/004/MHRA

Emerade Device Recall – due to potential device failure (alternatives available)

- Please contact your doctor or pharmacist (via telephone) now to get replacements for you or your child's Emerade 500 micrograms or Emerade 300 micrograms auto-injector(s) - also referred to as Emerade pen(s).
- The MHRA, in conjunction with the Department of Health & Social Care (DHSC), has established that there are sufficient supplies of alternative auto-injectors to allow for a recall at patient level.
- Once you have two replacement pens in a different brand (EpiPen or Jext), return your Emerade 500 micrograms or Emerade 300 micrograms pen(s) to a pharmacy, even if they are still in date.
- **When you collect your new device make sure you receive training on how to use it. It is vital that you receive training to ensure you are completely familiar with how the new device works.** This is because each brand of adrenaline auto-injector works has a different action.
- Patients should continue to carry two devices at all times.

Reasons for Recall of Emerade Devices

According to our records, you have been prescribed Emerade 500 micrograms or Emerade 300 micrograms auto-injector(s) (adrenaline pen(s)). The UK's regulator of medicines (the Medicines & Healthcare products Regulatory Agency [MHRA]) has received information from the company that makes Emerade adrenaline pens.

Pens were tested and an issue identified where some pens failed to activate as required. As a precautionary measure, all batches of Emerade 500 micrograms and Emerade 300 micrograms pens are being recalled. Therefore, no further supplies will be available of Emerade and patients will need to be switched to an appropriate alternative (EpiPen or Jext).

Replacement of Emerade Devices

You, and/or your parent or carer, should make an urgent appointment with your doctor, or speak to your local pharmacist about replacing the prescription for each Emerade 500 or 300 micograms pen. Ensure that you have two alternative pens of the same brand prescribed.

The alternative pen will be either EpiPen or Jext, both of which are safe and effective in the treatment of anaphylaxis (severe allergic reactions).

Your replacement pens will be either 300 micrograms (0.3 milligram) strength EpiPen or Jext pens, both of which are suitable replacements for a single Emerade 500 micrograms pen. This is based on recently available results from a study, which compared blood levels of adrenaline following injection of Emerade 500 micrograms pens. The study found that there was no difference in results with those following EpiPen 300 micrograms or Jext 300 micrograms pens.

You must continue to always carry two adrenaline pens with you at all times. As soon as you have obtained two new replacement pens you should return all Emerade auto-injector(s) to a local pharmacy.

If you are unwell or unable to collect your prescription because you have been asked to stay at home, please use alternative arrangements to ensure that you receive your new pen(s), such as arranging for a family member to collect the prescription for you.

Training on alternative devices

You and the people around you will need to ensure you know how to use your new EpiPen or Jext pens. These pens work in a different way from Emerade auto-injector pens. Your doctor, nurse or pharmacist can help you with training in how to use your new pen.

You and those around you must therefore take particular care to read the instructions on how to use your new pen in the leaflet contained in the box. You should also consult the manufacturer's website for the particular pen you have been supplied with. Training videos on how to use the pens and other information are available on these websites.

- EpiPen® 0.15mg: https://www.medicines.org.uk/emc/product/4290/rmms
- EpiPen® 0.3mg: https://www.medicines.org.uk/emc/product/4289/rmms
- Jext® 150 Training Video: https://www.medicines.org.uk/emc/product/5747/rmms
- Jext® 300 Training Video: https://www.medicines.org.uk/emc/product/5748/rmms

The manufacturers will also provide training pens that do not contain adrenaline. You are strongly recommended to order these, by contacting the manufacturer directly, and practice regularly with them so you are fully prepared for using a real pen in an emergency. Ensure you or your child knows to carry two adrenaline pens at all times.

What to do if you suspect anaphylaxis

- administer an adrenaline auto-injector device without delay, even if there is doubt whether it is anaphylaxis
- call an ambulance (999) immediately after giving the injection and say this is an emergency case of anaphylaxis
- if you are not already lying down, then do so
- administer a second auto-injector 5 minutes after the initial dose, if no improvement is seen or if the patient deteriorates after an initial improvement
- patients should be advised to use a second adrenaline auto-injector immediately if the first adrenaline autoinjector pen fails to activate despite pressing firmly against the thigh (pictorial guidance on whether an Emerade pen has activated or not is given below)
- make further attempts to activate a failed adrenaline autoinjector pen while waiting for the ambulance if the patient is not improving, even if one pen has worked, as this may suggest a need for a second or more doses. The purpose of adrenaline pens is to start treatment for anaphylaxis that is continued by the emergency services.

For further information please refer to the MHRA's Adrenaline Auto-Injectors (AAIs) safety campaign https://www.gov.uk/government/publications/adrenaline-auto-injectors-aais-safety-campaign

Medicines & Healthcare products Regulatory Agency

Pictorial guidance – Emerade pen activation troubleshooting

WHAT DOES MY EMERADE PEN LOOK LIKE BEFORE USE? Fig. 1

BEFORE USE

Instructions:

1. An unused Emerade pen, with front cap in place (Fig. 1).
2. For instructions on how to use your Emerade pen please consult the Patient Information Leaflet (PIL).
3. During this period, when activation failure is a possibility, you should press the Emerade pen very firmly against your thigh.

HAS MY EMERADE PEN ACTIVATED? Fig. 2

ACTIVATED
When Emerade Pen has been activated the needle cover will extend and lock.

Instructions:

1. After using an Emerade pen following the instructions found on product labelling, verify that the pen has activated.
2. An Emerade pen that has been activated, will have an extended needle cover (Fig. 2 – circled section of image)
3. Call 999 for an ambulance and state “Anaphylaxis” even if you start to feel better
4. Lie flat with your legs up to keep your blood flowing. However, if you are having difficulty breathing, you may need to sit up to make breathing easier
5. Proceed to administer your second pen if you are not improving after 5 to 15 mins in case you need a second dose of adrenaline

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WHAT DO I DO IF MY EMERADE PEN HAS NOT ACTIVATED? Fig. 3

NOT ACTIVATED
If the needle cover has not extended, the pen has not activated.

Instructions:

1. If the needle cover has not extended, the pen has not activated (Fig. 3 – circled section of image).
2. If the pen has not activated despite firm pressure, use the second pen immediately.
3. Call 999 for an ambulance and state “anaphylaxis” even if you start to feel better.
4. Perform additional attempts to activate, if
- both pens have failed, and no dose has been given;
- one pen has failed, one pen has worked, but a second dose is needed

This should only be attempted once all pens have been tried.
5. Retain any suspected, un-activated pen for reporting to the MHRA via the Yellow Card (further information on page 9) and investigation purposes.

National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

Recall of Emerade 500 micrograms and Emerade 300 micrograms auto-injectors, due to the potential for device failure

Date of Issue:	09-May-23	**Reference No:**	NatPSA/2023/004/MHRA

This alert is for action by: primary and secondary care, specifically those involved in General Practice (GP) and pharmacy services, including dispensing general practices.

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards) supported by Chief Pharmacists, or equivalent roles, as well as leaders in general practice and community pharmacy.

DMRC Medicines Defect Classification	NatPSA equivalent to Class 1 Recall Notification

Explanation of identified safety issue:

Pharmaswiss Česka republika s.r.o. and distributor Bausch & Lomb UK Limited is recalling all unexpired batches of Emerade 500 micrograms and Emerade 300 micrograms adrenaline auto-injectors (also referred to as pens) from patients. This is due to an issue identified during an ISO 11608 Design Assessment study where some auto-injectors failed to deliver the product or activated prematurely.

Specifically, the 1-metre free-fall (vertical orientation) pre-conditioning resulted in damage to internal components of the auto-injector, leading either to failure to deliver the product or premature activation. This damage was not visibly apparent following the pre-conditioning but was evident only on subsequent functional testing. It is unclear what impact this has on auto-injectors in clinical use, however as a precautionary measure and owing to the inability to identify this issue before the auto-injectors are used, the auto-injectors are being recalled.

The MHRA, in conjunction with the Department of Health & Social Care (DHSC) has established that there are sufficient supplies of alternative auto-injectors to allow for a recall at patient level. Pharmaswiss Česka republika s.r.o. and distributor Bausch & Lomb UK Limited has confirmed that future production of Emerade 500 micrograms and Emerade 300 micrograms auto-injectors is on hold. Therefore, no further supplies will be available, and patients will need to be switched to an appropriate alternative.

Healthcare professionals should inform patients, or carers of patients, who carry Emerade 300 or 500 microgram auto-injector pens to obtain a prescription for and be supplied with an alternative brand. They should then be informed to return their Emerade 300 or 500 microgram pens to their local pharmacy.

Actions required

Actions required to complete by 12 May 2023:

The action to recall should be coordinated by the Chief Pharmacist/Superintendent Pharmacist/Responsible Pharmacist, Dispensing GPs and GP practices in the first instance. The below actions should be initiated by General Practitioners (GPs) and Pharmacy Teams immediately.

1. Stop supplying the impacted products immediately. Quarantine all remaining stock and return it to your supplier/MAH using your supplier's approved process.

2. Identify patients who have been supplied with Emerade 500 micrograms and Emerade 300 micrograms auto-injectors and ensure that they are reviewed by their prescriber to determine whether their adrenaline auto-injector prescription is still appropriate and in line with existing guidance.

3. Immediately inform patients and carers to request a new prescription to replace each Emerade 500 micrograms and Emerade 300 micrograms auto-injector with an equivalent strength adrenaline pen in an alternative brand. Healthcare professionals should be aware that the licensed dosing recommendations for each brand of pen are not identical. Dosing recommendations are available in the Summary of Product Characteristics (SmPC) and should be followed.

4. Inform patients to return Emerade 500 micrograms and Emerade 300 micrograms auto-injectors to any pharmacy after they have obtained a total of two equivalent strength adrenaline pens in an alternative brand.

General Practitioners (GPs) and Pharmacy Teams should send the linked letter "Advice for patients who have been prescribed Emerade auto-injectors", to all patients and carers who have been prescribed Emerade auto-injectors. See reference information on page 2 for link.

For further detail, resources and supporting materials see: www.gov.uk/drug-device-alerts

For any enquiries about this alert contact: DMRC@mhra.gov.uk

Additional information:

Product Information: Pharmaswiss Česka republika s.r.o. and distributor Bausch & Lomb UK Limited
Defective Medicines Report Centre Reference: MDR 020-05/23

- **Emerade 500 micrograms solution for injection in pre-filled syringe - PL 33616/0015**
- **Emerade 300 micrograms solution for injection in pre-filled syringe - PL 33616/0014**

Further advice for healthcare professionals: inform patients: that they should carry two in-date adrenaline auto-injectors with them at all times in case they need to administer a second dose of adrenaline before the arrival of the emergency services; that they need to receive training so they are confident in being able to use any new devices (see further information in the attached document); of the signs of anaphylaxis and the actions they should take immediately (see Management of Anaphylaxis in the recall notification for further advice).

Healthcare professionals should be aware that this recall also applies to Emerade 500 micrograms and Emerade 300 micrograms auto-injectors currently held by schools and in emergency anaphylaxis kits held by healthcare professionals, such as dental surgery kits etc. See further information in the links below.

Different brands of adrenaline pens work differently. Patients and carers should be told of these important differences. Healthcare professionals – doctors, nurses and pharmacists – should, where possible, ensure that they provide training to patients and carers in correct use of their new pen. Instructions for use can be found in the SmPC (prescriber's information) and in the Patient Information Leaflets (PILs) supplied with the different pens and on the respective manufacturers' websites, where training videos are available. Training pens that do not contain adrenaline can also be obtained free of charge from manufacturers. Healthcare professionals and patients are strongly recommended to obtain these to assist with training. The trainer pens can be used repeatedly, allowing patients to practice regularly with them so they are prepared for use in an emergency. The following links provide training materials for the different devices:

- EpiPen® 0.15mg: https://www.medicines.org.uk/emc/product/4290/rmms
- EpiPen® 0.3mg: https://www.medicines.org.uk/emc/product/4289/rmms
- Jext® 150 Training Video: https://www.medicines.org.uk/emc/product/5747/rmms
- Jext® 300 Training Video: https://www.medicines.org.uk/emc/product/5748/rmms

What to do if you suspect anaphylaxis

- administer an adrenaline auto-injector device without delay, even if there is doubt whether it is anaphylaxis
- call an ambulance (999) immediately after giving the injection and say this is an emergency case of anaphylaxis
- if you are not already lying down, then do so
- administer a second auto-injector 5 minutes after the initial dose, if no improvement is seen or if the patient deteriorates after an initial improvement
- patients should be advised to use a second adrenaline auto-injector immediately if the first adrenaline autoinjector pen fails to activate despite pressing firmly against the thigh (pictorial guidance on whether an Emerade pen has activated or not is given below)
- make further attempts to activate a failed adrenaline autoinjector pen while waiting for the ambulance if the patient is not improving, even if one pen has worked, as this may suggest a need for a second or more doses. The purpose of adrenaline pens is to start treatment for anaphylaxis that is continued by the emergency services.

For further information please refer to the MHRA's Adrenaline Auto-Injectors (AAIs) safety campaign - GOV.UK (www.gov.uk) We encourage patients and carers to read this fact sheet with advice on the use of adrenaline auto-injectors. The risk of device mishandling or device failure exists with all adrenaline auto-injectors and is something that patients and carers should be aware of. The chance of a successful outcome is increased if adrenaline is administered promptly at the first signs of anaphylaxis. Even with an apparently successful response to adrenaline auto-injector administration, patients may relapse some hours later, which underlines the importance of the emergency services being called.
Reference Information:

1. Class 1 Medicines Recall Notification including patient specific information – Click Here
2. Letter - Advice for patients who have been prescribed Emerade auto-injectors – Click Here (see download document section)

Defective Medicines Report Centre/ Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London, E14 4PU | Telephone +44 (0)20 3080 6574 / DMRC@mhra.gov.uk

Please check website www.gov.uk/drug-device-alerts for when actions should be ceased or advice to check for date restrictions are lifted.

Medicines & Healthcare products
Regulatory Agency

Advice for patients who have been prescribed an Emerade 500 micrograms or Emerade 300 micrograms auto-injector. Reference: NatPSA/2023/004/MHRA

Emerade Device Recall – due to potential device failure (alternatives available)

- Please contact your doctor or pharmacist (via telephone) now to get replacements for you or your child's Emerade 500 micrograms or Emerade 300 micrograms auto-injector(s) - also referred to as Emerade pen(s).
- The MHRA, in conjunction with the Department of Health & Social Care (DHSC), has established that there are sufficient supplies of alternative auto-injectors to allow for a recall at patient level.
- Once you have two replacement pens in a different brand (EpiPen or Jext), return your Emerade 500 micrograms or Emerade 300 micrograms pen(s) to a pharmacy, even if they are still in date.
- **When you collect your new device make sure you receive training on how to use it. It is vital that you receive training to ensure you are completely familiar with how the new device works.** This is because each brand of adrenaline auto-injector works has a different action.
- Patients should continue to carry two devices at all times.

Reasons for Recall of Emerade Devices

According to our records, you have been prescribed Emerade 500 micrograms or Emerade 300 micrograms auto-injector(s) (adrenaline pen(s)). The UK's regulator of medicines (the Medicines & Healthcare products Regulatory Agency [MHRA]) has received information from the company that makes Emerade adrenaline pens.

Pens were tested and an issue identified where some pens failed to activate as required. As a precautionary measure, all batches of Emerade 500 micrograms and Emerade 300 micrograms pens are being recalled. Therefore, no further supplies will be available of Emerade and patients will need to be switched to an appropriate alternative (EpiPen or Jext).

Replacement of Emerade Devices

You, and/or your parent or carer, should make an urgent appointment with your doctor, or speak to your local pharmacist about replacing the prescription for each Emerade 500 or 300 micograms pen. Ensure that you have two alternative pens of the same brand prescribed.

The alternative pen will be either EpiPen or Jext, both of which are safe and effective in the treatment of anaphylaxis (severe allergic reactions).

Your replacement pens will be either 300 micrograms (0.3 milligram) strength EpiPen or Jext pens, both of which are suitable replacements for a single Emerade 500 micrograms pen. This is based on recently available results from a study, which compared blood levels of adrenaline following injection of Emerade 500 micrograms pens. The study found that there was no difference in results with those following EpiPen 300 micrograms or Jext 300 micrograms pens.

You must continue to always carry two adrenaline pens with you at all times. As soon as you have obtained two new replacement pens you should return all Emerade auto-injector(s) to a local pharmacy.

If you are unwell or unable to collect your prescription because you have been asked to stay at home, please use alternative arrangements to ensure that you receive your new pen(s), such as arranging for a family member to collect the prescription for you.

Training on alternative devices

You and the people around you will need to ensure you know how to use your new EpiPen or Jext pens. These pens work in a different way from Emerade auto-injector pens. Your doctor, nurse or pharmacist can help you with training in how to use your new pen.

You and those around you must therefore take particular care to read the instructions on how to use your new pen in the leaflet contained in the box. You should also consult the manufacturer's website for the particular pen you have been supplied with. Training videos on how to use the pens and other information are available on these websites.

- EpiPen® 0.15mg: https://www.medicines.org.uk/emc/product/4290/rmms
- EpiPen® 0.3mg: https://www.medicines.org.uk/emc/product/4289/rmms
- Jext® 150 Training Video: https://www.medicines.org.uk/emc/product/5747/rmms
- Jext® 300 Training Video: https://www.medicines.org.uk/emc/product/5748/rmms

The manufacturers will also provide training pens that do not contain adrenaline. You are strongly recommended to order these, by contacting the manufacturer directly, and practice regularly with them so you are fully prepared for using a real pen in an emergency. Ensure you or your child knows to carry two adrenaline pens at all times.

What to do if you suspect anaphylaxis

- administer an adrenaline auto-injector device without delay, even if there is doubt whether it is anaphylaxis
- call an ambulance (999) immediately after giving the injection and say this is an emergency case of anaphylaxis
- if you are not already lying down, then do so
- administer a second auto-injector 5 minutes after the initial dose, if no improvement is seen or if the patient deteriorates after an initial improvement
- patients should be advised to use a second adrenaline auto-injector immediately if the first adrenaline autoinjector pen fails to activate despite pressing firmly against the thigh (pictorial guidance on whether an Emerade pen has activated or not is given below)
- make further attempts to activate a failed adrenaline autoinjector pen while waiting for the ambulance if the patient is not improving, even if one pen has worked, as this may suggest a need for a second or more doses. The purpose of adrenaline pens is to start treatment for anaphylaxis that is continued by the emergency services.

For further information please refer to the MHRA's Adrenaline Auto-Injectors (AAIs) safety campaign https://www.gov.uk/government/publications/adrenaline-auto-injectors-aais-safety-campaign

WHAT DOES MY EMERADE PEN LOOK LIKE BEFORE USE? Fig. 1

BEFORE USE

Instructions:
1. An unused Emerade pen, with front cap in place (Fig. 1).
2. For instructions on how to use your Emerade pen please consult the Patient Information Leaflet (PIL).
3. During this period, when activation failure is a possibility, you should press the Emerade pen very firmly against your thigh.

HAS MY EMERADE PEN ACTIVATED? Fig. 2

ACTIVATED
When Emerade Pen has been activated the needle cover will extend and lock.

Instructions:
1. After using an Emerade pen following the instructions found on product labelling, verify that the pen has activated.
2. An Emerade pen that has been activated, will have an extended needle cover (Fig. 2 – circled section of image)
3. Call 999 for an ambulance and state “Anaphylaxis” even if you start to feel better
4. Lie flat with your legs up to keep your blood flowing. However, if you are having difficulty breathing, you may need to sit up to make breathing easier
5. Proceed to administer your second pen if you are not improving after 5 to 15 mins in case you need a second dose of adrenaline

WHAT DO I DO IF MY EMERADE PEN HAS NOT ACTIVATED? Fig. 3

NOT ACTIVATED
If the needle cover has not extended, the pen has not activated.

Instructions:
1. If the needle cover has not extended, the pen has not activated (Fig. 3 – circled section of image).
2. If the pen has not activated despite firm pressure, use the second pen immediately.
3. Call 999 for an ambulance and state “anaphylaxis” even if you start to feel better.
4. Perform additional attempts to activate, if
- both pens have failed, and no dose has been given;
- ne pen has failed, one pen has worked, but a second dose is needed
This should only be attempted once all pens have been tried.
5. Retain any suspected, un-activated pen for reporting to the MHRA via the Yellow Card and investigation purposes.