# Chief Medical Officer Directorate Pharmacy and Medicines Division



Dear Colleague

## MEDICINE SUPPLY ALERT NOTICE

Medicine/Drug in short supply: Adrenalin auto-injectors

Priority: For information & updated advice

Valid until: Ongoing

Issue

1. The Medicines and Healthcare products Regulatory Agency (MHRA) issued a Class 4 drug alert for all strengths of Emerade® auto-injectors. More details are included in paragraph 6. The market supply of adrenaline auto-injectors is being closely monitored by the Department of Health and Social Care (DHSC). There are currently sufficient supplies overall to meet normal patient demand. However, due to the supply issues with some brands, it may be necessary to switch patients to an alternative brand that they may be unfamiliar with. Annex A details the current supply situation with all brands of adrenaline auto-injectors; Annex B details the situation with adrenaline for anaphylaxis kits.

# **Expiry dates**

- 2. To ease the supply situation, the MHRA has approved the extension of expiry dates for specific batches of EpiPen® 300 micrograms and Jext® 150 micrograms and 300 micrograms by four months beyond the labelled expiry date.
- 3. The **expiry date** means that the adrenaline auto-injectors should not be used after the **end of the month** listed (see paragraph 4 below). This applies to the original expiry date or the extended expiry date.
- 4. The company websites list the specific batches that can have their original expiry date extended:

Mylan UK: <a href="http://www.epipen.co.uk/">http://www.epipen.co.uk/</a> ALK-Abello Ltd: <a href="https://jext.co.uk/">https://jext.co.uk/</a> 11 October 2019

#### Addressees:

#### For action

NHS Directors of Pharmacy
NHS Medical Directors
Pharmacy Primary Care Leads
Medicines Information
Pharmacists
Community Pharmacy Scotland
NHS National Procurement
Scottish Prescribing Advisor
Network

For information
Director Practitioner Services,
NHS NSS
NHS Scotland Chief Executives
NHS Directors of Finance

## **General Enquiries to:**

Margaret Syme or Alison Strath Pharmacy & Medicines Division

Email: <a href="mailto:PharmacyTeam@gov.scot">PharmacyTeam@gov.scot</a>

www.gov.scot

#### **Advice**

5. Clinicians should check with patients requesting new **EpiPen**<sup>®</sup> **300 micrograms or Jext**<sup>®</sup> **150 micrograms and 300 micrograms** to establish if they currently hold one of the batches that can be used beyond the listed expiry. If one of the listed batches is held, further supplies should be delayed until the extended expiry date, counselling the patient on the extended expiry.

# **Safety Alert (for information)**

6. On 3 October 2019, a Class 4 drug alert was issued for all strengths of Emerade auto-injectors following reports from the manufacturer, Bausch & Lomb UK Limited, of Emerade auto-injectors failing to activate. In this situation, the needle of the pen is not released from the auto-injector when used, and a dose of adrenaline cannot be delivered. The issue makes it particularly important that users carry two adrenaline auto-injectors at all times. The link below provides further information:

https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-emerade-150-300-and-500-microgram-solution-for-injection-in-pre-filled-syringe-mdr-57-08-19

### **Action**

- 7. Health Board Medical Directors and Directors of Pharmacy are asked to cascade this Medicines Supply Alert Notice to general practices, community pharmacies, and other relevant professionals in their Health Board area.
- 8. Healthcare professionals are asked to note the content and actions outlined in this circular and Annexes; and circulate as appropriate.

Yours sincerely,

**Rose Marie Parr** 

LoseMalrie Park

Chief Pharmaceutical Officer/

Deputy Director Pharmacy & Medicines Division

# Overview of the current supply situation with all brands of adrenaline auto-injectors

Adrenaline auto-injector brand	Strength	MA Holder	Stock Availability
EpiPen Junior	150 micrograms	Mylan UK	Available under prescription validation**
EpiPen*	300 micrograms	Mylan UK	Available under prescription validation**
Jext	150 micrograms	ALK-Abello	Available
Jext	300 micrograms	ALK-Abello	Available from w/c 14th October
Emerade	150 micrograms	Bausch & Lomb	Available
Emerade	300 micrograms	Bausch & Lomb	Available from w/c 14th October
Emerade	500 micrograms	Bausch & Lomb	Available from 18th October***

<sup>\*</sup> Sufficient supplies available to meet normal patient demand of 300 microgram and 500 microgram adrenaline autoinjectors during this time

<sup>\*\*</sup> Primary care: Pharmacies can place an order for up to a maximum of two devices per prescription. Anonymised prescriptions should be sent to Alliance Healthcare's prescription validation service, either by fax (0330 332 8126) or email (<a href="mailto:scriptvalidation@alliance-healthcare.co.uk">scriptvalidation@alliance-healthcare.co.uk</a>) and include the Alliance Healthcare account number. Secondary care: Hospitals should request EpiPen's from the Mylan customer services team (<a href="mailto:mguk\_customer.services@mylan.co.uk">mguk\_customer.services@mylan.co.uk</a>) including the number of the auto-injectors required, the reason for need and the Alliance Healthcare account number.

<sup>\*\*\*</sup>Please refer to the Central Alerting System (CAS) alert issued 1st August 2019 for advice on clinical management during this time: <a href="https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102885">https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102885</a>

Annex B

## ADRENALINE FOR ANAPHYLAXIS KITS

- Adrenaline 1:1000 ampoules are currently available in sufficient quantities to meet normal demand.
- Some healthcare professionals may be holding Emerade<sup>®</sup>, or other adrenaline autoinjectors, in preference to adrenaline ampoules, to treat anaphylactic reactions; this should not be necessary.
- All healthcare professionals providing services where anaphylaxis treatment may be required, including but not exclusive to flu vaccination services, should have the competency to draw up and administer intramuscular adrenaline from ampoules with a normal syringe and needle.
- During the current shortage, please use ampoules and not auto-injectors to replenish anaphylaxis kits. Remember to include the relevant dosing charts, syringes and needles.
- The <u>Green Book</u> and <u>Resuscitation Council</u> guidance provides additional advice to healthcare professionals on the use of adrenaline in response to anaphylaxis.
- There is an expectation that healthcare professionals should use adrenaline ampoules in preference to Emerade® or other adrenaline auto-injectors.