

10th October 2019

Dear Colleagues,

- On 3rd October 2019, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a Class 4 drug alert for all strengths of Emerade auto-injectors following reports from the manufacturer, Bausch & Lomb UK Limited, of Emerade auto-injectors that have failed 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. Please see the link below for 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>

- The market supply of adrenaline auto-injectors is being closely monitored by the Department of Health and Social Care (DHSC) and 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 are unfamiliar with.
- Clinicians should support switching and ensure patients know how to use the alternative product that is supplied.
- Specific training and advice are required for each of the devices. Please follow the links to the relevant training videos below:

EpiPen: <http://www.epipen.co.uk/demonstrationvideo/>
 Jext: <https://hcp.jext.co.uk/>
 Emerade: <https://www.emerade-bausch.co.uk/patient/how-to-use-emerade>

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

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 14 th October
Emerade	150 micrograms	Bausch & Lomb	Available
Emerade	300 micrograms	Bausch & Lomb	Available from w/c 14 th October
Emerade	500 micrograms	Bausch & Lomb	Available from 18 th October***

* Sufficient supplies available to meet normal patient demand of 300 microgram and 500 microgram adrenaline auto-injectors during this time

** 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 (scriptvalidation@alliance-healthcare.co.uk) and include the Alliance Healthcare account number.

Secondary care: Hospitals should request EpiPen's from the Mylan customer services team (mguk_customer.services@mylan.co.uk) including the number of the auto-injectors required, the reason for need and the Alliance Healthcare account number.

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

- 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.
- The **expiry date** means that the adrenaline auto-injectors should not be used after the **end of the month** listed. This applies to the original expiry date or the extended expiry date.
- The company websites list the specific batches that can have their original expiry date extended:

Mylan UK: <http://www.epipen.co.uk/>
ALK-Abello Ltd: <https://jext.co.uk/>

- Clinicians should check with patients requesting new EpiPen 300 micrograms or Jext 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.

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, or other adrenaline auto-injectors, 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 [Green Book](#) and [Resuscitation Council](#) guidance provides additional advice to healthcare professionals on the use of adrenaline in response to anaphylaxis. Pharmacists providing vaccination services may also wish to refer to [PSNC FAQs](#). There is an expectation that healthcare professionals should use adrenaline ampoules in preference to Emerade or other adrenaline auto-injectors.

This information should be shared with all health care professionals in primary, secondary or specialist healthcare services who prescribe, dispense or administer adrenaline auto-injectors.

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk

We hope this information is helpful and thank you for your assistance with this issue.

Yours sincerely,

DHSC Medicines Supply Team