



Llywodraeth Cymru
Welsh Government

Directors of Education

2 October 2018

Dear Colleague

Action Required: Disruption to the supply of EpiPen®.

Please inform nurseries, schools and pupil referral units of the following:

Issue

You may already be aware from recent press articles of an ongoing supply issue affecting EpiPen® and EpiPen Junior® adrenaline auto-injectors (AAIs) which are supplied by Mylan. AAIs are devices for the administration of adrenaline in treating emergency anaphylaxis.

As a means of managing current supply, the Medicines and Healthcare products Regulatory Agency (MHRA) has agreed to extend the use of specific batch/lot numbers of **EpiPen® 300mcg** auto-injectors, beyond the labelled expiry date by four months.

Action Required

The following applies to pupils own AAIs and any spare AAIs for emergency use the school/setting may hold:

- Ensure staff trained to use AAIs are made aware of the extension of expiry dates; and
- Put a copy of the table below in any emergency kit holding AAIs.

Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Parc Cathays / Cathays Park
Caerdydd / Cardiff
CF10 3NQ

Canolfan Cyswllt Cyntaf / First Point of Contact Centre
0300 0604400

The extended use only applies to the batches of EpiPen® 300mcg auto injectors specified in the table below. It is safe to use the products listed here until the extended expiry date. Further information about this can be found here: <http://www.epipen.co.uk/> .

Batch/Lot Number	Labelled Expiry Date (end of the month)	Extended Expiry Date (end of the month)
6FA794J	07.2018	11.2018
6FA795Y	07.2018	11.2018
7FA112F	09.2018	01.2019
7FA106B	09.2018	01.2019
7FA283B	10.2018	02.2019
7FA251D	10.2018	02.2019
7FA250B	10.2018	02.2019
7FA265C	11.2018	03.2019
7FA265B	11.2018	03.2019

The extended use does not apply to EpiPen Junior® 150mcg auto-injectors or any batch number of EpiPen® 300mcg auto injectors not specified in the table above. Users must continue to adhere to the labelled expiry date on any EpiPen® not listed above.

It is important to note that when validating the expiry date of an AAI, the product expires on the last day of the month indicated. For example, a device labelled 'April 2019' does not expire until the end of April 2019.

Further information

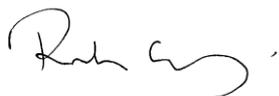
In October 2017 we published '[Guidance on the use of emergency adrenaline auto-injectors in schools in Wales](#)' following changes to UK regulations which allow schools to obtain, without prescription, AAIs for emergency use. Nurseries, schools and pupil referral units may, therefore, hold AAIs for use in emergencies. This guidance is unchanged except it is appropriate to use the above listed products until the extended expiry date.

The issue is due to manufacturing delays from Mylan's contract manufacturer, Meridian Medical Technologies, a Pfizer company in the United States. Stabilising supply is taking longer than anticipated and is affecting countries globally. At this time supply is expected to be critically affected until the end of the year. The Department of Health and Social Care (DHSC) are taking measures to manage the UK supply.

Two alternative AAIs are available: Emerade®, supplied by Bausch and Lomb and Jext®, supplied by ALK. Both companies manufacture adult and paediatric AAIs. Both companies are aware of the supply disruptions affecting EpiPen® and EpiPen Junior® and have been working with their supply chains to increase supplies of their products to the UK for the remainder of this year. If schools/settings are unable to obtain a supply of their usual AAI they should speak to the community pharmacist who supplies their AAI about alternative AAIs. Schools/settings will need to be aware that the instructions for use of Emerade® and Jext® AAIs may differ from those for EpiPen® AAIs. Accordingly schools/settings will need to take appropriate measures to ensure staff administering AAIs are aware of this and appropriately trained in the administration of the relevant device.

If parents are having difficulty in obtaining an EpiPen® they should contact their GP or pharmacist for advice on using an alternative adrenaline auto-injector device.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Ruth Conway', with a stylized flourish at the end.

Ruth Conway