# WRITTEN STATEMENT

# BY

# THE WELSH GOVERNMENT

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| **TITLE** | **Disruption to the supply of EpiPen® Adrenaline Auto Injectors** |
| **DATE** | **08 October 2018** |
| **BY** | **Vaughan Gething, Cabinet Secretary for Health & Social Services** |

In the last week significant concerns have been expressed about the limited availability of EpiPen® products in the UK. I am making this written statement to inform Members of the detail of the steps being put in place to address the current situation and provide assurance that appropriate action is being taken to mitigate any risk.

This is a global issue and one we are working actively with the UK Government and the Medicines and Healthcare Regulatory Agency (MHRA) to address.

The limited availability of EpiPen® is due to manufacturing delays from Mylan’s, the manufacturer of EpiPen® products, contract manufacturer Meridian Medical Technologies, a Pfizer company in the US. Stabilising supply is taking longer than anticipated and is affecting countries globally.

Whilst the availability of EpiPen® products is currently limited, alternative adrenaline auto-injectors continue to be available and their manufacturers are working with their supply chains to increase UK supplies.

On 28 September, the Department of Health and Social Care (DHSC) issued guidance for healthcare professionals about the supply issue. This guidance, which was drawn up by NHS allergy experts, provides supply and clinical management advice.

In the UK alternative adrenaline auto-injector devices are available; Emerade®, supplied by Bausch and Lomb, and Jext®, supplied by ALK, are both available in adult and paediatric presentations. Both manufacturers 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.

All suppliers of adrenaline auto-injector devices are working with their wholesaler partners to put processes in place to put reasonable limits on the number of devices that can be supplied per prescription.

Mylan UK, has obtained agreement from the MHRA to extend the use of specific batch numbers of EpiPen® 300mcg auto‐injectors, beyond the labelled expiry date by four months. The expiry dates on adrenaline auto-injector devices applies until the final day of the month shown on the packaging. e.g. a device labelled ‘April 2019’ does not expire until the 30th of April 2019.

Details of the affected batches have been disseminated to healthcare professionals. Any patient or carer concerned about the expiry date of their EpiPen® should consult their pharmacist or GP who will be able to advise whether their EpiPen® has had its shelf life extended.

In addition, healthcare professionals have been advised to:

* prescribe AAIs prudently
* make patients aware of the extended product expiry periods
* prescribe alternative products when appropriate

Some schools in Wales may hold EpiPen® and EpiPen Junior® devices for the purpose of emergency treatment of anaphylaxis.

The Welsh Government has written to local authorities asking them to make schools aware of the situation and of the extension of product expiry dates for some batches.

Most importantly, any patient unable to obtain supplies of EpiPen® should speak to their clinician about using an alternative adrenaline auto-injector device.