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25<sup>th</sup> September 2019  
 EPI-2019-0283

Direct Healthcare Professional Communication on the Extended Use Beyond Labelled Expiry  
 Date for Specific Lots of EpiPen® 0.3mg Adrenaline Auto-Injectors

Dear Healthcare Professional,

**Extended use for specific lot numbers of EpiPen® 0.3mg Adrenaline Auto-injectors**

This letter is sent in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) to inform you of the following:

Summary

- Mylan UK have obtained acceptance from the MHRA to extend the use of specific lot numbers of EpiPen® 0.3mg auto-injectors, by four months beyond the labelled expiry date
- The affected lot numbers are listed in the table below:

**EpiPen® 0.3mg (single pack)**

LOT	Labelled Expiry Date (end of the month)	Extended Use-by Date (end of the month)
8FA092T	09/2019	01/2020
8FA273E	11/2019	03/2020
8KB332M	02/2020	06/2020
8FA366K	02/2020	06/2020
8FA367B	02/2020	06/2020

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8KB478B	04/2020	08/2020
8KB474B	04/2020	08/2020
8KB481B	04/2020	08/2020
8KB510G	05/2020	09/2020
8KB523G	05/2020	09/2020
8KB648B	06/2020	10/2020
8KB587B	06/2020	10/2020
8KB630C	06/2020	10/2020
8KB587F	06/2020	10/2020
8KB671R	07/2020	11/2020
9KB087B	10/2020	02/2021
9KB148B	10/2020	02/2021
9KB177AE	11/2020	03/2021
9KB262B	12/2020	04/2021

**EpiPen® 0.3mg (twin pack)**

<b>LOT</b>	<b>Labelled Expiry Date (end of the month)</b>	<b>Extended Use-by Date (end of the month)</b>
8KB558C	05/2020	09/2020
8KB630D	06/2020	10/2020
8KB671F	07/2020	11/2020
9KB148J	10/2020	02/2021
9KB177E	11/2020	03/2021

EPI-2019-0283

Date of preparation: September 2019

9KB252P	11/2020	03/2021
9KB301J	12/2020	04/2021

**Important: the extended use only applies to the lots of EpiPen® 0.3mg auto-injectors listed above. Patients can continue to use the EpiPen® 0.3mg auto-injectors of these specified lots safely until the extended use by date as stated above.**

**This extended use does not apply to EpiPen® 0.15mg auto-injectors or any lot number of EpiPen® 0.3mg auto-injectors not specified. Patients must continue to adhere to the labelled expiry date on any EpiPen® not covered by the lot numbers above.**

**Further information on the extended use of the listed lots of EpiPen 0.3mg auto-injectors**

There has been an interruption in the supply of adrenaline auto-injectors in the UK. The overall market supply of adrenaline auto-injectors is being monitored by the Department of Health and Social Care.

To make sure patients can access their medicines during the supply shortage, the specific lots of EpiPen® 0.3mg auto-injectors (listed above) can be used 4 months beyond the labelled expiry date.

This 4-month extended use beyond the labelled expiry date for the specific lots listed above is based on supportive stability data for EpiPen® 0.3mg auto-injectors and has been reviewed by the MHRA. The EpiPen® 0.3mg auto-injectors of these specific lots will continue to work safely and as intended within the extended use by date. The EpiPen® auto-injectors should continue to be stored as labelled on the pack.

At the end of the extended use period (the end of the month listed under “Extended Use-by Date” in the table above), a new auto-injector will still need to be obtained.

**Further information on recommendations to healthcare professionals**

- Tell patients and caregivers about the extended use-by date of the specified lots of EpiPen® 0.3mg auto-injectors as listed above. This does not apply to other lots of EpiPen® 0.3mg auto-injectors and does not apply to any of EpiPen® 0.15mg auto-injectors.
- Show patients and caregivers where to find the lot numbers on their device (on the end-flap of the box and if necessary, on the EpiPen® itself) and encourage them to sign up for the Expiry Alert Service.

- Reassure patients and caregivers that their device will continue to work safely over the extended use period.
- Remind patients and caregivers that they should still obtain a new device at the end of the extended use period.

### **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 ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website - <https://yellowcard.mhra.gov.uk/> or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing [yellowcard@mhra.gov.uk](mailto:yellowcard@mhra.gov.uk)
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789 or
- by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

### **Company contact point**

If you want further information relating to the above, please contact

Mylan Medical Information  
Building 4, Trident Place  
Mosquito Way, Hatfield  
AL10 9UL, UK  
Info.uk@mylan.co.uk  
Tel: +44 (0)1707 853 000 (option 1)

For further information about EpiPen® please see the Summary of Product Characteristics (SmPC)

available from: <http://www.medicines.org.uk/emc/medicine/26974>  
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Yours Sincerely,



**Julian De Gabriele**

Head of Medical Affairs UK, Ireland & Malta

Mylan Products Ltd.