Supply of Adrenaline Auto Injectors

The supply situation for the Epipen Juniors has worsened over the last week and Mylan are now out of stock. It is expected that supplies will remain constrained for several months. This has been escalated within the company and through the MHRA. The DHSC are working with the MHRA and the company to see if the expiry dates can be extended.

To support patient access to the product during this supply constraint, healthcare professionals are encouraged to manage prescription renewals diligently. It is important to note that when validating the expiry date of an adrenaline auto-injector, the product expires on the last day of the month indicated.

Epipen supply update- info provided as of 18th Sep

- DHSC has been in contact with the UK supplier of Epipens, Mylan, for several months regarding the ongoing supply issues affecting this product.
- Mylan have informed us that due to manufacturing delays from their contract manufacturer, Meridian Medical Technologies, a Pfizer company, there continue to be supply constraints of EpiPen Adrenaline Auto-Injectors in the UK.

0.3mg Adrenaline Auto-injectors:

- Currently supplies are available of EpiPen 0.3mg via a stock management process.
 Pharmacies are allocated stock on a prescription-only basis and can place orders for up to a maximum of two EpiPen 0.3mg Auto-Injectors per prescription.
- Also Pfizer recently made available to Mylan a limited volume of EpiPen 0.3mg Auto-Injectors that will expire in February 2019. This supply is not subject to the current prescription validation process, as outlined above, and will be available for pharmacists to order and hold in stock.
- Further information regarding this stock and a statement from Mylan is available via the following link: http://www.epipen.co.uk/
- There are two alternative adrenaline auto-injector products available in the UK, Emerade and Jext.
- Supplies of both presentations are currently available but may be limited due to the ongoing Epipen supply issues.
- Emerade also supply a 0.5mg adrenaline auto-injector.

0.15mg Adrenaline Auto-injectors:

- This issue is now also affecting EpiPen Jr 0.15mg Adrenaline Auto-Injector in the UK
- Mylan recently informed us that EpiPen Jr 0.15mg Adrenaline Auto-Injectors is now out of stock until the next shipment arrives, estimated to be by the end of September.
- Due to the supply situation with EpiPen Jr 0.15mg, supplies of both Jext and Emerade
 0.15mg adrenaline auto-injectors have been rapidly depleted and are currently unavailable.
 However, additional supplies of Jext are expected early next week and Emerade by the end
 of September. However, supplies will be limited and the over situation is likely to be
 constrained until the Mylan situation has resolved.

Further information:

- Mylan have shared a statement, which is available on their website <u>www.epipen.co.uk</u>.
- Mylan is working closely with Pfizer to increase production and anticipates supply will stabilise in the fourth quarter of 2018; however, it is important to note that currently supply

from Pfizer continues to vary and, as such, may not always be available for pharmacies to order.

- Further supplies of both Jext and Emerade are currently expected by the end of September.
- We are in contact with the manufacturers of these alternative devices to keep them updated on the situation. They both have additional deliveries of both adult and paediatric presentations arriving over the coming weeks and they are working to expedite future deliveries and bring additional stock to the UK where possible.
- During this period if patients are unable to obtain a supply of their usual adrenaline autoinjector we would encourage patients to speak to their healthcare provider about alternate
 adrenaline auto-injectors. Further advice is also available via the Anaphylaxis UK website:
 https://www.anaphylaxis.org.uk/2018/08/09/updated-statement-from-mylan-on-the-availability-of-epipen-0-3mg-and-epipen-ir-0-15mg-adrenaline-auto-injector/
- We are also working with Mylan and the MHRA to determine if it is possible to extend the
 expiry of certain batches of Epipens, as has been done with selected batches of Epipen
 0.3mg in the US, to help alleviate the situation in the short term.
- We are continuing to work closely with all the manufacturers of adrenaline auto-injectors, the MHRA, Anaphylaxis UK and other stakeholders to try to resolve these issues and improve the situation where possible.