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East Lancashire Health Economy Medicines Management Board
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Risk of Emerade® pre-filled Syringe failing to deliver correct dose of adrenaline

July 2019

The MHRA has been informed of a risk of the Emerade® product failing to deliver a dose of adrenaline from the syringe due to blockage of the needle. The issue was first detected in June 2018 during routine stability testing of the syringe component but believed to be a rare event potentially affecting 1.5 in every ten thousand pens. Recent information however, indicates that the potential occurrence of needle blockage in batches on the market is higher than first estimated and we are therefore bringing it to the attention of patients.

The potential for devices on the market to have a blockage of the needle which could lead to Emerade® failing to deliver a dose when activated is now estimated to be 0.23%, which would affect 2.3 in every thousand pens. However, if the patient follows the existing advice to carry two in-date pens with them at all times, the risk of not being able to deliver a dose of adrenaline before the emergency services arrive is substantially reduced from 0.23% to 0.000529%.

It should be emphasised that two pens are already recommended to be carried at all times in case the patient does not improve after the first injection which may occur for a number of reasons. **This notification of potential for needle blockage applies to Emerade® devices of all strengths. It does not apply to the other marketed brands of adrenaline auto-injectors.** The manufacturer has conducted extensive investigations and has implemented corrective actions. Emerade® manufactured with all the corrective processes are expected to be introduced into the market from mid-July 2019.

The MHRA is not recalling batches of Emerade®. In the UK there are two alternative adrenaline auto-injector devices available. However, the different brands of adrenaline auto-injectors are not used in exactly the same way and therefore specific training and advice is required for each of the devices. Furthermore, there are insufficient supplies available of alternative brands to support the removal of one brand.

Action for healthcare professionals and patients

- Healthcare Professionals should contact all patients, and their carers, who have been supplied with an Emerade® device to inform them of the potential defect and reinforce the advice to always carry two in-date adrenaline auto-injectors with them at all times.
- This advice is provided in the approved patient information leaflet for Emerade®, which should be provided to the patient or caregiver at dispensing.
- Patients experiencing any problem with Emerade® failing to activate should report this via the MHRA's Yellow Card system and keep the pen for further examination: https://yellowcard.mhra.gov.uk/

Additional advice to reiterate to patients:

- Check expiry date and replace the pen before it expires
- Use the auto-injector at first signs of anaphylaxis (The chance of a successful outcome is increased if there is prompt administration of adrenaline at the first signs of anaphylaxis)
- Call 999, ask for an ambulance and say anaphylaxis (pronounced as 'anna -fill-axis'). *Even with an apparently successful response to adrenaline auto-injector administration, patients may relapse some hours later which underlines the importance that the emergency services should always be called.*
- Lie flat if possible with your legs up to keep your blood flowing
- Use second pen if still unwell after 5-15 minutes
- The risk of device mishandling or device failure exists with all adrenaline auto-injectors and is something that patients and carers should be aware of.

For further information, please contact the Medicines Management Team on 01254 282087 (BwD CCG) or 01282 644807 (EL CCG)