

**From the Chief Medical Officer
Professor Sir Michael McBride**



HSS(MD) 33/2023

FOR ACTION

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Dear Colleague

MHRA DRUG SAFETY UPDATE: ADRENALINE AUTO-INJECTORS (AAIS): NEW GUIDANCE AND RESOURCES FOR SAFE USE

The Medicines and Healthcare products Regulatory Agency (MHRA) has launched new guidance to highlight the latest safety advice on the steps to take during anaphylaxis. This new guidance includes an easy step-by-step guide on what to do in an emergency and provides updated advice on body positioning.

Resources for the safe use of adrenaline auto-injectors (AAIs)

On 19 June 2023, the MHRA, with the support of allergy awareness advocates, has launched a [safety campaign to raise awareness of anaphylaxis and provide advice on the use of adrenaline auto-injectors \(AAIs\)](#). The launch coincides with the World Allergy Week, an annual initiative led by the [World Allergy Organization](#).

A toolkit of resources is now available for health and social care professionals to support the safe and effective use of AAIs.

The resources are freely available for download from the MHRA's guidance page on [Adrenaline Auto-Injectors \(AAIs\)](#) and include:

- [infographic about the correct use of your AAI](#)
- videos about the correct use of your AAI are available within the [MHRA Drug Safety Update June 2023](#).

Advice for healthcare professionals:

- use the materials to inform patients and caregivers what to do if they suspect anaphylaxis and how to use adrenaline auto-injectors (AAIs)
- prescribers should prescribe 2 AAIs to make sure patients always have a backup
- talk to your colleagues about the safe use of AAIs and the signs of anaphylaxis using the mnemonic A, B, C for Airway, Breathing and Circulation
- report any suspected defective AAIs to the [Yellow Card scheme](#). Keep defective AAIs for investigation. Your report improves the safety of medicines and medical devices.

Advice for healthcare professionals to provide to patients and carers:

- adrenaline auto-injectors (AAIs) should be used without delay if anaphylaxis is suspected, even if in doubt about the severity of the event
- signs may include swelling in the throat or tongue, wheezing or breathing difficulty, dizziness, tiredness and confusion
- immediately dial 999 to summon emergency medical help after administering adrenaline; say anaphylaxis (“ana-fill-axis”)
- if you are not already lying down, lie down flat and raise your legs (if you’re pregnant, lie on your left side); this will assist blood flow to the heart and vital organs
- stay lying down even if you feel better
- if you struggle to breathe, you can gently sit up - don’t change position suddenly; you should then lie down again as soon as you can
- do not stand up even if someone encourages you to
- use your second AAI if you haven’t improved after 5 minutes
- you should always carry 2 AAIs at all times; check the expiry dates and see a pharmacist if you need a replacement
- report any suspected defective AAIs to the [Yellow Card scheme](#). Keep defective AAIs for investigation. Your report improves the safety of medicines and medical devices.

About adrenaline auto-injectors (AAIs)

Adrenaline auto-injectors (AAIs) (product names Epipen or Jext) deliver adrenaline by means of an auto-injector device for the emergency treatment of anaphylaxis, a life-threatening severe allergic reaction.

In October 2019 the Commission on Human Medicines (CHM) endorsed the formation of an Adrenaline Auto-injector Expert Working Group (AAI EWG) to examine a range of issues to support the effective and safe use of AAIs for the emergency treatment of anaphylaxis.

One of the agreed actions for the group was to develop a communication campaign so that patients, healthcare professionals and the wider public can be better equipped to understand the importance of AAIs as potentially life-saving healthcare products.

View the full Public Assessment Report: [Recommendations to support the effective and safe use of adrenaline auto-injectors](#).

AAIs are intended for self-administration by the patient or for administration by the patient's carer. AAIs should always be carried by the patient considered to be at risk of anaphylaxis. An AAI should be administered early, at the first signs of anaphylaxis, in line with clear evidence that this improves patient outcome. This requires the patient and carer to be confident in recognising the early signs of anaphylaxis and in distinguishing a severe, life-threatening allergic reaction from one that is less severe and does not require adrenaline. Making this distinction can be challenging, given the wide range of signs and symptoms of anaphylaxis. If there is doubt about the severity of an episode, adrenaline should be administered without delay as the risks of delay outweigh the potential risks from unnecessary administration of adrenaline.

Report adverse drug reactions on a Yellow Card

Please continue to report any suspected adverse drug reactions to the Yellow Card scheme.

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the [Yellow Card website](#)
- the Yellow Card app; download from the [Apple App Store](#) or [Google Play Store](#)
- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

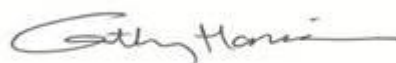
When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates. When reporting for a biological medicine or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch number.

The complete MHRA Drug Safety update is available at the following link [MHRA Drug Safety Update-Adrenaline auto-injectors \(AAs\): new guidance and resources for safe use](#).

Yours sincerely



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Chief Medical Officer



Professor Cathy Harrison
Chief Pharmaceutical Officer

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This letter is available on the Department of Health website at
<https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications>