29 April 2014
EMA/242569/2014/Rev.1

Review of adrenaline auto-injectors started

The European Medicines Agency has started a review of adrenaline auto-injectors, which are used as first-aid treatment of anaphylaxis (severe allergic reactions) prior to calling for emergency medical assistance.

This review was requested by the UK medicines agency, the MHRA, following a national review of all adrenaline auto-injector products approved in the UK. Although the product information of adrenaline auto-injectors states that the devices deliver adrenaline into a muscle, the UK review concluded that there is no robust evidence that this is the case for all patients. Depending on individual factors such as skin-to-muscle depth, adrenaline may instead be injected under the skin (but not into a muscle), which may result in a different absorption profile (uptake of the medicine by the body).

The European Medicines Agency will now review the available data on the delivery of adrenaline from auto-injectors and on whether the product information contains clear and detailed instructions for appropriate use, and issue an opinion on the marketing authorisations of these medicines across the European Union (EU).

It is important that patients continue to carry an adrenaline auto-injector with which they are familiar, so that they can use it confidently in an emergency if needed. Patients who suffer an anaphylactic reaction should use their injector as prescribed and seek emergency medical assistance straightaway.

More about the medicine

Adrenaline (epinephrine) auto-injectors are given to people who are thought to be at risk of anaphylaxis (severe allergic reaction) or have had a previous episode of anaphylaxis, to use as a first-aid measure in case of emergencies prior to calling for emergency medical assistance.

An anaphylactic reaction can cause a drop in blood pressure and breathing difficulties. An injection of adrenaline helps to relieve the symptoms of anaphylaxis quickly, by narrowing the blood vessels (thereby increasing the blood pressure) and by opening up the airways to help with the breathing.

Adrenaline auto-injectors have been approved through national procedures in all the EU Member States.

---

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

More about the procedure

The review of adrenaline auto-injectors has been initiated at the request of the United Kingdom, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's final opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision in due course.