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Better training tools recommended to support patients using adrenaline auto-injectors

Training device and audio-visual material expected to promote appropriate use of auto-injectors

The European Medicines Agency (EMA) has recommended several measures, including the introduction of more effective educational material, to ensure that patients and carers use adrenaline auto-injectors successfully. Adrenaline auto-injectors are potentially life-saving treatments for anaphylaxis (severe allergic reactions) while the patient waits for emergency medical assistance.

EMA carried out a review of adrenaline auto-injectors following concerns that currently available devices may deliver adrenaline under the skin instead of into a muscle, and this may delay response to treatment.

Having assessed all the available data, EMA's Committee for Medicinal Products for Human Use (CHMP) acknowledged that giving the medicine by injection into the muscle is the preferred way to obtain a rapid response in anaphylaxis. However, the CHMP noted that several factors may affect whether adrenaline is actually delivered into a muscle; these include needle length, the thickness of fat under the skin, the way the auto-injector works (e.g. if it is spring loaded or not), the angle at which the device is placed on the skin and the force used to activate the device as well as how well the user follows the instructions for injection.

The CHMP concluded that training of the user is of paramount importance. The companies that market adrenaline auto-injectors will therefore be asked to develop more effective educational material for patients, as well as for healthcare professionals, to ensure their optimal use. This will include a training device with which patients can practise; audio-visual material to show in detail how the device is to be used; and a checklist for prescribers to ensure that sufficient information is given to the patient before they use the auto-injector. The product information of adrenaline auto-injectors will also be updated with further warnings and precautions, including a recommendation that patients should be prescribed two auto-injectors which they should carry at all times and a recommendation for family members, carers or teachers to be trained on how to use the auto-injector.

The CHMP also concluded that further data should be generated to better understand how adrenaline penetrates body tissues when given with each of the different auto-injectors.

The CHMP recommendation will now be sent to the European Commission for a legally binding decision that will be valid throughout the EU.

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Information for patients

- Adrenaline auto-injectors are used to treat severe allergic reactions, while the patient awaits emergency medical assistance. They are designed so that they can be easily used by the patient themselves or a carer.
- The review of adrenaline auto-injectors showed that patients could benefit from further training to use the auto-injector successfully.
- You will receive training from your doctor or nurse on how to use your adrenaline auto-injector. A training device will also be developed so that you can practise with it before you need the auto-injector in an emergency. A training video will be produced to show you in detail how to use the injector properly.
- It is important that you use the auto-injector correctly so that the adrenaline is delivered into your muscles and works as quickly as possible.
- If you have been prescribed an adrenaline auto-injector because you are at risk of severe allergic reactions, you should ensure you are familiar with it and carry it with you at all times.
- It is likely that your doctor will recommend that you carry 2 injectors, in case a second dose is needed while you wait for emergency assistance.
- Your family members, carers or teachers should also be instructed in the correct use of the auto-injector.
- If you have any question or concern, speak with your doctor or pharmacist.

Information for healthcare professionals

- The review of adrenaline auto-injectors confirmed that intramuscular injection is the preferred route of administration in the treatment of anaphylaxis in order to obtain a rapid response.
- Several factors may affect whether adrenaline reaches the muscle layer. These include: needle length, the skin-to-muscle depth, the way the auto-injector works (e.g. if it is spring loaded or not), the angle of placement on the skin and the force used to activate the device.
- Because of the uncertainties over drug delivery from adrenaline auto-injectors and the consequent uncertainties around the onset of pharmacodynamic response, it is recommended that healthcare professionals prescribe 2 auto-injectors, which patients should carry at all times.
- Educational material will be developed to ensure that patients or carers use adrenaline auto-injectors successfully. This will include a training device that patients can practise with, audio-visual material and a prescriber checklist.
- A study in 2013 by Brown *et al.* showed that 15% of the mothers were unable to use the auto-injector successfully in their children. This supports the introduction of proper training and comprehensive educational material for patients and healthcare professionals.
- The companies that market adrenaline auto-injectors will be asked to carry out a pharmacokinetic/pharmacodynamic study to better understand how adrenaline penetrates body tissues when given through an auto-injector.

References

The review looked at data from several studies including:

Bhalla, M. C., B. D. Gable, et al. (2013). "Predictors of epinephrine autoinjector needle length inadequacy." Am J Emerg Med **31**(12): 1671-1676.

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Simons, F. E., X. Gu, et al. (2001). "Epinephrine absorption in adults: intramuscular versus subcutaneous injection." J Allergy Clin Immunol **108**(5): 871-873.

Simons, F. E., J. R. Roberts, et al. (1998). "Epinephrine absorption in children with a history of anaphylaxis." J Allergy Clin Immunol **101**(1 Pt 1): 33-37.

Song, T. T., M. R. Nelson, et al. (2005). "Adequacy of the epinephrine autoinjector needle length in delivering epinephrine to the intramuscular tissues." Ann Allergy Asthma Immunol **94**(5): 539-542.

Stecher, D., B. Bulloch, et al. (2009). "Epinephrine auto-injectors: is needle length adequate for delivery of epinephrine intramuscularly?" Pediatrics **124**(1): 65-70.

Wang, C., R. Wolf, et al. (2013). Comparison of Needle Penetration Depth Probabilities of Two Epinephrine Auto-Injectors. ALLERGY AND ASTHMA PROCEEDINGS, OCEAN SIDE PUBLICATIONS INC 95 PITMAN ST, PROVIDENCE, RI 02906 USA.

More about the medicine

Adrenaline (epinephrine) auto-injectors are given to people who are 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 while waiting for emergency medical assistance.

Anaphylaxis is a life-threatening reaction that causes 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 opening up the airways to help with the breathing.

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

More about the procedure

The review of adrenaline auto-injectors was initiated at the request of the United Kingdom in April 2014, under Article 31 of Directive 2001/83/EC. This followed a national review of all adrenaline auto-injector products approved in the UK, which concluded that there was no robust evidence that the devices deliver adrenaline into a muscle for all patients.

The review has been carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has adopted the Agency's final opinion. The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

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