Emerade 300 and 500 micrograms adrenaline pens recalled from consumers

The marketing authorisation holder of Emerade adrenaline pens, Pharma Swiss Česká republika s.r.o, has issued a patient-level recall of the products out of abundance of caution. The Marketing Authorisation Holder chose to initiate this voluntary action due to the potential risk that the auto-injector may fail to activate or activate prematurely when dropped. As a precautionary measure and due to the inability to identify this issue before the auto-injector is used, the auto-injectors are being recalled.
There is no risk for patients who already used the medicinal product and adrenaline was successfully administered.

Medication users who are in possession of an Emerade pen of any batch shall return the product to a pharmacy. The pen is not an interchangeable product. To receive a substituting product, patients must contact their doctor for a prescription for the substitute product. Patients shall acquire a new adrenaline pen simultaneously or before returning the Emerade pen to a pharmacy.

The marketing authorisation holder has provided pharmacies with instructions on the practical procedures related to the returning of the products.

Emerade pens are used as a first-aid measure in difficult, sudden and life-threatening allergic reactions that require treatment (anaphylaxis), caused by, for example, an insect sting or bite, food, medication or physical exercise.

If you have an unexpired Emerade adrenaline pen:

- **Contact your attending physician to get a prescription for a substitute product.**
- **Return the Emerade pen to a pharmacy.**
- **Before returning the pen, make sure you have acquired a substitute product and know how to use it.**

Contact 112 in all cases involving anaphylaxis

Medeca Pharma AB issues a reminder that all adrenaline autoinjectors are meant to be used as a first-aid measure. Patients shall always seek medical treatment after using an adrenaline pen. Always contact the general emergency number 112, call an ambulance and mention anaphylaxis, even if the patient's symptoms would seem to be already disappearing. It is advisable to bring the used autoinjector with you to the hospital.

For further information, please contact Medeca Pharma AB, Tel. 018 25 85 30 or info@medeca.se