

### **Annex III**

#### **Amendments to relevant sections of the summary of product characteristics and package leaflet**

*Note:*

This Summary of Product Characteristics and package leaflet is the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the Reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

**For all adrenaline auto-injectors referred to in Annex I**

**A. Summary of Products Characteristics**

**Section 4.2 - Posology and method of administration**

*[The section should be amended to reflect the following wording]*

*[...]*

In the absence of clinical improvement or if deterioration occurs, a second injection with an additional [Invented name] may be administered 5–15 minutes after the first injection. It is recommended that patients are prescribed two [Invented name] pens which they should carry at all times.

*[...]*

**Section 4.4 - Special warnings and precautions for use**

*[The section should be amended to reflect the following wording]*

*[...]*

All patients who are prescribed [Invented name] should be thoroughly instructed to understand the indications for the use and the correct method of administration (see section 6.6). It is strongly advised also to educate the patient's immediate associates (e.g. parents, caregivers, teachers) for the correct usage of the [Invented name] in case support is needed in the emergency situation.

*[...]*

**Section 6.5 - Nature and contents of container**

*[The section should be amended to reflect the exposed needle length of the device(s)]*

*[To be completed nationally]*

**For all adrenaline auto-injectors referred to in Annex I**

**B. Package Leaflet**

**Section 3 – How to use [Invented name]**

*[The section should be amended to reflect the following wording]*

*[...]*

Sometimes a single dose of adrenaline may not be sufficient to completely reverse the effects of a serious allergic reaction. For this reason, your doctor is likely to prescribe more than one [Invented name] for you. If your symptoms have not improved or have deteriorated within 5-15 minutes after the first injection, either you or the person with you should give a second injection. For this reason you should carry more than one [Invented name] with you at all times.

*[...]*

It is recommended that your family members, carers or teachers are also instructed in the correct use of [Invented name].

*[...]*

**Section 6 – Contents of the pack and other information**

*[...]*

**What [Invented name] looks like and contents of the pack**

*[The section should be amended to reflect the exposed needle length of the device(s)]*

*[To be completed nationally]*

**For EpiPen/Nepipe and associated names**

**B. Package Leaflet**

**Section 3 – How to use [Invented name]**

[...]

*[The MAH(s) should submit improved diagram in the instructions for use by increasing the size and ensuring that it clearly shows that the injection should be in the antero-lateral aspect of the thigh]*

[...]