Annex IV

Conditions to the marketing authorisations

Conditions to the marketing authorisation

The Marketing Authorisation Holder (MAH) shall submit to the national competent authority, within one month of the European Commission decision on this procedure (EMEA/H/A-31/1337), an EU risk management plan for the product according to the EU Good Vigilance Practices which includes the safety concern of gas embolism.

The MAH shall ensure that, at the time of the European Commission decision for this procedure (EMEA/H/A-31/1337), all users of the spray application of this product are provided with educational material. This material shall inform about the

- risk of life-threatening gas embolism if the product is sprayed incorrectly
- use of pressurized CO_2 only
- restriction to open surgery
- correct pressure and distance from tissue
- requirement to dry the wound using standard techniques (e.g. intermittent application of compresses, swabs, use of suction devices) prior to using the product
- requirement to closely monitor blood pressure, pulse rate, oxygen saturation and end tidal CO_2 when spraying the product, for the occurrence of gas embolism.
- which regulator(s) should be used, in line with manufacturer recommendations and the SmPC instructions for use

The material shall include the latest Summary of Product Characteristics and the section titled “The following information is intended for medical or healthcare professionals only” of the latest package leaflet.

The MAH shall offer an educational program to all users of the spray application of this product. The program shall teach the content of the mentioned educational material.

The Marketing Authorisation Holder shall agree the exact content and format of the educational material and educational program with the national competent authority.

The MAH shall ensure that, within three months of the European Commission decision on this procedure (EMEA/H/A-31/1337), all users of the spray application of this product are provided with

- labels for the pressure regulator that inform about the correct pressure and distance in open surgery
- a warning card that informs about the correct pressure and distance for the spray application for open surgery
- a yellow tag, to be placed on the device air hose, which provides instructions for use. If the tag is provided as part of the medicinal product, it should be incorporated in the product information via a variation procedure

The MAH shall ensure that, within two years of the European Commission decision on this procedure (EMEA/H/A-31/1337), the product can only be used with a pressure regulator that caps the maximum pressure at 2.5 bars.