



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Committees Support Division
Scientific Committee Support Department

Scientific recommendation on classification of advanced therapy medicinal products

Article 17 – Regulation (EC) No 1394/2007

Disclaimer: This document is a summary for public release of a scientific recommendation on classification of advanced therapy medicinal products. The original text adopted by the Committee for Advanced Therapies (CAT) has been redacted to delete commercially confidential information.

The present scientific recommendation refers exclusively to the case as presented to the European Medicines Agency (EMA) without prejudice to future evaluations by the Agency

Brief description (or name where available) of the active substance(s)

Autologous cells of stromal vascular fraction of adipose tissue

Brief description of the finished product

Sterile suspension of autologous cells of stromal vascular fraction of adipose tissue in Lactated Ringers solution

Proposed indication

Pain associated with joint osteoarthritis

EMA/CAT conclusion

The committee adopted on 25th November 2015 the following scientific recommendation.

On the basis that:

- the product is composed of manipulated cells derived from stromal vascular fraction and;
- the product is used to treat pain associated with joint osteoarthritis via immunological action.

the EMA/CAT considers that the Product falls within the definition of a advanced therapy medicinal product (somatic cell therapy medicinal product) for the indication of the treatment of pain associated with joint osteoarthritis, as provided in Article 2(1)a of Regulation (EC) No 1394/2007.

