



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

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.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

Short descriptor (or name when available) of the proposed active substance

Autologous cells of Stromal Vascular Fraction (SVF) of adipose tissue

Brief description of the proposed finished product

Autologous SVF in a cryoprotective solution

Proposed indication

Cosmetic lipofilling in combination with fresh lipoaspirate

EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC (definition of medicinal product – see Annex A)

- SVF containing adipose stem cells (ASCs) is considered to be a substance that is intended to be used in human beings with a view to restoring physiological functions by exerting a pharmacological and/or metabolic action.



Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007 (definition of advanced therapy medicinal product – see Annex A)

- CAL contains viable cells but these cells have not been but these cells have not been subjected to a substantial manipulation.
- The essential function of CAL (formation of adipocytes and vascular cells and maintaining of stem cells in the administrated fat graft) is considered to be the same as in the donor's fat tissue.

Based on the above considerations, it is considered that the product does not fall within the definition of an advanced therapy medicinal product.

EMA/CAT conclusion

On the basis that:

- the cells have not been subjected to a substantial manipulation, and
- the essential function of cells is considered to be the same as in the donor's fat tissue,

the EMA/CAT considers that the product does not fall within the definition of an advanced therapy medicinal product.