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, non-manipulated lipoaspirate containing adipocytes and stromal vascular fraction

Brief description of the proposed finished product

Cryopreserved adipocytes in stromal vascular fraction

Proposed indication

No medical or therapeutic claims are pursued. The product is intended to act as a natural, autologous lipofiller.

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EMA/CAT comment

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

- The product consists of autologous lipoaspirate, containing adipocytes and stromal vascular fraction. The cells are not subjected to substantial manipulation.

- The product acts as a natural, autologous filler. Thus the cells cannot be considered 'engineered' by non-homologous use, as the preparation is intended to be used for the same essential function (restoration of subcutaneous fat tissue) in the recipient site as in the donor site.

Based on the above considerations, it is considered that the product does not fall within the definition of an advanced therapy medicinal product, as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.

EMA/CAT conclusion

On the basis that:

- the product is composed of non-manipulated adipocytes in their natural environment (stromal vascular fraction)
- the product acts as a natural, autologous filler, intended to be used for the same essential function in the recipient site as in the donor site (restoration of subcutaneous fat tissue)

The EMEA/CAT considers that the product does not fall within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.