



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

The product consists of autologous collagen (AC) derived from human adipose tissue.

Brief description of the proposed finished product

Cryopreserved purified autologous collagen in PBS.

Proposed indication

Cosmetic dermal filling.

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 collagen and does not contain cells.
- The product does not contain or consist of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, adding or deleting a genetic sequence.



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 consists of autologous collagen and does not contain cells.
- The product does not contain or consist of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, adding or deleting a genetic sequence.

the EMA/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.