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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

Adult Autologous Regenerative Cells for Subcutaneous Administration

Brief description of the proposed finished product

Suspension of viable, adult, autologous, unexpanded, and uncultured regenerative cells of stromal vascular fraction of subcutaneous adipose tissue.

Proposed indication

The product is indicated for regeneration, repair, or replacement of weakened or injured subcutaneous tissue.

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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 contains viable cells that have not been subjected to a substantial manipulation.

- The mode of action of the product (contribute to and enhance tissue renewal and turnover of the subcutaneous tissue) is considered to be homologous to the donor 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 for homologous use,

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