EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/234882/2019
Inspections, Human Medicines Pharmacovigilance & Committees Division

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.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

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

Autologous viable adipose-derived regenerative cells extracted from human subcutaneous fat from liposuction aspirates obtained by enzymatic isolation (using a proprietary system from manufacturer 2).

Brief description of the finished product

Suspension for injection.

Proposed indication

Treatment of burn scars.

EMA/CAT conclusion

The procedure was finalised on 22 February 2019 for the following recommendation.

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On the basis that the product:

- contains cells that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;
- contains cells which are not intended to be used for the same essential function or functions in the recipient as in the donor and is presented as being administered to human beings with a view to regenerating and repairing a human tissue,

the EMA/CAT considers that the product falls within the definition of a tissue engineered product, as provided in Article 2(1) of Regulation (EC) 1394/2007.