27 October 2016
EMA/693827/2016
Inspections, Human Medicines Pharmacovigilance Division
Committees and Inspections Department

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)

Human autologous stromal vascular fraction cells and human autologous adipose-derived mesenchymal stem cells.

Brief description of the finished product

Stromal vascular fraction of adipose tissue and adipose-derived mesenchymal stem cells expanded in vitro, administrated in fibrin gel.

Proposed indication

Treatment of *cutis laxa senilis.*

EMA/CAT conclusion

The committee adopted on 7 October 2016 the following scientific recommendation.

On the basis that the product:

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- the product consists of engineered cells that have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved,
- the product is administered to human beings with a view to regenerating, repairing or replacing a human tissue,

the EMA/CAT considers that the Product falls within the definition of a tissue engineered product.