23 April 2019
EMA/234869/2019
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.

Brief description of the finished product

Suspension for injection.

Proposed indication

Treatment of progressive hemifacial atrophy (Parry-Romberg syndrome).

EMA/CAT conclusion

The procedure was finalised on 6 February 2019 for the following recommendation.

On the basis that the product:

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- does not contain cells that have been subject to substantial manipulation;
- contains cells that are intended to be used for the same essential function(s) in the recipient,

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) of Regulation (EC) 1394/2007.