



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 October 2017
EMA/699357/2017
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)

Viable autologous adipose-derived regenerative cells.

Brief description of the finished product

Autologous adipose-derived regenerative cells encapsulated in carboxymethylcellulose.

Proposed indication

Autologous dermal filling.

EMA/CAT conclusion

The procedure was finalised on 4 April 2016 for the following recommendation.

On the basis that no medical or therapeutic claims are made, CAT cannot conclude on the classification of this product.

