EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2017
EMA/417402/2017
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)

Allogeneic suspension of unexpanded and uncultured human amniotic fluid-derived cells.

Brief description of the finished product

Allogeneic suspension of unexpanded, uncultured human amniotic fluid-derived cells suspended with dried and cryofractured amniotic tissue.

Proposed indication

Treatment of chronic, non-healing wounds.

EMA / CAT conclusion

The procedure was finalised on 6 June 2017 for the following recommendation.

On the basis that the product:

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- contains engineered cells that are not intended to be used for the same essential function or functions in the recipient as in the donor;
- is administered to human beings with a view to regenerating 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.