EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/575232/2018
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)

Extracellular matrix (ECM) isolated from adipose tissue.

Brief description of the finished product

Adipose tissue derived ECM in physiological solution.

Proposed indication

Treatment of soft tissue damage (fistula-in-ano, trophic ulcers, burns), cartilage defects as well as large tissue damage after cancer resection.

EMA / CAT conclusion

The procedure was finalised on 20 May 2016 for the following recommendation.

On the basis that the product:

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- does not contain an active substance which contains a recombinant nucleic acid administered to human beings with a view to regulate, delete, replace or repair a genetic sequence;
- does not contain or consist of cells or tissues,

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.