



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 August 2018
EMA/575478/2018
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)

Human autologous keratinocytes.

Brief description of the finished product

In vitro cultured human autologous keratinocytes suspended in fibrin sealant.

Proposed indication

Treatment of non-healing wounds, burns, trophic ulcers.

EMA/CAT conclusion

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

On the basis that the product:



- consists of engineered cells or tissues, which 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;
- 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, as provided in Article 2(1) of Regulation (EC) 1394/2007.