19 July 2017
EMA/417460/2017
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)

The active substance of the product is a cell population composed of human dermal fibroblasts and human epidermal keratinocytes.

Brief description of the finished product

Human cultured dermal fibroblasts and human epidermal keratinocytes embedded in/on collagen hydrogel.

Proposed indication

Treatment of partial deep dermal and full thickness burn 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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- 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.