EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Committees Support Division
Scientific Committee Support 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

Brief description (or name where available) of the active substance(s)

Cultured epithelial autografts (CEA); cultured fibroblasts

Brief description of the finished product

Cells seeded on transgenic porcine acellular dermal matrix

Proposed indication

Treatment of deep and extensive burns, chronic wounds, skin donor sites

EMA / CAT conclusion

The committee adopted on 22nd January 2016 the following scientific recommendation.

On the basis that:

- the product Autologous fibroblasts and keratinocytes co-culture seeded on transgenic porcine acellular dermal matrix consists of engineered cells or tissues, which have been subject to substantial

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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 transgenic porcine acellular dermal matrix can be considered an integral medical device component,

the EMA/CAT considers that the product falls within the definition of a tissue engineered product, combined Advanced Therapy Medicinal Product.