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Procedure Management & Business 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)

Viable, autologous keratinocytes and melanocytes grown on AS210 matrix. The active component of tissue engineered dermis consists of viable, autologous fibroblasts.

Brief description of the finished product

Autologous bi-layered skin construct in a three dimensional structure consisting of a fully differentiated reconstructed epidermis on a fibroblast populated dermal matrix.

Proposed indication

Wound healing

EMA/CAT conclusion

On the basis that:

- The product is composed of in vitro expanded, viable autologous human keratinocytes, melanocytes and fibroblasts. The cells are subjected to substantial manipulation and they are cultured and formed to a three dimensional structure in vitro.

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- The product is intended for the treatment of ulcers and is aimed to replace skin and/or regenerate new skin.

- The product does not include a medical device or an active implantable device, combined with the product.

the EMA/CAT considers that the product falls within the definition of a Tissue engineered product.