Scientific recommendation on classification of advanced therapy medicinal products


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)

Allogeneic human keratinocytes and human umbilical cord mesenchymal stem cells

Brief description of the finished product

Cells seeded on acellular dermal matrix

Proposed indication

Treatment of burns and non-healing wounds

EMA/CAT conclusion

The committee adopted on 29th January 2016 the following scientific 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.