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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)

Transgenic porcine acellular dermal matrix

Brief description of the finished product

Decellularized porcine dermal matrix

Proposed indication

Treatment of various skin injuries

EMA/CAT conclusion

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

On the basis that:

The product

- does not contain viable tissue or cells;
- does not contain or consist of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, adding or deleting a genetic sequence.

The EMA/CAT considers that the product does not fall within the definition of an ATMP

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