



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

Short descriptor (or name when available) of the proposed active substance

Ex-vivo expanded autologous human corneal epithelium containing stem cells.

Brief description of the proposed finished product

Ex-vivo expanded autologous human corneal epithelium containing stem cells on human amniotic membrane.

Proposed indication

Ophthalmology: treatment of limbal stem cell deficiency.

EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC (definition of medicinal product – see Annex A)

- The product consists of autologous human corneal epithelium containing stem cells which are considered a 'substance' in accordance with article 1(3) of Directive 2001/83/EC, administered to humans.



- The claim made for this product is for treatment of limbal stem cell deficiency.
- According to Article 1(2), the restoration, correction or modification of the physiological function is to be mediated by the substances that exert "a pharmacological, immunological or metabolic action". As the product consists of viable cells it can be agreed that the product acts via pharmacological, immunological and/or metabolic means.

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007 (definition of advanced therapy medicinal product – see Annex A)

- The product is an epithelial viable cell sheet manufactured using a defined industrial process including an *ex-vivo* cell expansion step, which is considered a substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved. The product is therefore meeting the definition of "engineered cells" as defined in Article 2 (1)(c) of Regulation (EC) No 1394/2007;
- As the product is intended for the corneal epithelial regeneration, it meets the definition of the Tissue Engineered Product as provided in Article 2(1)(b) of Regulation (EC) No 1394/2007.

Based on the above, it is considered that the product falls within the definition of advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007 and falls within the classification of a Tissue Engineered Product as provided in Article 2(b) of the same Regulation.

EMA/CAT conclusion

On the basis that:

- The product is an epithelial viable cell sheet considered to be composed of autologous "engineered cells";
- The product is intended for the corneal epithelial regeneration in patient's cornea meeting the intended action of tissue repair;

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