EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2012
EMA/494515/2012
Patient Health Protection

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

Allogeneic human dermal fibroblasts suspended in hypothermic storage medium

Brief description of the proposed finished product

The product comprises allogeneic human dermal fibroblasts (HDF) derived from neonatal human foreskins suspended in hypothermic storage medium, formulated for intradermal injection.

Proposed indication

Treatment of dermal scars, hypertrophic scars and contractures.

EMA/CAT comment

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

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

- The product is presented as having properties for treating disease in human beings i.e. the treatment of dermal scars, hypertrophic scars and burn contractures caused by partial deep dermal and full thickness burns;
- The substance in the meaning of the pharmaceutical legislation is of human origin i.e. Allogeneic human dermal fibroblasts (HDF) derived from neonatal human foreskins;
- Based on the above considerations, it is considered that the product falls within the definition of a medicinal product

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

- The cells have been subject to substantial manipulations (inter alia cell isolation from foreskin biopsies, cell expansion, cell stocking, final cell culture and formulation for intradermal administration). The product contains or consists of engineered cells or tissues so that biological characteristics, physiological functions and structural properties relevant for the intended regeneration and repair are achieved.
- The mechanism of action and the claimed indication being to contribute to the restoration of a tissue organisation (e.g. the treatment of scars, hypertrophic scars and contractures). The product is presented as having properties for, or is used in, or administered to, human beings with a view to regenerating, repairing or replacing a human tissue.

EMA/CAT conclusion

- On the basis of the elements provided by the company, the EMA/CAT considers that the product falls within the definition of an ATMP.

On the basis that:

- The product contains viable cells of human origin considered as "engineered cells" active substance
- The product is intended for tissue repair
- The EMEA/CAT considers that the product falls within the definition of an 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(c) of the Regulation (EC) No 1394/2007.