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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)

Human amniotic membrane mesenchymal stem cells (hAMMSCs)

Brief description of the finished product

Human amniotic membrane mesenchymal stem cells seeded on acellular dermal matrix

Proposed indication

Treatment of burns, scars, nonhealing wounds

EMA / CAT conclusion

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

On the basis that:

- the product human amniotic membrane mesenchymal stem cells seeded on acellular dermal matrix 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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- 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