



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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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)**

MSCs derived from human burn eschar and debrided adipose tissue cells and keratinocytes

### **Brief description of the finished product**

MSCs isolated from human burn eschar and debrided adipose tissue cells, keratinocytes isolated from skin of living donor seeded onto acellular amniotic matrix

### **Proposed indication**

Treatment of deep and extensive burns, chronic wounds and skin donor sites

### **EMA/CAT conclusion**

The committee adopted on 3<sup>rd</sup> March 2016 the following scientific recommendation.

On the basis that:

- the product co-culture of keratinocytes and hBEDATCs as seeded on acellular amniotic 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 and



- 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.