



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance & Committees Division

## 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.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

### **Brief description (or name when available) of the active substance(s)**

Autologous cultured fibroblasts.

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

Autologous fibroblasts with augmented viability resuspended in physiological saline (0,9 %) sodium chloride ready to skin injection.

### **Proposed indication**

Treatment of tissue loss and to close chronic non-closing injuries (such as diabetic foot and venous ulcers), and treatment of acne scars.

### **EMA/CAT conclusion**

The procedure was finalised on 20 May 2016 for the following recommendation.

On the basis that the product:



- 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;
- 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, as provided in Article 2(1) of Regulation (EC) 1394/2007.