



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

### Brief description of the active substance(s)

Cultured autologous chondrocytes

### Brief description of the finished product

The product consists of cultured autologous chondrocytes in fibrin based excipient of human origin.

### Proposed indication

Treatment of focal non-arthritis cartilage defects of Outerbridge Classification Grade III or IV of the femoral condyle including the trochlea

### EMA/CAT conclusion

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, and administered to human beings with a view to regenerating, repairing and replacing a human tissue.

The EMA/CAT considers that the product falls within the definition of a tissue engineered product, as provided for in Article 2(1)(b) of Regulation (EC) No. 1394/2007.

