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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)

Viable chondrocytes cultured within a 3D hydrogel.

## Brief description of the finished product

Viable chondrocytes cultured within a 3D hydrogel.

## Proposed indication

Treatment of articular cartilage defects of the knee.

## EMA/CAT conclusion

The procedure was finalised on 14 September 2017 for the following recommendation.

On the basis that:

- active substance contains cultured viable chondrocytes and is combined with a three dimensional structure (a hydrogel scaffold) which is part of the finished product;

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

- the product consists of engineered cells, 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, combined advanced therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007.