13 May 2015
EMA/556423/2015
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)

Autologous expanded viable chondrocytes

Brief description of the finished product

Suspension of autologous expanded viable chondrocytes combined with three dimensional structure (biphasic collagen scaffold)

Proposed indication

Articular cartilage defect of the knee

EMA / CAT conclusion

The committee adopted on 13th May 2015 the following scientific recommendation.

On the basis that:

- Active substance contains autologous expanded viable chondrocytes combined with a three dimensional structure (biphasic collagen scaffold)
- The manufacturing process involves substantial manipulation;

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- The product would be indicated for regeneration of cartilage defects.
- The claimed primary mechanism of action of the product is the regeneration, repair, and replacement action.
- The product incorporates, as an integral part, a medical device (biphasic collagen scaffold).

The EMA/CAT considers that the Product falls within the definition of a Tissue engineered product (Combined ATMP) as provided in Article 2 (1)(b) and Article 2 (1) (d) of Regulation (EC) No 1394/2007.