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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)

Autologous expanded viable chondrocytes

Brief description of the finished product

Suspension of autologous expanded viable chondrocytes embedded in a cross linked hydrogel

Proposed indication

Articular cartilage defect

EMA / CAT conclusion

On the basis that:

The committee adopted on 28th October 2015 the following scientific recommendation.

- Active substance contains autologous expanded viable chondrocytes embedded within a hydrogel;
- The manufacturing process involves substantial manipulation;
- 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 EMA/CAT considers that the Product falls within the definition of a tissue engineered product (combined ATMP)

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