



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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)

Allogeneic mesenchymal precursor cells

Brief description of the finished product

Vials containing allogeneic mesenchymal precursor cells

Proposed indication

Treatment of chronic lumbar back pain

EMA/CAT conclusion

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

On the basis that:

- The product contains viable mesenchymal precursor cells;
- The cells have been expanded in culture which is considered substantial manipulation;
- The cells are involved in regeneration, repair or replacement of disc-specific tissue.

The EMA/CAT considers that the product falls within the definition of an advanced therapy medicinal product, tissue engineered product.

