



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 (or name where available) of the active substance(s)

Bone marrow aspirate enriched in autologous mesenchymal stromal cells.

Brief description of the finished product

Bone marrow aspirate enriched in autologous mesenchymal stromal cells.

Proposed indication

Repair of bone in case of bone fracture.

EMA/CAT conclusion

On the basis that:

The product

- does contain cells or tissues with biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement



- does contain cells or tissues that are not intended to be used for the same essential function in the recipient and the donor;
- is presented as having properties for or is administered to human beings with a view to repairing a human tissue.

the EMA/CAT considers that the Product does fall within the definition of a Tissue Engineered Product.