



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 May 2014
EMA/326911/2014
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 substances

Autologous bone marrow cell aspirate in autologous plasma

Brief description of the finished product

Autologous bone marrow cell aspirate in autologous plasma for intra-articular administration

Proposed indication

Treatment of osteoarthritis and osteochondral lesion

EMA/CAT conclusion

On the basis that:

Product

- consists of cells or tissues that are not intended to be used for the same essential functions in the recipient and the donor;
- is presented as having properties for being administered to human beings with a view to regenerating, repairing a human tissue;

the EMA/CAT considers that the Product does fall within the definition of a an advanced therapy medicinal product as a tissue-engineered medicinal product.

