Scientific recommendation on classification of advanced therapy medicinal products


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 osteoarthrosis 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 an advanced therapy medicinal product as a tissue-engineered medicinal product.