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EMA/661080/2013
Patient Health Protection

# 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.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

## Short descriptor (or name when available) of the proposed active substance

Autologous cell concentrate from bone marrow aspirate

## Brief description of the proposed finished product

Concentrate of autologous, uncultured, custom-prepared bone marrow aspirate

## Proposed indication

Avascular necrosis e.g. of the femur head

## EMA/CAT comment

### *Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007 (definition of advanced therapy medicinal product – see Annex A)*

The Bone Marrow Aspirate Concentrate is not an Advanced Therapy Medicinal Product according to the definition in Article 2(1) (b) of Regulation (EC) No 1394/2007 as:

- The product consists of concentrated viable cells from bone marrow aspirate in remaining plasma.

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- The intended indication foresees the use of the product as natural and effective repair mechanism and for the same function – namely bone repair – in the recipient site as in the donor site. Indeed bone marrow cells are actively involved in non-haematopoietic functions. Bone marrow cells have been shown to demonstrate Osteopoesis as follows:
    - Nonmesenchymal Bone Marrow stem/progenitor cells are active in osteoblast formation.
    - Bone Marrow hematopoietic stem and progenitors cells were able to differentiate in the both hematopoietic and osteocytic pathways.
    - Certain stromal cells do not contribute to hematopoietic reconstitution.

Therefore, the product is intended to be used for the same essential functions in the recipient as in the donor. Hence it can be concluded that the product shall be considered 'for homologous use´.
Based on the above considerations, it is considered that BMAC does not fall within the definition of an Advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.

# EMA/CAT conclusion

On the basis that,
- The product is presented as having properties for regenerating a human tissue;
- The product contains viable human cells
- The product harvested from bone marrow is intended to be used for the same essential function after re-administration by bolus injection via cannulated drill into the necrotic bone segment (i.e. femur head) for bone regeneration.

the EMA/CAT considers that the product does not fall within the definition of an Advanced Therapy Medicinal Product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.