22 November 2016
EMA/758163/2016
Inspections Human Medicines Pharmacovigilance Division
Committees and Inspections 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.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

Brief description (or name when available) of the active substance(s)

Bone marrow-derived autologous non-haematopoietic stem cells.

Brief description of the finished product

Cell suspension for infusion.

Proposed indication

Multiple sclerosis.

EMA/CAT conclusion

The committee adopted on 4 November 2016 the following recommendation.

On the basis that the product:

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- Consists of engineered cells that are not intended to be used for the same essential function or functions in the recipient as in the donor;
- is administered to human beings with a view to treating a disease through the metabolic/ immunological action of the active substance and repair/regeneration of a human tissue,

the EMA/CAT considers that the Product falls within the definition of a tissue engineered product as provided in Article 2(4) of Regulation (EC) No 1394/2007.