



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)

Allogeneic cord blood cells, *ex vivo* modulated with 16,16 dimethyl prostaglandin E2

Brief description of the finished product

Cell suspension for IV administration

Proposed indication

Treatment of patients undergoing a haematopoietic stem cell transplantation

EMA/CAT conclusion

On the basis that:

- the product contains viable cells of human origin;
- the cells are substantially manipulated;
- the product is presented as having properties for, or is administered to human beings with a view to treating a disease; and



- the mechanism of action fulfils aspects of both (a) somatic cell therapy (immunological, metabolic and pharmacological action) and (b) tissue engineering (regeneration, repair and replacement of tissue)

The EMA/CAT considers that the Product falls within the definition of a Tissue Engineered Product as provided for in Article 2(4) of Regulation (EC) No. 1394/2007.