



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Committees 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)

Bone marrow-derived autologous non-hematopoietic stem cells

Brief description of the finished product

Bone marrow-derived autologous non-hematopoietic stem cells suspended in PBS/EDTA buffer enriched with 0.5% human serum albumin

Proposed indications

Treatment of patients after ischemic stroke

EMA/CAT conclusion

The committee adopted on 21st December 2015 the following scientific recommendations.

On the basis that the product:

- 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 regenerating, repairing or replacing a human tissue

the EMA/CAT considers that the product falls within the definition of a tissue engineered product.