



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 April 2017
EMA/270760/2017
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)

Autologous bone marrow derived mesenchymal stem cells.

Brief description of the finished product

Cryopreserved or fresh suspension of autologous mesenchymal stem cells.

Proposed indication

Coma (traumatic brain injury, stroke).

EMA/CAT conclusion

The procedure was finalised on 29 March 2017 for the following recommendation.

On the basis that:



- the product is intended to be used for the treatment of coma caused by traumatic brain injury or by stroke;
- the product contains human cells;
- the cells have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;
- the cells are administered to human beings with a view to treating a disease through their pharmacological action,

the EMA/CAT considers that the Product falls within the definition of a somatic cell therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007.