21 February 2017
EMA/126953/2017
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)

Allogeneic cytomegalovirus-specific cytotoxic T lymphocytes.

Brief description of the finished product

Suspension for Injection.

Proposed indication

Treatment of Cytomegalovirus-associated viraemia or disease after allogeneic haematopoietic cell transplant or solid organ transplant after failure of at least two different antiviral therapies.

EMA/CAT conclusion

The procedure was finalised on 27 January 2017 for the following recommendation.

On the basis that the product:

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- consists of cells that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;
- is presented as having properties for / administered to human beings with a view to treating and / or preventing a disease through the immunological action of its cells,

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.