21 March 2019
EMA/189324/2019
Inspections, Human Medicines Pharmacovigilance & Committees Division

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 cultured postnatal thymus tissue-derived product.

Brief description of the finished product

Cultured thymus tissues slices.

Proposed indication

Treatment of immune reconstitution in patients with congenital athymia.

EMA/CAT conclusion

The procedure was finalised on 20 December 2018 for the following recommendation.

On the basis that:

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- the product consists of engineered tissue, which has been subject to substantial manipulation so that the biological characteristics, physiological functions or structural properties relevant for the intended repair or replacement are achieved;
- the product is administered to human beings with a view to repairing or replacing a human tissue,

the EMA/CAT considers that the product falls within the definition of a tissue engineered product, as provided in Article 2(1) of Regulation (EC) 1394/2007.