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EMA/235526/2019
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, *ex vivo* expanded, umbilical cord blood-derived, haematopoietic CD34+ progenitor cells, and allogeneic, non-expanded, umbilical cord blood-derived, haematopoietic mature myeloid and lymphoid cells.

Brief description of the finished product

Suspension of cells in cryopreservation solution.

Proposed indication

Haematopoietic reconstitution of patients who are medically indicated for allogeneic haematopoietic stem cell transplantation.

EMA/CAT conclusion

The procedure was finalised on 28 March 2019 for the following recommendation.

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On the basis that:

- the *ex vivo* expanded cell fraction of the product consists of cells that have been exposed to substantial manipulation;
- the product is administered to human beings with a view to replacing and repairing human tissue,

the EMA/CAT considers that the *ex vivo* expanded cell fraction of the product to be used in combination with the non-expanded fraction falls within the definition of a tissue engineered product, as provided in Article 2(1) of Regulation (EC) 1394/2007.