19 July 2017
EMA/416862/2017
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 human mesenchymal stem cells derived from Wharton's jelly tissue of umbilical cord.

Brief description of the finished product

Cryopreserved or fresh suspension of allogeneic mesenchymal stem cells.

Proposed indication

Treatment of Chronic obstructive pulmonary disease (COPD).

EMA/CAT conclusion

The procedure was finalised on 6 June 2017 for the following recommendation.

On the basis that:

- the product is intended to be used for the treatment of chronic obstructive pulmonary disease;

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- the product contains human cells;
- the product consists of engineered cells, which have been subject to substantial manipulation;
- the cells are administered to human beings with a view to treating a disease through their pharmacological, immunological or metabolic action;
- the product is administered to human beings with a view to regenerating, repairing or replacement a human tissue,

the EMA/CAT considers that the Product falls within the definition of a tissue engineered product as provided in Article 2(4) of Regulation (EC) 1394/2007.