22 November 2016
EMA/758391/2016
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)

Wharton jelly derived allogeneic mesenchymal stem cells, cultured *in vitro*.

Brief description of the finished product

Cell suspension.

Proposed indication

Acute myocardial infarction, chronic ischaemic heart failure, no-option critical limb ischaemia.

EMA/CAT conclusion

The committee adopted on 4 November 2016 the following recommendation.

On the basis that the product:

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- consists of engineered cells which have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved and;
- is presented as having properties for and is used in or administered to human beings to regenerate 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) No 1394/2007.