25 April 2016
EMA/291903/2016
Procedure Management & Committees Support Division
Scientific Committee Support 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

Brief description (or name where available) of the active substance(s)

Human adult allogenic mesodermal progenitor cells

Brief description of the finished product

Human adult allogenic mesodermal progenitor cells suspended in solution

Proposed indication

Treatment of incomplete revascularisation as an adjunct to CABG in patients with congenital coronary artery malformations

EMA / CAT conclusion

The committee adopted on 29th January 2016 the following scientific recommendation.

On the basis that:

The product:

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- consists of engineered cells or tissues, 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,

- is administered to human beings with a view to regenerating and repairing a human tissue

the EMA/CAT considers that the product falls within the definition of a tissue-engineered product.