01 April 2016
EMA/240965/2016
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)

Viable adipose-derived regenerative cells extracted from human abdominal subcutaneous fat

Brief description of the finished product

Suspension of adipose derived regenerative cells encapsulated in hyaluronic acid

Proposed indication

Treatment of articular cartilage and bone defects including osteoarthrosis or osteochondral lesions

EMA / CAT conclusion

The committee adopted on 25th November 2015 the following scientific recommendation.

On the basis that:

- the product consists of engineered cells that have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the

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intended regeneration, repair or replacement are achieved, and that are not intended to be used for the same essential function or functions in the recipient as in the donor,

- the product is administered to human beings with a view to regenerating, repairing or replacing a human tissue,
- the product incorporates, as an integral part of the product a medical devices, hyaluronic acid

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