EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 July 2014
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Procedure Management & Business 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

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

Viable autologous adipose tissue-derived mesenchymal stem cells

Brief description of the finished product

The product is a suspension of viable autologous adipose tissue-derived mesenchymal stem cells (ADSCs) in Hyaluronic Acid contained within a sterile, single-use syringe, ready to be implanted intra-articularly.

Proposed indication

Treatment of degenerative arthritis, osteoarthritis (OA), articular cartilage defects in the knee, ankle or hip joints.

EMA/CAT conclusion

On the basis that:

The product:

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(a) Consists of cells that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered
(b) is administered to human beings with a view to regenerating, repairing or replacing a human tissue.

EMA/CAT considers that the Product falls within the definition of Tissue Engineered Product as provided in Article 2(1) of Regulation (EC) No 1394/2007.