4 April 2016
EMA/556256/2015
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)

Allogeneic ex-vivo expanded placental mesenchymal-like adherent stromal cells

Brief description of the finished product

Cell dispersion for parenteral use

Proposed indication

Treatment of Peripheral Arterial Occlusive Disease (PAOD)

EMA/CAT conclusion

The committee adopted on 17th April 2015 the following scientific recommendation.

On the basis that:

- the product consists of viable cells that have been subject to substantial manipulation, so that the biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;

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- the product is to be administered to human beings with a view to treating a disease through the pharmacological action, and also by regenerating or repariring human tissues, via the excretion of various growth or paracrine factors

the EMA/CAT considers that the product falls within the definition of both somatic cell therapy medicinal product and tissue engineered product and based on that is considered as Tissue Engineered Product as provided in Article 2(4) of Regulation (EC) No 1394/2007.