3 May 2018
EMA/277112/2018
Inspections, Human Medicines Pharmacovigilance & Committees Division

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)

Autologous enriched CD31+ cell fraction from peripheral blood**.**

Brief description of the finished product

CD31+ cells embedded in a fibrin induced blood clot.

Proposed indication

Surgical care of bone fractures**.**

EMA/CAT conclusion

The procedure was finalised on 28 March 2018 for the following recommendation.

On the basis that the product:

- does not contain cells that have been subject to substantial manipulation;

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- does contain cells that are intended to be used for the same essential function(s) in the recipient and the donor,

the EMA/CAT considers that the product does not fall within the definition of an advance therapy medicinal product, as provided in Article 2(1) of Regulation (EC) 1394/2007.