13 November 2017
EMA/751584/2017
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)

Freshly isolated autologous CD34+.

Brief description of the finished product

Freshly isolated autologous CD34+ suspended in platelet-rich fibrin.

Proposed indication

Regeneration of soft and hard tissues of temporomandibular joints.

EMA/CAT conclusion

The procedure was finalised on 17 October 2017 for the following recommendation.

On the basis that the product:

- consists of cells which are not intended to be used for the same essential function(s) in the recipient and the donor;

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- is presented as having properties for, or is administered to human beings with a view to treating a disease through the pharmacological, action of its cells;
- is administered to human beings with a view to regenerate or repair a human tissue,

the EMA/CAT considers that the product falls within the definition of a tissue engineered product, combined advanced therapy medicinal product as provided in Article 2(4) of Regulation (EC) 1394/2007.