16 November 2015
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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)

Ex vivo expanded human umbilical tissue-derived cells

Brief description of the finished product

Suspension of *ex vivo* expanded human umbilical tissue-derived cells

Proposed indication

Improvement of visual acuity in patients with vision loss from geographic atrophy secondary to age-related macular degeneration.

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EMA/CAT conclusion

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

- The product consists of a suspension of *ex vivo* expanded human umbilical tissue-derived cells. The cells have been subjected to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered.
- The cells are acting through the secretion of factors that result in the preservation of the RPE function.

Based on the above considerations, EMA/CAT considers that the product falls within the definition of somatic cell therapy medicinal product as provided in Article 2 (1) (a) of Regulation (EC) No 1394/2007.