16 March 2016
EMA/204251/2016
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)

Autologous engineered anti-CD19 Chimeric Antigen Receptor (CAR+) T-cells

Brief description of the finished product

Suspension of CAR+ T-cells

Proposed indication

Treatment of various types of cancer

EMA/CAT conclusion

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

On the basis that:

-the product contains an active substance which contains a recombinant nucleic acid administered to human beings with a view to adding a genetic sequence;

-its therapeutic effect relates directly to the product of genetic expression of this sequence.

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The EMA/CAT considers that the product falls within the definition of a Gene Therapy Medicinal Product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.