EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 October 2017
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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)

DNA plasmid encoding for the extracellular domain of human TNFα p55 receptor linked to the human IgG1 Fc domain.

Brief description of the finished product

Solution to be injected into the ciliary muscle.

Proposed indication

Treatment of refractory chronic non-infectious uveitis.

EMA/CAT conclusion

The procedure was finalised on 4 April 2016 for the following recommendation.

On the basis that:

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- the product contains a biological medicinal product as the active substance;
- the product is administered to humans with the view of adding a genetic sequence;
- the therapeutic effect of the medicinal product relates directly to the product of genetic expression of this sequence,

the EMA/CAT considers that the product falls within the definition of a gene therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007.