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EMA/235528/2019
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)

In vitro transcribed messenger RNA molecules encoding IFNα2b, IL-12, IL-15sushi and GM-CSF cytokines.

Brief description of the finished product

Concentrate for solution for intratumoral injection.

Proposed indication

Treatment of solid tumours.

EMA/CAT conclusion

The procedure was finalised on 28 March 2019 for the following recommendation.

On the basis that:

- the product contains a biological medicinal product as the active substance;

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- the active substance is recombinant nucleic acids administered to human beings with a view to adding genetic sequences;
- its therapeutic effect relates directly to the products of genetic expression of these sequences,

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.