



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

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.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

Short description of the proposed active substance

Pseudomonas aeruginosa bacteria genetically modified to secrete oncoproteins of Merkel cell carcinoma

Brief description of the proposed finished product

Solution or powder for suspension for injection

Proposed indication

Treatment of Merkel Cell Carcinoma

EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC

- The product consists of genetically modified *Pseudomonas aeruginosa*, containing a recombinant plasmid expressing oncogenes which can be considered a 'substance' in the meaning of the pharmaceutical legislation (in accordance with article 1(3) of



Directive 2001/83/EC), which is administered to humans with a view to restoring physiological functions.

- The product is presented as having properties for treating a disease in human beings: Treatment of Merkel Cell Carcinoma

According to Article 1(2), the restoration, correction or modification of the physiological function is to be mediated by the substances that exert “a pharmacological, immunological or metabolic action”. The product fulfils the conditions expressed in Article 1(2) of Directive 2001/83/EC, as it is presented as acting via immunological means.

Based on the above, it is considered that the product, as presented, falls within the definition of a medicinal product.

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007

- The active substance consists of genetically modified *Pseudomonas aeruginosa* containing a recombinant nucleic acid.
- The medicinal product is used or administered to human beings 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

Based on the above, it is considered that the product falls within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007 and more specifically under the definition of a gene therapy medicinal product.

EMA/CAT conclusion

On the basis that:

- The medicinal product consists of genetically modified *Pseudomonas aeruginosa* containing a recombinant plasmid expressing oncogenes.
- The medicinal 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 by majority that the product falls within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007 and more specifically under the scope of the definition of a gene therapy medicinal product.