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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

Brief description (or name where available) of the active substance(s)

The active substance is a double-stranded naked DNA plasmid encoding an inactive human telomerase reverse transcriptase protein fused to ubiquitin

Brief description of the finished product

The product is a sterile solution for intradermal injection in the arm and/or the upper part of the thighs followed by electroporation under local anaesthesia.

Proposed indication

Immunotherapy for the treatment of various malignancies and the prevention of tumour relapse

EMA/CAT conclusion

On the basis that the product:

a) contains an active substance that consists of a plasmid nuclear acid sequence that is directly related to the transient local expression and processing of the Ubi-hTERT fusion protein, which subsequently specifically stimulates the patient's immune system to mount an immune response against telomerase over-expressing tumor cells;

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b) is administered to human beings with a view to treating various malignancies and preventing tumour relapse through an immunological action;

c) does not contain any cells or tissues

the EMA/CAT considers that the Product falls within the definition of a Gene therapy medicinal product.