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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 descriptor (or name when available) of the proposed active substance

The product contains a suspension of oncolytic adenovirus.

Brief description of the proposed finished product

The product is formulated as solution for intra-venous injection.

Proposed indication

Treatment of colorectal cancer.

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007 (definition of advanced therapy medicinal product – see Annex A)

The product is a chimeric adenovirus obtained by a process of bio-selection. As such, it contains no additional gene. Its mechanism of action is through the direct infection and replicating-lysing properties of the virus and not through the action of any recombinant nucleic acid sequence or to the product of genetic expression of this sequence.

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Based on the above considerations, it is considered that the product does not fall within the definition of an advanced therapy medicinal product.

EMA/CAT conclusion

On the basis of the various elements put forward by the company, the EMA/CAT considers that the product does not fall within the definition of an ATMP.