EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Committees 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)

Live-attenuated, double-deleted *Listeria monocytogenes* expressing human mesothelin

Brief description of the finished product

Suspension of live-attenuated, double-deleted *Listeria monocytogenes* expressing human mesothelin for intravenous infusion

Proposed indication

Treatment of malignant pleural mesothelioma

EMA / CAT conclusion

The committee adopted on 25th September 2015 the following scientific recommendation.

On the basis that:

- The product contains an active substances which contains a recombinant nucleic acid that is administered to human with a view of adding a genetic sequence; and

- Its therapeutic effect relates directly to the product of genetic expression of this sequence

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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) No 1394/2007.