EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 plasmid encoding a mutation-inactivated E7-E6 fusion protein from Human Papillomavirus 16 linked to the human chemokine hMIP-1α via a dimerization module derived from human IgG3.

Brief description of the finished product

A sterile solution for injection.

Proposed indication

Prevention and treatment of HPV16 induced pre-malignancies and malignancies.

EMA/CAT conclusion

On the basis that:

- The product is presented as having properties for treating of a disease in human beings: prevention and treatment of HPV16 induced pre-malignancies and malignancies.

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- The medicinal product consists of a genetically modified DNA plasmid containing a recombinant nucleic acid expressing a fusion protein consisting of the oncoproteins HPV E6/E7 and the cytokine human MIP 1-α.

- 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 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.