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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)

Adenovirus serotype 5 expressing the Core protein, the Polymerase protein and selected domains of the Envelope protein of Hepatitis B Virus

## Brief description of the finished product

Sterile suspension of viral particles

## Proposed indication

Treatment of chronic hepatitis B

## EMA / CAT conclusion

The committee adopted on 3rd March 2016 the following scientific recommendation.

With reference to Section 2.1 of Part IV of Annex I to Directive 2001/83/EC, which stipulates that gene therapy medicinal products shall not include vaccines against infectious disease, the EMA/CAT considers that the product does not fall within the definition of an advanced therapy medicinal product as provided in the article 2(1)(a) of the Regulation (EC) No 1394/2007.

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