EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance & Committees Division

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.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

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

Four independent DNA plasmid vectors encoding respectively the HBV genotype A consensus large surface antigen (LHBs-A), the HBV genotype C consensus large surface antigen (LHBs-C), the HBV genotype A, B, C, D and E consensus core antigen (HBc) and human interleukin-12.

Brief description of the finished product

Combination of four individual plasmids into one finished product.

Proposed indication

Antigenic clearance of chronic hepatitis B virus infection.

EMA / CAT conclusion

The procedure was finalised on 15 July 2016 for the following 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

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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.