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)

Dystrophin expressing chimeric cells obtained by *ex vivo* fusion of defective myoblasts from a Duchenne Muscular Dystrophy patient with normal myoblasts.

Brief description of the finished product

Suspension for injection.

Proposed indication

Treatment of Duchenne muscular dystrophy.

EMA/CAT conclusion

The procedure was finalised on 5 July 2018 for the following recommendation.

On the basis that the product:

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- consists of cells, which have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration are achieved;
- is administered to human beings with a view to repairing a human tissue,

the EMA/CAT considers that the product falls within the definition of a tissue engineered product, as provided in Article 2(1) of Regulation (EC) 1394/2007.