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 of the active substance

Ex vivo expanded autologous skeletal myoblasts.

Brief description of the finished product

The finished product is a cell suspension containing autologous skeletal myoblasts.

Proposed indication

The product is intended for treatment of oculopharyngeal muscular dystrophy.

EMA/CAT conclusion

On the basis that:

- The final product is composed of *in vitro* expanded, viable skeletal muscle cells. The cells are subject to substantial manipulation; following dissociation form the muscle tissue, cells are cultured in vitro in order to achieve the number of cells needed for administration.

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- The product is intended for the treatment of oculopharyngeal muscular dystrophy. In the final *in vivo* muscle environment, the cells are expected to regenerate/replace the diseased muscle tissue.

- The product does not include a medical device or an active implantable device, combined with the product.

the EMA/CAT considers that the product falls within the definition of a Tissue engineered product.