EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

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.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

Short descriptor (or name when available) of the proposed active substance

Autologous skeletal muscle-derived-cells.

Brief description of the proposed finished product

The finished product consists in an autologous skeletal muscle-derived cells injection suspension.

Proposed indication

The product is intended for the repair of deficient external anal sphincter in patients suffering from faecal incontinence.

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EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC (definition of medicinal product – see Annex A)

- The product consists of human autologous skeletal muscle-derived cells which can be considered a 'substance' in the meaning of the pharmaceutical legislation (in accordance with article 1(3) of Directive 2001/83/EC), administered to humans with a view to correcting/restoring a physiological function.
- The product is presented as having properties for treating disease in human being: it is intended for repair of deficient external anal sphincter in patients suffering from faecal incontinence.

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007 (definition of advanced therapy medicinal product – see Annex A)

- The product manufacturing process includes culture and expansion of the cells which has been considered as a substantial manipulation.
- The product is intended to promote regeneration and repair of the external anal sphincter in patients suffering from faecal incontinence.

Based on the above considerations, it is considered that the product falls within the definition of an advanced therapy medicinal product, and more specifically of a Tissue engineered product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.

EMA/CAT conclusion

On the basis that:

- The product consists of engineered cells,

- The product is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing 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)(a) of Regulation (EC) No 1394/2007.