



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 mesenchymal stem cells (MSC) committed to cardiovascular lineage.

Brief description of the proposed finished product.

Autologous MSC committed to cardiovascular lineage suspended in cryopreservation medium.

Proposed indication

Treatment of chronic heart failure symptoms by improvement in exercise capacity of NYHA class II and III chronic heart failure patients receiving standard therapy.



EMA/CAT comment

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

- The product consists of autologous mesenchymal stem 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 of regenerating tissues.
- The product is presented as having properties for treating disease in human being.
- According to Article 1(2), the restoration, correction or modification of the physiological function is to be mediated by the substances that exert "a pharmacological, immunological or metabolic action". As the product consists of autologous mesenchymal stem cells, it can be agreed that the product acts via metabolic means.

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

- The product is intended to be placed on the market in the Member States. It will be manufactured under GMP methodologies at an external facility and is therefore regarded as manufacturing by a method involving an industrial process.
- The product can be considered as a not combined ATMP and a tissue engineered product according to the definition in Article 2(1)(b) of Regulation (EC) No 1394/2007 as:
 - it contains engineered cells according to the definition of Article 2(1)(c) second paragraph of Regulation (EC) No 1394/2007, and;
 - it is administered to human beings with a view of regenerating a human tissue;
 - it does not contain medical devices as an integral part of the product and its cellular part contains viable cells.

Based on the above considerations, it is considered 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.

EMA/CAT conclusion

On the basis that:

- The product contains engineered cells according to the definition of Article 2(1)(c) second paragraph of Regulation (EC) No 1394/2007, and
 - The product is administered to human beings with a view to regenerating a human tissue,
 - The product does not contain medical devices as an integral part of the product and its cellular part contains viable cells.

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.