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

Bone marrow derived autologous suspensions of hematopoietic and mesenchymal stem cells depleted from erythrocytes and lymphocytes.

Brief description of the proposed finished product

The product consists of bone marrow derived autologous hematopoietic and mesenchymal stem cells obtained by centrifugation and depleted from erythrocytes and lymphocytes and suspended in autologous serum. The product is aseptically produced and filled in a final container for intrathecal administration.

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Proposed indication

The medicinal product is intended for the treatment of complete or incomplete traumatic spinal cord injury.

EMA/CAT comment

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

- The product consists of bone marrow derived autologous suspensions of hematopoietic and mesenchymal stem cells depleted from erythrocytes and lymphocytes 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 restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.
- The product is presented as having properties for treating or preventing disease in human being. It is intended for the treatment of complete or incomplete traumatic spinal cord injury.
- 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". The product consists of bone marrow derived autologous suspensions of hematopoietic and mesenchymal stem cells depleted from erythrocytes and lymphocytes, it can be agreed that the product acts via pharmacological, immunological or metabolic action means.

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

- The product consists of bone marrow derived autologous hematopoietic and mesenchymal stem cells depleted from erythrocytes and lymphocytes. All manufacturing steps to which the cells are subjected are included in Annex I of the Regulation (EC) No 1394/2007 listing the manipulations considered as non substantial. The cells are thus not subjected to substantial manipulation.
- The product consists of bone marrow derived cells which will be injected intrathecally to treat complete or incomplete traumatic spinal cord injury. The cells or tissues are thus not intended to be used for the same essential function or functions in the recipient site as in the donor site.
- The administration intends to reduce paralysing the effect of the injury by decreasing apoptosis, reducing glial scar tissue, promoting tissue reconstruction and regrowth of functional nerve fibres. It is thus presented as having properties for regenerating, repairing or replacing a human tissue.

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)(b) of Regulation (EC) No 1394/2007.

EMA/CAT conclusion

On the basis that:

- The product consists of bone marrow derived autologous hematopoietic and mesenchymal stem cells depleted from erythrocytes and lymphocytes which have not been subjected to substantial manipulation.

- The cells or tissues are not intended to be used for the same essential function or functions in the recipient site as in the donor site: the product consists of bone marrow derived cells which will be injected intrathecally to treat complete or incomplete traumatic spinal cord injury.

- The product is intended to reduce the paralysing effect of the injury by decreasing apoptosis, reducing glial scar tissue, promoting tissue reconstruction and regrowth of functional nerve fibres. It is thus presented as having properties for regenerating, repairing or replacing a human tissue.

The EMEA/CAT considers that the product falls within the definition of a tissue engineered product as provided in Article 2(1)(b) of Regulation (EC) No 1394/2007.