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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 description of the proposed active substance

Mesenchymal stem cells suspension extracted from bone (Ilium) marrow and cultivated during 18 days.

Brief description of the proposed finished product

Autologous bone marrow-derived mesenchymal stem cells suspension.

Proposed indication

Treatment of chronic myocardial ischemia with left ventricular dysfunction.

EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC

Autologous bone marrow-derived mesenchymal stem cells can be considered as 'substance' in the meaning of the pharmaceutical legislation (in accordance with Article 1(3) of Directive 2001/83/EC), which is administered to humans with a view to restoring physiological functions. The product is presented as having properties for treating and preventing disease in human being:
Treatment of chronic myocardial ischemia with left ventricular dysfunction.

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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 fulfils the conditions expressed in Article 1(2) as they act *via* metabolic means.

The product should thus be considered as a medicinal product.

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007

Based on the current knowledge of the proposed mechanism of action, Autologous bone marrow-derived mesenchymal stem cells:

(1)contain or consist of engineered cells or tissues
- the cells or tissues have been subject to substantial manipulation, as they are cultivated during 18 days, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved
- the cells or tissues are not intended to be used for the same essential function in the recipient as in the donor, the cells are injected in an infarct area in view to commit cardiomyocytes and/or paracrine effect of these cells

(2) are 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: cardiac tissue.

Based on the above considerations, it is considered that Autologous bone marrow-derived Mesenchymal cells do fall within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007 and more specifically under the scope of the definition of tissue engineered product: the Autologous bone marrow-derived Mesenchymal cells are intended to treat Chronic Myocardial Ischemia with left ventricular dysfunction via cells differentiation into cardio-myocytes and/or paracrine effect of this cells.

EMA/CAT conclusion

On the basis of that, the EMA/CAT considers the product does fall within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007 and more specifically under the scope of the definition of tissue engineered product: autologous bone marrow-derived mesenchymal stem cells are intended to treat chronic myocardial ischemia with left ventricular dysfunction via cells differentiation into cardiomyocytes and/or paracrine effect of these cells