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

Allogeneic Mesenchymal Precursor Cells (MPCs)

## Brief description of the proposed finished product

MPCs suspended in a freezing solution.

## Proposed indication

The product is indicated for treatment of rheumatoid arthritis.

## EMA/CAT comment

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

- The product consists of allogeneic mesenchymal precursor cells (MPCs) 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 rheumatoid arthritis.

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- 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 mesenchymal stromal cells, it can be agreed that the product acts via pharmacological, metabolic or immunological means.

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

- The product contains living cells.
- The product has been subject to substantial manipulation such as immunoselection and expansion in culture.
- The underlying mechanism of action for this effect is not completely elucidated. The applicant states that mesenchymal cells may ameliorate the symptoms of rheumatoid arthritis via several mechanisms acting in concert, including the induction/activation of T-reg cells, establishment of T-cell anergy and/or a shift in TH1/TH2 responses with reduced levels of proinflammatory cytokines such as TNF-alpha, IL-6, IL-17 and MCP-1, and increased anti-inflammatory cytokines such as IL-10. It can be agreed therefore that the product has immunomodulatory activities that can be used to treat rheumatoid arthritis.

Based on the above considerations, it is considered that the product falls within the definition of Somatic Cell therapy medicinal 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 substantially manipulated living cells

- The product is presented as having properties for treating a disease in human being

- The product is presented as acting via immunological means

The EMEA/CAT considers that the product falls within the definition of somatic cell therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.