



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/534818/2017  
Inspections Human Medicines Pharmacovigilance Division  
Committees and Inspections Department

## 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.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

### **Brief description (or name when available) of the active substance(s)**

Stromal vascular fraction cells.

### **Brief description of the finished product**

Suspension of cells.

### **Proposed indication**

The product is indicated to relieve symptoms of osteoarthritis.

### **EMA/CAT conclusion**

The procedure was finalised on 30 June 2017 for the following recommendation.

On the basis that the product:



- contains cells that are not intended to be used for the same essential function in the recipient and the donor;
- is administered to human beings with a view to treating a disease through the pharmacological and immunological action of its cells,

the EMA/CAT considers that the product falls within the definition of a somatic cell therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007.