



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Procedure Management & Committees Support Division  
Scientific Committee Support 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

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

Human mesenchymal stem cells derived from bone marrow

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

Autologous bone marrow derived mesenchymal stem cells suspended in freezing solution

### **Proposed indication**

Amyotrophic lateral sclerosis (ALS)

### **EMA/CAT conclusion**

The committee adopted on 27th October 2015 the following scientific recommendation.

On the basis that:

- the product is intended to be used for the treatment of Amyotrophic lateral sclerosis (ALS),
- the product consists of human cells,



- the cells have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered
- the cells are administered to human beings with a view to treating a disease through their pharmacological, or metabolic action

the EMA/CAT considers that the product, Autologous bone marrow derived mesenchymal stem cells suspended in freezing solution falls within the definition of a somatic cell therapy product.