



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

01 April 2016  
EMA/240988/2016  
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)**

Mesenchymal stem cells isolated from umbilical cord

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

Mesenchymal stem cells isolated from umbilical cord as a sheet

### **Proposed indication**

Burns, non-healing wounds

### **EMA/CAT conclusion**

The committee adopted on 29<sup>th</sup> January 2016 the following scientific recommendation.

On the basis that the product:

- consists of cells have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement have been altered,



- the cells are administered to human beings with a view to regenerating, repairing or replacing a human tissue,

the EMA/CAT considers that the Product falls within the definition of a tissue engineered product.