



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Procedure Management & Business 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 Wharton's jelly tissue of umbilical cord

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

Allogeneic, human Wharton's jelly derived mesenchymal stem cells suspended in freezing solution

### **Proposed indication**

Acute and chronic Graft-versus-Host Disease.

### **EMA/CAT conclusion**

On the basis that:

- the product is intended to be used for the treatment of acute and chronic Graft-versus-Host Disease
- 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, immunological or metabolic action

the EMA/CAT considers that the product Allogeneic, human Wharton's jelly derived mesenchymal stem cells suspended in freezing solution falls within the definition of a somatic cell therapy medicinal product as provided for in Article 2(1)(a) of Regulation (EC) No. 1394/2007.