



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**

Cerebral palsy

### **EMA/CAT conclusion**

On the basis that:

- the product is intended to be used for the treatment of cerebral palsy,
- 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 (but excluding the manipulations listed in Annex I to Regulation (EC) No 1394/2007,

- the proposed mechanism of action is based on the regeneration, repair or replacement of human tissue.

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