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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 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

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,

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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- 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, allogeneic Wharton's jelly derived mesenchymal stem cells suspended in freezing solution falls within the definition of a somatic cell therapy product.