17 April 2015
EMA/556059/2015
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)

Autologous mononuclear cells derived from human cord blood

Brief description of the finished product

Autologous mononuclear cells derived from human cord blood

Proposed indication

Paediatric brain damage, hypoxic-ischaemic encephalopathy, and cerebral palsy

EMA / CAT conclusion

The committee adopted on 17th April 2015 the following scientific recommendation.

On the basis that:

- The product contains viable cord blood cells
- The cells do not undergo substantial manipulation

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- The cells are not intended for the same essential function
- The cells are considered as having properties for regenerating, repairing or replacing a human tissue.

The EMA/CAT considers that the Product falls within the definition of a Tissue Engineered Product as provided in Article 2 (1)(b) of Regulation (EC) No 1394/2007.