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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)

Allogeneic peripheral blood mononuclear cells induced to an early apoptotic state

Brief description of the finished product

Cell suspension for intravenous administration

Proposed indication

Prevention of graft versus host disease

EMA/CAT conclusion

On the basis that:

- the product is intended to be used for prevention of graft versus host disease,

- the product consists of human cells,

- the manufacturing process includes substantial manipulation that leads to changes in the cell characteristics (early apoptotic state) relevant for its intended use,

- the proposed mechanism of action is based on the immunological action

the EMA/CAT considers that the product falls within the definition of a somatic cell therapy product.

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