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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)

Autologous mature dendritic cells pulsed with tumour antigen-derived synthetic peptides (MAGE-1, HER-2, AIM-2, TRP-2, gp100, and IL-13Rα2)

Brief description of the finished product

Cell suspension for injection

Proposed indication

Treatment of glioblastoma

EMA/CAT conclusion

On the basis that:

- the product consists of viable cells that have been subject to substantial manipulation, so that the biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered,

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 product is to be administered to human beings with a view to treating a disease through the immunological action,

the EMA/CAT considers that the product falls within the definition of a somatic cell therapy medicinal product as provided in Article 2 (1) of Regulation (EC) No 1394/2007.