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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 activated leukocytes

Brief description of the finished product

Suspension of allogeneic unrelated, buffy coat-derived and activated viable leukocytes in donor serum

Proposed indication

Treatment of chronic lower extremity ulcers in adult diabetic patients.

EMA/CAT conclusion

On the basis that product:

(a) contains somatic cells that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;

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(b) is presented as having properties for, or is administered to human beings with a view to treating a disease through the pharmacological, immunological or metabolic action of its cells

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