EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 antigen-specific regulatory T lymphocytes

Brief description of the finished product

Autologous antigen-specific regulatory T lymphocytes suspended in a cryopreservation medium.

Proposed indication

Treatment of inflammatory eyes diseases and inflammatory articular diseases.

EMA/CAT conclusion

On the basis that the product:

a) contains somatic cells that have been subject to substantial manipulation, through differentiation, stimulation and in vitro expansion so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered,

b) is administered to human beings with a view to treating inflammatory eye diseases or inflammatory articular diseases, through the immunological action of its cells,

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c) does not include a medical device or an active implantable device,

the EMA/CAT considers that the product falls within the definition of a Somatic Cell Therapy Medicinal Product.