13 May 2015
EMA/556557/2015
Procedure Management & Committees 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 human gamma-delta T lymphocytes activated *in vitro* by cytokines and monoclonal antibody

Brief description of the finished product

Suspension of autologous human gamma-delta T lymphocytes in saline solution for intravenous infusion.

Proposed indication

Chronic Lymphocytic Leukaemia, Acute Lymphoblastic Leukaemia

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EMA/CAT conclusion

The committee adopted on 13th May 2015 the following scientific recommendation.

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;
- 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) (a) of Regulation (EC) No 1394/2007.