28 May 2014
EMA/328354/2014
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)

Tracheal scaffold seeded with autologous bone marrow derived mononuclear cells

Brief description of the finished product

The product consists of a tracheal scaffold seeded with autologous bone marrow derived mononuclear cells.

Proposed indication

Reconstruction of trachea subsequent to damage or stenosis due to cancer, injury or infection.

EMA/CAT conclusion

On the basis that:

the product fulfils the definition of a biological medicinal product,

the product consists of substantially manipulated cells seeded on a tracheal scaffold that can be considered an integral medical device component,

the product is applied with a view to replacing and regenerating a human tissue,

the EMA/CAT considers that the Product falls within the definition of a tissue engineered product, combined Advanced Therapy Medicinal Product.

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