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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)

Decellularised cadaveric tracheal scaffold seeded with autologous bone marrow derived mesenchymal stromal cells.

## Brief description of the finished product

Autologous expanded mesenchymal cells seeded onto an allogeneic human decellularised trachea scaffold

## Proposed indication

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

## EMA / CAT conclusion

The committee adopted on 28th October 2015 the following scientific recommendation.

On the basis that the product:

- fulfils the definition of a medicinal product;
- consists of substantially manipulated cells seeded on a decellularised tracheal scaffold;
- 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.

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