20 February 2015
EMA/555388/2015
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)

Engineered extracellular matrix proteins produced by human fibroblasts cultured *in vitro* on an absorbable polymer scaffold.

Brief description of the finished product

The product is composed of human extracellular matrix proteins (mainly Collagen I and glycosaminoglycans) and residual absorbable polymer, supplied as a lyophilized (dry) and ethylene-oxide sterilised product that is to be rehydrated in physiological solution before application. The product is acellular and contains no nucleic acids.

Proposed indication

The product would be indicated for surgical or interventional treatment of congenital heart defects, thereby correcting anatomic malformations.

EMA / CAT conclusion

The committee adopted on 20th February 2015 the following scientific recommendation.

- The product does not contain an active substance which contains a recombinant nucleic acid administered to human beings with a view to regulate, delete, replace or repair a genetic

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

sequence.

- It does not contain cells or tissues.

Based on the above considerations, it is considered that the product does not fall within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007