EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

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Inspections Human Medicines Pharmacovigilance Division
Committees and Inspections 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.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

Brief description (or name when available) of the active substance(s)

Resorbable, viscoelastic matrix.

Brief description of the finished product

The finished product is the reconstituted hydrogel matrix combined with human stromal vascular fraction cells.

Proposed indication

The classification request was for the matrix prior to combination with the cells. As such, no medical claim can be attributed to the matrix on its own.

The hydrogel serves as a temporary resorbable 3-dimensional matrix when combined with cells. Over time this matrix is resorbed and replaced with natural extracellular matrix.

EMA/CAT conclusion

The procedure was finalised on 6 June 2017 for the following recommendation.

On the basis that:

- The resorbable matrix component does not contain genes, cells or tissue,

the EMA/CAT considers that the resorbable matrix component does not fall within the definition of an Advanced therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007.

However, the marketed matrix is designed to facilitate the delivery of human cells and is not intended to be applied on its own.

The classification of the matrix as non-ATMP does not pre-empt the classification as an ATMP of the matrix combined with cells.