



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)

Viable genetically engineered ARPE-19 cells of human origin secreting glucose-binding fluorescent biosensor protein.

Brief description of the finished product

Viable genetically engineered ARPE-19 cells of human origin secreting glucose-binding fluorescent biosensor protein encapsulated in an implantable continuous glucose monitoring (CGM) system, comprising an active implantable device, a wearable external device and a smartphone application.

Proposed indication

Adjunct glucose monitoring in diabetes patients.

EMA/CAT conclusion

The procedure was finalised on 29 March 2017 for the following recommendation.



On the basis that:

- the product contains an active substance which contains a recombinant nucleic acid administered to human beings with a view to adding a genetic sequence;
- its diagnostic effect relates directly to the product of genetic expression of this sequence,

the EMA/CAT considers that the Product falls within the definition of a gene therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007.