



6 June 2018  
EMA/381105/2018  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## 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)**

Autologous adipose cells.

### **Brief description of the finished product**

Washed and spin-dried autologous adipose cells.

### **Proposed indication**

Treatment of anal fistula.

### **EMA/CAT conclusion**

The procedure was finalised on 26 April 2018 for the following recommendation.

On the basis that the product:

- contains the cells, that are not intended to be used for the same essential function or functions in the recipient as in the donor;



- is administered to human beings with a view to regenerating or repairing a human tissue,
- the EMA/CAT considers that the product falls within the definition of a tissue engineered product, as provided in Article 2(4) of Regulation (EC) 1394/2007.