EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2014
EMA/557278/2015
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)

Autologous differentiated adipocytes derived from the subcutaneous adipose tissue

Brief description of the finished product

Suspension of non-substantially manipulated autologous differentiated adipocytes in solution for injection

Proposed indication

Treatment of primary perianal fistula

EMA/CAT conclusion

On the basis that:

- The product consists of autologous differentiated adipocytes in solution for injection. There is no device or structural component integrated into the product.

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

- The differentiated autologous adipocytes are considered "engineered" as they are not intended to be used for the same essential function or functions in the recipient as in the donor
- The product is intended for the treatment of perianal fistula. The claimed mechanism of actions is that upon physiological stimuli the cells from adipose tissue are able to repair, regenerate or replace the injured tissue and promote closure of perianal fistula.

The EMA/CAT considers that the Product falls within the definition of an advanced therapy medicinal product, a tissue engineered product as provided for in Article 2(1)(b) of Regulation (EC) No. 1394/2007.