



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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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)**

Medicinal product composed of living, genetically modified *Lactococcus lactis* bacteria, containing the gene for anti-human tumor necrosis factor-alpha protein.

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

Oral formulation of living, genetically modified *Lactococcus lactis* strain sAGX0354, engineered to excrete a humanized anti-TNF alpha antibody fragment.

### **Proposed indication**

Reduction of signs and symptoms, and induction and maintenance of clinical remission in patients with moderately active ulcerative colitis (UC).

### **EMA/CAT conclusion**

The committee adopted on 17<sup>th</sup> October 2014 the following scientific recommendation.

On the basis that:

- The *L. lactis* is genetically modified to secrete anti-TNF alpha



- The product is administered to human beings with a view of treating disease
- The introduced recombinant sequence is directly related to the therapeutic effect

the EMA/CAT considers that the Product falls within the definition of a gene therapy medicinal product