



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 April 2016  
EMA/291914/2016  
Procedure Management & Committees 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)**

The active substance consists of autologous blood-derived cells which are filtered to remove other blood components

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

Suspension of autologous blood cells, contained in a syringe.

### **Proposed indication**

Treatment of critical limb ischemia (CLI)

### **EMA/CAT conclusion**

The committee adopted on 22<sup>nd</sup> January 2016 the following scientific recommendation.

On the basis that the product:

- does not contain an active substance which consists of a recombinant nucleic acid administered to human beings with a view to repairing/adding/deleting a genetic sequence;
- does not contain cells or tissues that have been subject to substantial manipulation;



- the cells are not intended to be used for the same essential function or functions;
  - is intended for regeneration, repair or replacement of blood vessels in the diseased tissues,
- the EMA/CAT considers that the product falls within the definition of a tissue engineered product.