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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)

Autologous bone marrow mononuclear cells (BM-MNC).

Brief description of the finished product

Cell suspension for infusion, for autologous use.

Proposed indication

To improve limb perfusion/restore blood flow to previously ischemic tissue, and improve the mobility and quality of life (QoL) of patients with peripheral artery disease and critical limb ischemia.

EMA / CAT conclusion

The committee adopted on 24th July 2015 the following scientific recommendation.

On the basis that:

- The product will be administered to human beings with a view to restoring physiological functions by exerting pharmacological, immunological and metabolic actions.

- The cells are not intended to be used for the same essential function.

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- The product is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing and replacing a human tissue.

the EMA/CAT considers that the Product falls within the definition of a tissue engineered product.