EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2016
EMA/692834/2016
Inspections, Human Medicines Pharmacovigilance Division
Committees and Inspections 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.

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)

Living, genetically modified *Lactobacillus reuteri* bacteria, with a plasmid containing the gene for human CXCL12-1a with an inducible promoter; and an activating peptide.

Brief description of the finished product

Freeze-dried formulation of living, genetically modified *Lactobacillus reuteri* for topical administration. The finished product also contains an activation peptide.

Proposed indication

Treatment of chronic skin wounds in diabetic patients.

EMA/CAT conclusion

The committee adopted on 7 October 2016 the following scientific recommendation.

On the basis that the product:

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- the product fulfils the definition of a biological medicinal product,
- the proposed mechanism of action is stromal derived factor 1a mediated wound healing,
- the product contains an active substance which contains a recombinant nucleic acid administered to human beings with a view to adding a genetic sequence,
- the therapeutic effect relates directly to the product of genetic expression of the recombinant sequence (recombinant stromal derived factor 1a),

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