Scientific recommendation on classification of advanced therapy medicinal products

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)
Killed spores of *Bacillus subtilis* incorporating a non-toxic antigen of *Clostridium difficile*.

Brief description of the finished product
Oral / sublingual suspension

Proposed indication
Prevention of *Clostridium difficile* infections in elderly patients

EMA/CAT conclusion
On the basis that:

- The product does not contain or consist of human cells, tissues or genes,

the EMA/CAT considers that the Product does not fall within the definition of an Advanced Therapy Medicinal Product.