



Glossary

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Advanced therapy medicinal products (ATMPs)

Definition Advanced therapy medicinal product means any of the following medicinal products for human use:

- Gene therapy medicinal products
- Somatic cell therapy medicinal products
- Tissue-engineering medicinal products
- Combined advanced therapy medicinal products

Gene therapy medicinal products: contain or consist of a recombinant nucleic acid capable of inducing a therapeutic, prophylactic or diagnostic effect. Gene therapy medicinal products can adjust, repair, replace, add or delete a gene sequence. In the case of genetic diseases in which a gene is defective or absent, gene therapy consists of transferring the functioning copy of the gene in question.

Somatic cell therapy medicinal products: contain or consist of cells or tissues that have been significantly manipulated to change their biological characteristics, physiological functions or structural properties, or that are not intended to be used for the same original functions in the organism. The aim of somatic cell therapy is to treat, prevent or diagnose diseases. The cells or tissues may be autologous (derived from the patient himself), allogeneic (obtained from a donor) or xenogenic (derived from a donor of an animal species other than man).

Tissue-engineering medicinal products: contain cells or tissues that have undergone substantial manipulation or are not intended to be used for the same original functions in the body, for the purpose of repairing, regenerating or replacing human tissue.



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Combined advanced therapy medicinal products: contain one or more medical devices as an integral part of the cell- or tissue-based medicinal product.

Synonyms -

References *Agenzia Italiana del Farmaco*
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Regulations (CE) 1394/2007 e ss.mm.ii.
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