

Definitions

Advance Therapy Medicinal Products are medicinal products which are prepared industrially or manufactured by a method involving an **industrial process**. ATMPs fall into three categories; **Gene Therapies**, **Somatic Cell Therapies** and **Tissue Engineered Products**.

Gene Therapies refers to products obtained through a set of manufacturing processes aimed at the transfer, to be performed either *in vivo* or *ex vivo*, of a prophylactic, diagnostic or therapeutic gene (i.e. a piece of nucleic acid), to human / animal cells and its subsequent expression *in vivo*. The gene transfer involves an expression system contained in a delivery system known as a vector, which can be of viral, as well as non-viral origin. The vector can also be included in a human or animal cell.

Somatic Cell therapies include the use in humans of autologous (emanating from the patient himself), allogeneic (coming from another human being) or xenogeneic (coming from animals) somatic living cells, the biological characteristics of which have been substantially altered as a result of their manipulation to obtain a therapeutic, diagnostic or preventive effect through metabolic, pharmacological and immunological means. This manipulation includes the expansion or activation of autologous cell populations *ex vivo*, the use of allogeneic and xenogeneic cells associated with medical devices used *ex vivo* or *in vivo*

Tissue Engineered Products are products that contain or consists of **engineered** cells or tissues, and is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue. A tissue engineered product may contain cells or tissues of human or animal origin, or both. The cells or tissues may be viable or non-viable. It may also contain additional substances, such as cellular products, bio-molecules, biomaterials, chemical substances, scaffolds or matrices.

Engineered

Cells or tissues are considered as engineered if they are not intended to be used for the same essential function or functions in the recipient as in the donor. Alternatively, cells or tissues are considered 'engineered' if they have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved (not including cutting, grinding, shaping, centrifugation, soaking in antibiotic or antimicrobial solutions, sterilization, irradiation, cell separation, concentration or purification, filtering, lyophilisation, freezing, cryopreservation or vitrification)

A **Combination ATMP** incorporates as an integral part of the product, one or more medical devices or implantable medical devices as well as a cells or tissue component. The cells or tissue component of the product must contain viable cells or the non-viable cell or tissue

component of the product must be liable to act on the human body with action that can be considered as primary to that of the device.

'Custom made'

Using a one off formulation or a formulation that has been tailored to the individual patient and prepared within the same hospital

'Industrial process'

An industrial process would general take place in an external facility and not within the same hospital

'Non Routine'

A procedure which is not regular or performed on a repeated basis and does not follow a fixed set of instructions