Biological products

Consultez la version française

Cell therapy preparations

Cell therapy **preparations are human cells used for the purposes of autologous therapies (i.e. the donor and the recipient are the same person), or** allogenic therapies (the recipient and the donor are two different people in this case), regardless of the degree of processing and including their derivatives, which do not match the definition of an innovative therapy medicine.
Cell therapy preparations are **authorised by ANSM** after the quality, non-clinical and clinical data have been assessed.
ANSM authorises sites involved in the storage and distribution activities of cell therapy preparations.
Surveillance of these preparations is based on biovigilance, which ensures the surveillance, assessment, prevention, and management of incidents or risks associated with the use cell therapy products or other elements or products of human origin (organs, tissues, breast milk, etc.) for therapeutic purposes.
The French Biomedicines Agency (ABM) is the competent authority in relation to biovigilance, i.e. surveillance of tissue-related incidents and reactions.

Innovative therapy medicines (MTIs)

Gene therapy medicines

A gene therapy medicine is a **biological medicine** which has the following characteristics:

- it contains a recombinant **nucleic acid** which is administered to individuals with a view to regulating, repairing, replacing, adding, or removing a genetic sequence;
- its **therapeutic, preventive or diagnostic effect** is directly dependent on the recombinant nucleic acid sequence that it contains or on the product of the genetic expression of this sequence.

Gene therapy medicines do not include infectious disease vaccines.

Gene therapy medicines (manufactured industrially) or pharmaceutical gene therapy products are required to obtain, prior to their release to market, an **authorisation granted by the European Commission**.
They must be manufactured by an authorised pharmaceutical site.

Cell therapy medicines

A cell therapy medicine is a medicine which has the following characteristics:

- **it contains cells or tissues** which have undergone substantial processing so as to modify their biological characteristics, their physiological functions or their structural properties, or cells or tissues which are not intended to be used for the same purposes in recipients and donors;
- it is described as having properties for treating, preventing or diagnosing a disease via the metabolic, immunological or pharmacological action of its cells or tissues, or is used in an individual or administered to an individual for such a purpose.

Medicines derived from tissue engineering

A medicine derived from tissue engineering is a product which has the following characteristics:

- **it contains cells or tissues derived from cell or tissue engineering**, such as cells or tissues that have undergone substantial processing, or which are not intended to be used for the essential purpose in recipients and donors;
- it is described as having properties for regenerating, repairing or replacing a human tissue, or is used in humans or administered to humans for this purpose.

Some combined innovative therapy medicines incorporate a medical device in addition to its tissue or cellular part.

Labile blood products

Labile blood products (LBPs) are **products derived from a donor's blood, intended for transfusion into a patient**. They particularly consist of whole blood, plasma and blood cells of human origin, as well as their derivatives.

Among these products, a distinction is made between autologous products (the blood donor and the recipient are the same person), and homologous or allogenic products (the blood donor and the recipient(s) are different people).

Labile blood products authorised in France are registered on the LBP list and characteristics, decided by ANSM following a review by the French National Blood Service (EFS) and the Army Blood Transfusion Centre (CTSA). Blood-derived medicines are not governed by the same authorisation rules as other medicines.
Only the labile blood products included in this list can be distributed or dispensed for therapeutic purposes.

The therapeutic use of these products is subject to a vigilance system referred to as '**haemovigilance**" which consists of monitoring and assessing incidents, and adverse reactions occurring in LBP donors or recipients. Haemovigilance covers the entire transfusion chain, from LBP collection to recipient follow-up. It also includes the epidemiological follow-up of donors.

Ancillary therapeutic products

Ancillary therapeutic products (referred to as PTA) are products which, prior to their therapeutic use in humans, come into contact with organs, tissues, cells or products of human origin or animal origin during their storage, preparation, processing, packaging, or transport.

As of early 2016, PTA status has been revoked, and PTA Marketing Authorisations (MA) holders have had to submit an application for MA or to bring into compliance with MD devices (CE mark in particular).

Tissues of human or animal origin

A tissue is a group of cells of similar structure, specialised in the same function. For example, it may consist of corneas, bones, parts of the locomotor system, heart valves, vessels - arteries and veins -, skin, endocrine tissue.

Tissues are **authorised by ANSM** after the quality, non-clinical and clinical data have been assessed. Their surveillance is based on biovigilance like that for cell therapy preparations

ANSM authorises sites involved in tissue preservaton and distrubution activities.