Authorisation of blood products and other biological products

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Before being released to market, all biological products (with the exception of breast milk and routinely transplanted organs) must the assessed and authorised by ANSM or included in a list stipulated by decision of ANSM’s Director General (labile blood products).

Their assessment is based on the same essential benefit and risk criteria as those applied to medicinal products: therapeutic benefit, efficacy, safety of use, quality.

Due to the origin of these products derived from living tissue, the risk of viral or microbiological contamination or contamination by other infectious biological agents is particularly closely monitored. ANSM therefore assesses the viral safety with regard to transmission risk.

For this reason, labile blood products (LBPs) derived from donated blood, tissues of human origin (corneas, bones, parts of the locomotor system, valves, etc.), and cell therapy preparations are authorised by ANSM after assessing the extraction, preparation and preservation processes.

ANSM also authorises the import and export of stem cells and lymphocytes for transplants.

What are biological health products of human origin ?

- Labile blood products (LBPs) used in blood transfusions, organs, tissues and cells used for transplants, and breast milk for therapeutic use.
- This term also includes products, formerly known as ancillary therapeutic products (ATPs), which come into contact with biological products for their storage, preparation, processing, packaging or transport prior to any therapeutic use in humans.