Advanced Therapy Medicinal Product (ATMP)

1. Does it contain an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence?

   - Yes
     - Does its therapeutic, prophylactic or diagnostic effect relate directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence?
       - Yes
         - Is the medicinal product a vaccine against infectious diseases?
           - No
             - no ATMP
           - Yes
             - Gene therapy medicinal product*
       - No
         - no ATMP
   - No

2. Does it contain or consist of cells or tissues?

   - Yes
     - Have the cells or tissues been subject to substantial manipulation?
       - Yes
         - Are the cells or tissues not intended to be used for the same essential function(s) in the recipient and the donor (so called "non homologous use")?
           - Yes
             - no ATMP
           - No
             - no ATMP
       - No
         - no ATMP
   - No
     - no ATMP

3. Does the medicinal product contain or consist of cells or tissues that are viable?

   - Yes
     - Does the medicinal product contain or consist exclusively of non-viable human or animal cells and/or tissues, but does it act principally by pharmacological, immunological or metabolic action?
       - Yes
         - Somatic cell therapy medicinal product*
       - No
         - no ATMP
   - No
     - no ATMP

*Advanced Therapy Medicinal Product (ATMP)