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Cell & Gene Therapies vs. Medicines, where is the bordeline?

The aim of the study is to define when cell therapies become the medicinal products under the European pharmaceutical regulation.

Design of the studies contains systematic analysis of regulatory requirements for advanced therapy medicinal products.

Results: There are no clear bordelines between cell&gene therapies and medicines, the decision always based on case by case evaluation. Medicinal products, which are based on cells, tissues and genes are regulated as Advanced therapy medicinal products (hereafter – ATMP) in the European Union. Because of the novelty, complexity and technical specificities, a specific legislation for ATMP is in place since 2008 (Regulation (EC) 1394/2007 of The European Parliament and the Council (hereafter – ATMP Regulation). ATMP Regulation forseen the classification procedure provided by its Scientific Committe (CAT), so that any applicant developing a product based on genes, cells or tissues may request a scientific recommendation of the European Medicines Agency with a view to determining whether the referred product falls, on scientific grounds, within the definition of an advanced therapy medicinal product. Classification of ATMP is challenging process. CAT classification procedure is based on existing scientific knowledge of cell biology and may vary according to the evolution of science. The main difficulties discussed in classification procedures are bordelines between the categories of ATMP, transplant/tranfusion, ATMP or not – ATMP, genetically modified bacteria/ gene therapy medicinal products combined ATMPs versus non-combined ATMPs.