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Abstract:

The article concerns the most important issues of the responsibility for the application of the advanced therapy medicinal product – hospital exemption (ATMP-HE) in the frame of an experimental therapy with use of stem cells. The text is of interdisciplinary character and adresses various biotechnological isses and problems. Legal analysis is supplemented with considerations on commercial treatments named dubiously as stem cell therapies. The important thread of considerations concerns EU Regulation No. 1394/2007 and incompatibility of the Polish law with the EU law. The article discusses main consequences of the exploitation of Polish law i.e. manufacturing and an application of the ATMP-HE. The main content of the article concerns principles of the responsibility for the ATMP-HE, i.e. tort liability as well as contractual liability. The article contains also the analysis of the ATMP-HE as a unsafe product and the responsibility based on product liability provisions. This is the first publication which concerns the lability for the ATMP-HE under the private law.