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**SOME ISSUES OF LEGAL REGULATION OF BLOOD AND ITS COMPONENTS DONATION**

***Formulation of the issue.*** Ukraine's healthcare sector is undergoing a transformation period characterized by attempts to change legislation. Such specific activity as donation of blood and its components has not been overlooked. However, the analysis of the legislation on the activities of the Ukrainian blood service institutions and its comparison with acts of secondary law of the European Union does not prove it to be useful. Furthermore, it can be called the most outdated system of economic and medical measures for the organization and legal support of donation in Ukraine. Although, blood and its components donation are key to the development of high-tech medical care and, as a consequence, the quality and efficiency of health services.

In general, the following legislative acts, together with the Law of Ukraine “On Blood and its Components Donation,” regulate the issue of blood and its components donation: 1) The Fundamentals of Legislation of Ukraine on Healthcare; 2) the Law of Ukraine “On Ratification of the Association Agreement between Ukraine, on the One Part, and the European Union, the European Atomic Energy Community and Their Member States, on the Other Part” (Association Agreement); 3) the Law of Ukraine “On Ensuring the Sanitary and Epidemiological Well-being of the Population”; 4) the Law of Ukraine “On Protection of the Population against Infectious Diseases”; 5) The Law of Ukraine “On the Response to the Spread of Diseases Caused by the Human Immunodeficiency Virus (HIV), and the Legal and Social Protection of People Living with HIV”.

Incidentally, according to Art. 428 of the Association Agreement, Ukraine is gradually bringing its legislation and jurisprudence closer to the principles of the EU acquis, in particular in the field of communicable diseases, blood services, tissue and cell transplantation, as well as tobacco consuming. In turn, in Annex XLI to Chapter 22 “Public Health” of Section V “Economic and Industrial Cooperation” regarding blood services, Ukraine has undertaken to introduce, within 3 years from the date of entry into force of this Agreement, the next provisions: 1) Directive No. 2002/98 / EC of the European Parliament and of the Council of January 27, 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and its components, and amending Directive 2001/83 / EC; 2) Commission Directive 2004/33 / EC of March 22, 2004 on the implementation of Directive 2002/98 / (EC) of the European Parliament and of the Council as regards certain technical requirements for blood and blood components; 3) Commission Directive 2005/62 / EC of September 30, 2005 implementing Directive 2002/98 / EC of the European Parliament and of the Council concerning Community standards and specifications related to a quality system for blood establishments; 4) Commission Directive 2005/61 / EC of September 30, 2005 implementing Directive 2002/98 / EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.

It should be noted that the integration of Ukraine into the EU, in accordance with the Association Agreement, involves the harmonization of the basic elements of the legal systems and the creation of an in-depth and comprehensive free trade area. From the point of view of the national blood service, this means that the EU legal system, the EU member states and Ukraine shall be coordinated on the basis of the best European experience of state building. For this reason, the legislation of Ukraine and the EU on the various aspects related to blood, its components donation and preparations thereto should use the same terminology and introduce uniform rules of regulation. However, the analysis of the current legislation of Ukraine and registered bills on blood and its components donation, along with other areas of healthcare activity, suggests that there are significant gaps in the legal regulation of the activity of this field. Among other issues, it should be noted that the Law of Ukraine “On ratification of the Association Agreement” came into force on September 27, 2014. That is, Ukraine no longer fulfills its international commitments on blood and its components donation, which in fact violates patients' rights to high-quality and effective medical care.

***Analysis of recent sources and publications***. Theoretical problems of of activities in the field of healthcare legal regulation and protection of patients' rights, including the provisions of criminal law, attract the attention of many scholars. They were researched, in particular, by: R.A. Maidanyk, I.Y. Senyuta, Z.S. Hladun, I.O. Bogomazova, E.A. Grekov, A.O. Garkusha and others. However, the peculiarities of activities in the field of blood and its components donation, were left without due attention of researchers, including specialists in medical law.

***Formulating goals.*** The purpose of thas article is to study the state of legal regulation in Ukraine of blood and its components donation by analyzing the current legislation of Ukraine in this area and the practice of its application.

The research used scientific publications of leading experts in the field of medical law, current Ukrainian legislation and jurisprudence. The research is based on an organic combination of general scientific and specific legal research methods.

***Presenting main material***. The Law of Ukraine “On blood and its components donation” is not only obsolete, but also in some cases is of a formal nature.

The necessity of improving the regulatory and legal support of the blood service is also determined by the revision of the regulatory framework in the area of organizing the activities of the national blood service, shifting the main emphases in the direction of quality control and the effectiveness of the use of donor blood, its components and preparations made therein, improving the level of protection of the rights of donors and recipients, etc.

The implementation of the proposed changes to the legislation of Ukraine will ensure: 1) the elimination of terminological inconsistencies contained in the legislation of Ukraine and the implementation of EU terminology in this area; 2) the consolidation of the state policy principles regarding the development and functioning of the national blood service and its financing, the fundamentals of ensuring the economical use of donor blood and its components; 3) the definition of the organizational system of the activities of the national blood service and the establishment of the legal status of its participants and qualification requirements for them; 4) the consolidation at legislative level the tasks of the national blood service and powers of the central executive body, which ensures the formation of state policy in the field of health, state regulation in relation to the implementation of these tasks; 5) legislative regulation of the authority of the state control body to ensure the quality and safety of donor blood, its components and preparations made from them; 6) the establishment of requirements related to the quality and safety of donor blood and its components related to these procedures in the institutions of the national blood service and introduction of the institution of the authorized person of the institution of the national blood service; 7) comprehensive approach in legislative regulation of hemo-monitoring system for the circulation of donor blood and its components, prevention of the spread of infectious diseases, the procedure for testing donor blood samples; 8) the establishment of special provisions on information policy in the institutions of the national blood service; 9) determination of legal principles of blood and its components circulation, including those regarding their taking, storage, transportation, processing, sale, import and export from the territory of Ukraine; 10) detailed regulation of the legal status of blood and its components donors, in particular regarding the requirements for persons who may become donors, the conditions for their fulfillment of donor functions, their rights and duties, and benefits provided to donors; 11) prerequisites for the introduction of the register of donors of blood and its components, determination of the legal basis for the organization of its conduct; 12) the regulation of the peculiarities of liability for violation of the legislation on the national blood service.

***Conclusions.*** The current state of legal regulation of relations in the field of donation of blood and its components in Ukraine is unsatisfactory. Extremely obsolete and controversial legislation is a significant obstacle to ensuring adequate coverage of Ukrainian patients with high-quality and safe blood and its components donations, as well as violating international legal obligations of Ukraine in accordance with the Association Agreement.

While adopting updated legislation in this area, it is necessary, by analogy with the definition of the means of regulating the state's influence on economic activity, as defined in Art. 12 of the Civil Code of Ukraine, to introduce such means of legal regulation of blood and its components donation: 1) maintenance of the State Register of blood and its components donors, to which can contain and process the biometric personal data of the donor; 2) renewal of such a means of regulating the state's influence on economic activity related to the processing of donor blood and its components, the manufacture of preparations from them, in addition to the activities of banks of umbilical cord blood, other tissues and human cells, as licensing; 3) reference to the means of regulating the influence of the state on the establishment and differentiation of individual rights of paid and free donors; 4) introduction of the institution of an authorized person of the national blood service, responsible for ensuring the quality of blood and its components with the legislative determination of the qualifications of such person.

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