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GENETIC INFORMATION: LEGAL NATURE AND CONCEPTUAL AND CATEGORICAL APPARATUS

INFORMAÇÕES GENÉTICAS: NATUREZA JURÍDICA E APARATO CONCEITUAL E CATEGÓRICO

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ABSTRACT

The authors conduct a thorough analysis of the legal nature of genetic information and its definition in the context of Ukrainian and European Union legislation. It is established that genetic information, which is the basis for the development of medicine, opens up new horizons for improving the diagnosis, prevention and treatment of not only patients with rare diseases, but also any diseases, but the circulation of such genetic information raises a number of legal challenges. The article examines the existing approaches to legal regulation of such relations, in particular, the issue of defining the concept of "genetic information". A comparative analysis of approaches to the definition and regulation of relations regarding genetic information in the laws of Ukraine and the European Union is made, with an emphasis on the need to harmonise Ukrainian legislation with international standards. The authors emphasises the importance of developing a clear and effective regulatory framework that would ensure a balance between the protection of human rights and the possibilities of using genetic information for the public good. The problems arising from the different interests of the parties that have access to genetic data, including government agencies, insurance companies and medical institutions, are revealed. The author offers recommendations for improving Ukrainian legislation aimed at increasing the level of protection of genetic information and its compliance with international standards. Particular attention is focused on the need to improve the terminology used in national legal acts in order to avoid legal uncertainty and ensure

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clearer regulation of genetic data. It is stated that this study is an important contribution to the study of the legal aspects of genetic information, and the author emphasises the need to continue working on optimising the legal environment which would take into account both the human right to privacy and the general interests of society.

Keyword: Data; Information; Genetic information; Genomic information; Legal regulation; Confidentiality; Genetic data; International standards; Ukraine; European Union.

RESUMO

Os autores realiza uma análise minuciosa da natureza jurídica da informação genética e sua definição no contexto da legislação ucraniana e da União Europeia. Está estabelecido que a informação genética, que é a base para o desenvolvimento da medicina, abre novos horizontes para melhorar o diagnóstico, a prevenção e o tratamento não apenas de pacientes com doenças raras, mas também de qualquer doença, mas a circulação dessa informação genética levanta uma série de desafios legais. O artigo examina as abordagens existentes para a regulamentação jurídica de tais relações, em especial a questão da definição do conceito de “informação genética”. É feita uma análise comparativa das abordagens para a definição e regulamentação das relações relativas às informações genéticas nas leis da Ucrânia e da União Europeia, com ênfase na necessidade de harmonizar a legislação ucraniana com os padrões internacionais. O autor enfatiza a importância de desenvolver uma estrutura regulatória clara e eficaz que garanta um equilíbrio entre a proteção dos direitos humanos e as possibilidades de uso de informações genéticas para o bem público. São revelados os problemas decorrentes dos diferentes interesses das partes que têm acesso aos dados genéticos, incluindo agências governamentais, companhias de seguro e instituições médicas. Os autores oferecem recomendações para aprimorar a legislação ucraniana com o objetivo de aumentar o nível de proteção das informações genéticas e sua conformidade com os padrões internacionais. É dada atenção especial à necessidade de aprimorar a terminologia usada nos atos jurídicos nacionais para evitar incertezas jurídicas e garantir uma regulamentação mais clara dos dados genéticos. Afirma-se que esse estudo é uma contribuição importante para o estudo dos aspectos legais das informações genéticas, e o autor enfatiza a necessidade de continuar trabalhando para otimizar o ambiente legal que levaria em conta tanto o direito humano à privacidade quanto os interesses gerais da sociedade.

Palavra-Chave: Dados; Informações; Informações genéticas; Informações genômicas; Regulamentação legal; Confidencialidade; Dados genéticos; Padrões internacionais; Ucrânia; União Europeia.

1 INTRODUCTION

Over the past two decades, we have seen significant improvements in our technical capabilities for large-scale sequencing of genetic data. Today, researchers

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are using these volumes of genetic information for a variety of purposes, including uncovering factors that increase our susceptibility to certain diseases and developing personalised treatments. This potential also includes new approaches to genetic diagnosis, prevention and treatment of disease, and the development of new drugs or therapies based on our genetic information. This is the new world of medicine, which makes it more efficient and personalised with an emphasis on prevention and intervention. The circulation of genetic information certainly has great potential, but its development is associated with a number of serious legal, ethical, social, cultural and financial issues.

Given the current conditions in Ukraine, including the possibility of direct use of military force against Ukraine, intensification of European and Euro-Atlantic integration, as well as other factors, there is a need for a comprehensive study of international standards for regulating the legal aspects of genetic research and the specifics of genetic information circulation. The turnover of such information and legal regulation of genetic research is relevant because this relatively new area of social relations combines both public and private interests. In this regard, legal regulation should take into account the principles of balance between public and private interests, protection of human rights and freedoms, ensuring confidentiality protected by law, ensuring national interests of the state, etc

People generally consider genetic information about themselves to be personal. While each person's genome, encompassing all of their DNA, is unique, specific variations in a person's genome may be shared by biological relatives or even the entire human population (Haque, F. N., Gottesman, I. I., & Wong, A. H. C., 2009). The dual nature of the genome, acting both as a unique individual set and as a collection of widely shared elements, creates a complex interplay of private and public significance. This complexity poses a challenge when discussing policies related to genetic privacy.

This article provides a resonant exploration of the definition of genetic information. Similar to other new medical fields, genetic information has several challenges associated with its use due to two defining gaps. Firstly, there is the time lag between the discovery of the genetic basis of a disease and the development of therapies to prevent, treat or cure the disease. Therefore, genetic information may indicate a risk, for example, for Alzheimer's disease, for which little or nothing can be done to prevent or alleviate the condition. Secondly, there is the time lag between the genetic test that identifies an individual's increased risk of a disease and the onset of symptoms. During this period of time, when a person is in a medical condition, numerous organisations with an economic interest in their future health, such as various insurance companies, tend to use genetic information to limit risk. None of these characteristics are unique to genetics (Clayton, E. W., Evans, B. J., Hazel, J. W., & Rothstein, M. A., 2019).

It is important for Ukraine to have a clear definition of "genetic information", as proper regulation of such relations will help to avoid abuse and ensure the protection of human rights, including the rights to privacy and non-discrimination in connection with identified genetic diseases. Since none of the above features is unique to genetics, it is necessary to harmonise Ukrainian legislation with international standards to ensure the protection of people's interests in the context of the rapid development of this industry.

The relevance of the topic chosen for the study is primarily due to the fact that the current legislation of Ukraine contains a significant list of definitions of genetic (gene, genomic, etc.) information, and in science and everyday life one can find such concepts as "human genes", "genetic engineering", "human genome", "national gene pool", which, at first glance, have the same lexical roots, but differ when analysed more deeply, especially in terms of the correctness of the use of certain designations in law, as well as in determining the place of genetic information in the system of information rights objects.

And it is important to carry out a comparative analysis of the terminology vocabulary on the subject matter of the study in Ukraine and the European Union countries in order to formulate our own conclusions on the best practices of regulating relations in the field of genetic information for both countries.

2 METHODS

A number of scientific methods were used to achieve the objectives of the study and to reveal the legal nature and conceptual and categorical apparatus of genetic information. The main method was a systemic and structural analysis, which allowed to study genetic information as a legal category, its place and role in the system of legal relations. This method was used to analyse the main legislative acts of Ukraine and the European Union regulating the circulation of genetic data in order to identify common features and differences in approaches to legal regulation.

The comparative legal method was used to correlate the national legal norms of Ukraine with those of the European Union. This made it possible to identify differences in approaches to the regulation of genetic information, as well as to determine which European practices can be adapted and integrated into Ukrainian legislation in order to harmonise it with international standards.

The historical and legal method helped to reveal the evolution of legal regulation of genetic information both in Ukraine and internationally. This made it possible to trace trends in the development of the legal field and understand the prerequisites for modern approaches to the protection of genetic information.

The analysis of legislation and doctrinal sources, including international acts such as the General Data Protection Regulation (GDPR) and the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention), provided a solid basis for formulating conclusions and recommendations for improving Ukrainian legislation.

Additionally, the methods of logical analysis and generalisation were used to formulate recommendations based on the identified gaps and contradictions in the current legislation of Ukraine, as well as to identify prospects for further research in the field of legal regulation of genetic information.

Therefore, the use of these methods ensured a comprehensive approach to the study and allowed for scientifically sound conclusions that can be used to improve the legal regulation of genetic information in Ukraine.

3 RESULTS

Genetic information is unique as it is personal, prognostic, and family-related. The results of genetic sequencing may be significant not only for the patient but also for their family members, as such information may indicate the risk of developing a disease or passing it on to descendants. Notifying relatives plays a key role in facilitating timely diagnosis, treatment, or access to reproductive screening technologies.

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The adoption of the Law of Ukraine No. 2391-IX "On State Registration of Human Genomic Information" is crucial for fulfilling international obligations, particularly the requirements of the Council of Europe Convention No. 108 on the protection of individuals with regard to the automated processing of personal data. The legislative definition of "human genomic information" essentially pertains to genetic information, specifically the information contained in genomic material (nucleic acids – DNA and RNA).

Ukrainian legislation provides legal grounds for the protection of personal information; however, the lack of clear categorization of genetic information as personal data creates legal challenges concerning its processing, storage, and transfer.

4 DISCUSSION

The management of patients with rare diseases, which in Europe are defined as disorders affecting less than one patient per 2,000 people, is associated with several challenges: delayed diagnosis due to the diversity (more than 8,000 rare diseases have been identified to date), the complexity and rarity of these disorders, lack of access to specialised medical care, information or support, and the financial burden on patients and their families.

Genetic information is unique in that it is personal, prognostic and family-based. The results of genetic sequencing can be important not only for the patient, but also for their family members. Such information may indicate that a family member is at risk of developing a disease or passing the disease on to their children, and thus informing relatives can play a key role in initiating diagnosis, treatment or access to reproductive screening technologies.

Due to the diversity of stakeholders, their different interests, the growing impact of genetic technologies and the many ways in which genetic data are managed, establishing universal legal principles of genetic privacy is a complex task. This problem has been a recurring theme since the debate on genetic privacy began several decades ago, as public policy attempts to balance individual rights to keep their genetic information confidential with the rights of others and the public to access such information. These trade-offs often involve considerations of both personal and public

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interest, with variations depending on the specific context. Issues related to governmental screening of newborns for genetic diseases are different from those related to the use of genetic information by insurers for health, life, disability or long-term care insurance, each of which presents its own set of challenges. In addition, the diversity of subjects and locations of screening is governed by different regulations.

The concept of the legal construct "human genomic information" is enshrined in the Law of Ukraine "On State Registration of Human Genomic Information" No. 2391-IX dated 09.07.2022 (hereinafter - Law No. 2391-IX), by which the legislator means information about human genetic characteristics. Given the definition, we will highlight the following characteristic features of human genomic information: 1) it is data; 2) this data contains human genetic characteristics. Given the brevity of the definition, it is necessary to conduct a more thorough scientific search to understand the regulatory intent.

In Part 1 of Article 7 of the Law of Ukraine "On Personal Data Protection" there is a single mention of this type of information with the designation "genetic data". The Law of Ukraine "On Information" - the main special regulatory act in the field of information relations - is characterised by a wider coverage of types of information, so we can see that the legislator has included the information of interest to us in the concept of such type of information as "information about an individual" (part 1 of Article 10), which is understood as personal data of such person, namely "information or a set of information about an individual who is identified or can be specifically identified" (part 1 of Article 11). It should be noted that the legislator has clearly outlined the rules for the use of such information, which is important for further elaboration of the topic of this article: "collection, storage, use and dissemination of confidential information about a person without his/her consent is not allowed, except in cases determined by law, and only in the interests of national security, economic welfare and protection of human rights" (part 2 of Article 11).

However, genetic information is not included in the non-exclusive list of types of confidential information about an individual, which includes data on his or her nationality, education, marital status, religious beliefs, address, date and place of birth, except that the legislator indirectly and partially mentioned it in the context of information on health status, but we have already seen and will try to prove in the future that this approach does not give an idea of such a complex and multifaceted phenomenon as genetic information. Paragraph two of part 2 of Article 11 of the Law of Ukraine "On Information" contains an extremely important rule, according to which everyone is provided with free access to information that concerns him or her personally, except in cases provided for by law. This approach, if consistent, should also apply to genetic information as information about an individual.

It is unclear whether information about unborn life is personal data. In our legislation, embryos and fetuses are not persons. Legal personality also ceases with death. Thus, data about subjects who have not yet been born or have already died cannot be considered medical personal data. However, they are protected in certain areas of law. Thus, in the strict sense of the word, data on embryos, fetuses and deceased subjects would not be personal data. Indeed, there is no reference to an individual. Nevertheless, this data may be considered "personal data by extension". Data on unborn life may reveal something about living people, namely the biological mother and father. The medical data of a deceased person may also allow us to draw conclusions about the current or future health of living relatives (Callens, S., 1995). This is especially true of genetic data. In addition, it is generally recognised that the protection of a person's interests does not cease with the death of a person. This point of view is important when it comes to the protection of genetic data (Tack, S., & Dierickx, A., 2008). After all, information about unborn and deceased persons also contains information about parents or children.

According to the Explanations of the Ukrainian Parliament Commissioner for Human Rights on the main provisions of the Procedure for Notifying the Commissioner to Determine the Processing of Personal Data that Pose a Particular Risk to the Rights and Freedoms of Personal Data Subjects dated 08.01.2014, genetic data is information relating to all data on the hereditary properties of a person or on the way of inheriting characteristics within a particular group of people, and also applies to all data on the content of any genetic information (genes) relating to any It should be noted that the main bylaw defining the issues of medical genetic assistance in Ukraine is the Order of the Ministry of Health of Ukraine and the Academy of Medical Sciences of Ukraine "On Improvement of Medical Genetic Assistance in Ukraine" of 31.12.2003 No. 641/84 (hereinafter - Order No. 641/84). The legislator did not use the term "genetic information/data" in this document; contrary to this seemingly logical approach, the Order contains a variety of designations, for example, "information on the hereditary nature of the disease in the proband" (i.e. the person from whom the family tree is drawn up in the process of genealogical analysis), "information on the detected changes in the genetic apparatus".

Thus, we should pay special attention to the fact that the departmental act on medical genetic assistance uses the term "information", which points us to the second necessary component of this study, the understanding of which is equally important for drawing conclusions about the legal nature and content of the concept of "genetic information".

International acts also set out the definition of the definition under study. Article 6 of the Council of Europe Convention No. 108 for the Protection of Individuals with regard to Automatic Processing of Personal Data requires that personal data may not be subjected to automatic processing unless domestic law provides appropriate safeguards. The same rule applies to personal data of persons subject to genetic research. Therefore, first of all, the adoption of this Law No. 2391-IX is important for fulfilling the requirements of international treaties.

The period following the completion of the complete sequencing of the human genome in 2003 has led to significant changes in both the law and life sciences. UNESCO has developed two international declarations to regulate genetic technologies. The first of these, the Universal Declaration on the Human Genome and Human Rights (UDHG), was adopted in 1997, and the second, the International Declaration on Human Genetic Data (IDHGD), appeared in 2003.

The UDHG was the first intergovernmental document specifically aimed at protecting human rights in the field of genetics and aims to prevent the use of genetic information in ways that are contrary to human rights and human dignity, but this declaration does not contain the vocabulary term "genetic information", but it is possible to clarify the essence of the genome, genetic inheritance and genetic testing. The Declaration refers to the human genome as part of the "heritage of mankind", a term that seeks to emphasise, first, that research involving genetic data is the responsibility of all mankind and that its results should benefit present and future generations, and second, that the human genome as such is not suitable for appropriation by any state or corporation.

The subsequent IDHGD Declaration is in some respects a continuation of the UDHG, setting out in more detail the rules governing the collection, use and storage of genetic data, as well as a comprehensive "framework of principles and procedures to guide states in the development of their legislation, policies and other instruments in

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the field of bioethics". The Declaration contains requirements for informed consent to genetic testing and confidentiality of genetic data, prohibits genetic discrimination, provides for the right to know one's genetic makeup and advocates international solidarity in genetic research and benefit sharing. However, the IDHGD also treats genetic data rights as individual rights, setting thresholds for individual consent to the processing of genetic data and granting genetic data rights on a case-by-case basis in its text. In this respect, both the IDHG and the UDHG perpetuate the understanding of privacy as an individual right whose broader contribution to the public good is best achieved through individualised rights and remedies in the event of their violation.

The Council of Europe's Convention on Human Rights and Biomedicine (Oviedo Convention) also addresses human rights and genetic data. As with the IDHGD, the Convention requires informed consent for genetic testing, provides for the right to confidentiality and the right to receive information about genetic status, and places restrictions on the use of predictive genetic tests.

Convention 108 specifically refers to genetic data in Article 6 as a "special category" of personal data.

Regardless of the fact that Chapter IV of the Oviedo Convention is entitled "The Human Genome", it is, for example, about genetic testing, not genomic testing. Similarly, the Additional Protocol to the Convention on Human Rights and Biomedicine, which deals with genetic testing in health care, does not contain a special designation of information. The general term "information" is used.

The Regulation of the European Parliament and of the Council (EU) 2016/679 of 27.04. 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation), genetic data is defined as personal data relating to the inborn or acquired genetic characteristics of an individual and obtained as a result of the analysis of a biological sample taken from a natural person, in particular chromosomal analysis, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or analysis of another component that allows obtaining similar information.

European Union legislation does not define the term "genetic data". As Cornelis, C. notes, genetics continues to evolve, what is not possible today may be possible in a few years (Cornelis, C., 2021). Thus, the legal framework should not only be adapted to the current state of science, but should also take into account future developments.

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Belgian law does not contain a definition of genetic information. The Dutch, French and German legislation also does not define genetic information.

In contrast to other countries, Belgium does not have a general legal framework for the use of genetic tests for the collection and use of genetic information (Hoge Gezondheidsraad, 2012). There is not even a legal framework specifically aimed at the collection and use of medical data in the course of concluding or performing a private insurance contract (Defloor, S., & Nys, H., 2011). Only a few specific pieces of legislation or articles of law are available, such as the Royal Decree on Human Genetics Centres, the Patients' Rights Act, legislation on population studies or special provisions in the context of labour law and insurance law.

The Belgian legislator was one of the first to introduce a legal ban on the use of genetic data; genetic data cannot be transferred or used for risk assessment, for example, to insurance companies. In Belgium, one of the most frequent criticisms of the Belgian rules on the use of genetic data is the lack of definitions of what exactly is meant by "genetic information". Article 58 of the Insurance Act of 2014 in the context of the notification obligation states: "genetic data may not be transferred". The provision excludes the use of genetic information without defining what genetic information is. However, it is important to know what data falls under this concept. Data that should be considered genetic data are completely excluded from the notification obligation. Data that is not of a genetic nature is excluded from the prohibition and must be reported.

The only legal definition of genetic information available at the European level is that contained in the GDPR. The Belgian Commission for the Protection of Privacy has agreed to this definition, which is automatically applied in Belgium, so this definition is part of Belgian law (De Hert, P., & De Schepper, T., 2016). The definition in the GDPR is only applicable in the context of data protection, so this definition may not be sufficient in some other legal relationships. Despite the legal terminological gap, scholars do not propose doctrinal solutions.

According to such scientists as Cornelis S., Anans G., A. De Paot, the definition includes only data obtained as a result of the analysis of a biological sample, which is a genetic test (De Paor, A., 2017). Genetic testing includes data obtained as a result of genetic research, as well as information obtained as a result of the analysis of other elements. It may not be a purely genetic test, such as classical medical examinations or symptom-based diagnoses. Going back to the analysis of the biological sample,

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there are still questions about information obtained from other sources, such as genealogical information (Cornelis, C., 2021).

Anans G.J. who was involved in genetic research to define genetic information. The first definition he proposed was very broad: "Private genetic information means any information about any identifiable person that has been derived: (1) from the analysis of the DNA of an individual; (2) from the analysis of the DNA of an individual to whom the individual is genetically related; or (3) from knowledge of the status of an individual in a pedigree or family history that has been developed or analysed in relation to a particular hereditary condition; and which (4) confirms a diagnosis of a disease; (5) identifies the presence of a gene or genes, or a specific gene marker or gene markers; (6) indicates that a person is at increased or decreased risk of developing a disease as a result of inheriting a gene; or (7) establishes that a person is a carrier of a gene." However, this definition was deemed unacceptable and it was therefore proposed to limit it to DNA testing: "The term 'private genetic information' means any identifiable information about an individual that is derived from the presence, absence, alteration or mutation of a gene or genes, or the presence or absence of a particular DNA marker or markers, and that is derived: (1) from the analysis of the DNA of the individual; or (2) from the analysis of the DNA of a person to whom the individual is related (Annas, G. J., Glantz, L. H., & Roche, P. A., 1995).

In order to explore the legal construction of "genomic information" in depth, we will divide it into two components: genomic and information. A genome (German: genom, English: genome, from the Greek: γένος - genus, origin) is a complete set of genetic information of an organism encoded in DNA (or RNA for some viruses), or the complete DNA sequence of a haploid set of chromosomes. It includes genes and non-coding sequences. It is necessary to distinguish the genome as a material that carries genes from the actual information contained in the sequence of nucleotides of the DNA of an organism (gene sequence) (Bezrukov, V. F., 2006). The same Encyclopaedia defines genetic information as a set of information about the development, structure and properties of organisms that is inherited through genes. Another name is hereditary information (Kunakh, V. A., 2006).

In view of the above, we come to the interim conclusion that Article 1 of the Law of Ukraine "On State Registration of Human Genomic Information" actually refers to genetic information, namely, information recorded in genomic material (nucleic acids (DNA and RNA)).

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Continuing the definitional "wanderings" through the legislation of Ukraine, in order to scientifically substantiate the position on the correctness of the name of the construction under study in law, we should refer to the doctrinal provisions and the general information legal framework to clarify the essence of the second component of the concept sought - information as a category used to explain the terms "genome", "gene", "genetic", etc. and itself defined in the legislation of Ukraine through such concepts as information, data, etc. The relevance of these searches is added by discoveries and hypotheses in the field of biology and medicine, according to which it is already possible to transfer information from a healthy organism to a sick one in order to establish or correct its functions, to help an organ or organism function properly, and scientists are increasingly interfering with the human genome in order to study and improve it, which can be dangerous for all mankind if the legal limits of such interference are not established in time.

In general, speaking about information in law (medical law in particular), we draw attention to one of the most multifaceted and significant phenomena that is the subject of research in both natural and human sciences - so capacious and ambiguous that it is impossible to find answers to all questions without the help of representatives of these fields, including scientists who have devoted their numerous studies to private and public areas of information law. Along with such giants as matter, energy, time, information has emerged - which, as the father of cybernetics N. Wiener aptly put it, is "information, not energy or matter, but a designation of content received from the external world in the process of adaptation to it" - a phenomenon that, like the others mentioned above, characterises the quality of the entire material world (Wiener, N., 1950).

Specialised literature contains a significant number of definitions of information. For example, I. V. Aristova, having studied the works of a number of authors, concluded that the most sophisticated and idealistic interpretations of the concept of information were formulated in their works: K. von Weizsäcker, who reveals it through the concept of form and argues that mass and energy are equivalent to information, A. Bloch, G. Gunther, P. Snyder, who consider information as something third, "neutral", "intermediate" between spirit and matter, which, in our opinion, sounds very modern (Aristova, I. V., 2000).

In turn, the category of "data" is considered by scientists as an abstract category, its specific content is determined through the field of knowledge (Kalyuzhnyi, R. A., Krupchan, O. D., Pavlovskyi, et al 2002).

The definition of information can be found in a number of dictionaries. A modern dictionary of foreign words defines information as: 1) a message about something; 2) data that is the object of storage, processing and transmission, etc. It is also appropriate to consider information not only as a set of data and messages, but also as knowledge about objects, phenomena, processes, etc.

As we have seen, until the 20s of the last century, information was understood as "messages and data" transmitted by people in various ways, taking into account the translation of this word from Latin, which means "acquaintance, explanation, presentation", and since the middle of the last century, the understanding of information has expanded to the exchange of data between people, people and machines, between machines themselves (as technologies, including information technologies, were developing at a significant pace), the exchange of signals in the animal and plant world has supplemented this list, as well as the act of In general, since the creation of information theory, which dates back to the work of C. Shannon, biology has been considered to be the area of its universal application.

With regard to the concept of information in legal science, the legal category of the object of legal relations is an acceptable category within which to form an idea of this phenomenon of great complexity, therefore, focusing on an individual as a subject who has genetic information, the understanding of information should be sought primarily in the field of private law and understood as "an intangible non-property benefit of a special kind, which is inextricably linked to life, its emergence and termination, which manifests itself as a personal non-property benefit, as a result of influence on a person and other subjects and objects of law, as a result of intellectual creative activity and as information about persons, events and phenomena, objects, objects and processes regardless of the form of their representation" (Kohanovska, O. V., 2006).

Pursuant to Article 1 of the Law of Ukraine "On Information", information is any information and/or data that can be stored on material carriers or displayed electronically. A similar definition is contained in Article 200 of the Civil Code of Ukraine (hereinafter - the CC of Ukraine). Enshrining in Chapter 15 of the Book of First Information as an object important for individuals - subjects of relations in the field of private law - as a separate intangible good among other intangible goods, such as the results of intellectual, creative activity and personal non-property goods, is an undoubted achievement of the civil science of Ukraine, as it opens up significant opportunities for the entire civil law toolkit in the interests and for the protection of information rights of each individual. Thus, a subject of information private relations may demand elimination of violations of his/her right and compensation for property and moral damage caused by such offences (Article 200(2) of the Civil Code of Ukraine), which allows for effective protection of information rights of participants in such relations, and the procedure for using information and protecting the right to it is established by law (Article 200(3) of the Civil Code of Ukraine). The right to information is also enshrined in Article 302 of Book Two of the Civil Code of Ukraine as the right of an individual to freely collect, store, use and disseminate information, and such actions regarding the personal life of an individual without his or her consent are not allowed, except in cases determined by law, and only in the interests of national security, economic well-being and human rights. Thus, Book Two of the Civil Code of Ukraine considers information to be a personal non-property benefit, the right to which is protected primarily in accordance with its non-property intangible nature. At the same time, information is often a component of other objects of civil law, both intangible - life, health, secrets about health, respect for honour and dignity, business reputation, individuality, private life and its secrets, and many others, and tangible, which include both their content (information itself) and the material form in which it is presented or embodied.

If we focus on data as information, then according to Article 1 of the Law of Ukraine "On Electronic Documents and Electronic Document Management" of 22.05.2003, data is information in a form suitable for automated processing by means of computer equipment. Article 1 of the Law of Ukraine "On Electronic Communications" also defines data as information in a form suitable for automated processing by means of computer equipment, hardware and software.

It should also be noted that there is no statutory definition of the term "data", although there are more than enough definitions in the encyclopaedic and other literature. For example, the Explanatory Dictionary of the Ukrainian Language defines information as a message, certain factual data about someone or something. Therefore, we can conclude that information is a message that can be stored on material carriers and that in this context we are dealing not only with static (available

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factual data), but also with certain actions of the subject, which consist in communicating the necessary data to another person, or, more broadly, knowledge, in a form suitable for perception by another person, which we will not discuss in detail in this article, given its focus and purpose, but note that the concept of information is also consistent with the concept of "knowledge" and a number of other concepts in the field of information relations.

A systematic analysis of information legislation gives grounds to assert that the designation in the analysed construction with the word "information" is correct, as it includes all its components - data, information and messages. However, part 1 of Article 11 of the Law of Ukraine "On Information", as noted above, contains a definition of "information about an individual (personal data)", i.e. information or a set of information about an individual who is identified or can be specifically identified. From the above definition, it follows that information in this context is equal to data, which is information. We consider this definition to be controversial, although genetic information as a special type belongs to the circle of information about a person.

5 CONCLUSION

The significant importance of genetic information about a person contained in his or her DNA in various spheres of public life makes it necessary for States to provide for a clear and effective mechanism of legal regulation of these relations which would ensure not only protection of such information from unlawful collection, storage, use and dissemination, but also determination of a clear range of all potential persons to whom such information may be provided.

Summarising the semantic analysis with a view to providing a normatively adequate definition of the concept of "genetic information", we draw a number of conclusions and propose:

1) to amend Article 1 of the Law of Ukraine "On State Registration of Human Genomic Information", fixing the definition of "genomic information" in the context of this law as information subject to registration, which means data, and to formulate this term in a new wording: "human genetic information (hereinafter referred to as genetic information) - data on human genetic traits";

2) it is incorrect to refer to genomic information through the prism of data, given, in particular, the preamble to the Law of Ukraine "On State Registration of Genomic Information", which states that the Law defines the legal basis for processing human genomic information for the purpose of its state registration in Ukraine. Therefore, taking into account the definition of the term "data" in the Law of Ukraine "On Electronic Documents and Electronic Document Management", genomic information is primarily data, not information, so the designation of information as information should be exclusively from the Law of Ukraine "On State Registration of Human Genomic Information", taking into account its purposes;

3) the general definition of the legal construct "genetic information" can be formulated as information and/or data on hereditary traits of a person or on hereditary traits within a relevant group of people, as well as any information and/or data on human health or disease;

4) to balance the information conceptual and categorical apparatus in all laws of Ukraine regulating information relations in order to avoid "circular" definitions such as "information about an individual (personal data)", which do not reveal the essence and peculiarities of information phenomena, but rather confuse the understanding of the terms "information", "data", "information", which are known and have long been studied by the doctrine of information private and public law;

5) in accordance with Ukrainian legislation, genetic information is classified as information about an individual and is a component of personal data.

In order to fully disclose the topic of this article, it is also important to determine the correlation between two concepts used in Ukrainian legislation: "genetic information" and "medical information". Art. 3 of the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care" defines medical information as information about a person's medical care or its results, set out in a unified form in accordance with the requirements established by law, including information about the state of health, diagnoses and any documents relating to health and limitations of daily functioning/life of a person. According to the definition provided in clause 2 of the Procedure for the Functioning of the Electronic Healthcare System, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 411 dated 25.04.2018, medical information means information about the patient's health status, diagnosis, information obtained during a medical examination, including relevant medical documents related to the patient's health.

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The analysis of these definitions gives rise to a number of conclusions and proposals:

1) medical information and genetic information are two information systems that have a common area for research when they intersect, namely in the context of genetic information on human health or disease; at the same time, genetic information is often auxiliary to fill the medical information system;

2) it is appropriate to unify the definitions of the legal construct "medical information" contained in the Law of Ukraine "Fundamentals of Legislation of Ukraine on Healthcare" and the bylaw - the Procedure for the Functioning of the Electronic Healthcare System, since currently the regulatory "templates" are different;

3) it is incorrect to equate and define information, in particular through documents, as it is enshrined in the Law of Ukraine "Fundamentals of Legislation of Ukraine on Healthcare" in the formulation of the term "medical information". Art. 1 of the Law of Ukraine "On Information" states that a document is a material carrier containing information, the main functions of which are its preservation and transmission in time and space, and information is any information and/or data that can be stored on material carriers or displayed electronically.

Therefore, the definition of "medical information" should not include the phrase "any documents related to health". Medical information is a special type of information, as well as data, knowledge, etc., which are intangible and non-property in nature and constitute the content of any medium.

REFERENCES

ARISTOVA, I. V. (2000). State information policy: Organisational and legal aspects. In O. M. Bandurka (Ed.), *Kharkiv*, p. 9.

ANNAS, G. J., GLANTZ, L. H., & ROCHE, P. A. (1995). Drafting the Genetic Privacy Act: Science, policy, and practical considerations. *Journal of Law, Medicine & Ethics, 23*(4), 362.

BELGIUM. (1987). Koninklijk besluit van 14 december 1987 houdende vaststelling van de normen waaraan de centra voor menselijke erfelijkheid moeten voldoen. Belgisch Staatsblad, 25 december 1987.

BELGIUM. (2003). *Law of 28 January 2003 on medical examinations performed within the framework of employment relations*. Belgisch Staatsblad, 9 April 2003.

Submetido em: 03/09/2024
Aprovado em: 30/09/2025
Avaliação: Double Blind Reviewe
ISSN: **2316-753X**

BELGIAN GOVERNMENT. (2014). *Wet van 4 april 2014 betreffende de verzekeringen [Law of April 4, 2014 on Insurance].*Belgian Official Gazette. Retrieved from https://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2014040423&table_name=wet

Bezrukov, V. F. (2006). Genome. In I. M. Dziuba, A. I. Zhukovskyi, M. H. Zhelezniak [et al.] (Eds.), *Encyclopedia of Modern Ukraine* [Electronic resource]. Institute of Encyclopedic Research of the NAS of Ukraine. Retrieved from https://esu.com.ua/article-29086
CLAYTON, E. W., EVANS, B. J., HAZEL, J. W., & ROTHSTEIN, M. A. (2019). The law of genetic privacy: Applications, implications, and limitations. Journal of Law and the Biosciences, 6(1), 1–36. https://doi.org/10.1093/jlb/lsz007 (accessed 21.07.2024).

CALLENS, S. (1995). Goed geregeld? Het gebruik van medische gegevens voor onderzoek. Antwerpen: Maklu.

CORNELIS, C. (2021). *Genetische Gegevens En Verzekeringen.* Antwerpen: Universiteit Antwerpen.

COUNCIL OF EUROPE. (1997). Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine. Retrieved from https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164

DE PAOR, A. (2017). *Genetics, disability and the law: Towards an EU legal framework.* Cambridge: Cambridge University Press.

DE HERT, P., & DE SCHEPPER, T. (2016). The new European data protection regulation of 27 April 2016. *CBR Yearbook 2015/2016*, 23.

DEFLOOR, S., & NYS, H. (2011). Patiëntengegevens en verzekeringen: Een onmogelijke relatie? In *Over grenzen. Liber Amicorum Herman Cousy* (pp. 496). Antwerpen: Intersentia.

EXPLANATORY DICTIONARY OF THE UKRAINIAN LANGUAGE. (2024). Retrieved from https://slovnyk.ua/index.php?swrd=%D0%B2%D1%96%D0%B4%D0%BE%D0%BC%D0%BE%D1%81%D1%82%D1%96

HAQUE, F. N., GOTTESMAN, I. I., & WONG, A. H. C. (2009). Not really identical: Epigenetic differences in monozygotic twins and implications for twin studies in psychiatry. *American Journal of Medical Genetics Part C: Seminars in Medical Genetics, 151C*, 136.

HOGE GEZONDHEIDSRAAD. (2012). *Advies nr. 8714 - Genetische zelftests, april 2012.*

Submetido em: 03/09/2024
Aprovado em: 30/09/2025
Avaliação: Double Blind Reviewe
ISSN: **2316-753X**

KALYUZHNYI, R. A., KRUPCHAN, O. D., PAVLOVSKYI, V. D., HUTSALIUK, M. V., TSYMBALIUK, V. S., & SHVETS, M. Y. (2002). *Informatisation, law, management: Organisational and legal issues* (M. Y. Shvets & O. D. Krupchan, Eds.). Kyiv.

KOHANOVSKA, O. V. (2006). *Theoretical problems of information relations in civil law: Monograph.* Kyiv: Kyiv University Publishing and Printing Centre.

KUNAKH, V. A. (2006). Genetic information. In I. M. Dziuba, A. I. Zhukovskyi, M. H. Zhelezniak [et al.] (Eds.), Encyclopedia of Modern Ukraine [Electronic resource]. Institute of Encyclopedic Research of the NAS of Ukraine. Retrieved from https://esu.com.ua/article-29067

TACK, S., & DIERICKX, A. (2008). Nader gebruik van lichaamsmateriaal voor wetenschappelijk onderzoek: Toelaatbaarheid getoetst vanuit het recht op respect voor het privéleven (art. 8 EVRM). *T.Gez.*, 2008-09, 391.

VERKHOVNA RADA OF UKRAINE. (2022). *On state registration of human genomic information: Law of Ukraine of 09.07.2022 No. 2391-IX.* Retrieved from https://zakon.rada.gov.ua/laws/show/2391-20#Text

VERKHOVNA RADA OF UKRAINE. (2010). *On the protection of personal data: Law of Ukraine of 01.06.2010 No. 2297-VI.*Retrieved from https://zakon.rada.gov.ua/laws/show/2297-17#Text

VERKHOVNA RADA OF UKRAINE. (1992). *On information: Law of Ukraine of 02.10.1992 No. 2657-XII.* Retrieved from https://zakon.rada.gov.ua/laws/show/2657-12#Text
VERKHOVNA RADA OF UKRAINE. (2003). *On electronic documents and electronic document management: Law of Ukraine of 22.05.2003 No. 851-IV.* Retrieved from https://zakon.rada.gov.ua/laws/show/851-15#Text

VERKHOVNA RADA OF UKRAINE. (2020). *On electronic communications: Law of Ukraine of 16.12.2020 No. 1089-IX.*Retrieved from https://zakon.rada.gov.ua/laws/show/1089-20#Text

VERKHOVNA RADA OF UKRAINE. (2003). *Civil Code of Ukraine: Law of 16.01.2003 No. 435-IV.* Retrieved from https://zakon.rada.gov.ua/laws/card/435-15

VERKHOVNA RADA OF UKRAINE. (1992). *Fundamentals of the Legislation of Ukraine on Healthcare: Law of Ukraine of 19 November 1992 No. 2801-XII*. Retrieved from https://zakon.rada.gov.ua/laws/show/2801-12#Text.

UN EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANISATION (UNESCO). (1997). *Universal Declaration on the Human Genome and Human Rights.* Retrieved from https://www.ohchr.org/en/instruments-mechanisms/instruments/universal-declaration-human-genome-and-human-rights

WIENER, N. (1950). *The human use of human beings: Cybernetics and society.* Boston: Houghton Mifflin. Retrieved

Submetido em: 03/09/2024
Aprovado em: 30/09/2025
Avaliação: Double Blind Reviewe
ISSN: **2316-753X**

from https://books.google.com.ua/books/about/The_Human_Use_of_Human_Beings.html?id=QqwgAAAAMAAJ&redir_esc=y