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THE GENETIC TESTING FOR HEALTH PURPOSES AND BIOMEDICAL RESEARCHES

Abstract. The Article interprets the provisions of the Oviedo Convention and the Protocol on Biomedical Research for Genetic Testing and Biomedical Research for Health Purposes, thereto. The main gaps in the national legislation of Azerbaijan are indicated. Unfortunately, the issues regulated by both the Protocol on Genetic Testing for Health Purposes and the Protocol on Biomedical Research are either not included in the legislation or are referred to very superficially. The Law on Protection of the Public Health can only be adopted as a framework document in the concerned area. Therefore, the Article concludes that in order to regulate the relevant issues, the Law on Genetic Testing for Health Purposes and the Law on Biomedical Research should be adopted.

In this case, Germany as one of the developed countries can be a good example in choosing the best title for the new legal norm and the title of the new law can be also a Law on Genetic Engineering. However, given the global nature of the issue, the regulatory title of the Law from the perspective of the Oviedo Convention and its relevant Protocols may be more systematic. Of course, the ratification of the Oviedo Convention and its respective Protocols can be ensured as a last resort.

Keywords: biomedicine; international law; bioethics; biotechnology; law.

The legal regulation of biotechnological and biomedical activities in genetic testing specified the adoption of specific international legal acts. And, this is of particular interest from the perspective of the unification of legislative frameworks of separate States[1]. Particularly, the study of the relationship between legislative frameworks, judicial practice and international legal norms

[1] R Andorno, 'Biomedicine and international human rights law: in search of a global consensus' [2002] 80 (12) Bulletin of the World Health Organization 956; 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 (Council of Europe 1997) <https://rm.coe.int/168007cf98> (accessed: 14.11.2021).

of technology states are of utmost importance. In several circumstances, the legislative practices of different countries significantly affected international legal regulation. Germany, where a Nurnberg Code has been originated from, is one such country. The regulation and surveillance of biotechnological processes have always been important for this country. The first legal act on genetic engineering was solely adopted in 1990 in the Federative Republic of Germany. The legal acts are enacted in other countries to protect society from the adverse effects of genetic engineering[2]. The U.S. Act on the Risks of Practices Related to Possible Pollution of the Environment, French Law on the Regulation of Research, Teaching, Practice, Production and Commercial Activities in the Field of Genetically Modified Microorganisms and Organisms, Canadian Biotechnology Norms: Guidelines for Users and other legal acts address the bioethical issues in genetic engineering.

The legislative initiatives, normative regulatory measures of different countries in genetic engineering promoted adopting international legal acts. The main requirement of international legal norms was related to the protection of human dignity[3]. The Preamble of the 2005 Universal Declaration on Bioethics and Human Rights states that recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person. Chapter IV of the Convention on Human Rights and Biomedicine (Oviedo Convention) and 2008 the Additional Protocol on Genetic Testing for Health Purposes (Strasbourg) allow genetic testing for medical purposes only. By doing so, the Protocol promotes fulfilling the provisions of the Protocol[4]. However, the Protocol does not consider the regulation of genetic testing, such mandate is enshrined by the national legislation. The Protocol envisages provisions about the right of a patient to proper information about genetic tests and his/her right to consent

[2] Е Караваева, Р Кравцов, 'Биомедицинские технологии: вопросы правового регулирования и ответственности. Вопросы конституционного права' (2005) 3 Сибирский юридический вестник 7.

[3] Andorno (n 1) 962; R Andorno, 'The Oviedo Convention: a European Legal Framework at the intersection of Human Rights and Health Law' (2005) 02 JIBL 134; Convention on Human Rights and Biomedicine (n 1); Y Devos et al, 'Ethics in the societal debate on genetically modified organisms: A (re) quest for sense and sensibility' (2007) 21 Journal of Agricultural and Environmental ethics 30; Henriette Roscam Abbing, 'The Convention on Human Rights and Biomedicine. An Appraisal of the Council of Europe Convention' (1998) 5 European Journal of Health Law 380; Ismini Kriari-Catranis, 'The 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' (2002) 12 Eubios Journal of Asian and International Bioethics 90; Maurice A de Wacher, 'The European Convention on Bioethics' [Jan.-Feb 1997] 27(1) The Hastings Center Report 14; Gregor Puppinck, 'Synthetic analysis of the ECJ Case. C-34/10 Oliver Brustle v. Greenpeace e.v. and its ethical consequences European Centre for Law and Justice' (January 10th 2013) <https://7676076fde29cb34e26d-759f611b127203e9f2a0021aa1b7da05.ssl.cf2.rackcdn.com/eclj/Synthetic%20analysis%20of%20the%20ECJ%20case%20of%20Br%C3%BCstle%20v%20Greenpeace%20and%20its%20ethical%20consequences.pdf> (accessed: 14.11.2021); Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004L0023> (accessed: 14.11.2021); M Bhardway, 'Global bioethics and international governance of biotechnology' [2003] 6 (1) Asian Biotechnology and Development Review 51.

[4] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes, 27.XI.2008 <https://rm.coe.int/1680084824> (accessed: 14.11.2021).

to such tests, along with genetic counseling. Article 1 of the Protocol states that Parties to this Protocol shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the tests to which this Protocol applies in accordance with Article 2. Article 2 establishes the issues regulated but not applied. This Protocol applies to tests, which are carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development (hereinafter referred to as "genetic tests"). This Protocol does not apply to genetic tests carried out on human embryos or fetuses (Article 2(2)). This international legal document also established genetic analyses and biological samples. As in Oviedo Convention, the primacy of dignity and honor of human being was enshrined (Article 3). The non-discrimination clause was envisaged under Article 4 of the Additional Protocol[5].

Pursuant to Article 5 of the Protocol, the quality of genetic services should be ensured. The genetic tests meet generally accepted criteria of scientific validity and clinical validity (a); a quality assurance program is implemented in each laboratory for genetic tests and those laboratories are subject to regular monitoring (b); persons providing genetic services have appropriate qualifications. Of the main provisions of the Protocol is to have *free and informed consent* during the medical testing (Article 9). As in the Oviedo Convention the confidentiality of private life during the genetic testing was specifically paid attention. The only legal document in this area is the general rules for genetic testing. The participation of a patient in genetic testing and the perspective on the prospect of ensuring this on a commercial basis in the future is regulated. The General rules for carrying out the genetic test is envisaged in respect of incapacitated persons. Nowadays, the clinic utility enshrined in Article 6 of the Protocol became a more actual problem. The existence of serious disagreements by different countries with regard to the utility of vaccines prepared to prevent COVID-19 infection, in some cases, the commercial nature of the issue underscored the importance of the Convention and the Protocol. For instance, due to recognizing the importance of treatment of four vaccines (Pfizer/BioNTech, AstraZeneca, Moderna and Johnson & Johnson), the controversiality of the results of some vaccines (Sputnik-V and Sinovac) and unrecognition by the EU "vaccine passport" law[6] demonstrates once again the importance of the Oviedo Convention (Article 3), Declaration on Human Rights and Bioethics and other international legal acts. Article 7 of the Protocol

[5] Additional Protocol to the Convention on Human Rights and Biomedicine 27.XI.2008 (n 4).

[6] 'EU Digital COVID Certificate' <https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en> (accessed: 14.11.2021).

provides carrying out a direct experiment. A genetic test for health purposes may only be performed under individualized medical supervision[7].

Article 8 of the Protocol provides that when a genetic test is envisaged, the person concerned shall be provided with prior appropriate information in particular on the purpose and the nature of the test, as well as the implications of its results. Article 12 of the Oviedo Convention does not restrict the right to diagnostic intervention during genetic testing in order to detect whether an embryo has a disease (Article 12). However, in this circumstance, it should be taken appropriate measures to prevent benefit sharing of the third parties. The Oviedo Convention prohibits predictive genetic tests for scientific researches not for health purposes even so a patient has consent. The Convention only permits performing genetic testing to prevent a disease (Article 12).

The Protocol further clarifies this matter. It is noted that the clinical use of a genetic test should be a basic criterion for deciding whether to present this test to an individual or a group of individuals. Under Article 12 the Convention prohibits the carrying out of predictive genetic tests for reasons other than health-related research as part of pre-employment medical examinations. However, in particular circumstances, when the working environment could have prejudicial consequences on the health of an individual because of a genetic predisposition, predictive genetic testing may be offered without prejudice to the aim of improving working conditions. Insofar as predictive genetic testing, in the case of employment does not have a health purpose, it entails a disproportionate interference in the privacy of an individual. The insurance companies will not be entitled to subject the conclusion or modification of an insurance policy to the holding of a predictive genetic test. However, as provided in Article 26 (1) of the Convention, the performance of a test predictive of a genetic disease outside the health field may be allowed to be performed for "common reasons"[8].

The Protocol contains a provision about the regulation of the predictive genetic tests in Article 8. Such tests include tests predictive of a monogenic disease; tests serving to detect a genetic predisposition or genetic susceptibility to a disease; tests serving to identify the subject as a healthy carrier of a gene responsible for a disease. Genetic counseling shall be given in a non-directive manner. Article 13 of this Protocol provides that a genetic test on an incapacitated person to consent may only be carried out for his or her direct benefit. Articles 11, 12, 13 regulate the subjects related to information given prior to authorization, genetic counselling and support. Article 14 of

[7] M Matijevic, 'Historical and Philosophical Background of Genetic Engineering in the EU Contexts' (2019) 3 EU and Comparative Law Issues and Challenges Series 278.

[8] A H Scott, 'Genetically Modified Crop Regulation: The Fraying of America's Patchwork Farm Lands' (2015) 26 Villanova Environmental Law Journal 149.

the Protocol stipulates performing tests on biological materials when it is not possible to contact the person concerned[9].

Article 15 of the Additional Protocol regulates tests performed on diseased persons. The legal norms enshrine that genetic test for the benefit of other family members may be carried out on biological samples: – removed from the body of a deceased person, or – removed, when he or she was alive, from a person now deceased, only if the consent or authorization required by law has been obtained.

Article 41 of the Law on Protection of Public Health in Azerbaijan states that pathological and anatomical examination (autopsy) is carried out by a physician in order to obtain information on the causes of death and diagnosis of the disease, and the rules of its conduct are determined by the relevant executive authority. The Protocol states also respect for privacy and the right to information under Article 16. Everyone has the right to respect for his or her private life, in particular to the protection of his or her personal data derived from a genetic test. Everyone undergoing a genetic test is entitled to know any information collected about his or her health derived from this test. Article 17 provides that biological samples shall only be used and stored in such conditions as to ensure their security and the confidentiality of the information which can be obtained therefrom. The Protocol also regulates the appropriate measures to facilitate access for the public to objective general information on genetic tests, including their nature and the potential implications of their results. (Article 20). A health screening program involving the use of genetic tests may only be implemented if it has been approved by the competent body (Article 19)[10].

The Oviedo Convention and its Additional Protocol concerning Genetic Testing for Health Purposes (2008 (Strasbourg) (No. 208) cover a particularly important area regarding genetic testing for health purposes. Unfortunately, there is a huge gap in the concerned area in the national legislation. One of the problems tried to be superficially regulated in the Law of Azerbaijan "On Protection of Public Health" is biomedical research.

Despite the fact that a requirement for a provision of specialized medical care in cases where a citizen's disease requires special examination (Article 34), preventive treatment, diagnosis and treatment methods, application of complex medical technologies, '<…> diagnostic and treatment methods that are not allowed to be used, but are being considered in the prescribed manner' (Article 36), are stipulated in the Law, the legal norm does not provide any regulatory mechanism.

Only in Article 37 of the Law, the issues related to the involvement of a human being in any biomedical research in the form of an object are expressed

[9] Additional Protocol to the Convention on Human Rights and Biomedicine 27.XI.2008 (n 4).
[10] Ibid.

in a very superficial way. However, international law has taken a more detailed approach to resolve this issue. As there is no internal norm to compare, we will try to analyze relevant international acts.

The Fifth Chapter of the Oviedo Convention and its 2005 Additional Protocol concerning Biomedical Research[11] to which currently 12 States are a party, provides the primacy of a human being taking account of biomedical researches for human life (Article 3).

Guiding on the principles stated in the Oviedo Convention, the Protocol requires terminating carrying out biomedical research that is contrary to human dignity and human rights. The main biomedical duty is to protect the guaranteed human rights and freedoms of all human beings subjected to any research (Article 1). The Protocol regulates the issues relating to risks and benefits (Article 6), Approval (Article 7), protection of persons not able to consent to research (Article 15), scientific quality (Article 8), and benefits (Articles 6, and s26), the confidentiality of private life (Article 25), infringement of the rights and compensation for damages (Articles 30 and 31) and non-interference with clinical interventions (Article 23) and other issues, along with the main principles stated in the Convention. It covers a full range of biomedical research, including intervention in the human body. This Protocol does not apply to research on embryos *in vitro.* It does apply to research on foetuses and embryos *in vivo* (Article 2)[12].

Pursuant to Articles 15, 18 and other provisions, as well as under the 2008 Additional Protocol to the Convention concerning Genetic Testing for Health Purposes the creation of embryos in vitro for the purposes of scientific research is expressly prohibited13. Only by conducting medical research in accordance with the Protocol on Biomedical Research can a genetic modification be made to a sperm or egg cell. However, this intervention must not be related to the creation of an embryo. Indeed, it is true that *in vitro* fertilization or artificial insemination is possible under the observation of ethical rules of the special control body. In this case, intervention is possible for the treatment of malignant diseases. The importance of the Protocol is that it stipulates scientific research on humans with no alternative. Article 5 says that research on human beings may only be undertaken if there is no alternative of comparable effectiveness. Under Article 6 the Protocol provides that research shall not involve risks and burdens to the human being disproportionate to its potential benefits. The research on a person who is not in a state to give consent, may be carried out, only in specific situations and under the protective conditions provided by the Law, and which will be related to the direct benefits for the health of

[11] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Researchs, 25.I.2005 <https://www.coe.int/t/dg3/healthbioethic/Activities/01_Oviedo%20Convention/195%20 Protocole%20 recherche%20biomedicale%20e43.pdf> (accessed: 14.11.2021).
[12] Ibid.
[13] Ibid.

a person concerned, who are subjected to clinical research. Such consent may be freely withdrawn by the person at any phase of the research. Refusal to give consent or the withdrawal of consent to participation in research shall not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care (Article 14). This clause was also considered in Article 37 of the National Law on the Protection of the Public Health in wording as such that even so in a limited form, '<…> a citizen has the right to freely withdraw consent to research at any time irrespective of its phase'[14].

Article 7 of the Protocol stipulates approval of results of research projects by the competent body. The Article states so 'research may only be undertaken if the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability'[15]. Whereas, Article 37 of the National Law mentioned above solved this issue by 'permitting to conduct biomedical research in state and non-state health facilities based on the results of laboratory experiments'[16]. Nevertheless, this matter is clarified in three broad contents under Article 9 of the explanatory report of the Protocol as an international legally binding document. That provision addresses that each research project shall be given to the independent ethics committee. Parties to the Protocol shall take measures to have such ethics committees for the examination of their scientific merit and ethical acceptability. This Committee, consisting of appropriately qualified researchers, has to be interested in the protection of the rights of research participants (Article 12). The legislation does not exclude the establishment of such committees.

Article 37 of the Law on Protection of the Public Health uses wording that 'when a citizen has consent to biomedical research, he has the right to be informed about the purpose of the examination, side effects, possible risks, duration and results <…>'[17]. In comparison, Article 13 of the Protocol covers the important procedures for the research participants related to access to information and consent. Persons being asked to participate in a research project shall be given comprehensive documented information on the purpose, the overall plan and the possible risks and benefits, and the opinion of the ethics committee shall be included.

The Article regulates the provision of the information of a person concerned with nature, extent and duration of the procedures involved, details of any burden imposed, available preventive, and therapeutic procedures, the arrangements for responding to adverse events or the concerns of research

[14] Law of the Azerbaijan Republic of June 26, 1997 No. 360-IQ About public health care <https://cis-legislation.com/document.fwx?rgn=5809> (accessed: 14.11.2021).
[15] Additional Protocol to the Convention on Human Rights and Biomedicine 25.I.2005 (n 11).
[16] Law of the Azerbaijan Republic of June 26, 1997 No. 360-IQ About public health care (n 14).
[17] Ibid.

participants; arrangements to ensure respect for private life and ensure the confidentiality of personal data, arrangements for access to information relevant to the participant arising from the research and to its overall results; the arrangements for fair compensation in the case of damage, any foreseen potential further uses, including commercial uses, of the research results, data or biological materials[18].

Articles 17–20 of the Protocol regulate the issues related to research with minimal risks and minimal burden (17), research during pregnancy and breastfeeding (18), research on persons in emergency clinical situations (19), and research on persons deprived of liberty (20).

The national Law earlier noted does not provide any provision about health status of the research participants. Whereas, Article 22 of the Protocol stresses taking all necessary steps to assess the state of health of human beings prior to their inclusion in research, to ensure that those at increased risk in relation to participation in a specific project be excluded.

One of the global issues discussed during the COVID-19 pandemic is the lack of unconditional confirmed results of vaccines. As regards, Article 23 of the Protocol has a significant role, because the provisions state that in research associated with prevention, diagnosis or treatment, participants assigned to control groups shall be assured of *proven methods of prevention, diagnosis, or treatment*.

The use of a placebo is permissible where there are no methods of proven effectiveness, or where withdrawal or withholding of such methods does not present an unacceptable risk or burden.

Another important provision of the Protocol is related to the responsibility of scientific researchers. Under Article 29, sponsors or researchers within the jurisdiction of a Party to this Protocol that plan to undertake or direct a research project in a State not a party to this Protocol shall ensure that, without prejudice to the provisions applicable in that State, the research project complies with the principles on which the provisions of this Protocol are based and where necessary, the Party shall take appropriate measures to that end.

Conclusion. Of course, we can continue to analyze the Oviedo Convention and the Protocol on Biomedical Research, thereto, but the main purpose here is to show the main gaps in the legislation of Azerbaijan. Unfortunately, the issues regulated by both the Protocol on Genetic Testing for Health Purposes and the Protocol on Biomedical Research are either not included in the legislation or are referred to very superficially. The Law on Public Health Protection can only be adopted as a framework law in the concerned area. The Law on Genetic Testing for Health Purposes and the Law on Biomedical Research should be adopted in order to regulate the relevant issues.

[18] Additional Protocol to the Convention on Human Rights and Biomedicine 27.XI.2008 (n 4).

In this case, Germany as one of the developed countries can be a good example in choosing the best title for the new legal norm and the title of the new law can be also a Law on Genetic Engineering. However, given the global nature of the issue, the regulatory title of the Law from the perspective of the Oviedo Convention and its relevant Protocols may be more systematic. Of course, the ratification of the Oviedo Convention and its respective Protocols can be ensured as a last resort.

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ГЕНЕТИЧНЕ ТЕСТУВАННЯ ДЛЯ ЦІЛЕЙ ОХОРОНИ ЗДОРОВ'Я ТА БІОМЕДИЧНИХ ДОСЛІДЖЕНЬ

Анотація. Стаття тлумачить положення Ов'єдської конвенції та протоколів про біомедичні дослідження та про генетичне тестування в медичних цілях до неї. Вказано на основні прогалини в національному законодавстві Азербайджану. На жаль, питання, що регулюються як Протоколом про генетичне тестування в медичних цілях, так і Протоколом про біомедичні дослідження, або не включені до законодавства, або згадуються дуже поверхово. Закон про охорону здоров'я може бути застосований лише як рамковий документ у відповідній сфері. Отже, у статті робиться висновок, що для врегулювання відповідних питань необхідно ухвалити хакони "Про генетичне тестування в цілях охорони здоров'я" та "Про біомедичні доісліджения".

У цьому випадку Німеччина як одна із розвинених країн може бути хорошим прикладом у виборі найкращої основи нової правової норми, а назва нового закону також може бути Законом про генетичну інженерію. Однак, враховуючи глобальний характер питання, нормативна основа Закону з точки зору Ов'єдської конвенції та відповідних протоколів до неї може бути більш систематизованою. Звичайно, ратифікація Ов'єдської конвенції та відповідних протоколів до неї може бути забезпечена в крайньому випадку.

Ключові слова: біомедицина; міжнародне право; біоетика; біотехнологія; закон.