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THE LEGAL REGULATION  
OF BIOBANKS

## National Report: Slovakia



CENTER FOR ETHICS AND LAW  
IN BIOMEDICINE





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Judit Sándor, Judit Schvéger, Petra Bárd  
THE REGULATORY FRAMEWORK OF THE  
ESTABLISHMENT, MANAGEMENT  
AND FUNCTIONING OF BIOBANKS IN SLOVAKIA

As partners in the European Union Framework Project entitled “GeneBanC: Genetic bio and dataBanking: Confidentiality and protection of data” we are exploring the legal regulations of databanks. (<http://www.genebanc.eu/>) The Center for Ethics and Law in Biomedicine established at the Central European University, Budapest (<http://www.ceu.hu/celab>) aimed to investigate the existing regulatory framework of biobanks across the EU and focus on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks across Europe. An important objective was to look at the similarities and differences in such legislation and regulations, in order to formulate recommendations towards a harmonization of European practices and regulations. The European jurisdiction was divided up into two parts

between CELAB and the Belgian project partner, the Centre for Biomedical Ethics and Law, K.U.Leuven. CELAB was focusing on the regulatory framework of Cyprus, the Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic, and Slovenia. The present booklet is one in the series of country reports prepared by CELAB.

*We would like to express our gratitude to Professor Jan Koller from the Central Tissue Bank, University Hospital Bratislava and Professor Daniel Kuba from the Slovak Centre for Organ Transplantation and professor at the Slovak Medical University Bratislava who kindly introduced us into the regulatory framework and also the everyday operation of Slovak biobanks, and thereby immensely contributed to the present report.*

*Budapest, 1 April 2010*

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## I. CLASSICAL AND POPULATION BIOBANKS

### 1. DEFINITION OF BIOBANKS

The Slovak Republic has not adopted special regulative framework on the establishment and management of biobanks in Slovakia, however the country has adopted other legislative measures, which are potentially applicable to biobanks. Although there is no comprehensive legal document in the respective domain, a number of general pieces of national legislation (such as constitutional provisions, laws, regulations, codes of practice and so forth) and international instruments are governing the field.

Although the Slovak Republic has not adopted a specific law on biobanks or on genetic data, the Act on healthcare and healthcare related services and on the amendment and

supplementing of certain laws (hereinafter referred to as Health Care Act)<sup>1</sup> and related regulations on the execution of the previous act, adopted during the 2004 healthcare reform, contain rules concerning the establishment of tissue and cell banks.

According to Article 35 Section (1) of the Health Care Act, “[R]emoval, conservation and transfer of organs, tissue and cells for transplantation and scientific research purposes can be performed by providers on the basis of a license as per a separate regulation.” The same article also provides that such health care service providers are entitled to establish a “[...] tissue bank [that are] executing performances connected with removal, treatment, conservation and distribution of tissue and cells for the purposes of transplantation”.

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<sup>1</sup> Zákon č. 576/2004 Z. z. o zdravotnej starostlivosti, službách súvisiacich s poskytovaním zdravotnej starostlivosti a o zmene a doplnení niektorých zákonov. Available in Slovakian at <http://www.health.gov.sk/redsyst/rsi.nsf/0/29C63CCD3C85FCA0C12572B4002C0655?OpenDocument>. In English: Act 576 of 2004 on health care, adopted by the National Council of the Slovakian Republic, with effect from: 01/11/2004, effective from: 06/01/2006, in force: 12/31/2007.

## 2. RELEVANT LAWS

In Slovakia, bioethics was deemed an important domain of fostering the first health care reform, prepared by the Slovak Ministry of Health between 1990-1992<sup>2</sup>. After the Republic of Slovakia has become an independent and sovereign state in 1993, many of its legal fields, including the legal domain of healthcare and the legal-ethical aspects of medical treatment, have been subjected to new legislative regulations. Although several legislative amendments have been implemented into national law, one of the most significant newly adopted legislation was applied in the field of biomedicine with the aim to follow up principles and norms covered by international conventions.

The Slovak Republic signed and made no reservations to the Oviedo Convention on 4 April 1997, whereupon it was ratified by the Slovakian National Council on 15 January 1998<sup>3</sup>. Article 11 of the Constitution of the Republic of Slovakia<sup>4</sup> stipulates that international treaties on human rights and basic liberties ratified by the

Slovak Republic and promulgated in a manner determined by law take precedence over its own laws, provided that they secure a greater extent of constitutional rights and liberties than national law. Ratified and published treaties shall be applied directly, therefore as of its enforcement the Convention and its related Protocols became part of the Slovakian domestic law and have a superior force to any national legislation and are directly applicable in all legal procedures. It is also worth mentioning that the Convention as well as the work undertaken by the Steering Committee on Bioethics (CDBI) within the Council of Europe have also influenced a number of national legislation in the field of biomedicine in the country.

Due to the fact that Slovakia has not adopted any specific legislation concerning biobanks, the relevant legal regulation consist of generally applied provisions of legal instruments such as legislation in relation to data protection or health care as well as certain pieces of legislation concerning the regulation of trans-

<sup>2</sup> For further detail please see: Jozef GLASA, Helena GLASOVA, Country Report – Slovak Republic, Institute of Medical Ethics and Bioethics n. f Bratislava, Slovak Republic In: *Medicínska etika & Bioetika – Medical Ethics & Bioethics*, Volume 16, 2009, Supplementum 1, pages 1 – 32, ISSN 1335-0560, Available in English at: <http://www.bioethics.sk/files/journal/Suppl%201%202009%20brief.pdf>

<sup>3</sup> Dohovor o ľudských právach a biomedicíne (podpis: 4.4.1997, ratifikácia: 15.1.1998) (Oviedo 4. apríl 1997) In English Convention on Human Rights and Biomedicine (Signature: 4.4.1997, ratified 15.01.1998) (Oviedo, 4 April 1997). Further reference is available at: [http://www.foreign.gov.sk/servlet/content?MT=/App/WCM/main.nsf/vw\\_ByID/ID\\_BDFA0F8449A80739C125763500337369\\_SK&NCH=Y&OpenDocument=Y&LANG=SK&MENU=medzinarodne\\_zmluvy-vsetky\\_zmluvy&TG=BlankMaster&URL=/LDM/contractmzv.nsf/%28vw\\_ByID%29/ID\\_7C3403A8995B4026C1256BA50035FF6E](http://www.foreign.gov.sk/servlet/content?MT=/App/WCM/main.nsf/vw_ByID/ID_BDFA0F8449A80739C125763500337369_SK&NCH=Y&OpenDocument=Y&LANG=SK&MENU=medzinarodne_zmluvy-vsetky_zmluvy&TG=BlankMaster&URL=/LDM/contractmzv.nsf/%28vw_ByID%29/ID_7C3403A8995B4026C1256BA50035FF6E)

<sup>4</sup> Ústava Slovenskej republiky č. 460/1992 Zb., ako vyplýva zo zmien a doplnení vykonaných ústavným zákonom č. 244 of 1998 Z. z., ústavným zákonom č. 90 of 1999 Z. z., ústavným zákonom č. 90 of 2001 Z. z., ústavným zákonom č. 140/2004 Z. z., a ústavným zákonom č. 323/2004 Z. z. Available in Slovakian at: <http://www-8.vlada.gov.sk/index.php?ID=1013> In English: Act No. 460 of 1992 Constitution of the Slovak Republic of September 1st, 1992 as amended.

plantation along with rules on tissues and cells. The Slovak Republic has already transposed relevant European directives in the respective legal domain into national law and the area that is most comprehensively covered by national legislation is the procurement and storage of human tissues and cells for transplantation purposes.

The main legal instrument in this field is the Health Care Act that is transposing Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

In addition to the above, the Ministry of Health also adopted several ministerial regulations on the implementation and execution of the Health Care Act, such as Regulation 20 of 2007 on the procurement, donation of tissue and cells, selection criteria for the donors of tissue and cells, laboratory tests required from

donors of tissue and cells, and on the procurement procedures of cells or tissue and on their take-over by the healthcare provider (hereinafter referred to as Tissue and Cell Regulation)<sup>5</sup>. The Tissue and Cell Regulation is also the implementation of Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells. Additionally, Directive 2006/86/EC is also implemented into the Slovakian national law by Act 578 of 2004 regarding the suppliers of health assistance, the medical employees, the professional health organizations as well as the alteration and inclusion of some of the laws (hereinafter referred to as Health Suppliers Act)<sup>6</sup>.

Additionally to the aforementioned legal measures, the Act on advertising and on amendment of certain acts<sup>7</sup> (hereinafter referred to as Advertisement Act) is also worthwhile to be mentioned in relation to

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<sup>5</sup> Nariadenie vlády Slovenskej republiky č. 20/2007 Z. z. o podrobnostiach o odberoch, darcovstve tkanív a buniek, kritériách výberu darcov tkanív a buniek, o laboratórnych testoch požadovaných pre darcov tkanív a buniek a o postupoch pri odberoch buniek alebo tkanív a pri ich prevzatí poskytovateľom zdravotnej starostlivosti. Available in Slovakian at: <http://www.zbierka.sk/zz/predpisy/default.aspx?PredpisID=19860&FileName=07-z020&Rocnik=2007> In English: Regulation of Slovak Republic No. 20 of 2007 on the procurement, donation of tissue and cells, selection criteria for the donors of tissue and cells, laboratory tests required from donors of tissue and cells, and on procurement procedures of cells or tissue and on their take-over by the healthcare provider.

<sup>6</sup> Zákon č. 578/2004 Z. z. o poskytovateľoch zdravotnej starostlivosti, zdravotníckych pracovníkoch, stavovských organizáciách v zdravotníctve a o zmene a doplnení niektorých zákonov. Available in Slovakian at: <http://www.zbierka.sk/zz/predpisy/default.aspx?PredpisID=18226&FileName=04-z578&Rocnik=2004>

In English: Act 578 of 2004 Coll. regarding the suppliers of health assistance, the medical employees, the professional health organizations as well as the alteration and inclusion of some of the laws.

<sup>7</sup> Zákon 147/2001 Z. z. o reklame a o zmene a doplnení niektorých zákonov. Act 147/2001 on advertising and on amendment of certain acts.

the advertisement of activities in connection with the donation of human tissues and cells.

The Act 581 of 2004 on Healthcare Insurance Companies and Surveillance over Health Care and on Amendment and Supplementation of Certain Acts (hereinafter Healthcare Insurance Companies Act) is also worthwhile to mention as the legal act that established the Health Care Surveillance Authority.

In addition to the above mentioned legislations the Personal Data Protection Act<sup>8</sup> is also relevant in the respective legal domain. Biobanks contain not only biological samples but also personal data about the donor of the biological material such as data related to health and genetic information. Therefore one of the main legal instruments on their regulations is the Data Protection Act which transposed Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data into national legislation in 2001.

According to Article 19 of the Constitution of the Slovak Republic, “[E]veryone has the right to the preservation of his and her human dignity and personal honor, and the protection of his and her good name.” Furthermore, everyone has

the right to protection against unwarranted interference in his and her private and family life and additionally everyone has the right to protection against the unwarranted collection, publication, or other illicit use of his and her personal data. In addition to the above mentioned provisions, Article 22 also sets out that the privacy of correspondence and secrecy of mailed messages and other written documents and the protection of personal data are guaranteed.

Furthermore the Slovak Penal Code<sup>9</sup> also proves to be important since Article 160 of the Code sets out legal provisions on the misuse of tissue and cells.

Additionally, in relation to the responsibilities of medical professionals the Deontological Code of the Slovak Medical Chamber is also worthwhile to mention. The Medical Code is an annex to Act 219 of 2002 on the profession of the medical professionals.

### 3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

In line with Article 35 Section (1) of the Health Care Act, in relation to the removal, conservation and transfer of organs, tissue and cells for transplantation and scientific research purposes service providers are entitled to establish

<sup>8</sup> Úplne znenie Zákona č. 428/2002 Z. z. o ochrane osobných údajov vrátane Zákona č. 90/2005 Z. z. Available in Slovak at: In English: Personal Data Act 428 of 2002. Available in Slovak at: [http://www.dataprotection.gov.sk/buxus/docs/Uplne\\_znenie\\_428\\_2002.pdf](http://www.dataprotection.gov.sk/buxus/docs/Uplne_znenie_428_2002.pdf)

<sup>9</sup> Zákon č. 300/2005 Z. z. Trestný zákon. Available in Slovakian at: <http://www.zbierka.sk/sz/predpisy/default.aspx?PredpisID=18749&FileName=05-z300&Rocnik=2005> In English: Act No. 300 of 2005 Coll. Penal Code



- a) “transplantation centres” which perform activities in connection with the removal, distribution and transfer of organs to the recipient;
- b) “removal centres” conducting activities in relation to the removal and distribution of organs; and
- c) “tissue banks” that are entitled to perform activities on the removal, treatment, conservation and distribution of tissue and cells for the purposes of transplantation.

Aforementioned service providers in order to be in compliance with the provisions of the Health Care Act are only entitled to set up such establishments in the country. Article 11 of the Health Suppliers Act also sets out that the Ministry of Health is entitled to grant a permission to the operation of biomedical research facilities, for the equipment used for the tissues, and also for the operation of tissue and cell biobank. Additionally, Article 13 of the Health Suppliers Act also provides, that the person requesting the authorization, will have to present the type of activity that it is intending to perform.

In line with Point o) of Article 45, the Ministry of Health shall keep the national health registers that include among other registries, the national registry of transplantation candidates [Article 38 Section (3)].

#### 4. PECUNIARY ASPECTS

According to Article 35 Section (8) of the Health Care Act in line with European and national ethical principles and legislation, as well as taking

account of the related provisions of the Oviedo Convention, human tissue and cells may only be donated on an unpaid, voluntary basis in the Slovak Republic. Therefore the Health Care Act declares that the procurement and the transfer of the organs, tissues and cells with the aim of financial or any other profit are forbidden. The organ, tissue or cell donation is voluntary and free. The donor can be granted with the financial compensation of the declared travel, room and board expenses, according to the individual prescription connected with the procurement of the organs, tissues or cells.

#### 5. CONSENT OF PEOPLE WITH FULL AND LIMITED LEGAL CAPACITY, PROVISIONS ON DECEASED PERSONS

The right of a patient to informed consent shall be deemed one of the basic patient rights in Slovakia. Additionally Article 16 of the Slovakian Constitution lays down the fundamental principles in relation to the right to the personal dignity and inviolability of the individual’s physical and mental integrity. With view to free and voluntarily given consent to therapeutic and medical treatments Article 17 of the Constitution declares that “[T]he law will specify in which cases a person can be admitted to, or kept in, institutional health care without his or her consent”.

Biobanks contain not only biological samples but also personal data about the donor of the biological material therefore to some extent the provisions of the Personal Data

Protection Act are also applicable in case of tissue and cell biobanks or tissue establishments in the Slovakian Republic. Article 4 Section (1) Point i) of the Personal Data Protection Act also provides that the data subject's consent shall mean any freely given specific and informed indication of his or her wishes by which the data subject knowingly signifies his or her agreement to personal data related to him or her being processed.

Furthermore Article 8 of the Personal Data Protection Act also sets out that the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, membership in political parties or movements, trade-union membership, and the processing of data concerning health or sex life shall be prohibited. However, in line with Article 9 of the same Act, the aforementioned prohibition relating to the processing of sensitive or special categories of personal data is permitted if the data subject gave a written consent to their processing.

According to Article 6 of the Health Care Act, the informed consent shall be given by the patient or by his or her legal representative if he or she is incapable to give his or her informed consent.

The information that has to precede the consent should be given in a comprehensible, understandable manner without any restraint, giving the patient sufficient time to make a decision. The information should also be given in a way that is adjusted to the intellect, the will and the health condition of the patient. Whoever is

entitled to information is also entitled to refuse it. Since an informed consent is explicitly defined as a proven consent with a medical intervention preceded by information or preceded by a refusal of that information, the refusal of information shall have no consequences regarding the validity of consent.

According to Article 6 of the Health Care Act, health care professionals are obliged to inform patients on the purpose, nature, consequences and risks of a medical treatment as well as the possibilities of the proposed procedures and the risks of refusal of medical care unless otherwise stipulated by the law. Such information shall be provided to the respective person to whom the health care service is provided, or the legal representative, guardian, another natural person like a parent who has custody of a minor child as well as the person who is a foster child custody, the person who has a child in foster care, a person wishing to become foster parent if the child is temporarily placed under his or her care, the guardian, if the person to whom health care is to be provided is a minor, a person deprived of legal capacity or a person with limited legal capacity (the person incapable of giving informed consent). In addition to the above such information shall also be provided for the legal representative of a person who is deprived of legal capacity or has limited legal capacity and is incapable of giving informed consent the appropriate way.

Article 37 of the Health Care Act also states that during the procurement of human tissues and cells, the

removal of organs, tissue or cells from the body of a dead donor can only take place if the person did not make a written declaration on disapproval with such intervention during his or her life. For the person unapt to give such an informed approval, his or her legal representative is entitled to make such written declaration during his or her lifetime.

The aforementioned written declaration with certified signature is to be submitted to the registry of persons declaring their disapproval with postmortal removal of their organs, tissue and cells is maintained by the Ministry of Health. The disapproval can be withdrawn anytime.

The Health Care Act does not specify the form in which the informed consent should be given. In line with of Article 6 Section (7), whoever is entitled to give an informed consent in accordance with the Section (1) of the same Article, shall also be entitled to withdraw it freely at anytime.

Furthermore, additionally to the aforementioned provisions of the Health Care Act, Article 13 of the Tissue and Cell Regulation also sets forth in case of living donors that the health professional responsible for obtaining the health history must ensure that the donor has understood the information provided, had an opportunity to ask questions and had been provided with satisfactory responses, and has to confirm that all the information provided is true to the best of his or her knowledge.

It is also worthwhile to mention that Articles 26-34 of the Health Care Act set out special provisions on the management of biomedical researches. According to Article 27, a written

informed consent along with certain information for the applicant is required in order to prove that he or she is entitled to take part in biomedical research.

Such informed consent must include the date the consent was granted and signed by the prospective participant in the biomedical research or his or her legal representative.

Such informed consent must include the date and signature of the prospective participant in the biomedical research or his or her legal representative. The guidance prior to the informed consent shall be given in line with Article 6 of the Health Care Act and shall cover:

- a) the possibility for the potential research participant to withdraw his or her consent at any time and without any explanation;
- b) the purpose, the proposed procedure, risks that can be assumed and the expected benefits of this research;
- c) the nature, scope and duration of all powers and procedures of participation in the research, especially those that describe the burdens and risks that may be expected;
- d) other available preventive, diagnostic and therapeutic procedures;
- e) certain measures dealing with adverse physical or mental reactions that might occur in connection with the research, measures that ensure privacy and data protection of the research participant.

Furthermore, the Health Care Act in connection with the withdrawal of a consent to a biomedical research

also sets out that the refusal to participate in biomedical research and the withdrawal of the informed consent of the research participant shall not adversely affect the provision of health care.

Article 35 Section (2) of the Health Care Act declares that only persons having full legal capacity shall be human tissue and cell donors, and only if they have given their written informed consent to such donation after having been duly informed. In case a person is unable to give informed consent, he or she shall become a donor on the basis of an informed consent of his or her legal representative if

- a) the removal relates to regenerative tissue;
- b) a suitable donor capable to give an informed approval is not available;
- c) the potential recipient is a brother or a sister of the donor; or
- d) the donation has a life-saving potential for the recipient.

Furthermore, Section (3) also provides that the aforementioned donor shall not be a person who is arrested or imprisoned.

In case of tissue and cell procurement from deceased persons the Tissue and Cell Regulation sets out in Article 13 that prior to tissue and cell procurement, an authorized person must confirm and record that no written declaration of the donor's disagreement with post-mortal procurement of tissues or cells made during the donor's life is recorded in the register of persons who declared their disagreement with post-mortal procurement of organs, tissues or cells

during their lives and how and by whom the donor has been reliably identified.

## 6. ACCESS TO DATA AND SAMPLES AND ANONYMITY

In line with Article 7 of the Tissue and Cell Regulation, during the procurement of human tissues or cells, standard operating procedures are applied in order to verify the identity of the donor, the fact that there is no written proclamation of the donor containing his or her disagreement with the removal of tissues or cells and the assessment of the selection criteria for donors as well as the assessment of the laboratory tests stated in line with the relevant provisions of the same Regulation.

Article 7 Section (5) also declares that the procurement of tissues and cells from living donors shall take place in an environment ensuring their health, safety and privacy.

In line with Article 39a of the Health Care Act, the service provider shall also use a unique numerical code, assigned to the donor and to all the products connected to him and her. The unique numerical code is assigned by the uniform coding system, which will be established in detail by the Government of the Slovak Republic. Moreover all the tissues or the cells have to be identified with labels including the information regarding the procurement of the tissues or cells, the treatment, the storage or the distribution of the tissues or cells.

Article 39b of the Health Care Act also sets out that the service provider

shall also keep the anonymity between the donor and the recipient and his or her family.

Article 16 of the Tissue and Cell Regulation sets out the relevant provisions on the requirements of donor documentation, according to which there must be a record for each donor containing the following data:

- a) name, surname and date of birth of the donor; in the case of mother and child donation, both the name and the date of birth of the mother and the name and the date of birth of the child if they are known;
- b) age, sex, medical and behavioural history that must be sufficient for the consideration of the exclusion criteria for the donor;
- c) the results of physical examination, if required;
- d) haemodilution formula, if required;
- e) for deceased donors, a written certificate documenting that no written declaration of the donor's disagreement with post-mortal procurement of tissues or cells made during the donor's life is recorded in the respective register;
- f) for living donors, an informed consent according to the Act;
- g) clinical data, results of laboratory tests and results of other tests conducted;
- h) autopsy report, when an autopsy was performed.

## 7. STORAGE

In line with Article 2 of the Tissue and Cell Regulation, "traceability" means

the ability to locate and identification of the tissue or the cell during any stage from its procurement, through processing, testing, storage to distribution, or its eventual disposal, and it also means to identify the donor and the provider receiving, processing or storing the tissue or the cell. Additionally traceability shall also mean the ability to identify the recipient and the provider applying the tissue or the cell to the recipient and to locate and identify all relevant data relating to products and materials coming into contact with those tissues or cells.

According to Article 39a of the Health Care Act, the service provider – as set out in Article 35 –, is obliged to establish a traceability system aimed at observing all the tissues and the cells that have been withdrawn, examined, stored or distributed on the territory of the Slovak Republic, or imported from the non-member states of the European Union or from contractual states from the European Economic Area, from the donor to the recipient and vice versa. This monitoring system will concern also all the relevant information, regarding the products and the materials that have been in contact with these tissues or cells.

The service provider is obliged to keep the records necessary to ensure the traceability of tissues and cells in all the activities listed in Article 35 of the Health Care Act.

In line with Article 7 Section (7) of the Tissue and Cell Regulation, a unique numerical code shall be allocated to the donor and to the donated tissues and cells that ensures proper identification of the donor and

the traceability of donated material. Encoded data are entered into a register that is maintained for this purpose. Furthermore, according to Article 39a of the Health Care Act the information required for the full traceability of tissues and cells shall be kept for at least 30 years.

The service provider is also obliged to apply internal control and appropriate control measures within the traceability system. The activities of the service provider shall be in accordance with the Health Care Act as well as with the conditions set out in the individual prescription for the respective service provider. The latter is also obliged to make available all documents relating to the quality system for the supervision of the Ministry of Health or the Health Care Surveillance Authority<sup>10</sup>.

In addition to the above a service provider that imports or exports or distributes tissues or cells from third countries, i.e. from outside the EU or the EEA has to possess a special permit for this kind of activities.

Article 39b of the Health Care Act also provides that the service provider shall keep the evidence of its activities, especially on the type and the quantity of tissues and cells previously withdrawn, tested, traded, stored, conserved or distributed, and information regarding the provenance and the use of the tissues or cells as well as information regarding the receiving and the rejection of the tissues and cells.

The service provider shall also provide an accurate, rapid and verifiable

procedure, enabling the cancelling of distribution and use of tissues or cells and derived products, in case of an adverse event or reaction and a procedure that assures that the packing of tissues or cells fulfils all the requirements of the scientific and technical development.

Besides its own standard working procedures the service provider shall also establish the procedure regarding the use of the tissues and cells destined to be cancelled, in order to avoid the contamination of other tissues or cells present in the personal or working environment. The provider is also obliged to guarantee the quality of the tissues and cells during the transportation.

## 8. SUPERVISION

In line with Article 37 of the Health Care Act, the competent authority in the field of the procurement and processing of tissues and cells is the Ministry of Health, which is responsible for the inspection and authorisation of tissue establishments. Such establishments are also obliged to report to the Department of Health of the Ministry of Health concerning their activities and any adverse event and reaction at tissue establishments.

In line with Article 39b of the Health Care Act, the service provider is obliged to submit annual reports to the Ministry of Health on its activities, every 1 March of the following calendar year.

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<sup>10</sup> In original language: Úrad pre dohľad nad zdravotnou starostlivosťou [http://www.udzs.sk/buxus/generate\\_page.php?page\\_id=1&lang=en](http://www.udzs.sk/buxus/generate_page.php?page_id=1&lang=en)

The Slovak Centre for Organ Transplantation (SCOT) is also worthwhile to mention, as SCOT is the organisation that coordinates centrally the donation and transplantation system in the country. The role of SCOT is primarily to manage the national transplant registry of organ donors, and patients in accordance with the Health Care Act.

The SCOT is working as a national coordinating centre for organ transplantation and uses a validated electronic system, the so-called Transplantation Information System Slovakia (TISS). The SCOT maintains the registry of potential recipients (waiting lists), the registry of donors and the registry of persons who rejected to donate organs after death. It provides the donor-recipient pair selections for transplant centres and the confirmation that the potential donor is not in the registry of persons who rejected the donation. It performs the follow up of the transplanted patients.

According to Jan Koller, Medical Director of Central Tissue Bank, Head of Department, Ministry of Health since the beginning of 2009, a new centralized computer information system was established in the country, in order to assure confidentiality and privacy protection as well as full traceability of organs, tissues, cells and related products<sup>11</sup>.

Another institution to be referred to is the Healthcare Surveillance Authority. The Authority was established by

the Healthcare Insurance Companies Act as a legal person which is vested with the power to perform supervision and monitoring of the provision of health care and public health care insurance in the field of public administration.

### **8.1. Ethical Committees**

According to Article 5 of the Health Care Act ethical issues arising in healthcare and ethical acceptability of biomedical research projects shall be assessed by independent ethics committees. In line with the aforementioned provisions of the law the Ministry of Health is entitled to establish a central ethical committee. Furthermore the Ministry of Justice of the Slovak Republic, in agreement with the Ministry of Health is also entitled to establish ethical committees with the aim of reviewing ethical issues in relation to the provision of medical care, and health care services in medical facilities of prisons and detention centres.

In addition to the above, autonomous regions are also entitled to establish ethical committees at a regional level in order to assess the ethical acceptability of biomedical research projects and ethical issues. Regional ethical committees are appointed by the regional state authority. Furthermore health care service providers are also enabled by the Health Care Act to set up ethical committees to assess the ethical

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<sup>11</sup> Workshop Report - Second International Workshop of the Tiss.EU Project Budapest, 6-8 April 2009  
[http://www.tisseu.uni-hannover.de/index.php?option=com\\_content&task=view&id=62&Itemid=1](http://www.tisseu.uni-hannover.de/index.php?option=com_content&task=view&id=62&Itemid=1)

acceptability of biomedical research projects and ethical issues. The latter local ethical committees are established by directors of health care facilities or biomedical research institutions.

The same provision of the Health Care Act also provides that ethics committees have at least five members, composed of health workers and other professionals whose expertise is required for the operation of the ethics committee, and those without qualifications to pursue a health care profession or research. Each member of the ethics committee is a representative appointed by professional health care organizations. The number of members of the ethics committee without qualifications to pursue a health profession or research shall not exceed the absolute majority of all members of the ethics committee.

The first ethics committee in the Slovakian Republic, namely the Central Ethics Committee was established in 1990 and was based in research institutes and major teaching hospitals<sup>12</sup>. In 1993, some personal changes were introduced concerning the Committee's membership. Since then, during almost ten years, the Committee has not been very active. The continuity of its work, and of the international contacts and collaboration were sus-

tained<sup>13</sup>. The establishment of the predecessor of the National Commission on Medical Ethics as a central ethics committee also took place in the same year by the Ministry of Health. The Central Ethics Committee of the Slovakian Republic has assumed the role of a national ethics council since 1993 and provides support and guidance to the local ethics committees and it also considers and drafts legislation in the fields of health care, medicine and biomedical research.

The development of these committees was driven by scientists, bioethicists and the good clinical practice requirements of pharmaceutical companies.

The operation of the local ethical committees were determined by the opinions and guidelines of the central ethics committee, that provided advice on and control of the formation of local ethics commissions both in the field of clinical ethics and for the examination of research projects, as well as of ethics commissions engaged in both kinds of advisory activity and examination. The guidelines on the establishment and work of ethics committees in healthcare institutions and in biomedical research institutions adopted by the central ethics commission were submitted to the Ministry of Health as a recommendation in June 1992.

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<sup>12</sup> For further detail please see Michael FUCHS, National ethics councils. Their backgrounds, functions and modes of operation compared, 5. Central and Eastern Europe, Slovak Republic, Published by the German National Ethics Council, 2005. p. 52. Available at: [http://www.ethikrat.org/\\_english/publications/Fuchs\\_International\\_Ethics\\_Councils.pdf](http://www.ethikrat.org/_english/publications/Fuchs_International_Ethics_Councils.pdf)

<sup>13</sup> Ethics in the New Member States The European Group on Ethics in Science and New Technologies to the European Commission EGE Secretariat, June 2004. [http://ec.europa.eu/european\\_group\\_ethics/publications/docs/rptnwnec\\_en.pdf](http://ec.europa.eu/european_group_ethics/publications/docs/rptnwnec_en.pdf)



The National Commission on Medical Ethics (NCME) in line with its legal status act<sup>14</sup> shall be considered as it is a professional advisory body to the Ministry of Health and it mainly performs the assessment of legislative proposals in relation to the health sector. Although the main duty of the NCME is to serve the needs of the Ministry of Health in the first place, it could also be approached for an opinion/advice/information on bioethical issues by other state institutions; and it also serves as a consulting body for the local and regional ethical committees in the country.

Furthermore the NCME only performs the ethics review of projects or protocols for a specific research project in special cases, e.g. if there is no other relevant or responsible ethics committee for the specific project.

As it is mentioned above, in line with Article 5 of the Health Care Act, the composition of the NCME is interdisciplinary and its members are coming from a variety of professional, religious, philosophical and ethical backgrounds.

For clinical trials, the approval of the State Institute for Drug Control<sup>15</sup> is required in addition to the approval of the local ethical committees. The final decision regarding research is

taken by the director of the institute using recommendations of the local ethical committees as guidance.

The Institute of Medical Ethics and Bioethics<sup>16</sup> as an independent organization established in 1992 is also worthwhile to mention. The Institute was founded as a joint institute of and the result of collaboration between the Slovak Medical University and the Faculty of Medicine of the Comenius University in Bratislava. The Institute of Medical Ethics and Bioethics along with the Foundation of the Institute of Medical Ethics and Bioethics operated as a representative of interests of ethical committees and is presently taking care of the ethical committees' needs, education and development, also in relationship with relevant state authorities.

## 8.2 Penalties

According to Article 160 of the Penal Code any person who illegally owns a dead body, or tissue or cell of a deceased person is punished by imprisonment from six months up to three years.

It is also worthwhile to mention that in line with Article 7a of the the Advertisement Act, advertising the

<sup>14</sup> S˘tatút Etickej komisie MZ SR, Ministerstvo zdravotníctva, 26.09.2005 Available in Slovakian at: [http://www.health.gov.sk/redsys/rsi.nsf/0/53D05582986A80B5C1257088003B85FD/\\$FILE/EK\\_MZSR.pdf](http://www.health.gov.sk/redsys/rsi.nsf/0/53D05582986A80B5C1257088003B85FD/$FILE/EK_MZSR.pdf) In English: Statute of the Ethical Committee of the Ministry of Health, Ministry of Health, 26.09.2005. For further information please consult:

[http://www.health.gov.sk/redsys/rsi.nsf/vdb\\_Sections?OpenView&ID=PAR987272977341&TYPE=S&LANGUAGE=S&LENGTH=S&MNU=MNU377883005743](http://www.health.gov.sk/redsys/rsi.nsf/vdb_Sections?OpenView&ID=PAR987272977341&TYPE=S&LANGUAGE=S&LENGTH=S&MNU=MNU377883005743) (in Slovakian).

<sup>15</sup> S˘tátny ústav pre kontrolu liečiv (State Institute for Drug Control) Further information is available at: <http://www.sukl.sk/sk>

<sup>16</sup> Ústav medicínskej etiky a bioetiky n. f. (Institute of Medical Ethics and Bioethics) <http://www.bioethics.sk/>

necessity or availability of organs, tissues and cells, with the aim of offering or obtaining financial profit or similar advantages, is prohibited. Therefore Article 11 of the same Act sets out the penalties imposed on those who failed to comply with the aforementioned prohibition.

## 9. PUBLIC DEBATE

The regulation of biobanks did not invoke a public debate in the Slovak Republic. The controversies have been discussed in professional circles mainly.

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## II. FORENSIC BIOBANKS

### 1. RELEVANT LAWS

There is no specific law on forensic databanks in the Slovak Republic. However according to the current practice the Slovak Police Force is entitled to collect any information of an evidential nature in the interest of criminal investigation. With reference to the applicable legislative measures in the respective domain, the Article 69 of the Act 171 of 1993 on the Police Force of the Slovak Republic<sup>17</sup> sets out that the Police is entitled to collect and process personal data and information in order to perform its duties. The Police is also entitled to supervise the forensic database of the Slovak Republic that was established in 2004 and is managed by the Institute of Forensic Science of the Slovakian Police Corps<sup>18</sup>. In relation to the Police Act, Act 417 of 2002 on the use of DNA for the person's identification<sup>19</sup> (hereinafter referred to as the Person Identification Act) also has to be noted.

The relevant provisions of the Data Protection Act are also applicable to forensic databases and the collection of genetic information in Slovakia for investigating purposes. Apart of the above mentioned provisions set forth in the Data Protection Act, the Penal Code and the Criminal Procedure Code<sup>20</sup> are worth mentioning.

### 2. MANAGEMENT AND SUPERVISION

As it is mentioned above the Slovak Police Force is entitled to manage the forensic database of the Slovak Republic. According to Article 5 of the Personal Identification Act, a database containing the profiles of DNA samples is constituted and operated by the Police.

The management of the forensic database maintained by the Police shall be subject to the provisions of the Personal Data Protection Act. However, according

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<sup>17</sup> Zakon 171/1993 o Policajnom zbore. Available in Slovakian at: <http://www.regionzilina.sk/files/odborry/doprava/rok-2008/5.tyzen/pravne-predpisy/zakon-171-1993-Z-z.doc> In English: Act No. 171 of 1993 on the Police Force

<sup>18</sup> Kriminalisticky a expertizny ustav Policajneho zboru (KEU PZ) Further information is available at: <http://www.forensicsociety.sk/> In English: Institute of Forensic Science (IFS).

<sup>19</sup> 417/2002 Zákon z 21. júna 2002 o používaní analýzy deoxyribonukleovej kyseliny na identifikáciu osôb, In English: Act 417 of 2002 on the use of DNA for the personal identification. Available in Slovakian at <http://www.zbierka.sk/zz/predpisy/default.aspx?PredpisID=16619&FileName=02z417&Rocnik=2002>

<sup>20</sup> Zakon 301/2005 Zbierka zakonov. In English: Act No. 301 of 2005 on the Penal Procedure Code of the Slovak Republic.

to Article 2 of the Personal Data Protection Act, certain provisions of the latter Act shall not be applicable to the prevention, preclusion, detection and documentation of criminal offences, as well as to the disclosure of their perpetrators, and the investigation and prosecution of criminal offences.

### 3. SAMPLES AND SAMPLE TAKING, CONSENT

According to Article 2 of the Personal Identification Act, sample shall mean a biological material taken from the human body. Article 3 of the same Act also provides that samples can be taken for the purpose of the DNA analyzes.

There are no restrictions to the collection of DNA samples from crime suspects, convicted offenders and unidentified crime scene stains.

Article 3 Section (3) also prescribes that sample taking be conducted by a member of the police or by a member of the rail police or of an organisation active in criminal investigation, or the sample can be taken by the person itself by the presence of the above authorised persons. If a sample has been taken in a manner that violates bodily integrity or is taken from the genitals, it shall be done by a sanitary worker upon the request of a policeman or an otherwise authorised person. The method of sample taking shall neither endanger the health of the person nor his or her dignity.

### 4. PURPOSE AND SCOPE OF COLLECTION

According to the Article 2 of the Personal Identification Act, the identifi-

cation of the person shall mean the individual identification of a living person, a dead body or of divided parts of the human body.

Article 5 of the Personal Identification Act also sets forth that the forensic databank of DNA samples shall contain the profiles and DNA samples in line with the international obligations of the Slovak Republic, as well as personal data of the person whose DNA profile has been taken, such as the name and surname, date and place of birth, identity number, in case of foreigners passport number, address and citizenship as well as other characteristics. Additionally, the database shall also contain facts about the crime or investigation in connection with which DNA has been collected.

### 5. ACCESS TO DATA AND SAMPLES

According to Article 6 of the Personal Identification Act, the Police has the obligation to protect the items saved in the database against theft, lost, injury, destruction, change, distribution or unauthorized access.

However Article 7 also sets out that the database is the property of the Police, and the providing is regulated by the individual Act. (Act 171/1993 on the Police Force, Articles 13 and 14 of Act 52/1998 on privacy in information systems). It is also worth mentioning that the Slovakian Police also makes use of and received access to Interpol's DNA database through the International DNA Gateway portal. In addition to the above Slovakia as a Member State of the

European Union, takes part in the DNA data exchange and matching system used by the EU member states<sup>21</sup> in line with Council Decisions 2008/615/JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime and 2008/616/JHA on the implementation thereof<sup>22</sup>.

## 6. STORAGE

The Personal Identification Act has also established the organisational and technical logistical procedures and measures for the protection of personal and confidential data administered by the police in the forensic database. In line with Article 6 of the Act, the Police has the obligation to protect the items saved in the database against theft, lost, injury, destruction, change, distribution or unauthorized access.

According to Article 8 of the Act, the agency affiliated with and appointed by the Ministry of Interior, that is entitled to carry out the analysis of DNA samples, is obliged to destruct any information about the person against

whom the criminal sanction ceased, if the charges against such person were proven to be uncertain or false, or such charges were proven to be based on false accusation. In addition to the above, the relevant organisation of the Ministry shall also destruct the information about the person against whom the criminal sanction cannot be enforced, or if such person is not responsible for the crime or has been exempted from the accusation, or after 100 years after the birth of the individual.

The authority that dropped the criminal action against the person, whose DNA-profile is secured in the database has the obligation to inform the organisation in charge of the analysis about this fact within three working days after the dropping of the criminal action.

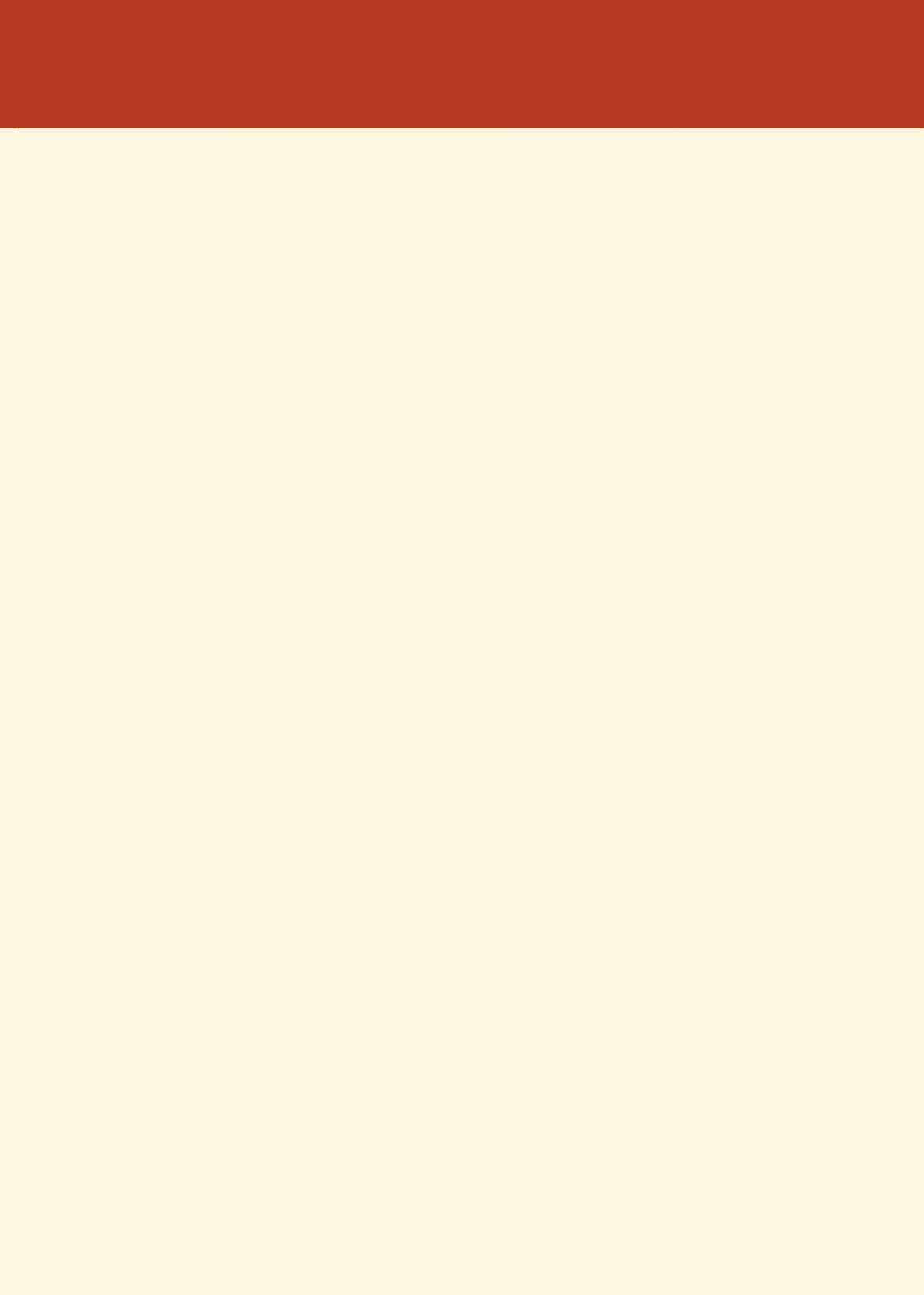
Additionally, according to Article 69 of Police Act, the Police is obliged to destroy without undue delay any information, if the Police do not need these data for the fulfilling of their tasks. Police officials are obliged to check at least once every three years whether storage of these data is still necessary.

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<sup>21</sup> Further details on the DNA exchange of the Member States of the European Union are available for example at the DNA database management review and recommendations of the ENFSI DNA Working Group, April 2009. Available at: [http://www.enfsi.eu/get\\_doc.php?uid=345](http://www.enfsi.eu/get_doc.php?uid=345).

<sup>22</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:210:0012:0072:EN:PDF>







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