

PATIENT RIGHTS IN THE EU



HUNGARY

EUROPEAN ETHICAL - LEGAL PAPERS N° 11

EuroGentest

PATIENT RIGHTS IN THE EU HUNGARY

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HUNGARY

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FOREWORD



Within the Centre for Biomedical Ethics and Law of the Catholic University of Leuven - one of the leading bioethical and legal research centres in Europe - we are involved as coordinator, partner or participant in different European research projects. Biomedical ethics and law are rapidly evolving disciplines. Although there exists already a great number of specialized peer reviewed journals and series of books in both disciplines we felt a growing need for a medium through which the results of our research can directly be presented to the research community and the interested community at large. To meet this need we decided to start the *European Ethical-Legal Papers*. Such papers will also contribute to the transparency we owe to society that finances our research efforts. We also hope that it will contribute to the discussion and the exchange of information and ideas among researchers in Europe and elsewhere.

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I. INTRODUCTION



EuroGentest is a five-year EU funded program that aims to develop the necessary infrastructure, tools, resources, guidelines and procedures that will lead to the establishment of harmonized, qualitative genetic testing services in Europe. Within EuroGentest we are dealing with the ethical and legal issues of genetic testing. Harmonization of the technical aspects of genetic services in Europe requires a legal and ethical framework that respects cultural, religious, philosophical and other domestic characteristics of a given country and its population(s), but at the same time conforms to basic and universally accepted human rights. To continuously supervise the legal and ethical developments regarding the promotion and protection of the rights of patients and users of health services and to make the results of our research publicly available, is a permanent challenge. This publication in the European Ethical-Legal Papers aims to contribute to it.

Opened for signature more than 10 years ago (in Oviedo, Spain, on 4 April 1997), the European Convention on Human Rights and Biomedicine is now becoming increasingly important as a standard to evaluate the efforts and the progress made by the Member States of the European Union to promote and protect the rights of patients and users of health services. In this eleventh issue we present the results of this evaluation for Hungary, one of the EU Member States that have ratified the Convention.

The content of this publication is as follows.

In an introductory chapter we briefly describe Hungary with respect to some of its main features related to its political and legal background and its health care system.

This is followed by an encompassing overview of the rights of patients in Hungary. In a first paragraph the legal status of the Biomedicine Convention is situated against the background of Hungarian constitutional law. Then we turn to a description of the national legislation on patient rights. Many different enumerations of patient rights exist. Since we are particularly interested in the way the

Biomedicine Convention has been received by the Member States of the European Union, we follow the structure of the Convention. The right to informed consent (articles 5, 6, 8 and 9 of the Convention) comes first, followed by different aspects of the right to private life and the right to information (article 10 of the Convention) such as: patient rights regarding the medical file, the right to medical secrecy/confidentiality and the right to privacy and protection of private life. This part of the analysis ends with the right to complain in case of unlawful infringement of a patient right (article 23 of the Convention) and the right to compensation for undue damage (article 24 of the Convention). In the next chapter we look at the rights of patients as users of genetic services: are the rights of patients complemented by more specific rights for users of genetic services? (articles 11 and 12 of the Convention). With some concluding remarks we finish this paper N° 11 of the Ethical-Legal Papers.

Without the help of Judit Sándor (Professor of law, Center for Ethics and Law in Biomedicine, Central University Budapest) and Zsuzsanna Tomka (Ministry of Health of Hungary) we could not have accomplished this work. They provided us with valuable information on the status of patient rights in Hungary and answered our questions accurately and patiently. In the footnotes we refer to the information provided by them as “personal communication of”. The possible mistakes and wrong interpretations are our responsibility. We are also aware of the limitations of this endeavor not the least because of differences in languages. Nevertheless we hope that this publication will stimulate the discussion on the promotion and protection of patient rights in Hungary. Therefore we welcome all reactions on www.cbmer.be.

Leuven, December 2007

The research for this publication was supported by the Eurogentest Network of Excellence of the EU, FP6 – 512148 and its coordinator Prof. Dr. J.J. CASSIMAN

II. BRIEF DESCRIPTION OF HUNGARY



§ 1. Political and legal system

After regaining its full sovereignty and independence in 1989, Hungary became a parliamentary republic. According to the Hungarian Constitution all power is vested in the people, which exercise its powers through elected representatives, seated in the National Assembly. The unicameral National Assembly consists of 386 members, all elected for a four-year term. The election system is a combined system, which means that voters cast one vote for an individual candidate and another for a regional political party list.

The head of state of the Republic of Hungary is the President. He is elected by the National Assembly for a term of five years and he is eligible for one re-election. The presidential role is to a large extent ceremonial. He participates neither in the legislative nor in the executive power and he generally needs the countersignature of the Prime Minister or the competent minister to exercise his powers as president.

The executive power is vested in the Government. This political decision making body is headed by the Prime Minister. He is elected by members of the Parliament on the proposal of the President and has a leading role in the executive branch. The other ministers are proposed by the Prime Minister and appointed by the President. The Government is accountable for its functioning to the National Assembly and has to report upon its work on a regular basis.

The judicial system in Hungary is three-tiered: local and labor courts, the metropolitan court (of Budapest) and the county courts, the Courts of Appeal and the Supreme Court of the Republic of Hungary. The local and labor courts operate as courts of first instance. The metropolitan court (of Budapest) and the county courts proceed as courts of first instance in specific cases and also as courts of second instance. They review appeals entered against decisions of local and

labor courts. The Courts of Appeal pass judgment on the decisions of local or county courts in specific cases. The Supreme Court of the Republic of Hungary assures the unity of law application by the courts and assesses appeals against decisions of the metropolitan courts, the county courts or the Courts of Appeals.

The Constitutional Court is the supreme body protecting the Hungarian Constitution. The Court has the power to challenge legislation on the grounds of unconstitutionality. The eleven members of the Constitutional Court are elected by the National Assembly for nine years. They elect a president and a vice president among themselves for a term of three years.

The Hungarian public administration consists of 19 counties. The capital Budapest is independent of any of those county governments. Since the admission to the European Union in 2004, Hungary is divided into 7 Euroregions. There are also 23 urban counties which are not independent territorial units, but have extended powers.

§ 2. Health care system

The reform of the Hungarian health care system has been a relatively consistent process since the collapse of the communist system in 1989. Decentralization and privatization were the two dominant tendencies and characterized the large-scale reform of the health sector.¹ Since important competences were transferred from central to local government, local governments became key actors in the health care system. This devolution went along with the privatization of certain health care services. However, privatization has been limited to the pharmaceutical industry, to primary care and to a few hospitals.²

According to the Constitution (article 70 D) everyone living in the territory of Hungary has the right to the highest possible level of physical and mental health. This right is to be implemented through the organization of medical care. Due to decentralization efforts, the

¹ A.DEN EXTER, *Health care law-making in Central and Eastern Europe. Review of a legal-theoretical model*, Antwerpen, Intersentia, 2002, 139-140.

² P.GAÁL, "Hungary", in A. RIESBERG (ed.), *Health Care Systems in Transition*, European Observatory on Health Systems and Policies, 2004, 31.

health care sector became a multi-actor system with responsibilities divided between diverse players such as the National Assembly, the National Government, the Ministry of Health, Social and Family Affairs (later referred to as Ministry of Health), the National Public Health and Medical Officer Service, the National Health Council, the local governments and professional organizations such as the Hungarian Medical Chamber and the Hungarian Chamber of Pharmacists.

The Hungarian Constitution determines that the Government not only has to ensure sufficient funds, but also has to define the public system of social welfare and health care services. Consequently the National Government determines the health policy and is therefore the main regulator.³ The local governments on the other hand are the dominant service providers. The Act on Local Governments of 1990 made them responsible for making health service available to the local population.

Health services in Hungary are funded according to a dual financing system. Recurrent costs are covered by social health insurance from the Health Insurance Fund. The Fund provides cash benefits such as sickness allowances.⁴ It is administered by the National Health Insurance Fund Administration, which is controlled by the Ministry of Health. Capital expenditures such as restoration and development are mainly financed by the owners of health care facilities which are primarily the local governments. They usually recover their costs from general or local taxation.

³ P.GAÁL, "Hungary", in A. RIESBERG (ed.), *Health Care Systems in Transition*, European Observatory on Health Systems and Policies, 2004, 15.

⁴ P.GAÁL, "Hungary", in A. RIESBERG (ed.), *Health Care Systems in Transition*, European Observatory on Health Systems and Policies, 2004, 21.

III. GENERAL PATIENT RIGHTS



§ 1. Legal status of the Convention on Human Rights and Biomedicine

After signing it on 7 May 1999, Hungary ratified the European Convention on Human Rights and Biomedicine on 9 January 2002 by the Parliamentary Act No. VI of 2002. The Convention entered into force on 1 May 2002.

According to article 7 (1) of the Hungarian Constitution the legal system is of the dualistic kind. Despite of the direct applicability, the treaty has to be transformed into a national law before it can enter into force. The Convention on Human Rights and Biomedicine has been implemented in the Hungarian legal system through various regulations.

The draft text of the European Convention on Human Rights and Biomedicine has been taken into consideration while the Health Care Act of 1997 (see §2) was being prepared.⁵ Chapter II concerning the rights and obligations of the patient is to a large extent also based on the WHO Amsterdam Declaration on the Promotion of the Rights of Patients of 1994.⁶

Hungary has made a restriction based upon article 26 of the Convention concerning the right of refusal of medical intervention.⁷ According to article 20 of the Health Care Act of 1997 competent patients have the right to refuse treatment unless the omission of the treatment would endanger the life or physical integrity of others. Life-supporting or life-saving interventions may only be refused if the

⁵ Personal communication of J. SÁNDOR.

⁶ A.DEN EXTER, *Health care law-making in Central and Eastern Europe. Review of a legal-theoretical model*, Antwerpen, Intersentia, 2002, 153.

⁷ H.NYS, L.STULTIËNS, et al., "Patient rights in EU Member States after the ratification of the Convention on Human Rights and Biomedicine", *Health Policy* 2007, 228.

patient suffers from a serious illness which -according to the current state of medical science- will lead to death within a short period of time even with adequate health care, and is incurable. A female patient may not refuse a subsistence treatment or a life-saving intervention if she is pregnant and she is presumably able to carry the pregnancy to full term.

§ 2. National legislation on patient rights

The primary legal sources of patient rights are the Parliamentary Act No. CLIV of 1997 on health care and the Parliamentary Act No. XLVII of 1997 on the processing and the protection of health care data and associated personal data.

The Health Care Act of 1997 is considered to be the main piece of legislation in the health sector. It replaced Act II of 1972 which had become obsolete.⁸ The Health Care Act of 1997 sets out a significant framework of rules regulating the health care. Apart from the organizational provisions, the Act defines the rights and obligations of patients (chapter II) and health care workers (chapter VI). The Health Care Act stipulates also specific rights of psychiatric patients in Chapter X. The protection of the patient rights is one of the most important reforms accomplished by the Health Care Act of 1997.⁹ The Act introduced the concept of patient autonomy and enforceable patient rights, as opposed to the paternalistic relationship between the doctor and his patient in which the patient was almost totally neglected.¹⁰ This intention is also reflected in the General Reasoning (Explanatory Memorandum): “The Act in force does not clearly regulate the rights and obligations of the parties in the relations within the health care system. For example, certain entitlements of the patients are only expressed as obligations of the health care staff -as

⁸ EÜM, "Legal and operational environment of the health care system" 22 September 2004, www.eum.hu (accessed on 22 October 2007).

⁹ J.SÁNDOR, "Hungary - Supplement 31", in H. NYS (ed.), *International Encyclopedia of Laws - Medical Law* 2003, vol. 2, 55.

¹⁰ J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopedia of Laws - Medical Law* 2003, vol. 2, 56.

the opposite party- although such rights should have been declared as subjective ones in order to render their enforcement possible.”¹¹

The rights listed expressively in the Health Care Act are the right to health care, the right to human dignity in health care, the right to have regular and flexible access to relatives during the course of treatment and the right to leave the health care institutions. The patient also has the right to be informed, the right to self-determination and the right to refuse medical treatment. Besides the right to access medical documentation, he is entitled to medical secrecy and privacy protection. Furthermore he has the right to enforce patient rights, the right to complain and the right to a patients’ rights representative.

Since its foundation in 1989 the Hungarian Constitutional Court has not only interpreted the Health Care Act, but also played an important role in the further realization and strengthening of the patient rights.¹²

The Health Data Processing Act of 1997 contains detailed regulations related to the processing and protection of health care data and health related personal data. The Act entitles patients to gain access to their medical records. A patient’s request to receive information about his medical record may not be refused by the health care institution. The Act was drafted since the Act on Protection of Personal Data and Disclosure of Data of Public Interest (Act No. LXIII of 1992) did not provide patients the necessary legal instruments to guarantee their rights.¹³

¹¹ Point 5 of the General Reasoning as cited in the decision 22/2003 of the Hungarian Constitutional Court of 28 April 2004, III-3, available on the website of the Constitutional Court, www.mkab.hu, English version, under decisions (accessed on 22 October 2007).

¹² H.NYS, L.STULTIËNS, et al., "Patient rights in EU Member States after the ratification of the Convention on Human Rights and Biomedicine", *Health Policy* 2007, 228.

¹³ A.DEN EXTER, *Health care law-making in Central and Eastern Europe. Review of a legal-theoretical model*, Antwerpen, Intersentia, 2002, 151.

§ 3. Right to informed consent

Article 5 of the Biomedicine Convention:

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

A. Right to informed consent as a basic requirement

In comparison with the Biomedicine Convention, the Hungarian Health Care Act grants more detailed protection standards to patients.¹⁴

Section 2 of the Health Care Act stipulates as one of the fundamental principles that the rights of patients shall be protected in the course of delivering health care services and measures. A patient's personal freedom and right of self-determination shall be restricted exclusively in cases and in a manner justified by his health status and defined in the Health Care Act.

The right of self-determinations is also guaranteed by section 15 of the Health Care Act. The first paragraph of this section provides that the patient's right to self-determination can only be restricted in the cases defined by law and in the manner specified by law. In accordance with the right to self-determination the patient is, according to the second paragraph of section 15, free to decide whether he wants to utilize health care services and which medical interventions he accepts or refuses. The third paragraph of section 15 states that the patient has the right to be involved in the decisions concerning his examination and treatment. The patient's informed consent -free from deceit, threats and pressure- is a precondition of all medical interventions, unless otherwise provided for in the Health Care Act.

¹⁴ J.LORINCZ, "Country Report Hungary", in J.TAUPITZ (ed.), Berlin, Springer, 2002, 615.

In accordance with the jurisdiction of the Hungarian Constitutional Court, the Health Care Act contains provisions guaranteeing the right to human dignity -as defined under the first paragraph of section 54 of the Constitution- in regard of the patient's right to self-determination. The Court states: "The patient's right to self-determination includes - among others- the right to consent or to refuse medical interventions or care. According to Section 15 para. (3) of the Health Care Act, unless otherwise provided for in the Act, the patient's informed consent is a precondition of implementing any medical intervention. In addition to the above general provision, the Health Care Act contains further rules on exercising the right of consent, e.g. by naming the specific cases when a written consent is needed (section 19 para. (1), section 159 para. (1) item e), and in certain cases it underlines the importance of consent (e.g. section 129 para. 82)".¹⁵

Section 173/H "Crimes against the Order of Medical Interventions and Medical Research, and against Self-determination Related to Health Issues" of the Hungarian Criminal Code concerns biomedical ethics and became effective on 1 July 1998.¹⁶ This section of the Criminal Code relates to the violation of the right of self-determination in regard to medical procedures. Any person who performs certain listed medical interventions -which are subject to prior consent, permission and information disclosure- without the consent or permission of the entitled person or who fails to disclose the information required by law, commits a felony offense and shall be punishable with imprisonment of up to three years.

B. Contents of information preceding informed consent

The Health Care Act of 1972 had already recognized the duty to inform patients in two substantially different cases.¹⁷ On the one hand

¹⁵ Decision 36/2000 of the Hungarian Constitutional Court of 24 October 2004, III-2.1, available on the website of the Constitutional Court, www.mkab.hu, English version, under decisions (accessed on 22 October 2007).

¹⁶ J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopaedia of Laws - Medical Law* 2003, vol. 2, 45.

¹⁷ J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopaedia of Laws - Medical Law* 2003, vol. 2, 63.

the physician had to provide during the entire treatment general information on the diagnosis and the future prospects of the patient, on the other hand he had to give information as part of the decision-making process before medical treatment. Its successor, the Health Care Act of 1997, went much further in elaborating the concept of informed consent. The first draft contained a very detailed list of necessary information.¹⁸ The final version of the Act however, described the content of information in a much simpler way.

The third paragraph of section 15 concerning the right to self-determination stipulates in broad terms that the patient's consent shall be based upon appropriate information. Such a general formulation can also be found in section 13 concerning the right to information. This section provides that the patient shall have a right to receive comprehensive and individualized information. The first paragraph of section 135 concerning the obligation of healthcare workers to provide information stipulates that the attending physician shall be attentive in informing the patient and shall do so gradually when necessary, considering the patient's condition and circumstances.

In accordance with section 13 (2) the patient has the right to receive thorough information concerning:

- his state of health, including his medical evaluation;
- the recommended examinations and interventions;
- the possible benefits and risks of performing or not performing the recommended examinations and interventions;
- the planned dates for performing the examinations and interventions;
- his right to decide in respect of the recommended examinations or intervention;
- the possible alternative procedures and methods;
- the course of care and the expected outcome
- additional services;
- the recommended lifestyle following the intervention.

The patient has the right to be informed after every examination and medical intervention during his treatment about the results, about

¹⁸ J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopaedia of Laws - Medical Law* 2003, vol. 2, 63.

eventual failure, about unexpected outcomes and its reason (section 13 (4)). He has also the right to be informed about the names, professional qualifications and status of all persons directly involved in his treatment (section 13(6)).

In addition to this detailed information the patient has a right to pose further questions during and subsequent to the information given by the physician (section 13 (3)).

Information provided to the patient has to be disclosed in a manner which is comprehensible for the patient and which corresponds to his age, education, knowledge, emotional condition and his wishes in this regard. If the patient's needs require an interpreter or a sign language interpreter, one will be made available to the extent that it is possible (section 13 (8)). According to section 135 (2) concerning the obligation of the health care worker to provide information, special attention shall be given to the generally known, the significant side effect of the treatment, the possible consequences and the possible outcomes of interventions as well as the frequency in which they occur. The physician has to ascertain that the patient has understood the information. When necessary, he has to see to it that the patient receives psychological care.

The conditions necessary for the assertion of the right to receive information shall be guaranteed by the stakeholders of the health care facility (section 13 (7)).

There is no specific provision in the Health Care Act of 1997 concerning the burden of proof of the fact that information preceding consent was given or not. This means that the general rules of the Act on Civil Procedure will be applicable. The burden of proof is on the party whose interest is the acceptance of the fact as real by the court.¹⁹ The defendant -in this case the hospital or the physician- must prove that he acted in accordance with the law in the given situation and that the proper information was given and consent was obtained. As a result of this reversal of the burden of proof, the patient is not required

¹⁹ Personal Communication of Z. TOMKA.

to prove that the hospital or physician mistreated him by not giving him sufficient information.²⁰

C. Form of informed consent

According to section 15 (4) of the Health Care Act the patient can give his consent verbally, in writing or it can even be deduced from his behavior, unless otherwise provided by this Act.

Invasive procedures however shall be subject to the patient's written consent or to his verbal statement or other declarations made in the joint presence of two witnesses (section 15 (5)). In accordance with section 3 m) an invasive procedure is a physical intervention penetrating into the patients' body through the skin, mucous membrane or an orifice, excluding interventions which pose negligible risks to the patient from a professional point of view.

Written consent is required for medical experiments as well (article 4 (5) of the Decree of the Minister of Health 23/2002 on Biomedical Research on Human Beings).

D. Exceptions to the requirement of informed consent

Article 8 Biomedicine Convention

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

The patient's consent shall be assumed to be given if the patient is unable to make a statement of consent as a result of his health condition and obtaining a declaration from the person who is entitled to exercise the right to consent and refuse in stead of the patient, would result in delay (section 17 (1) a)). These last words were challenged in front of the Hungarian Constitutional Court in 2003. The petitioners stated that this unclear wording would result in legal

²⁰ J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopaedia of Laws - Medical Law* 2003, vol. 2, 49.

uncertainty which could lead to completely emptying the right to self-determination. The Court declared the petition as unfounded, substantiated as followed: “According to the Constitutional Court, the legislature cannot be expected to give an exhaustive statutory definition of the situations where obtaining the declaration of the person designated by the patient can be dispensed with in view of the danger of delay, as there can be numerous situations of different natures during medical practice. Therefore, any statutory definition of the concept of delay would inevitably limit the possibilities of performing medically justified and necessary interventions. When adopting the Act, one could not foresee and define the exhaustive list of situations -e.g. the person designated by the patient is away at an unknown place- that could justify the application of section 17 para. (1) item a) of the Health Care Act. The Constitutional Court holds that giving an exhaustive list as the definition of delay would pose a threat to legal certainty, as in practice, new situations the legislature could not think of may emerge on a continuous basis, for which reason there can be situations with respect to which the legislature did not allow dispensing with the declaration of the person designated by the patient”.²¹ The patient’s consent shall also be assumed to be given if in case of invasive interventions, the patient is unable to make a statement of consent as a result of his health condition and obtaining a declaration from the person who is entitled to exercise the right to consent and refuse in stead of the patient, would result in delay and the delayed performance of the intervention would lead to a serious or lasting impairment of the patient’s state of health (section 17 (1) b)).

Consistent with section 17 (2) of the Health Care Act the patient’s consent shall not be required if the absence of the intervention would seriously endanger the health or physical safety of others -including a fetus older than 24 weeks-, or if the patient’s life is directly endangered. This restriction was challenged in front of the Constitution Court in 2000. The petitioner requested the review of the causes of restricting a certain right of the patients that are based on endangering the physical integrity or the health of others as regulated in section 17 (2). The Court stated that the consent to decisions

²¹ Decision 22/2003 of the Hungarian Constitutional Court of 28 April 2003, XI-1, available on the website of the Constitutional Court, www.mkab.hu, English version, under decisions (accessed on 22 October 2007).

related to medical care may necessarily be restricted. The restrictions are justified by the protection the lives, health or physical integrity of others.²²

Section 18 (1) stipulates that if during an invasive intervention an unforeseeable extension of it becomes necessary, in the absence of consent to such extension, the intervention can only be carried out if it is justified by medical emergency or the non-execution of the extension would impose a disproportionately serious burden on the patient. If the extension would lead to the loss of an organ or a part of the body, or to the complete loss of the function thereof, according to section 18 (2) the intervention may only be extended if the patient's life is in direct danger or if the non-execution of the extension would impose a disproportionately serious burden on the patient. This provision was alleged to restrict the essence of the patient's right to self-determination in a manner contrary to the requirement of legal certainty under the rule of law as defined in the Hungarian Constitution. In order to refute this assertion the Constitutional Court stated that "it undoubtedly follows from an interrelated analysis of paragraphs (1) and (2) of section 18 of the Act that in both cases of extending an invasive intervention as regulated by the Act, the legislature intended to allow only the least and -in the patient's interest- absolutely necessary restriction of the patient's right to self-determination". The Court goes on "it is emphasized that due to the indefinitely wide spectrum of illnesses of very different natures necessitating invasive interventions, the age and the general state of health of the patient, the state of medical knowledge, and many other circumstances occurring only in the case of a particular intervention, the legislature cannot be expected to define for each kind of intervention the cases where a failure to extend the intervention would qualify as a burden of disproportionate weight for the patient. Due to the nature of invasive interventions, applying an unnecessarily rigorous regulation of the criteria for extending interventions would in fact hinder the performance of successful medical interventions". The Constitutional Court also determines that the conduct of the physician in case of unexpected circumstances during invasive interventions, is

²² Decision 36/2000 of the Hungarian Constitutional Court of 24 October 2004, III-1.2, available on the website of the Constitutional Court, www.mkab.hu, English version, under decisions (accessed on 22 October 2007).

regulated not only by section 18 of the Health Care Act, but also by the rules of the medical profession, physicians' code of ethics and the wide range of norms on legal liability, which are all aimed at ensuring that the patient's right to self-determination is taken into account when it is necessary to extend an invasive intervention.²³

E. Refusal and withdrawal of consent

The Health Care Act acknowledges the right of patients to refuse medical treatment. This innovative aspect of the Act is under constant criticism.²⁴ According to section 20 (1) competent ("a patient with full disposing capacity") patients have the right to refuse medical treatment unless its lack would endanger the lives or physical integrity of others. Together with section 17 (2) concerning an exception to the requirement of informed consent, section 20 (1) was challenged in front of the Constitutional Court in 2000. The provisions were alleged to violate the freedom of conscience and religion guaranteed in article 60 (1) of the Hungarian Constitution as well as article 8 (2) concerning the restriction of fundamental rights, because the section did not allow the refusal of medical care on the grounds of conscience or religious conviction. As stated above, the Constitutional Court decided that the consent to decisions related to medical care (section 17 (2)) and the refusal of such care (section 20 (1)) may necessarily be restricted on the grounds of protecting the lives, health or physical integrity of others.²⁵

According to section 20 (2) if the lack of the refused medical treatment would result in serious or permanent damage to his health, the patient may only refuse the treatment if he makes an expressive statement in a notarial deed, in a fully conclusive private deed or, in the case of inability to write, in a declaration made before two

²³ Decision 22/2003 of the Hungarian Constitutional Court of 28 April 2003, XI-2, available on the website of the Constitutional Court, www.mkab.hu, English version, under decisions (accessed on 22 October 2007).

²⁴ J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopaedia of Laws - Medical Law* 2003, vol. 2, 66.

²⁵ Decision 36/2000 of the Hungarian Constitutional Court of 24 October 2004, III-1.2, available on the website of the Constitutional Court, www.mkab.hu, English version, under decisions (accessed on 22 October 2007).

witnesses. In the latter case, the refusal must be recorded in the patient's medical record and certified with the signatures of the witnesses.

Consistent with the third paragraph of section 20, life-supporting or life-saving interventions may only be refused, thereby allowing the illness to follow its natural course, if the patient suffers from a serious illness which -according to the current state of medical science- will lead to death within a short period of time even with adequate health care and is incurable. The refusal of life-supporting or life-saving interventions must comply with the formal conditions set out in the second paragraph of section 20. Furthermore the refusal of this kind of medical treatment shall in accordance with section 20 (4) only be valid if a committee composed of three physicians has examined the patient and has unanimously declared in a written form whether the patient has made his decision in full cognizance of the consequences and whether the legal requirements set out in paragraph 3 were satisfied. The three physicians of the committee have to be the patient's attending physician, a qualified doctor specialized in the field corresponding to the nature of the illness and who is not involved in the treatment of the patient, and a qualified psychiatrist (section 20 (5)). The patient has to repeat in the presence of two witnesses his intention to refuse the treatment on the third day following the declaration of the committee. According to section 3 (4) of the Government Decree 117/1998 on the detailed rules of refusing certain forms of medical care the refused care shall be terminated or it shall not even be started if on the third day following the decision by the committee, the patient repeats his will to refuse. If the patient does not consent to the examination of the medical committee, his refusal may not be taken into account.

When a patient has refused medical treatment in accordance with the second and the third paragraph of section 20, an attempt shall be made to identify the reasons underlying the patient's decision through personal interviews and an attempt shall be made to alter the decision. In the course of this attempt, the patient shall be informed once again of the consequences of not intervening (section 20 (7)).

In accordance with section 20 (8), the patient can withdraw his statement of refusal at any time and without any formal requirements, even if he has already refused health care.

In Hungarian law there is a restriction on the right of refusal of medical intervention. According to section 20 (6) of the Health Care Act a female patient can not refuse a life-supporting or life-saving intervention if she is pregnant and is considered to be able to carry the pregnancy to full term. As stated above, this restriction on the exercise of the right to informed consent stipulated in the European Convention on Human Rights and Biomedicine is based upon article 26 of the Convention.

As regards the withdrawal of consent, section 15 (6) of the Health Care Act stipulates that a patient may withdraw his consent. If however the patient withdraws his consent without good cause, he may be obliged to reimburse any justified costs that will have incurred as a result of such withdrawal. There are no formal prescriptions to withdraw consent.²⁶

In accordance with section 23 (1) life-supporting or life-saving interventions (if the patient suffers from a serious incurable illness which -according to the current state of medical science- will lead to death within a short period of time even with adequate health care) may only be terminated or dispensed with if the will of the patient to that effect can be established clearly and convincingly. In case of doubt, the patient's declaration made ulterior and personally must be taken into account. In the absence of such declaration, the patient's consent to the life-supporting or life-saving intervention must be assumed. According to section 23 (2) the patient or the person who was appointed by the patient to exercise the right to draw up an advance directive in his stead can not be forced by any means to alter his decision in the course of refusing healthcare. Even in the case of refusal of life-supporting or life-saving interventions (if the patient suffers from a serious incurable illness which -according to the current state of medical science- will lead to death within a short period of time even with adequate health care), a patient shall have the right to receive healthcare intended to ease his sufferings and reduce his pain.

²⁶ Personal Communication of Z. TOMKA.

F. Previously expressed wishes

Article 9 Biomedicine Convention

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

The Health Care Act of 1997 contains detailed provisions concerning previously expressed negative wishes. According to section 22 a person with full disposing capacity may draw up an advance directive that might be relevant if later on he becomes incompetent. He may in the first place refuse certain medical treatment, unless the refusal of such treatment would endanger the life or physical integrity of others. He may also refuse life-supporting or life-saving interventions if he suffers from a serious incurable illness which -according to the current state of medical science- will lead to death within a short period of time even with adequate health care, or if he suffers from an incurable disease and as a consequence of that disease he is unable to care for himself physically or his pain cannot be eased with appropriate therapy (section 22 (1)). Furthermore, a competent person may in an anticipatory declaration name the competent person who shall be entitled to exercise the right to draw up an advance directive in his stead (section 22 (2)).

The previously expressed wishes have to take the form of a notarial deed. According to the third paragraph of section 22 the statement is only valid if a qualified psychiatrist has confirmed in a written opinion that the person made the decision in full awareness of its consequences. The medical opinion of the psychiatrist can not be older than one month. The statement has to be renewed every two years and may be withdrawn at any time, regardless of the patient's disposing capacity and without formal requirements. In Hungary there is no register of previously expressed wishes.

When the competent person who was appointed by the patient to exercise the right to refuse medical treatment in his stead, has made a

declaration of refusal, a committee composed of three physicians defined in paragraph 4 of section 20 shall make a declaration on whether the conditions set out in section 22 (1) exist and whether the person who is entitled to make those decisions in stead of the patient, has made the decision in full awareness of the consequences.

G. Informed consent in case of minor patients²⁷

Article 6 Biomedicine Convention

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

According to section 12 of the Hungarian Civil Code a minor shall be of diminished capacity (“limited disposing capacity”) if he or she has reached the age of fourteen years and is not incompetent. Persons who have not yet reached the age of eighteen years shall be deemed to be minors, unless they are married.

Section 13 (5) stipulates that the legally incapable patient or a patient with reduced disposing capacity shall also have the right to information corresponding to his age and mental state. According to SÁNDOR and TOMKA the second paragraph of article 14 states that the patient’s right not to be informed is also applicable to minors of 16

²⁷ L.STULTIËNS, T.GOFFIN, et al., "Minors and informed consent: a comparative approach", *European Journal of Health Law* 2007, 21-46.

years of age or older.²⁸ Section 16 (1) provides that a competent patient (“a patient with full disposing capacity”) may designate a person who is entitled to exercise the right to consent and of refusal instead of him and who is to be informed in line with article 13 in case he becomes unable to make a decision. According to SÁNDOR and TOMKA this provision also applies in the case of minor patients who are older than 16 years of age.²⁹

In regard to minor patients the Health Care Act contains several provisions which are also applicable to persons with limited disposing capacity, such as section 16 -with the exception of the second paragraph- and section 21. These sections apply to patients with no disposing capacity as well as persons with limited disposing capacity and will be examined in the next paragraph concerning informed consent in case of incapacitated adults.

H. Informed consent in case of incapacitated adults

Article 6 Biomedicine Convention

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure.

²⁸ Personal Communication of J. SÁNDOR and Z. TOMKA. This version of article 14 (2) has not been reflected in the translation of the Health Care Act to be consulted on www.ohchr.org/english/bodies.

²⁹ Personal Communication of J. SÁNDOR and Z. TOMKA. According to Z. TOMKA this rule can be found in section 16 (6) of the Health Care Act. However, this version of section 16 does not correspond with the translation of the Health Care Act to be consulted on www.ohchr.org/english/bodies.

The legally incapable patient or a patient with reduced disposing capacity shall also have a right to information corresponding to his age and mental state (section 13 (5)). In making decisions on the health care to be provided, the opinion of the patient with no disposing capacity or with limited disposing capacity shall be taken into account to the extent that is professionally possible. This is also the case when the right of consent and refusal is exercised by the patient's representative (section 16 (5)).

According to section 16 (1) of the Health Care Act a person with full disposing capacity may name the competent person who shall be entitled to exercise the right to consent and refuse in his stead and who shall be informed in line with section 13. He may also, without naming another person, exclude any of the persons who are enumerated in section 16 (2) and who shall be entitled to exercise the right of consent and refusal. This statement has to be incorporated into a notarial deed, into a fully conclusive private deed or -in the case of inability to write- a declaration made in the joint presence of two witnesses.

If the patient is incompetent ("has no disposing capacity") and he has not indicated any person who would be entitled to exercise the right to consent and refusal, the Health Care Act lists the persons who are entitled to exercise in the specified order these rights within the limits stipulated by section 16 (4). The specified order is the following:

- a) the patient's legal representative, in absence thereof;
- b) the following individuals with full disposing capacity and sharing household with the patient:
 - a. the patient's spouse or common-law spouse, in the absence thereof,
 - b. the patient's child, in the absence thereof,
 - c. the patient's parent, in the absence thereof,
 - d. the patient's sibling, in the absence thereof,
 - e. the patient's grandparent, in the absence thereof,
 - f. the patient's grandchild;
- c) in the absence of a relative indicated in paragraph b), the following individuals with full disposing capacity and *not* sharing household with the patient:
 - a. the patient's child, in the absence thereof,

- b. the patient's parent, in the absence thereof,
- c. the patient's sibling, in the absence thereof,
- d. the patient's grandparent, in the absence thereof,
- e. the patient's grandchild.

The old version of section 16 (2) applied the same restriction to self-determination related to medical care (the right of consent and refusal) to both incapable patients and patients with limited disposing capacity. The Constitutional Court stated that this was not proportionate to the purported objective: "The legislature's objective that independent legal declarations made in the course of medical care should be based on the patient's due discretion does not necessarily mean that in the case of persons with limited disposing capacity this purpose may only be achieved by absolutely restricting their rights of consent and refusal".³⁰ Consequently, the Court annulled the text "or limited disposing capacity".

According to the third paragraph of section 16 in the case of contrary statements made by the individuals qualified in the same line to make a statement, the decision that is likely to impact upon the patient's state of health shall be taken into account most favorably.

The persons defined in the second paragraph of section 16 are entitled to exercise the right of consent and refusal within the limits set out in section 16 (4). According to this section their statement has to be made exclusively after information in accordance to section 13 has been provided. The statement may refer to giving consent to invasive procedures recommended by the attending physician. With the exception of the refusal of life-supporting or life-saving interventions as defined in section 20 (3), the statement may not unfavorably affect the patient's state of health and in particular may not lead to serious or lasting impairment to the health. Immediately after he regains his full disposing capacity, the patient shall be informed of such statements. According to the Hungarian Constitutional Court the regulation contains a sharp dividing line along the patient's interests. This means

³⁰ Decision 36/2000 of the Hungarian Constitutional Court of 24 October 2004, III-1.2, available on the website of the Constitutional Court, www.mkab.hu, English version, under decisions (accessed on 22 October 2007).

that taking into account the patient's health status may prevail over the right of consent of his representative.³¹

An incompetent patient (“with no disposing capacity”) or a patient with limited disposing capacity may not refuse the provision of care when the absence of that care would be likely to result in serious or permanent impairment of his health. If in the case of incompetent patients and patients with restricted legal capacity, the life-supporting or life-saving interventions are refused when the patient suffers from an illness which -considering the actual state of medicine- would lead to death within a short period of time, the health care provider can file an action to obtain the required consent from the court. The physician has to provide the care that is appropriate to the health of the patient until the legally binding decision of the court will arrive. However, in the case of a direct threat to life, it shall not be required to obtain a substitute statement by the court for the required interventions to be carried out. If it is necessary, the physician may use the assistance of the police (section 21).

³¹ Decision 36/2000 of the Hungarian Constitutional Court of 24 October 2004, III-3, available on the website of the Constitutional Court, www.mkab.hu, English version, under decisions (accessed on 22 October 2007).

§ 4. Right to information about his or her health

Article 10 Biomedicine Convention

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

A. Right to information about his or her health as a basic requirement

Hungarian law provides the right to information about his health as a right independent of the right to informed consent. According to section 13 of the Health Care Act the patient has the right to receive comprehensive and individualized information. The second paragraph of section 13 elaborates this general formulation by stating amongst others that the patient shall have a right to receive detailed information on his state of health, including its medical evaluation. In section 134 (1) the right to information is also elaborated. The attending physician has the obligation to brief the patient on his medical condition to the best of his knowledge, with the regularity justified by the condition, in keeping with the level of knowledge expected of the physician and in accordance with the provisions set forth in section 13 of the Health Care Act. The third paragraph of section 134 states that the receipt of general informative leaflets prepared in bulk can not substitute for a provision of oral information. According to section 137 a written summary report (discharge summary) has to be prepared at the end of a therapeutic procedure consisting of several parts or at the end of care in an inpatient facility. This report must be given to the patient.

The legally incapable patient or a patient with reduced disposing capacity shall also have a right to information corresponding to his age and mental state (section 13 (5)). If the patient's disposing capacity is severely impaired or limited, the attending physician also

has to inform the person who is designated to be informed in his stead in accordance with section 14 (2) or the person who is entitled to exercise the right to consent and refuse in his stead.

A patient is entitled to information even in cases where his consent is not a precondition for initiating medical care, for instance because he has an infectious disease for which the treatment is compulsory (section 14 (3)).³²

B. Right not to know

A competent patient (“with full disposing capacity”) may waive the right of being informed unless his doctor decides that the patient has to be aware of the nature of his illness in order not to endanger the health of others (section 14 (1)). According to SÁNDOR and TOMKA this provision also applies in the case of minor patients who are older than 16 years of age.³³

C. Therapeutic exception

In Hungarian law, legal regulation of the therapeutic exception is not provided as such. However, section 135 (1) of the Health Care Act stipulates that the attending physician shall be circumspect in informing the patient and shall do so gradually when necessary, considering the patient’s condition and circumstances.

³² Hungarian Civil Liberties Union, "Patient Rights in Hungary - a compilation by the Hungarian Civil Liberties Union", 2.

³³ Personal Communication of J. SÁNDOR and Z. TOMKA. This version of article 14 (2) has not been reflected in the translation of the Health Care Act to be consulted on www.ohchr.org/english/bodies: “The patient with full disposing capacity shall have a right to designate a person in writing or in any other credible manner who is to be informed in his stead”.

§ 5. Patient rights regarding the medical file

Article 10 Biomedicine Convention

1. *Everyone has the right to respect for private life in relation to information about his or her health.*
2. *Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.*

A. Right to a medical file

A subdivision which encompasses section 136 and section 137 of chapter VI concerning the rights and obligations of healthcare workers is entitled “Obligation to document”. Section 24 of the Health Care Act also concerns the right to become acquainted with the medical record. Consequently, these provisions imply the existence of a right to a medical file.

B. Contents of the medical file

The Health Care Act defines the health and medical records as notes, records or data recorded in any other way, regardless of the carrier or form thereof, that contain medical and personal identification information related to the treatment of a patient and that will come to the knowledge of a health care worker in the course of delivering health care services (section 3 (p)). Besides this general formulation, section 136 determines the contents of the medical file in a more detailed manner. The health care documentation shall contain data related to the patient’s examination and treatment and shall be conducted in a manner that reflects the true course of the healthcare process (section 136 (1)).

According to the second paragraph of section 136 of the Health Care Act, health care documentation shall include the following:

- a) patient identification data;

- b) if a patient is in possession of full disposing capacities, a person to be notified in case of emergency, or in the case of a minor or a person with a guardian, the name, address and manner of accessing said patient's legal guardian;
- c) patient's history and the etiology of the disease;
- d) the results of the initial examination;
- e) the results of examinations/tests serving as a basis for diagnosis and therapy, and the dates on which said examinations/tests took place;
- f) the name of the disease justifying care, the underlying diseases, co-morbidities and complications;
- g) the names of other illnesses not directly requiring care and of the risk factors;
- h) the time and results of interventions;
- i) pharmaceutical and other therapies, and the results;
- j) patient data on over-sensitivity (allergies) to medications;
- k) the name of the healthcare worker recording the information on the chart and the date on which it was charted;
- l) a statement of the information provided to the patient and/or to other persons authorized to receive said information;
- m) the fact of patient consent (section 15 (3)) or denial of consent (section 20-23) and the date(s) on which it/they occurred;
- n) all other data and facts that can influence treatment outcome.

Furthermore, the third paragraph of section 136 stipulates that the following shall be maintained as part of health care documentation:

- a) findings from all laboratory tests;
- b) documents written during the course of treatment and during consultations;
- c) nursing care documents;
- d) copies of images taken during imaging diagnostic procedures;
- e) findings of tests on tissue samples taken from the patients body.

C. Right to access and copy the medical file

i. Right to access the medical file

According to section 24 (1) of the Health Care Act a patient has the right to become acquainted with the data contained in his medical record and has the right to request information on his health care data. The medical documentation is at the disposal of the health care provider, the data contained in the documentation is at the disposal of the patient (section 24 (2)). According to section 24 (3) the patient has the right not only to be informed of the management of the data related to the medical treatment, but also to become acquainted with the health care data relating to him. He has also the right to gain access to the medical record and to receive copies thereof at his own expense. Furthermore, the patient has the right to be given a discharge summary (as defined in section 137) from the health care institution and has the right to receive -if justified- a written summary or abridged opinion of his health data.

Section 24 (6) provides that the right to inspect the medical record of a person with no disposing capacity can be exercised by the person who is in accordance with section 16 (1) and (2), entitled to exercise the right to consent and refuse, and who has to be informed in line with section 13. This provision of the Health Care Act also determines who can exercise the right to access to the medical records in case of a person with limited disposing capacity. The right to access the medical file can be exercised by the person who is in accordance with point a) of section 16 (1), declared by the patient to be entitled to exercise the right to consent and refuse, and who has to be informed in line with section 13 or by the legal representative if the patient didn't make such a statement.

If personal notes of the physician are included, they are also accessible.³⁴ However, if the medical record contains data which could compromise the privacy of other persons, the right of access to data can only be exercised with regard to the data referring to the patient (section 24 (5)).

³⁴ Personal Communication of Z. TOMKA.

A patient has not only direct access, but also indirect access to his medical records. In the course of his health care treatment, the patient has the right to give written authorization to a person designated by him to inspect the medical record relating to him and the right to have copies made thereof (section 24 (7)). After the treatment, only the person being authorized by the patient in a fully conclusive private deed has the right to inspect the medical record and the right to have a copy made thereof (section 24 (8)). With regards to a psychiatric patient, the right to learn the contents of his health care documentation can exceptionally be restricted if there is a well founded reason to assume that accessing this information would seriously jeopardize the patient's improvement or if such access to the medical record would infringe upon the personal rights of another individual. However, a physician is the only one who is authorized to order this restriction.

Section 24 (12) of the Health Care Act states that the detailed rules of handling and protecting health care data and related personal data shall be established by a separate law. Data protection in the field of medicine is based on the Parliamentary Act No. XLVII of 1997 on Processing and Protecting Health and Connected Personal Data.³⁵

ii. Right to copy the medical file

Several provisions of the Health Care Act regulate the right to copy the medical file. According to point c) of section 24 (3) the patient has the right not only to gain access to the medical record but also to receive copies thereof at his own expense. Section 24 (7) and (8) mention the right to copy the medical file. This means that the person designated by the patient in accordance with those provisions to exercise the right to access may also make copies thereof.

iii. Post mortem access by relatives

The patient's spouse, immediate relative, brother or sister and partner ("common-law spouse") have the right to become acquainted with the

³⁵ English version of this Act was not available. See J.SÁNDOR, "Protection of health care data in Hungarian law", in D.BEYLEVELD, D.TOWNEND, S.ROUILLE-MIRZA and J.WRIGHT (eds.), Aldershot, Ashgate, 2004, 166.

medical data upon written request during the patient's life or after his death, if such health data is required in order to identify a reason that might influence their life or health, or in order to provide them health care and there is no other way to become acquainted with such health data or to establish the data by inference (section 24 (9)). In this case, only the data that is directly related to the mentioned cause can be accessed. The information shall be provided by the patient's attending physician or the director of medical services of the health care provider. If necessary, the information has to be provided based on consultation with the attending physician of the claimant. In providing the requested data the requirements concerning the provision of medical information have to be taken in account (section 24 (10)).

In case of the death of the patient, his legal representative, close relative or heir has the right -upon written request- to get access and receive copies at his own expense of the medical documentation that is or may be related to the cause of death and the data that is related to the medical treatment preceding death (section 24 (11)). A similar provision can be found in the Health Data Protection Act of 1997. According to section 7 (7) of this Act the legal representative of the patient, an immediate relative and/or descendant may in case of the death of the individual concerned -upon a written request- be given data related to or possibly related to the cause of death, medical treatment before death, and may receive copies of these documents at his own expense.

D. Right to correction, erasure and/ or demolition

A patient has the right to initiate completion or correction of his medical record if he deems it inaccurate or incomplete. It shall be included in the medical record by the attending physician or by another person handling such data, together with his professional opinion (section 24 (4)). Also according to this provision the incorrect medical data can not be deleted after the complaint. It has to be corrected in such a way that the data entered originally remains visible. However, according to SÁNDOR the Health Data Protection Act of 1997 provides that the incorrect health data in health

documentation, following the collection of data, is to be corrected or erased so that the originally collected data cannot be detected.³⁶

§ 6. Right to medical secrecy/ confidentiality

Article 10 Biomedicine Convention

1. *Everyone has the right to respect for private life in relation to information about his or her health.*

The obligation to respect medical secrecy is laid down in section 177 of the Hungarian Criminal Code. This provision states that the person who reveals a private secret learned by him as a result of his occupation or public mandate without good reason, commits a misdemeanor and shall be punishable with a fine. If the crime causes considerable injury of interest, the punishment shall be imprisonment of up to one year, labor in the public interest or fine.

The Health Care Act also assures the right to professional secrecy. According to section 25 (1) the patient has the right to have medical and personal data disclosed by the persons involved in his health care, to those persons entitled thereto. They are obligated to handle such data confidentially. He has also the right to make a statement as to who are to receive information on his illness and the expected outcome thereof and who are to be excluded from becoming partially or fully acquainted with his health care data (section 25 (2)). According to the third paragraph of section 25 the health care data of the patient shall be disclosed even in the absence of his consent thereto when it is ordered by law or when it is required in order to protect the lives, physical safety and health of others. When the lack of health care data would lead to the worsening of the patient's health, this data can be disclosed to a person in charge of a patient's further nursing and continuing care, without the consent of the patient concerned (section 25 (4)). Section 25 (7) stipulates that a patient has

³⁶ J.SÁNDOR, "Protection of health care data in Hungarian law", in D.BEYLEVELD, D.TOWNEND, S.ROUILLÉ-MIRZA and J.WRIGHT (eds.), Aldershot, Ashgate, 2004, 171.

the right to name the person who may be notified of his admission to an inpatient health care institution and the development of his state of health. He has also the right to exclude any person there from. The inpatient health care institution must inform the person named by the patient of his admission and any change in his placement, as well of any significant change in the patient's state of health.

Section 8 of the Health Data Protection Act of 1997 as cited by SÁNDOR states the following: "In addition to the health care provider, the individual's personally chosen physician, and a legal medical expert, the requirement to keep data secret also pertains to those providing medical care who have not assisted in medical examinations, identification of illness, or in treatment or operation, unless the release of such data is necessary for the identification of the affliction, or in the interests of the further treatment of the patient".³⁷ Based upon this Health Data Protection Act the following forms of health and related personal data are considered confidential: data collected or given to the data handler during treatment, information regarding necessary, ongoing or completed treatment and other data received in connection with treatment.³⁸

§ 7. Right to privacy/ protection of private life

Article 10 Biomedicine Convention

1. *Everyone has the right to respect for private life in relation to information about his or her health.*

The Health Care Act provides for a right to privacy as a patient right in paragraph 5 and 6 of section 25. According to these provisions a patient has the right to have his examination and treatment taken place under circumstances whereby he cannot be seen or heard by others

³⁷ J.SÁNDOR, "Protection of health care data in Hungarian law", in D.BEYLEVELD, D.TOWNEND, S.ROUILLÉ-MIRZA and J.WRIGHT (eds.), Aldershot, Ashgate, 2004, 168.

³⁸ J.SÁNDOR, "Protection of health care data in Hungarian law", in D.BEYLEVELD, D.TOWNEND, S.ROUILLÉ-MIRZA and J.WRIGHT (eds.), Aldershot, Ashgate, 2004, 167.

without his consent, unless this is unavoidable due to an emergency or a critical situation. During the course of his examination and medical treatment, the patient has the right to have only those persons present whose involvement is necessary in delivering such care, furthermore those persons to whose presence he has consented, unless provided otherwise by law. Such an exception can be found in section 17 (20) of the Health Data Protection Act of 1997 as cited by SÁNDOR: “Individuals taking part in health care professional training may be present during medical treatment with the permission of the patient (or his or her legal representative). Such professionals may be doctors, medical students, health care professionals, student and teachers at health care colleges, professional schools, or health care vocational schools. One of the most highly questionable exceptions allowed by law is that in institutions designated for the training of health care professionals, the permission of the patient (or his or her legal representative) is not required”.³⁹ More exceptions can be found in section 14 of the Health Data Protection Act of 1997. According to this provision other persons may be present without the permission of the patient when the treatment demands the handling of more than one patient at a time. Furthermore, police officials may be present without the patient’s consent when the individual requiring treatment is being held by the police. Finally, legal members of the criminal justice system may be present without the permission of the patient when the patient is serving a prison sentence and the security of those providing treatment must be ensured. They may be present if there is a need to prevent escape attempts, if the safety of the patients requires it, if it is in the interest of the pursuit of criminals and if the patient is in a state in which he is unable to state his wishes. Unless the patient expressly objects to their presence, others may also be present without the patient’s permission if they treated the patient earlier for this particular affliction, if they have been given permission to be present by the institution’s director or if they are responsible for the data out of professional or scientific interest.

³⁹ J.SÁNDOR, "Protection of health care data in Hungarian law", in D.BEYLEVELD, D.TOWNEND, S.ROUILLÉ-MIRZA and J.WRIGHT (eds.), Aldershot, Ashgate, 2004, 169-170.

A. Processing of data concerning health

The right to privacy in the field of medical data protection and medical secrecy has become in Hungary an overwhelmingly important right.⁴⁰ Everyone has the right to the protection of secrecy in private affairs and personal data. This right is guaranteed by article 59 of the Hungarian Constitution. Immediately after the creation of the Constitutional Court in 1989, the Court had to deal with a number of cases with regard to the privacy right.⁴¹ In one of those early decisions, the Constitutional Court has interpreted the right to protect personal data as a positive right. The Court argued that personal data could be collected and processed only with the permission of the concerned individual.⁴² The legislator regulated the protection of personal data and the right to access to data of public interest in the Act on Protection of Personal Data and Disclosure of Data of Public Interest in 1992.⁴³ Since this Data Protection Act did not provide patients the necessary legal instruments to guarantee their rights, a new act on processing and protecting medical data was drafted.⁴⁴ Data protection in the field of medicine is based on the Parliamentary Act No. XLVII of 1997 on Processing and Protecting Health and Connected Personal Data.⁴⁵ The range of application of both Acts suggests that with regard to the processing and protection of health data the Data Protection Act of 1992 can be considered the *lex generalis*, whereas the Health Data Protection Act of 1997 is the *lex specialis*. The Data Protection Act of 1992 is applicable to any instance of data handling unless the handling of specific data is

⁴⁰ J.SÁNDOR, "Cells, tissues, and health care data - Analysis of the Hungarian data protection laws in the light of the European norms", in A.DEN EXTER (ed.), Rotterdam, Erasmus University Rotterdam, 2004, 64.

⁴¹ A.DEN EXTER, *Health care law-making in Central and Eastern Europe. Review of a legal-theoretical model*, Antwerpen, Intersentia, 2002, 149.

⁴² Decision No. 15/1991 as cited by J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopaedia of Laws - Medical Law* 2003, vol. 2, 94.

⁴³ See English translation on www.privereal.org (Hungary).

⁴⁴ A.DEN EXTER, *Health care law-making in Central and Eastern Europe. Review of a legal-theoretical model*, Antwerpen, Intersentia, 2002, 151.

⁴⁵ English version of this Act was not available. See J.SÁNDOR, "Protection of health care data in Hungarian law", in D.BEYLEVELD, D.TOWNEND, S.ROUILLÉ-MIRZA and J.WRIGHT (eds.), Aldershot, Ashgate, 2004, 166-174.

covered by a separate Act, such as the Health Data Protection Act of 1997.⁴⁶

According to article 2 of the Data Protection Act of 1992 “special data” shall be defined among other things as any personal data relating to the state of health. Article 3 of the Act stipulates that special data can not be processed unless the data subject has given his written consent or it is ordered by an Act in other cases.

The Health Data Protection Act of 1997 gives a very broad definition of the scope of health care data.⁴⁷ Data related to the individual’s physical, intellectual or spiritual condition, to his addictions, to the circumstances of illness or death, to the causes of death, data on the individual that was given by the individual himself or by another person, data seen, heard, observed, examined, measured, imagined or derived by the health care system can be considered as health data. Furthermore, it is also any sort of information (for instance behavior, environment and employment) connected with the previously mentioned types of information (section 3 a) Health Data Protection Act).⁴⁸ According to section 3 b) identification data comprises family and first name, maiden name, sex, place and time of birth, the mother’s maiden name and first name, home address, location, social security number, all together or some of them if they serve or may serve to the identification of the person concerned.

According to section 1 of the Health Data Protection Act personal data can be processed in cases and to the extent that it is necessary to attain a legitimate aim. In line with this, section 4 of the Act states that data processing can be carried out in pursuit of the following purposes:

- the protection of health or assistance in the maintenance of health;
- the advancement of effective treatment;

⁴⁶ J.SÁNDOR, A.DÓSA, and Z.BÁRTGAI, "National Regulations on Ethics and Research in Hungary" , European Commission 2003, 16.

⁴⁷ J.SÁNDOR, "Cells, tissues, and health care data - Analysis of the Hungarian data protection laws in the light of the European norms", in A.DEN EXTER (ed.), Rotterdam, Erasmus University Rotterdam, 2004, 64.

⁴⁸ English version of this Act was not available. See J.SÁNDOR, "Protection of health care data in Hungarian law", in D.BEYLEVELD, D.TOWNEND, S.ROUILLE-MIRZA and J.WRIGHT (eds.), Aldershot, Ashgate, 2004, 167.

- the monitoring of the patient's state of health;
- the provision of actions necessary in the interest of public health and the prevention of epidemics.

In addition to these purposes, other cases defined by law also exist in which data may be collected for the following reasons:

- the training of health care specialists;
- medical analysis;
- biomedical or epidemiological testing;
- the planning of healthcare provisions;
- statistical testing;
- scientific research;
- social security care or the determining of social care provision;
- pursuit or prevention of crime;
- criminal proceedings;
- the determination of ability to work, etc.⁴⁹

Health care data and identification data may be processed also for other aims than those enclosed in the Health Data Protection Act if the person concerned or the person who is legally representing him gives his written informed consent. For the aims of data processing listed in the Act only those data can be processed that is absolutely necessary to achieve the aims.

Section 5 of the Health Data Protection Act specifies who is entitled within the health care system to handle and to transmit health care and identification data. According to section 6 of the Act the security of health care and identity data must be assured in the handling and processing of that data to prevent involuntary or intentional destruction, alteration, damage or release to the public. It also must be kept secure from unauthorized access. In accordance with section 7 of the Act the persons handling and processing the health care data are required to keep medical confidentiality, except if the person concerned or his legal representative gave his consent in writing to transmitting the health care and personal identification data. Transmitting this data is only possible within the limitations mentioned in the written consent and if the transmission of the health

⁴⁹ J.SÁNDOR, "Protection of health care data in Hungarian law", in D.BEYLEVELD, D.TOWNEND, S.ROUILLÉ-MIRZA and J.WRIGHT (eds.), Aldershot, Ashgate, 2004, 167-168.

care and identity data is required due to the regulations specified by law.

B. Right to access and right to receive a copy

The Data Protection Act of 1992 contains several general provisions concerning the rights of the data subject, such as the right to information. In accordance to article 12 of the Act, the data controller has to inform the data subject -upon his request- of the data processed by the data controller. The data controller also has to inform him of the purpose of the data processing, of its legal basis and duration, of the name, address and activity of the technical data processor in connection with the data processing and of those who received or will receive data and for what purpose. The data controller has to give the information in writing and in an easy to understand way, within the shortest possible time, but not later than 30 days after the data subject requested the information. The information is free of charge, unless the data subject already requested in the given calendar year for the same data. According to article 13 the data controller can not deny the information except where an Act authorizes him to do so in cases specified in article 16 of the Data Protection Act. It may be restricted by an Act in the interest of the external and internal security of the State, in the economic or financial interest of the State, local government or the European Union, for the prevention or exposure of professional disciplinary or ethical offences or of breaches of labor law or labor safety obligations, as well as for the protection of the rights of data subjects or of other people.

The Health Data Protection Act of 1997 includes specific regulations on access to health care data. According to section 20 of the Act a patient's health data may be used for statistical purposes when identification of the person is not made possible. This kind of information may be disseminated only with the written permission of the concerned individual. With the permission of the institution's director or the individual in charge of data protection, access may be provided to stored data for the purpose of scientific research. Health care and identity data may not be used in scientific reports in such a way that the patient's identity may be discovered. In the course of scientific research, copies of documents containing identity data

cannot be made (section 21). The latter provision on access to the stored data is ambiguous as it does not provide the purposes of storing and does not specify who may have an access for the purposes of research.⁵⁰ According to section 22 of the Act various health insurance companies, as well as the State Pension Fund and the Health Insurance Fund may have access to health care and identity data in compliance with legal regulations. However, the Data Protection Ombudsman stated in 1999 and in 2000 that insurance companies cannot request an unlimited and general waiver from medical confidentiality by their clients.⁵¹

C. Right to correction, erasure and/ or demolition

The Data Protection Act of 1992 guarantees the right to request the rectification or -except for data processing ordered by a rule of law- deletion of his personal data (section 11). Section 14 states that the data controller shall be bound to rectify any inaccurate personal data. Personal data shall be deleted if:

- a) the processing thereof is unlawful;
- b) requested so by the data subject in accordance with section 11;
- c) they are incomplete or inaccurate and they can not be corrected in a lawful way, provided that deletion is not precluded by an Act;
- d) the purpose of processing has ceased to exist, or the time limit for storage of data has expired;
- e) it has been ordered by the court or the Data Protection Commissioner.

⁵⁰ J.SÁNDOR, "Protection of health care data in Hungarian law", in D.BEYLEVELD, D.TOWNEND, S.ROUILLÉ-MIRZA and J.WRIGHT (eds.), Aldershot, Ashgate, 2004, 170.

⁵¹ *Ibid.*

§ 8. Right to complain and to compensation

A. Right to complain

Article 23 Biomedicine Convention

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Section 29 of the Health Care Act is entitled “Investigation of the Complaints of Patient”. According to this provision the patient has the right to file a complaint with the health service provider regarding the provided health care service. The health service provider is obligated to investigate the complaint and has to inform the patient of his findings in writing within 10 working days. The Act does not specify what kind of inquiry has to be made in connection with the complaint. The detailed rules of the investigation of complaints have to be laid down in the internal rules of the health service provider. The exercise of the right to complain does not affect the patient’s right to turn to other agencies in the interest of the investigation of the complaint, as defined in separate legal regulations. The service provider shall draw the patient’s attention to this fact. Complaints have to be registered. They have to be kept for five years, alongside all documents related to the inquiry.

The Hungarian Ombudsman is a Parliamentary Commissioner. There are four Parliamentary Commissioners in Hungary with expertise in areas such as minority rights and data protection. Although there is no specialized Ombudsman in the field of health, the Ombudsman can investigate when human rights and the rights of patients overlap.⁵²

⁵² See Annual Reports of the Data Protection Commissioner of Hungary (abiweb.obh.hu) and L.FALLBERG and S.MACKENNY, "Patient Ombudsmen in Seven European Countries: an Effective Way to Implement Patient's Rights?", *European Journal of Health Law* 2003, 352.

The Health Care Act introduced the institution of patients' rights representatives ("patient's advocate"). A patient rights advocacy system was created in the hope that basic rights would be observed in daily practice.⁵³ The patients' rights representative protects in accordance with section 30 (1) the rights of patients defined in the Health Care Act. His main task is to provide information on the patient rights and how to enforce them. The services provided by the patients' rights representative include the following:

- a) assistance to patients with having access to medical records, making comments and asking questions thereon;
- b) assistance to patients with verbalizing their complaints, and initiating the investigation thereof;
- c) based upon the patient's written authorization, lodging a complaint with the head of the health care institution or the maintaining entity, furthermore taking actions with the competent authorities in matters related to the patient's medical treatment, and representing the patient in the course of such actions;
- d) informing, on a regular basis, health care workers of the rules relating to patient's rights and any changes therein, as well as of the enforcement of patient's rights in the health care institution (section 30 (2)).

The patients' rights representative can only proceed in individual cases within the framework of the authorization granted by the patient (section 30 (3)). He has to inform the head of the service provider or the maintaining entity of any unlawful practice and other shortcomings in connection with the operation of the health service provider that he might have experienced in carrying out his duty. Furthermore, he makes suggestions for their termination. If this is unsuccessful, the representative has the right to turn to the competent agency or person (section 30 (4)). The representative has to pay special attention to the protection of the rights of those patients at a disadvantage due to their age, physical or mental disability, health status or social situation (section 30 (5)). He has the right to enter the premises of the health care provider, the right to have access to the relevant documents and the right to address questions to health care workers. The patients' rights representative is bound to professional

⁵³ J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopaedia of Laws - Medical Law* 2003, vol. 2, 72.

secrecy and is obligated to handle patients' personal data in compliance with the relevant legal rules (section 31).

Should there be a legal dispute between a patient and a health care facility, the parties may jointly initiate the settlement of such legal disputes within the framework of mediation proceedings (section 34).

B. Right to compensation

Article 24 Biomedicine Convention

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

In Hungary damage resulting from health services is compensated according to the rules of the Hungarian Civil Code.⁵⁴ Within civil law a distinction can be made between damages occurred outside of a contract (delictual liability) and damage resulted from contractual responsibilities. In Hungary the vast majority of civil law litigation that is initiated against health institutions is determined in accordance with the rules of delictual liability.⁵⁵

Section 339 (1) of the Hungarian Civil Code states the following: "A person who causes damage to another person in violation of the law shall be liable for such damage. He shall be relieved of liability if he is able to prove that he has acted in a manner that can generally be expected in the given situation".

Four preconditions have to be established to determine the responsibility of a health institution, that is to say damage, causality, ability to attribute guilt and the unlawful nature of the damage. When

⁵⁴ J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopaedia of Laws - Medical Law* 2003, vol. 2, 47-54

⁵⁵ J.SÁNDOR, "Hungary - Supplement 31", in H.NYS (ed.), *International Encyclopaedia of Laws - Medical Law* 2003, vol. 2, 47.

these four preconditions exist, the injured party may demand compensation from those who caused his injuries.

IV. RIGHTS OF USERS OF GENETIC SERVICES



§ 1. Introductory remark

Genetic testing in Hungary is mainly regulated by the legal framework that applies to health services as a whole. Consequently, the regulations on patient rights are *mutatis mutandis* applicable as rights of users of genetic services.

In January 2005 there was a proposal to the Government on the draft bill on the protection of human genetic data and the rules for genetic tests and research. This bill has not been approved until the date of writing.

A. Informed consent

The right of a patient to consent to diagnostic procedures (such as genetic tests) is established by section 15 of the Health Care Act. The patient's informed consent based on the appropriate information is a precondition of all medical interventions, unless otherwise provided for in the Health Care Act. The patient has the right to withdraw his consent. The patient can refuse (section 20 of the Health Care Act) medical treatment unless the lack of this treatment would endanger the lives or physical integrity of others. If the lack of the refused medical treatment would result in serious or permanent damage to his own health, the patient may only refuse the treatment if he makes a statement in a notarial deed, a fully conclusive private deed or in a declaration made before two witnesses in the case of inability to write. Life-supporting or life-saving interventions may only be refused if the patient suffers from a serious illness which will lead to death within a short period of time and is incurable according to the current state of medical science.

B. Right to information

Hungarian law provides the right to information about his health status as a right independent of the right to informed consent.

According to section 13 of the Health Care Act the patient has the right to receive comprehensive and individualized information. This general formulation is elaborated in the second paragraph of section 13 by stating amongst others that the patient has the right to receive detailed information on his state of health, including its medical evaluation. In section 134 of the Act the right to information is also elaborated. The attending physician has the obligation to brief the patient on his medical condition to the best of his knowledge, with the regularity justified by the condition, in keeping with the level of knowledge expected of the physician and in accordance with the provisions set forth in section 13 of the Health Care Act.

The patient also has the right not to know. He may waive the right of being informed unless his doctor decides that the patient has to be aware of the nature of his illness in order not to endanger the health of others.

C. Right to privacy

The right to privacy as a patient right is ensured in paragraph 5 and 6 of section 25 of the Health Care Act. According to these provisions a patient has the right to have his examination and treatment taken place under circumstances whereby he cannot be seen or heard by others without his consent, unless this is unavoidable due to an emergency or a critical situation. During the course of his examination and medical treatment, the patient has the right to have only those persons present whose involvement is necessary in delivering such care, furthermore those persons to whose presence he has consented, unless provided otherwise by law.

The right to privacy in the field of medical data protection and medical secrecy has become in Hungary an overwhelmingly important

right.⁵⁶ Everyone has the right to protection of secrecy in private affairs and personal data. The Data Protection Act 1992 is applicable to any instance of data handling unless the handling of specific data is covered by the Health Data Protection Act of 1997.

§ 2. Prohibition of discrimination on grounds of genetic heritage

Article 11 Biomedicine Convention

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited

Although there is no explicit prohibition of discrimination on grounds of genetic heritage, the general principle of non-discrimination is guaranteed by several provisions. Section 70 A of the Hungarian Constitution states that “the Republic of Hungary shall respect the human rights and civil rights of all persons in the country without discrimination on the basis of race, color, gender, language, religion, political or other opinion, national or social origins, financial situation, birth or on any other grounds whatsoever”. A similar provision can be found in the Health Care Act of 1997. According to section 7 (4) healthcare shall be considered free from discrimination if, in the course of delivering health care services, patients are not discriminated against on grounds of their social status, political views, origin, nationality, religion, gender, sexual preferences, age, marital status, physical or mental disability, qualification or on any other grounds not related to their state of health.

According to point h) of subsection 8 of Act CXXV of 2003 on equal treatment and promotion of equal opportunities, a provision constitutes direct discrimination if its result is that a person or group receives a less favorable treatment than a person or group in a comparable situation by reason of his/its real or supposed health status.

⁵⁶ J.SÁNDOR, "Cells, tissues, and health care data - Analysis of the Hungarian data protection laws in the light of the European norms", in A.DEN EXTER (ed.), Rotterdam, Erasmus University Rotterdam, 2004, 64.

§ 3. Use of predictive genetic tests

Article 12 Biomedicine Convention

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

No explicit regulations on the use of predictive genetic tests could be found in Hungarian medical law.

V. CONCLUDING REMARKS



1. Hungary ratified the *Convention on Human Rights and Biomedicine* on 9 January 2002. The Convention entered into force on 1 May 2002. Hungary has made a restriction based upon article 26 of the Convention concerning the right of refusal of a medical intervention. A female patient may not refuse a subsistence treatment or a life-saving intervention if she is pregnant and she is presumably able to carry the pregnancy to full term.

2. The draft text of the Convention has been taken into consideration while the Health Care Act of 1997 was being prepared. The primary legal sources of patient rights are the *Parliamentary Act No. CLIV of 1997 on health care* and the *Parliamentary Act No. XLVII of 1997 on the processing and the protection of health care data and associated personal data*.

3. The patient's *informed consent* is a precondition of all medical interventions, unless the Health Care Act provides otherwise. The information that has to precede the consent is comprehensive, individualized and disclosed in such a manner which is comprehensible for the patient.

4. Unless the Health Care Act or another Act stipulates otherwise, *the form of the given consent* can be verbally, in writing or it can even be deduced from his behavior.

5. The patient has *the right to refuse* medical treatment unless the lack of this treatment would endanger the lives or physical integrity of others. If the lack of the refused medical treatment would result in serious or permanent damage to his own health, the patient may only refuse the treatment if he makes a statement in a notarial deed, a fully conclusive private deed or in a declaration made before two witnesses in the case of inability to write. Life-supporting or life-saving interventions may only be refused if the patient suffers from a serious illness which will lead to death within a short period of time and is incurable according to the current state of medical science.

6. A competent person may draw up an *advance directive* that might be relevant if later on he becomes incompetent. In such a statement he can refuse certain medical treatment or name the person who shall be entitled to exercise the right to draw up an advance directive in his stead. The previously expressed wishes have to take form of a notarial deed. A qualified psychiatrist has to confirm in a written opinion that the person made the decision in full awareness of its consequences.

7. Hungarian law provides *the right to information* about his health as a right independent of the right to informed consent. The patient also has the right not to know. He may waive the right of being informed unless his doctor decides that the patient has to be aware of the nature of his illness in order not to endanger the health of others.

8. There is no legal regulation of *the therapeutic exception* in Hungarian Health Law. However, the Health Care Act stipulates that the physician has to be circumspect in informing the patient and has to do so gradually when necessary, considering the patient's condition and circumstances.

9. The patient has *the right to access the medical file*. If personal notes of the physician are included, they are also accessible. If the medical record contains data which could compromise the privacy of other persons, the right to access can only be exercised with regard to the data referring to the patient.

10. The Data Protection Act 1992 is applicable to any instance of *data handling* unless the handling of specific data is covered by the Health Data Protection Act of 1997.

11. The patient has *the right to file a complaint* with the health service provider regarding the provided health care service. The *Data Protection Commissioner* can investigate when human rights and the rights of patients overlap. The Health Care Act has also created the institution of *patients' right representatives*. Their main task is to provide information on the patient rights and how to enforce them.

12. Hungary has no specific law on *genetic testing*. The regulations on patient rights are *mutatis mutandis* applicable as rights of users of genetic services.

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