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# Patient rights in EU Member States after the ratification of the Convention on Human Rights and Biomedicine

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**Abstract**

The European Convention on Human Rights and Biomedicine was adopted by the Committee of Ministers of the Council of Europe on 19 November 1996 and opened for signature in Oviedo, Spain, on 4 April 1997. As of the moment of writing 11 Member States of the EU have ratified the Convention: Cyprus, Czech Republic, Denmark, Estonia, Greece, Hungary, Lithuania, Portugal, Slovakia, Slovenia and Spain. The overall purpose of this article is to analyze whether these ratifying EU Member States have fulfilled their obligation provided for in article 1 of Section 2 of the Convention ("each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention"). We further explored the legal consequences of ratification of the Convention. We analysed for each ratifying Member State whether and how the ratification of the Convention has influenced patient rights legislation and policies. Finally, we concluded by dividing the 11 Member States into 4 categories depending upon the already existing patient rights legislation at the moment of ratification and the constitutional provisions related to the ratification of an international treaty in general in a given Member State.


*Keywords:* Patient rights; Patient rights legislation; Convention on Human Rights and Biomedicine; Biomedicine Convention

## 1. Introduction

The European Convention on Human Rights and Biomedicine (hereafter: the Convention) was adopted by the Committee of Ministers of the Council of Europe on 19 November 1996 and opened for signature in Oviedo, Spain [1], on 4 April 1997 [2]. After the fifth ratification, that of Spain, the Convention entered into force on 1 December 1999. As of the day of writing, 11 Member States of the EU have ratified the Convention (see Table 1). The responsibility for the development and effective implementation of the Convention's norms lies primarily with each respective State Party, not with the common European institutions [3]. Article 1.2 is explicit in this respect: "Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention". This responsibility of the State Parties is reinforced by article 23 that obliges the Parties to provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in the Convention at short notice, and by article 25

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Table 1
EU Member States that have ratified the Convention

| | | Ratification (DD/MM/YYYY) | Entry into force (DD/MM/YYYY) |
|---|---|---|---|
| 1 | Slovakia | 15/01/1998 | 01/12/1999 |
| 2 | Greece | 06/10/1998 | 01/12/1999 |
| 3 | Slovenia | 05/11/1998 | 01/12/1999 |
| 4 | Denmark | 10/08/1999 | 01/12/1999 |
| 5 | Spain | 01/09/1999 | 01/01/2000 |
| 6 | Czech Republic | 22/06/2001 | 01/10/2001 |
| 7 | Portugal | 13/08/2001 | 01/12/2001 |
| 8 | Hungary | 09/01/2002 | 01/05/2002 |
| 9 | Estonia | 08/02/2002 | 01/06/2002 |
| 10 | Cyprus | 20/03/2002 | 01/07/2002 |
| 11 | Lithuania | 17/10/2002 | 01/02/2003 |

obliging them to provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in the Convention [4]. Thus, the internal law of the State Parties has to conform to the provisions of the Convention [5].

The overall purpose of this article is to analyze whether the ratifying EU Member States have fulfilled their obligation provided for in article 1 of Section 2 of the Convention. This analysis is limited to the articles of the Convention that govern what we call "general patient rights", notably article 5 (Consent – General rule), article 6 (Protection of persons not able to consent), article 8 (Consent – Emergency situation), article 9 (Consent – Previously expressed wishes) [6], article 10 (Private life and right to information) and article 26 (Restrictions on the exercise of the rights) [7].

The structure of this article is as follows. In paragraph 2 an overview is given of the EU Member States that have ratified the Convention. In paragraph 3 the legal consequences of ratification of the Convention are further explored. Paragraph 4 analyses for each ratifying Member State whether and how the ratification of the Convention has influenced patient rights legislation and policies. Paragraph 5 draws conclusions and contains some final remarks.

## 2. The actual status of ratification of the Convention within the EU

This table makes clear that as of the day of writing, 11 (of the 25) EU Member States have ratified the Convention. The majority of these 11 are Central or East European countries: Czech Republic, Estonia, Hungary, Lithuania, Slovakia and Slovenia. This dominance will be reinforced when Bulgaria and Romania enter the EU on 1 January 2007, because both countries have ratified the Convention (Bulgaria on 23 April 2003 and Romania on 22 April 2001). Four of the ratifying countries are South European countries: Cyprus, Greece, Portugal and Spain. Denmark is the only Scandinavian country to have ratified the Convention. It is interesting to cite IANEVA who gives the following explanation for the high number of Central and East European Member States that have ratified the Convention:

"Unlike in Western Europe, the push for legislation and policies on human genetics has not come from the civil society in the countries of Eastern Europe. It came rather under the influence of such European institutions like the Council of Europe and the European Parliament and the desire of governments and political leaders in Eastern Europe to promote the values of human dignity as part of the common heritage of Europe. [. . .] There is one very important characteristic of the new constitutions of most of the East European countries. By Constitutional law the norms of ratified international treaties are directly applicable [8] in the national legislation; so courts can rule based on the texts of international treaties, even if national laws have not yet adopted after the ratification. In reality this opportunity is still seldom used as few judges and lawyers are familiar with public international law, but there are already some legal cases in the field of human rights. *For this reason the ratification of existing international*

*treaties on genetics and biomedicine is the fasted way to regulate those matters and is becoming the venue of choice for the countries of Eastern Europe*" (italics by authors)" [9].

Italy is not mentioned in the preceding table although it has promulgated a law ratifying the Convention [10]. The reason for this is the following. The ratification procedure of an international treaty in a monistic system – as in Italy – has two phases [11]: an internal and an external phase. The internal phase usually comprises the adoption by the Parliament of a law to authorize ratification of the treaty and the promulgation of that law by the Head of State. The external phase is constituted by the deposit of the instrument of ratification. Because Italy has not yet deposited the instrument of ratification of the Convention and as this is an essential part of the procedure according to article 33.4 of the Convention, Italy does not appear as a country which has ratified the Convention on the website of the Council of Europe.

Since its last meeting the Comité Directeur de Bioéthique (C.D.B.I.—This is the Steering Committee on Bioethics of the Council of Europe) has started to encourage further ratifications by inviting the delegations of countries that have not yet ratified the Convention to provide an update concerning the status of the ratification process in their countries [12].

## 3. The legal consequence of ratification of the Convention

As already mentioned, article 1.2 of the Convention clearly imposes the responsibility for the development and effective implementation of the Convention's norms upon the States that have ratified it. In other words, conformity of internal law to the provisions of the Convention does imply that existing national legislation which does not comply with the Convention is void. In this respect it is clarifying to cite the Explanatory Report to the Convention:

"Conformity between the Convention and domestic law may be achieved by either applying directly the Convention's provisions in domestic law or by enacting the necessary legislation to give effect to them. With regard to each provision (of the Convention), the means will have to be determined by each Party in accordance with its constitutional law and taking into account the nature of the provision in question. In this respect, it should be noted that the Convention contains a number of provisions which may under the domestic law of many States qualify as directly applicable ('self-executing provisions')" [13].

This does not necessarily imply that existing national legislation has to be adapted or new national legislation should be enacted. Even if national laws have not yet been adapted after the ratification, courts can rule on the provisions of international treaties.

Whether adaptation of existing legislation or approval of new legislation is required, will depend upon whether a given provision of the Convention is directly applicable. With regard to this element, it is first of all important to remark that article 1 of Section 2 of the Convention does not preclude in any way the direct application of one or another provision of the Convention [14].

In order to be directly applicable the provisions of an international treaty – taking into account its context and in light of the object and purpose of the treaty – have to be unconditional and sufficiently precise to be applied as such in a particular case and to provide the basis for a specific decision [15].

Given this, for each provision of the Convention its direct applicability should be analysed. Therefore, "the substantive norms which form the 'core' of the Convention may be assumed to be directly applicable, id est articles 5 to 9 on informed consent; article 10.1 and 2 which deal with respect for private life and the right to information" [15]. This opinion is reflecting the consensus that seems to exist in this regard. According to ANDORNO "some norms concerning individual rights such as the right to information, the requirement on informed consent [. . .]" are directly applicable [16]. And the Explanatory Report to the Convention states that "this (the qualification of direct applicability) is the case, particularly, of the provisions formulating individual rights" [13].

The advantage of the direct applicability of provisions can only be used in countries with a monistic system. In countries with a dualistic system, such as Denmark and Hungary, every treaty has to be transformed into a national law before it can enter into force,

although this does not imply that there is no supremacy of international law.

Given that most of the countries that have ratified the Convention have a monistic system one may wonder – whether an analysis of the compliance with the Convention in these countries is really necessary. After all, once the Convention has been ratified the individual rights of patients protected by it have to be respected. Although from a strict legal point of view this argument is correct, we think that even in these countries specific legislation and jurisprudence can be extremely helpful in order to develop in more detail the – very general – principles included in the Convention and to adapt these principles to the specific socio-cultural values and the legal system of each State.

## 4. Conformity of internal law to the Convention in the ratifying EU Member States

The following overview is founded on the one hand on the results from literature research and the investigation of existing laws and jurisprudence in the ratifying countries, where available, and on the other hand on the information retrieved from contact persons in each of the ratifying countries: in a university setting and in public administration (Ministry of Health/Social Affairs) [17].

### *4.1. Cyprus*

After the ratification of the Convention on 20 March 2002, Cyprus has approved a law on the safeguarding and the protection of the rights of patients in 2005 (Law 1 (I) 2005) [18]. According to article 3 of this law its provisions are complementary to the rights deriving from international treaties relating to the protection of human rights ratified by the Republic, among which the Convention. Moreover, according to article 169 (2) and (3) of the Constitution of the Republic of Cyprus an international Convention has immediately superior force to any domestic law.

The law on the safeguarding and the protection of the rights of patients deals extensively with all the individual patient rights enumerated in the Convention.

Cyprus has made no restrictions (on the basis of article 26 of the Convention) on the exercise of rights and provisions contained in the Convention.

### *4.2. Czech Republic*

Basic patient rights are laid down in the Act No. 20/1966 on Health Care. This act is quite old and although it has been amended many times, it is not an adequate framework for the current protection of patient rights. A bill for a new act has been announced several times but its adoption is not expected in the near future. The ratification of the Convention was neither preceded nor followed by substantial changes in the legislation concerning patient rights. With respect to articles 5, 6, 8, 9 and 10 of the Convention the internal law of the Czech Republic is formally in conformity with the Convention because of the direct applicability of these provisions. In practice one may seriously doubt whether patient rights are adequately protected given (a) the inadequate protection offered by the Act No. 20/1966 on Health Care and (b) the lack of recent legislation to protect the rights of patients. DEN EXTER moreover, is even more critical: “the gaps in the Czech system are so systematic and serious that they undermine, to an unacceptable degree, the realization of patients’ rights. In view of the internationalization of patients’ rights and emergence of international mechanisms for their protection, the Czech Republic can be exposed to legal and political risk as patients would hold the government accountable for violations” [19].

The Czech Republic has not made restrictions on the exercise of rights contained in the Convention.

### *4.3. Denmark*

At the moment the most important act relating to patient rights is Law No. 482 of 1 July 1998 on patient rights. In addition there are a number of other acts which contain patient rights provisions (e.g. the Act on Abortion, Act on Assisted Reproduction, Act on Transplantation). Recently the Danish legislator adopted the Health Act – Law No. 546 of 24 June 2005 – putting together different acts related to patient rights. This new act will come into force on 1 January 2007. Most of the provisions in the new Health Act are similar to the provisions contained in the current acts including the patient rights act.

Conventions do not become part of Danish law immediately (article 19 of the Danish Constitution). The authorities may not apply the treaty provisions before they have been incorporated. This is concurrent

with the dualistic principle of Danish legal doctrinal tradition according to which international and national law are considered to be two essentially different systems of law.

At the time of the conclusion of a treaty, Danish authorities examine domestic law in order to determine whether it already complies with the treaty in question or whether amendments in domestic law are required. One way is to incorporate the text of a treaty into a Danish statute or administrative regulation. However, it has become more common to adopt a statute which merely refers to the treaty while stating that the treaty provisions shall have effect as part of Danish law [20].

The Convention is ratified by Parliamentary decision of 11 May 1999. The decision of the Parliament has the form of a legal statute announcing that the Convention is now part of Danish law. During the preparation of this decision it was assumed that Danish law was already in accordance with the Convention, except for article 10 (see next paragraph).

Denmark has made a restriction based on article 26 of the Convention regarding article 10.2 of the Convention. According to this provision, all persons are entitled to know any information collected about his or her health. However, the wishes of individuals not to be informed shall be observed. Danish legislation on registers provides that health information may be exempted from the registered person's right to information. Likewise, Section 10, paragraph 5 of the Public Administration Act (Act No. 572-19/12-1985) provides that material provided as a basis for the preparation of public statistics or scientific studies is not subject to access.

### 4.4. Estonia

The first draft of a law on patient rights was already prepared in 1993 (thus before the ratification of the Convention by Estonia), presented to government in 1994 and then passed on to the Parliament. However, its approval was blocked by the health care professional lobby, which requested the simultaneous preparation of a law on the protection of medical personnel. Several subsequent drafts have been prepared by the Ministry of Social Affairs over the years, in collaboration with representatives from patient organizations and health care professional associations. Some of these drafts made their way to the Parliament, but none have been approved. The idea of a specific patient rights law has not been completely abandoned. The position expressed by officials at the Ministry of Social Affairs in 2004 is to observe current regulations under the Law of Obligations (see next paragraph) and then to decide on the necessity of a law that specifically regulates patient rights [21].

Meanwhile medical practice has undergone extensive legal regulation. The principles of informed consent, professional liability, etc., have been introduced into Estonian law only in recent years and with great reluctance on the part of physicians who were accustomed to the concept of a community beneficence ethic that governed soviet medicine [22]. The rights and obligations of patients are laid down in the Law of Obligations Act 2001. According to the authors' appreciation the articles of this Law of Obligations Act that govern the rights and obligations of patients have clearly been inspired by the Dutch Act on patient rights, the so-called Medical Treatment Contract Act. The expression 'contract for provision of health care services', the definition of patient, the duty of the patient to pay a fee and his duty to provide information to the physician are all examples of the similarities between both acts. According to a privileged witness "the Convention is an inspiration for Estonia to legislate in this field" [23]. Moreover, according to article 123 of the Constitution of the Republic of Estonia international treaties ratified by the Parliament have immediately superior force to any domestic law [24].

Estonia has made no restrictions based on article 26 of the Convention.

### 4.5. Greece

Already before the ratification of the Convention, legislation directly addressing the rights of hospitalized patients was passed in 1992 (Law No. 2071/92 on the Modernization and Organization of the Health System, articles 47 and 61). These rules were based on the European Charter of Hospital Patients' Rights of 1979 [25]. Article 1 of the health care reform legislation of 17 July 1997 extended the provisions of article 47 have been extended from hospital patients to all citizens seeking health care by [26]. The Act of 28 November 2005 on the Code of Medical Ethics is also very important for the protection of the rights of patients, especially Chapter III that deals with the

relation between physician and patient [27]. Despite its title, this Code has not been written by the Greek Order of Physicians, but by an ad hoc committee of experts (academics, physicians and lawyers, including representatives from the Order) appointed by the Minister of Health. This committee prepared a draft bill that was introduced, debated and voted in the Parliament according to the regular legislative process. Although the Parliament had the competence to amend the bill, the Parliament did not change the original provisions of it. The Greek Parliament adopted the bill on 8 November 2005. According to a comment of the National Bioethics Commission "the new Code of Medical Ethics is consistent to the International Documents on Medical Ethics. It complies also with the relevant legal instruments (in particular the Oviedo Convention on Human Rights and Biomedicine)" [28]. According to one author, article 11 of the Code that governs the right of information of the patient is "certainly wider than what the Convention of Oviedo dictates" [29].

Although it has been stated that "the truth is, though, that the ratification of the Convention was a general instrument, a *lex imperfecta*, as it did not contain any sanctions" [30], one cannot neglect that "from the 1990s onwards (and particularly after the ratification of the Convention on Human Rights and Biomedicine) the situation has dramatically changed: draft laws are under discussion, new publications are devoted to the interwoven relation among law, ethics and biomedicine; ethics committees have been established . . ." [31]. Moreover, as article 28.1 of the Greek Constitution lays down the principle of the openness of the Greek legal order to international law, the provisions of the Convention form an integral part of domestic Greek law since 1 December 1999 and prevail over any contrary provision of the law [32].

Greece has not made restrictions based on article 26 of the Convention.

### 4.6. Hungary

The rights of patients are governed by Chapter II (Rights and obligations of patients) and Chapter VI (Rights and obligations of health care workers) of the Health Act CLIV of 1997, as amended. When this act was in the process of being elaborated, the draft text of the Convention has been taken into consideration. Thus, the Hungarian internal law contains regulations in order to implement the Convention. This is necessary because according to article 7 (1) of the Hungarian Constitution Hungary has a dualistic system [33]. Chapter II of the Health Act has to a large extent also been based on the WHO Amsterdam Declaration on the Promotion of the Rights of Patients of 1994 [34]. The intentions of the Hungarian legislator are clearly reflected in the "General Reasoning" that accompanies the Health Act Bill: "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 patient are only expressed as obligations of the health care staff – as the opposite party – although such rights should have been declared as subjective ones in order to render their enforcement possible" [35]. The Court's decision 22/2003 – referred to in footnote 37 – goes on as follows: "Another typical feature of the Act CLIV is the strengthening of patient's rights, partly expressed in 'the obligation of the State to ensure the enforcement of patients' general human and civil rights as well as of their rights as patients in the course of medical care' (General Reasoning, point 4)".

The Hungarian Constitutional Court has not only interpreted the Health Act but has also played an important role in the further elaboration and strengthening of the rights of patients.

In at least one decision the Constitutional Court has made explicit reference to the Convention. In its decision 36/2000 of 24 October 2004 the Court annulled the words "or limited disposing capacity" in article 16.2 of the Health Act. This paragraph provided that if a patient has no disposing capacity or limited disposing capacity and there is no person entitled to represent him, the right of consent and refusal are exercised by the persons enumerated in this paragraph. The Constitutional Court held that "restricting the right of self-determination related to medical care (the right of consent and refusal) of patients with limited disposing capacity to the same extent as in the case of incapable patients is a violation of article 54.1 of the Constitution" [36]. In assessing the enforceability of the right of self-determination on the basis of article 54.1 of the Constitution, the Court took into account the following aspects too:

"Point 3.5 of the Declaration on the Promotion of Patients' Rights (Amsterdam, March 1994) adopted in

the framework of the World Health Organisation of the UN provides that 'when the consent of a legal representative is required, patients – whether minor or adult – must nevertheless be involved in the decision-making process to the fullest extent which their capacity allows.'
Article 6 of the Council of Europe's Bioethical (*sic*) Convention (Oviedo, April 1997) expressly provides that only in the case of 'having no capacity to consent' it may be allowed to follow the decision of a person other than the patient regarding the patient's treatment. The Recommendation of the Council of Europe on the Principles concerning the Legal Protection of Incapable Adults (No. R. 99.4) provides that the legal environment available for the protection of the personal and economic interests of incapable adults should be sufficient, in scope or flexibility, to enable a suitable legal response to be made to different degrees of incapacity and various situations (Principle 2 Point 1). In addition, the recommendation contains that 'a measure of protection should not automatically deprive the person concerned of the right [. . .] to consent or refuse consent to any intervention in the health field' (Principle 3 Point 2)" [36].

Hungary has made a restriction based upon article 26 of the Convention concerning the right of refusal of a medical intervention. According to article 26.6 of the Health Act the patient cannot refuse subsistence treatment or life saving intervention if she is pregnant and presumably capable to bear the child to the full term. The competent patient cannot refuse health care treatment if the omission of the treatment would threaten the life or the bodily integrity of other persons.

### 4.7. Lithuania

With regard to patient rights, there are two pieces of distinct legislation. First, the Law on the Rights of Patients and Compensation for the Damage to their Health of 1996 and second the new Civil Code of Lithuania, which was adopted in 2000 and came into effect as of 1 July 2001.

According to Birmontiene the health law issues regulated by this new Civil Code may be classified into two major groups: (i) those establishing certain general issues of the rights of patients that are also reckoned among basic human rights; (ii) the second group encompasses the regulation of the rights of patients as one of the essential elements of a contract for health services. These rights are similarly regulated in the Law on the Rights of Patients and Compensation for the Damage to their Health of 1996 that was not abrogated when the new Civil Code came into effect [37]. The provisions of the Law on the Rights of Patients of 1996 are currently being harmonized with the provisions of the Civil Code, because the 1996 legislation should not provide for a different, less-favorable regulation for individuals than the Civil Code [38].

Separate provisions of the Convention have been implemented in the Civil Code, the Law on Human Tissue and Organ Donation and Transplantation, the Law on Mental Health Care, the Law on Legal Protection of Personal Data, and other legal acts. According to BIRMONTIENE "the Convention is an inspiration for Lithuania to legislate in this field" [23]. Also the WHO Declaration on the Promotion of the Rights of Patients in Europe 1994 has influenced the 1996 Law on the Rights of Patients [39]. For the working group that prepared the 1996 law it was a very big support to have a Declaration on the promotion of patient rights in Europe. Consequently, many provisions of the Lithuanian draft law are based on this Declaration [40]. It is also interesting to note that the regulation of the patient rights in the Civil Code as one of the elements of a contract for reimbursable services can be regarded as an example of the reception of the Dutch civil law by Lithuania [41] (see also in this respect Estonia).

Lithuania has not made any restrictions on the exercise of the rights and provisions contained in the Convention based upon article 26.

### 4.8. Portugal

Some provisions related to patient rights are laid down in the Law on Health 48/90 of 24 August 1990. There seems to exist a consensus among Portuguese academic writers that the ratification of the Convention has had important consequences for the protection of patient rights in Portugal. Article 8 of the Portuguese Constitution provides for the supremacy of international conventions. As a result "patient's rights Portuguese legal framework was recently enlarged by the approval and ratification of the 'Oviedo Convention' [. . .]. This Convention is part of the internal

juridical order after a Presidential Decree of 3 January 2001" [42].

According to de Oliveira, on the contrary: "some of the provisions of the Convention did not bring anything new to Portuguese law as the content of those provisions was the content of some Portuguese rules which were already part of the Portuguese legal system. As a matter of fact, rules about informed consent of both competent and incompetent adults, and of children, could be found in several Portuguese laws, the most interesting being Articles 156 and 157 of the Portuguese Penal Code, which punishes any treatment performed without previous consent of the patient concerned and clarifies what is the content of the so-called 'duty of information'. The technical interest of these provisions lies in the fact that they are separate from other provisions on medical intervention carried out in disrespect of technical professional standards. The same could be said about rules on respect for private life and control over information which concerns one's private life (article 10), which has been developed by Portuguese Fundamental law and some other laws many years ago" [43].

Lobato de Faria concludes "As we saw above, the Law, id est the Law of 24 August 1990 gives important rights to the citizens as users of the health services. Nevertheless, these norms are too vague and general to be of practical use. There are no specific regulations to guide the health provider on the detailed contents of the declared rights of a patient" [44].

Portugal has not made restrictions on the exercise of rights contained in the Convention.

### 4.9. Slovakia

Slovakia has been the first Eastern European country to ratify the Convention in 1998. The Convention has superior force to any domestic law in Slovakia according to article 11 of the Slovak Constitution. However, it soon became clear that ratification alone was insufficient. In the report "Patients' Rights in Slovak Republic" dated October 2000, covering the period November 1999–October 2000 and performed in the context of the "Phare programme" (one of the three pre-accession instruments financed by the European Union to assist the applicant countries of Central and Eastern Europe in their preparations for joining the European Union) analysis was made of the "current condition of patients' rights" resulting in the following observations:

a. Current legal regulations in patient's.
b. Right are too general and stringent.
c. Current legal regulations are not homogenous in respect of terms.
d. The legislation does not content overall and detailed specification of particular rights and responsibilities of patients.
e. Several rights of patients are literally scattered in different legal norms.
f. Some patient's rights are missing in legal regulations and some should be more detailed or better specified.
g. Current legal regulations in the area of patient's rights are not patient friendly [45].

Since then several initiatives have been taken in order to strengthen the protection of the rights of patients. "In April 2001 the 'Charter of Patients' Rights' was adopted by the Government of the Slovak Republic. To have a charter as a well defined summary of all patients' rights was the first step in improving the situation. The next step was applying these rights in everyday practice. The Dutch government was approached for the international cooperation and an expertise, and as a result the project "Promotion of Patients' Rights in Slovakia" was implemented and financed by the government of the Netherlands. [. . .] Two national conferences contributed to development of the national policy on patients' rights in Slovakia. [. . .] As a result of those two conferences the 'National Program of Patients' Rights' was adopted. This strategic document defines the current situation of patients' rights in Slovakia and areas of concern and indicates the concrete activities that are necessary to be implemented for efficient patients' rights promotion" [46]. The preamble of the Charter of Patients' Rights states: "This Charter was worked out in accordance with documents of the UNO, World Health Organisation, Council of Europe and European Union. It takes into account the experience of the European countries, in particular the Netherlands, Germany, Sweden, Austria and the United Kingdom."

The purpose of the Charter was to facilitate the orientation of citizens and health care professionals in the field. In comparison with other EU Member States, legislation on patient rights in Slovakia remained how-

ever insufficient. Drafting a separate law in order to supplement and extend patient rights in Slovakia was suggested [47].

The new government that emerged from the 2002 parliamentary elections developed a radical reform strategy "Health care reform: real reform for citizens". The Ministry of Health prepared the major part of the government's health care reform strategy: reform of all major health care laws. The reform package of six acts was submitted to the National Assembly in April 2004 and enacted – with several amendments – in October 2004 [48]. As of 1 November 2004, 6 new laws became effective, among which Act No. 576/2004 Coll. on health care and health care-related services.

The rights of patients are laid down in this Act. It is interesting to note that as in Estonia this act has clearly been influenced by the Dutch Law on the Medical Treatment Contract. Article 12 (1) indeed provides that "a legal relation subject of which is health care is established upon the health care agreement concluded between a person and a provider".

Slovakia has not made restrictions based on article 26 of the Convention.

### 4.10. Slovenia

The awareness towards the need for consumer rights protection was already strong before the ratification of the Convention and when new health legislation was prepared in 1992, a special concern was dedicated to citizens and patient rights. The rights are divided to those connected only to the insured persons (Law on Health Care and Health Insurance) and to the rights that cover all citizens under the same conditions (Law on Health Care Activity, also called the Health Services Act) [49]. The Health Services Act 1992 regulates the organization, status and the rights and obligations of health care providers. The Act also regulates patient rights in very general terms [50]. These regulations of the rights are considered to be harmonized with international rules and EU legislation [51].

Notwithstanding this and the supremacy of the Convention according to article 8 of the Slovenian Constitution there is a widespread feeling that the rights and duties of patients and their physicians will have to be more clearly defined, taking into account the patient/citizen's increasing participation within decision-making processes in the field of health care [52]. "In future, the patient/citizen's participation in the decision-making processes on health policy and medical interventions will be increased. The responsibilities and duties of every person to care for their own health and that of their family will be highlighted" [53].

The Government that was elected at the end of 2004, defined some basic priorities for the reforms in health care. Following the adoption of these priorities, the process has moved into the text phase [54]. A Law on patient rights has indeed been drafted and this draft contains provisions on matters of articles 4 to 10 of the Convention [55]. In June 2006 the draft was in the procedure of reconciliation of viewpoints and it is supposed to be adopted this year [56].

Slovenia has not made restrictions based on article 26 of the Convention.

### 4.11. Spain

The Convention has superior force to any domestic law in Spain according to article 96 (1) of the Spanish Constitution. Taking into account that the Convention offered a stronger protection than the existing Spanish law "the former should have priority for Spanish law" [57]. Despite of the direct applicability "the ratification of the Convention by Spain provoked the need for a reform of the existing legislation on health care because on the one hand many aspects of the 'General Health Law' were in contradiction with the Convention, and on the other, some of the new rights provided for in the latter, were not yet acknowledged in any legal provision" [58]. Thus, the Convention "triggered an avalanche of laws in this field" [59].

The Exposition of Reasons (Explanatory Memorandum) to the bill that has become the Basic Law 41/2002 on the Autonomy of the Patient and the Rights and Obligations with regard to Clinical Information and Documentation, refers to international norms and especially to the Convention as the main source of the Basic Law: "The importance of the rights of patients as a basic cornerstone of clinical-care relations is revealed by noting the interest that has been shown in them by virtually all international organizations with competence in the field. Since as far back as the end of World War II, organizations such as the United Nations, UNESCO or the World Health Organization, or more recently the European Union or the Council of Europe, among many others, have issued declarations or in some case

have passed juridical regulations on general or specific aspects related to this question. In this regard, it is necessary to mention the significance of the Universal Declaration of human rights of 1948, which has been the obligatory point of reference for all constitutional texts issued subsequent to it, or, in the field more strictly concerned with health, the Declaration on the promotion of the rights of patients in Europe, promoted in 1994 by the Regional Office for Europe of the World Health Organization, apart from a great many international declarations of greater or lesser scope and influence which have referred to those questions.

Finally, emphasis may be placed on the special relevance of the Convention of the Council of Europe for the protection of human rights and the dignity of the human being with regard to the applications of biology and medicine (Convention on the rights of man -*sic*- and biomedicine), signed on 4th April 1997, which came into force in the Kingdom of Spain on 1st January 2000. This Convention is a major initiative: in fact, unlike the various earlier international declarations, it is the first international instrument having a binding juridical nature on the countries signing it. Its special value lies in the fact that it establishes a common framework for the protection of human rights and human dignity in the application of biology and medicine. The Convention deals explicitly, at length and with considerable extent, with the need to acknowledge the rights of patients, among which it highlights the right to information, informed consent and the privacy of information relating to the health of persons, with the aim of achieving a standardization of legislations in this field in different countries. In this regard, it is highly advisable to bear the Convention in mind when it comes to tackling the challenge of regulating such important questions" [60].

Through the Basic Law 41/2002 the provisions of the Convention on general patient rights have been implemented.

The Basic Law on patient rights contains some restrictions based on article 26 of the Convention, particularly for reasons of the health of the patient or public health. That is the case with the right to information (the doctor is allowed not to inform the patient if he thinks it can be prejudicial to his/her health), and with informed consent, which can be limited in order to preserve the health of the patient, the health of third parties and public health.

## 5. Comparative analysis

According to Simonovic the ratification of the Convention "has been a relatively slow but steady process [. . .] which is a clear sign that the harmonization in this field is a very demanding but reachable goal" [61]. Without speaking of "harmonization", the results of our research seem to confirm her statement in this sense that the Convention has had in all but one of the Member States that have ratified the Convention a demonstrable impact upon the patient rights legislation and policies. However, this impact is not the result of a uni-dimensional process. Depending upon the already existing patient rights legislation at the moment of ratification on the one hand and the constitutional provisions related to the ratification of an international treaty in general in a given Member State on the other hand, the Member States that have ratified the Convention can be distinguished in four categories. The first category contains the Member States that have enacted patient rights legislation and policies *after* the ratification of the Convention (Section 5.1). A second group of Member States is formed by those that have enacted patient rights legislation and policies *before* the ratification of the Convention (Section 5.2). A third category are the Member States where ratification of the Convention did not lead to the enactment of patient rights legislation because this was not deemed necessary (Section 5.3). And finally there is the fourth category where the ratification of the Convention seems not to have had any significant impact upon the patient rights legislation and policy (Section 5.4).

### *5.1. Member States having enacted patient rights legislation after ratification*

This category, which is the largest, contains 5 of the 11 ratifying Member States: Cyprus, Greece, Slovakia, Slovenia and Spain.

After the ratification of the Convention on 20 March 2002 the Cyprian legislator has approved in 2005 a law on the safeguarding and protection of the rights of patients. According to article 3 of this law its provisions are complementary to the rights derived from the Convention.

When Greece ratified the Convention in 1998 some patient rights legislation already existed. It is generally recognized however that the ratification has served as a

trigger to modernize this legislation which resulted in 2005 in the Act on the Code of Medical Ethics.

Slovakia has been the first State that ratified the Convention in 1998. Since then several initiatives have been taken to strengthen the protection of patient rights. First through "soft law" mechanisms such as "the Charter of Patient Rights" in 2001, followed in 2004 by a law confirming rights of patients.

The situation in Slovenia is different than in the other four States, because in Slovenia the process of enacting patient rights legislation is not yet finished. A law on patient rights has been drafted which contains provisions on matters regulated by articles 5 to 10 of the Convention. The draft could be approved in 2006.

The ratification of the Convention by Spain in 1999 has provoked a need to reform and supplement existing legislation thus triggering "an avalanche of laws in this field". The Explanatory Memorandum of Basic Law 41/2002 on the autonomy of the patient and the rights and obligations with regard to clinical information and documentation refers explicitly to the "special relevance" of the Convention.

### *5.2. Member States having enacted legislation before ratification*

The following three Central-Eastern EU Member States belong to the second category of Member States where the Convention already had a significant impact upon patient rights legislation and policies *before* the ratification: Estonia, Hungary and Lithuania.

Estonia has ratified the Convention in 2002. The first attempts to legislate patient rights date back to 1993. These attemps failed, but in 2001 the rights and obligations of patients have been incorporated in the Law of Obligations. A privileged witness has testified that the Convention was already before its ratification "an inspiration for Estonia to legislate in this field" [62].

Hungary has ratified the Convention in 2002. The rights of patients and the rights and obligations of health care workers are laid down in the Health Act CLIV of 1997. However, when this act was in the process of elaboration, the draft text of the Convention has been taken into consideration. Also the Hungarian Constitutional Court has interpreted the Health Act in the light of the provisions of the Convention. Lithuania has with Estonia and Hungary in common that it ratified the Convention in 2002. It had already enacted patient rights legislation and policies before that date, in 1996 and in 2001. As in Estonia the Convention has served as a source of inspiration.

### *5.3. Member States that neither before nor after ratification changed their patient rights legislation under the influence of the Convention*

Denmark and Portugal belong to the third category although there are marked differences between both countries.

The most important act relating to patients rights in Denmark was (and still is until 1 January 2007) the Law on Patient Rights of 1998. Denmark ratified the Convention by a Parliamentary decision in 1999. This decision has made the Convention part of Danish law. During the parliamentary preparation of this decision it has been assumed that Danish law is in accordance with the Convention except for its article 10.

In Portugal the ratification of the Convention itself by a Presidential Decree in 2001 has been regarded as an enlargement of the legal framework for patient rights without any intervention by the legislature being necessary. The influence of the Convention is more outspoken in Portugal than in Denmark: in the latter country the existing level of protection of patient rights was considered to be in accordance with the Convention while in Portugal this was not the case. Moreover, there is a general feeling in Portugal that in different respects more detailed legal rules are required or at least wished which would bring Portugal in the first category of Member States.

### *5.4. Member States where ratification of the Convention has remained without significant effect*

The Czech Republic has ratified the Convention in 2001. Basic patient rights are laid down in an Act of 1996 which does not offer an adequate framework for the current protection of patient rights. The ratification of the Convention was neither preceded nor followed by substantial changes in the legislation. Because the Czech Republic has a monistic system there is formally no need to make their internal law in conformity with the Convention. But there is no evidence that the Convention has had significant impact upon the protection of patient rights.

## 6. Conclusion

This article has analyzed the influence of the Convention on the development of patient rights legislation and policies in the EU Member States that have ratified this Convention. The general conclusion is that the Convention has had a demonstrable impact upon patient rights legislation and policies. We are aware of the limitations of our approach and of the fact that more research needs to be done. For instance, it would be interesting to know how fast or slow these and other Member States have ratified other Conventions of the Council of Europe. Furthermore it is important to get more insight into the motives of Member States who have not yet ratified the Biomedicine Convention. Also the role played by Constitutional or Supreme Courts, by Ombudspersons and the like has only partially been analyzed in this article. These and other questions are currently on our research agenda and we intend to report on the results in the near future.

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