

THE EUROPEAN CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE : A EUROPEAN PATIENT RIGHTS INSTRUMENT

PROF.DR.HERMAN NYS

UNIVERSITY OF LEUVEN (BELGIUM)

1. INTRODUCTION

The Biomedicine Convention has from the very beginning been construed as a patient rights instrument although its concerns are broader (§2). As a patient rights instrument the Convention has markedly influenced the development of the rights of patients in many Member States (§3). At the supranational level, its role as a patient rights instrument has been reinforced through the jurisprudence of the European Court of Human Rights which will also have effects at the national level (§4).

2. The double concern of the Biomedicine Convention

The title of the Biomedicine Convention may be misleading as to its objectives. Terms like biology and biomedicine refer to genetics, cloning, (xeno) transplantation, reproductive medicine, medical research and other high-tech biomedical achievements and developments. The concern of the Convention is indeed that the individual “has to be shielded from any threat resulting from the improper use of scientific developments”.¹ However, this is not the Convention’s sole concern. The Convention as a whole “will provide a common framework for the protection of human rights and human dignity in both longstanding and developing areas concerning the application of biology and medicine”.² In this respect the Convention wants to protect the rights of patients in daily health care. For that reason the Convention is really a “patient

¹ Explanatory Memorandum to the Convention § 14

² Explanatory Memorandum to the Convention § 7

rights treaty”³: the Convention strengthens internationally the legal position of the patient in setting a minimum level of protection.

Chapter II is entitled “Consent” and contains the articles 5 to 9. Article 5 confirms an already in 1999 vested requirement: “An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it” (article 5). Article 9 however was a very innovative provision at that time as it relates to previous expressed wishes: “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”.

Chapter III relates to private life and right to information and contains only one but it is a very important and encompassing provision. Article 10.1 protects the right to private life: “Everyone has the right to respect for private life in relation to information about his or her health”.

Article 10.2 protects the right to know and not to know: “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”. According to article 10.3, “In exceptional cases, restrictions may be placed on the exercise of the rights contained in §2 in the interests of the patient”. (Therapeutic exception or therapeutic privilege).

Also the right of the patient to receive compensation for undue damage has been recognized in the 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” (article 24).

The Biomedicine Convention also protects in a specific way the rights and interests of patients who are not able to give consent themselves. The basic protective rule is contained in article 6.1. : “An intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit”. Moreover, “an intervention may only be carried out with the authorisation of his/her legal representative or an authority or a person or

³ Although the notion “patient” only appears once in the Convention : see article 10.3. Most of the time the expression “ the person concerned” is used.

body provided for by law” (article 6.2 and 6.3). However, the person concerned has also to be involved in the authorization procedure (article 6.2 and 6.3).

The Convention not only contains individual patient rights but also the social right to health care : “Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality” (Article 3).

3. The influence of the Convention on patient rights development in the Member States

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.⁴ 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 obliging them to provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in the Convention.⁵ Thus, the internal law of the State Parties has to conform to the provisions of the Convention. 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.⁶ With regard to this element, it is first of all important to remark that article 1.2. of the Convention does not preclude in any way the direct application of one or another provision of the Convention. 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

⁴ R.ANDORNO, “ The Oviedo Convention: a European framework at the intersection of human rights and health law”, *Journal of International Biotechnology Law*, 2005, 135-136

⁵ R.ANDORNO, “Towards an international bioethics law”, *Journal of International Bioethics*, 2004, 2/3, 149

⁶ O.GUILLOD, “Swiss perspective on the Convention of human rights and biomedicine”, in *Proceedings of the 8th European Conference of National Ethics Committees (COMETH)*, Dubrovnik, Croatia, 2005,31-32

sufficiently precise to be applied as such in a particular case and to provide the basis for a specific decision. 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” .⁷ 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.⁸ 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”.⁹

It is not possible here to give more details about the concrete influence of the Biomedicine Convention on the development of patient rights legislation in Member States. We refer the interested reader to other publications.¹⁰

4. Reinforcing the role of the Convention as a patient rights instrument

According to article 29 of the Biomedicine Convention the European Court of Human Rights may give, without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the Convention at the request of the Government of a Party, after having informed the other Parties and at the request of the CDBI. Until now this procedure has not yet been applied.

However, the role of the European Court is not limited to this advisory competence. Although the Biomedicine Convention itself does not give

⁷ O.GUILLOD, “Swiss perspective on the Convention of human rights and biomedicine”, in *Proceedings of the 8th European Conference of National Ethics Committees (COMETH)*, Dubrovnik, Croatia, 2005,32

⁸ R.ANDORNO, “ The Oviedo Convention: a European framework at the intersection of human rights and health law”, *Journal of International Biotechnology Law*, 2005, 135

⁹ Explanatory Memorandum to the Convention § 20

¹⁰ See in particular H.NYS.a.o. ‘Patient rights in EU member states after the ratification of the Convention on human rights and biomedicine’, *Health Policy*, 2007, 83, 223-235; T.GOFFIN .a.o. ‘Why eight EU member states signed, but not yet ratified the Convention for human rights and biomedicine’ , *Health Policy*, 2008, 86, 222-233. See also www.europatientrights.eu and www.europeanpatientrights.eu

individuals a right to bring proceedings before the European Court, facts which are an infringement of the rights contained in the Biomedicine Convention may be considered in proceedings under the European Convention of Human Rights, if they also constitute a violation of one of the rights contained in the latter Convention.¹¹ In this respect it is important to note that a certain overlap exists between both Conventions. Especially article 8 (protection of private life and family life) of the European Convention of Human Rights forms a bridge between both Conventions.

However, the most interesting development is that the European Court of Human Rights is increasingly referring to the Biomedicine Convention.¹² The first reference to the Convention was made by mr.Marcus-Helmons, a Belgian *ad hoc* judge in the inter-state case brought by Cyprus against Turkey.¹³ This is a bit ironic because Belgium did not even sign the Convention and has since 1999 approved legislation in the field of organ transplantation and the removal of human material that clearly runs counter to the Convention. In *Glass v. UK* the European Court considered: “ It would add that it does not consider that the regulatory framework in place in the United Kingdom is in any way inconsistent with the standards laid down in the Council of Europe’s Convention on Human Rights and Biomedicine in the area of consent”.¹⁴ By doing so, the Court is reviewing the British regulatory framework on parental consent under the Biomedicine Convention although the UK has neither signed nor ratified the Convention. In *VO v. France*¹⁵ the Court referred to the “Oviedo Convention on Human Rights and Biomedicine” and used it as an authoritative

¹¹ Explanatory Memorandum to the Convention §165

¹² See on this, H.NYS, “ Towards an international treaty on human rights and biomedicine? Some reflections inspired by UNESCO’s Universal Declaration on Bioethics and Human Rights”, *European Journal of Health Law*, 2006, 7; E.GLAD, “ The global significance of the Convention on Human Rights and Biomedicine” in J.K.M. GEVERS a.o. (ed), *Health Law, Human Rights and the Biomedicine Convention. Essays in honour of Henriette Roscam Abbing*, Leiden, Martinus Nijhoff, 2005, 44;

¹³ ECtHR, 10 April 2001, *Cyprus v. Turkey* - partly dissenting opinion of mr. Marcus-Helmons. For more details see R.LAWSON, “ Dwelling on the threshold: On the interaction between the European Convention on human rights and the Biomedicine Convention” in A.DEN EXTER (ed), *Human Rights and Biomedicine*, Antwerpen, Maklu, 2009, 31-32 (in press)

¹⁴ ECtHR, 9 March 2004, *Glass v. UK*

¹⁵ ECtHR,, 8 July 2004, *VO v. France*

argument.¹⁶ France has signed the Convention but until now has not ratified it. In the case of *Evans v.UK*¹⁷ and *Özalp v. Turkey*¹⁸ the European Court referred to article 5 of the Biomedicine Convention (requirement of free and informed consent). The until now final decision is which the European Court referred to the Convention is *Ada Rossi a.o. v.Italy*.¹⁹ The Court indicated that it would take into account the Biomedicine Convention in this case whereas Italy has signed but not ratified the Convention.

It may be true that after 10 years many Member States among which Germany, France and the UK have not ratified the Convention. The question is whether this is an impediment for the Convention to play its role as a patient rights instrument. As LAWSON has rightly remarked “ it may well be that the Oviedo Convention is quietly invited to use the backdoor, pass the threshold and take up its place in the realm of human rights”.²⁰ And I would add: patient rights as well.

¹⁶ R.LAWSON, “ Dwelling on the threshold: On the interaction between the European Convention on human rights and the Biomedicine Convention” in A.DEN EXTER (ed), *Human Rights and Biomedicine*, Antwerpen, Maklu, 2009, 32 (in press)

¹⁷ ECtHR, 10 April 2007, *Evans v.UK*

¹⁸ ECtHR, 11 October 2007, *Özalp v.Turkey*

¹⁹ ECtHR, 16 December 2008, *Ada Rossi a.o. v. Italy*

²⁰ R.LAWSON, “ Dwelling on the threshold: On the interaction between the European Convention on human rights and the Biomedicine Convention” in A.DEN EXTER (ed), *Human Rights and Biomedicine*, Antwerpen, Maklu, 2009, 36 (in press)