CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE: THE OVIEDO CONVENTION

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SUMMARY: I. *How does it achieve these objectives?* II. *What are the achievements of the Council of Europe in that field?* III. *A little bit of history.* IV. *The Oviedo Convention: a reference human rights instrument.* V. *The Convention as a patient rights Treaty.* VI. *Provisions applicable to specific fields.* VII. *What is the impact of the Oviedo Convention?* VIII. *Recent achievements and current activities.* IX. *Conclusions.*

This presentation aims at giving you an overview of the Oviedo Convention and the work carried out on the basis of this reference international legal instrument. I will first starts with some historical background on this convention, to then examine its content. I will end with a general presentation of the current topics on the agenda of the Committee on Bioethics (DH-BIO), which is the intergovernmental committee of the Council of Europe responsible for the activity on the protection of human rights in the biomedical field.

It is always useful to give a brief reminder about the Council of Europe. Set up in 1949, it is the first European intergovernmental organization. It is distinct from the European Union in its objectives and composition. Indeed, 47 European States are members of the Council of Europe. They include the 28 member states of the European Union, but the membership extends more towards the North with Iceland, for example, and towards

the East with Ukraine, Russia, Azerbaijan, Armenia and Georgia just to name a few.

The Council of Europe is also working closely with non-European states, including Mexico, who was granted observer status in 1999. In 2002, at its request Mexico was invited by the Committee of Ministers of the Council of Europe to accede the Oviedo Convention. Since then, Mexico has been actively participating in the work in bioethics and represented within the DH-BIO. The Council of Europe headquarters are in Strasbourg, in France, and its main aims are to strengthen human rights, democracy and rule of law in its member states.

I. How does it achieve these objectives?

The Council of Europe develops international legal standards, but has also in place monitoring mechanisms to follow their application. Cooperation and training activities facilitate the implementation of those principles and help addressing possible difficulties encountered in the member states.

The objective of Council of Europe work in bioethics is to ensure protection of dignity of the human being and of fundamental rights in the field of biomedicine, in line with one of the main pillar of Council of Europe activities i.e. the protection of human rights.

This objective can only be reach by a multidisciplinary approach. I wish to underline in this context the importance of interactions between the legal field and the biomedical field. This is well reflected in the composition of the DH-BIO with representatives of the Justice Ministry as well as the Health Ministry illustrating this multi-disciplinarity, as well as members with philosophical background. This multidisciplinary and the interactions between those different fields are extremely important to address bioethical issues.

The Council of Europe, in this field, has done a pioneering work, which continues to be unique at an international level by

its human rights approach. It has become a reference at the European level, but also at global level.

II. What are the achievements of the Council of Europe in that field?

The Convention on Human Rights and Biomedicine —the Oviedo Convention— is a framework legal instrument, which was then complemented by additional protocols complementing and developing the principles laid down in the Oviedo Convention in the specific field of biomedicine. Four additional protocols have been adopted so far.

One protocol concerning human cloning was not foreseen at the time the convention was elaborated. It was a decision taken after the announcement of the birth of Dolly the sheep, produced by nuclear transfer. The adoption of this protocol within a very short period of time after this announcement testified for an extremely strong political consensus and agreement on the Human Rights challenges raised by these technologies. This Protocol is the only legally binding instrument at international level prohibiting the cloning of human beings.

The three other additional protocols were foreseen, already, at the time the convention was elaborated and cover fields where developments raised particular concerns for the protection of human rights.

The Additional Protocol concerning transplantation of organs and tissues of human origin develops further the principles laid down in Chapter VI (Organ and tissue removal from living donors for transplantation purposes) of the Oviedo Convention and aims at the protection of donors and recipients. Its provisions address in particular living and deceased donation, protection of donors not able to consent, establishment of appropriate transplantation systems and prohibition of organ trafficking.

The Additional Protocol concerning biomedical research focuses mainly on the protection of the participant in biomedical research. It specifies the conditions for consent, access to information resulting from the research and care of research participants. It lays down specific requirements concerning ethical review of research project to assess the respect of human rights.

The Additional Protocol concerning Genetic Testing for Health Purposes is the most recent protocol, which addresses mainly the issues of privacy and non-discrimination in relation to genetic testing.[1] It includes specific provisions for the protection of persons not able to consent, in particular minors.

The Council of Europe is currently working towards the preparation of a fifth additional protocol concerning the protection of the right and dignity of persons with a mental disorder with regard to involuntary placement and involuntary treatment.

III. A LITTLE BIT OF HISTORY

After the Second World War, the international treaties were mainly regulating the relation between states and citizens. The founding text in the human rights field is the Universal Declaration in Human Rights adopted in 1948.

Series of international and regional treaties was developed after that date and in Europe the most significant instrument is the European Convention for the Protection of Human Rights and Fundamental Freedom, also referred to as the European Convention on Human Rights, which was adopted in 1950.

The aim was to take the first step for the collective enforcement of certain of the rights stated in the Universal Declaration. But at that time the biomedical field was remained a largely un-

[1] Lwoff, Laurence, "Council of Europe Adopts Protocol on Genetic Testing for Health Purposes", *European Journal of Human Genetics*, 17, 2009, pp. 1374-1377.

regulated and this was certainly true not only at an international level but also at national level.

From the 80's onward, the Council of Europe started working on human rights protection in the biomedical field. At the beginning, it addresses mainly the fields of genetics and transplantation, and prepared non-legally binding instruments. This corresponds also to a period where, in those fields, the evolution of technology made it increasingly possible to intervene on human life, raising concerns about possible challenges to the protection of human rights – hence, the need to develop some guidance at international level.

However, considering the diversity of situations in the member states, it was felt that this guidance was insufficient, and something stronger was necessary to ensure the protection of those fundamental principles on which there was an agreement at European level. It was in 1990, at the Conference of Justice Ministers in Istanbul, that the idea of a legally binding instrument on the protection of human rights in the biomedical field, was expressed. The Committee of Ministers of the Council of Europe then entrusted a committee with the preparation of such convention.

A preliminary draft was made public in July 1994 for consultation. The preliminary draft was then revised in the light of the comments received. In 1996, the Parliamentary Assembly of the Council of Europe was invited to give an opinion on a final draft Convention with a view to its adoption. The Convention was adopted by the Committee of Ministers on 19 November 1996 and opened for signature in April 1997 in Oviedo (Spain).

IV. The Oviedo Convention: a reference human rights instrument

The Oviedo Convention[2] is an integral part of the key human rights instruments of the Council of Europe. Whilst it has no

[2] Council of Europe, *http://www.coe.int/en/web/bioethics/oviedo-convention*.

formal link with the European Convention on Human Rights, it has close kinship with that text, from which it borrows several key concepts and terms with the aim of preserving the coherence of the European legal system. It should also be mentioned that it provides for the possibility of asking the Court of Human Rights (ECtHR) for advisory opinion on the interpretation of the Oviedo Convention concerning legal issues (Article 29). This possibility has never been used but it shows also the link with the ECtHR, for which this Convention has also become an instrument of reference. This is acknowledged by the development of the relevant case law of the ECtHR[3] and reference made by the Court to the Oviedo Convention, as well as to related legal instruments and work achieved at intergovernmental level.

This objective of human rights protection is well reflected in the Article 1 of the Oviedo Convention, which requires states party to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for the integrity and all the rights and fundamental freedom with regards to the applications of biology and medicine.

The drafters of the Oviedo Convention were guided by a double concern. First, that individuals have to be shielded from any threat resulting from the improper use of medical and scientific developments. Second, the need to provide a common framework for the protection of human rights and dignity in both longstanding and developing areas concerning the applications of biology and medicine – A far more challenging objective for a legal instrument addressing a field in constant evolution. It was therefore important to have in mind the long-standing value of the principle that will be established.

[3] Council of Europe/European Court of Human Rights, *Research Report. Bioethics and the case-law of the Court*, 2012. Available at: *http://www.echr.coe.int/Documents/Research_ report_ bioethics_ENG.pdf*.

V. The Convention as a patient rights Treaty

The Convention contains a first set of provisions applying to daily medical practice. Key principles include: the primacy of the human being over the sole interest of science and society (Article 2) - a particularly important principle in biomedical research where freedom of research is reaffirmed but subject to the protection of the human rights of the participants. The Convention also requires that states party take measures to ensure equitable access to healthcare for their citizens (Article 3).

The principle of free and informed consent prior to any intervention undertaken on a person (Article 5) is a pillar in biomedicine. In this context, the Convention addresses the situation of persons not able to consent (Article 6) and define specific conditions to ensure their protection. Those provisions are presented as general rules, which are then specified further in specific chapters dedicated respectively to genetics (Chapter IV), scientific research (Chapter V) and removal of organ and tissues from living donors for transplantation purposes (Chapter VI).

The Convention also requires for everyone respect for private life in relation to information about his or her health. It also affirms the right of everyone to know any information collected about his or her health. This implies also respect of the wish not to know – an increasingly important principle with the development of genetics as well as the applications of information and communication technologies in the biomedical field.

Finally I would like to underline the requirement that previously expressed wishes by a persons relating to a medical intervention be taken into account (Article 9). The provision was an important step in the development of patient rights at the time the Convention was drafted and is particularly relevant for example for patients with degenerative diseases or in end of life situations.

Those principles are attached to the medical practice and can be considered a patient rights principles – hence the reference to this Convention as the European Patient Rights Treaty.

The Convention contains two types of standards, those that are directly applicable by a judge, for example, the requirement for free and informed consent prior to any medical intervention. And provisions requiring States to take specific measures such as the provision on the equity of access to health care, not readily applicable, but requiring the state to take measures to ensure respect of that principle. Those are the two different types of principles in the convention.

VI. Provisions applicable to specific fields

But the Convention also lays down principles, which concerns specific fields where developments were raising particular concerns for human rights: biomedical research, organ and tissues removal for transplantation and genetics.

Here again the objective is not to go into details but to give an overview of the main principles laid down in the Convention.

1. *Genetics*

Chapter IV of the Convention is focusing on the human genome. The main concern is the non-discrimination on the basis of genetic characteristics (Article 11). The provision is taking over the wording of Article 14 of the European Convention on Human Rights to which it adds the criteria of the genetic characteristics of the person.

Protection of privacy is the second key concern in this chapter – protection of privacy for the persons concern, but also for their families, as we share part of our genetic materials with all our biological family members. This is duly taken into account when considering in particular predictive genetic testing (Article

12). The safeguards established by the Convention appear particularly relevant with the evolution of genetics and sequencing technologies.

In this context, it is important to draw attention on the provisions concerning intervention on the human genome (Article 13). They limit such intervention to preventive, diagnostic or therapeutic purposes, and only when its aim is not to introduce any modification in the genome of any descendants. If you have followed the latest scientific developments in genetics, you are aware of the new genome editing technologies, which is promoting debate among the scientific community. This technology makes it possible more easily, more precisely and in a cheaper way to modify a genome of the cells. And the ethical debate on this technology was raised by the potential application of the technology to the embryo and to germ lines. The limits and prohibition set by Article 13 is providing an important reference in this context.

2. *Biomedical research*

The Oviedo Convention is reaffirming for the first time in a legally binding instrument at international level, the principle of freedom of research. However, as indicated earlier, it acknowledges the fact that this freedom is not absolute but subject to the legal provisions ensuring the protection of the human being (Article 15). The main concern remains the protection of the research participants or potential research participants: the conditions to be met for any research project on persons to be undertaken, including independent examination of scientific merit and ethical acceptability, the information to be provided to the potential participants prior to consent, the requirement for consent given freely, expressly, specifically and documented. Particular attention is paid to the persons not able to consent who are particularly vulnerable and require specific safeguards for their protection.

3. *Organ and tissues removal for transplantation*

The Convention focuses on removal on living donors, which concern mainly kidney and liver, due to the risks for the persons concerned. It establishes the consent conditions for such removal and prohibits it when a person is not able to consent, with one exception and under specific safeguards, for regenerative tissues e.g. bone marrow.

The prohibition of financial gain (Article 21) is another key principle. It states that the human body and its parts shall not, as such, give rise to financial gain. This is not only relevant to organs and tissues removed for transplantation purposes. However, together with the principle of consent it provides the basis for a very recent Convention adopted by the Council of Europe on the 25th of March 2015 against trafficking in human organs (CETS no. 2016).[4]

VII. What is the impact of the Oviedo Convention?

The impact of the Oviedo Convention is addressed in more details by Dr. Javier Arias. However I would just like to highlight the profound impact this legal instrument had and continues to have at international level, both on legislation and practices. This is not restricting to countries Party to the Convention, but also a reality in countries that have not even signed it. This was the result of a survey made in 2009 in the Council of Europe member states. This impact is acknowledged in many different fields: patient rights, mental health, reproductive medicine, geriatric care, research etc. There is a whole list of national legal instruments for

[4] Council of Europe, Details of Treaty No. 216, *Council of Europe Convention against Trafficking in Human Organs*, 2015. Available at: *http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/216*.

which the Convention provided a basis or influenced the drafting. I am referring to the Convention but I should also mention the discussion, which lead to its adoption and also influenced national debate and outcome.

The Convention has also become a reference at European level. For the ECtHR this was already pointed out. But also within the EU whose Charter of Fundamental Rights borrows principles to the Oviedo Convention in particular concerning the protection of integrity (Article 3). It is also referred to in several EU directives and regulations and is part of the ethical rule for project funding.

But the Convention has become a reference at global level. It is indeed one of the rare regional instruments referred to in the UN texts, in particular the UN Declaration on Human Rights and Bioethics.

Finally, to testify for the reference value acquired by the Oviedo Convention, I wish also to mention the reference to the Oviedo Convention by the Inter-American Court of Human Rights in a decision against Costa Rica (case of Artavia Murillo *et al.* ["In vitro fertilization"] *vs.* Costa Rica).

VIII. Recent achievements and current activities

I would like to end this presentation by giving you an overview of recent achievements and current activities carried out by the Council of Europe inter-governmental Committee on Bioethics (DH-BIO).

1. *Implementation tools*

A substantial legal corpus has already been developed with the Convention and its additional protocols, not to mention the non-legally binding instruments addressing issues such as bio-

banking and xenotransplantation. If standards setting activities continue (see below) more emphasis is now placed on facilitating the implementation of adopted principles. A certain number of tools have been developed, that are not legal instruments, but are providing guidance for the applications of existing provisions by those directly concerned.

This is the case for example of the Guide for Research Ethics Committee Members. This guide develops elements and key references for the assessment of research projects involving intervention on human beings. It is now is available in 14 different languages, including Spanish.[5]

Another example of such a tool is a guide adopted in 2014, on a particularly sensitive subject i.e. the decision-making process concerning medical treatment in end-of-life situations. This Guide is also available on our website in so far 13 different languages.[6] It is intended for health professionals, but also patients, their families and all those who face problematic decisions with regard to medical treatment in end-of-life situations, and provides help for the development of good practices.

Other documents have been developed to the specific attention of the general public, such as a leaflet on genetic testing[7] to help the states providing general information to their citizens. It was translated in 30 languages with the support of the European Society of Human Genetics and the EU funded project Eurogentest. This leaflet has been distributed widely in the member states including by the private sector offering genetic testing.

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5 Council of Europe, Guide à l'intention des membres des comités d'éthique de la recherche. Available at: *http://www.coe.int/en/web/bioethics/guide-for-research-ethics-committees-members*.

6 Council of Europe, Guide on the decision-making process regarding medical treatment in end-of-life situations. Available at: *http://www.coe.int/en/web/bioethics/guide-on-the-decision-making-process-regarding-medical-treatment-in-end-of-life-situations*.

7 Council of Europe, Information brochure on Genetic Tests for Health Purposes. Available at: *http://www.coe.int/en/web/bioethics/information-brochure-on-genetic-tests-for-health-purposes*.

The DH-BIO contributed to the preparation of the Convention against Trafficking in Human Organs on Organ Trafficking. In this context, it adopted a declaration on prohibition on any form of commercialisation of human organs, which was taken over by the Committee of Ministers on 9 July 2014.[8] This statement underlined the importance of the fundamental principle of prohibition of financial gain enshrined in the Oviedo Convention and reaffirmed in this Additional Protocol concerning the Transplantation of Organs and Tissues of Human Origin.

2. *Cooperation activities*

Together with the development of tools, cooperation activities organised at the request of the member states aim also at raising awareness on adopted principles and addressing difficulties encountered in their implementation. The Council of Europe organises seminars and conferences in the member states, tailored to the needs of the country, in which professionals, competent authorities as well as other stakeholders concerned are invited to participate. Legal opinions on national bill, in the light of the Oviedo Convention and its Protocols are also requested by member states in this context.

3. *Re-examination of legal instruments*

The DH-BIO regularly re-examined adopted legal instruments in the light of development in the field concerned. This is currently the case of Recommendation Rec (2006)4 on research on biological materials of human origin. This re-examination led to the revision of this text with particular focus on biobanks and their governance.

[8] Council of Europe, Transplantation. Available at: *http://www.coe.int/en/web/bioethics/ transplantation*.

4. *Standards setting*

The legal corpus around the Oviedo Convention continues to be developed with a new Additional Protocol on the protection of the rights of persons with mental disorder with regard to involuntary placement and involuntary treatment.

A new Recommendation is also about to be finalised on the processing, for insurance purposes, of health-related data, including data resulting from genetic testing addressing in particular privacy and non-discrimination issues.

Finally, I wish to refer to new activities on emerging technologies, which probably will provide an agenda for the DH-BIO as well as other intergovernmental committees for a number of years. To launch this work, the DH-BIO organised, on 4-5 May 2015, an international conference[9] to address human rights challenges raised by emerging technologies. Nanotechnology, Biotechnology, Information and Cognitive Technology and their convergence were examined with a transversal approach based on the main concerns they raised for human rights. The outcome of the conference will now be analysed by the DH-BIO.

5. *Training*

To finish this very short overview of current activities, I would like to mention a project of development of special courses on legal human rights principles in the biomedical field. The Council of Europe has already a well-developed and successful training program on human rights for legal professionals, including on line courses. The idea would be to benefit from the methodology of this program for a course that would not only be for legal professionals but also for health professionals.

[9] The video recording is available at: *http://www.coe.int/en/web/bioethics/emerging-technologies*.

IX. Conclusions

In conclusion, the Oviedo Convention has been both an achievement and a starting point.

This Convention was the first and remains the only legally binding instrument at international level, addressing human rights in the biomedical field and defining a general framework for their protection with regard to the applications in that field.

But it is also a starting point because it was further developed through the additional protocols, and it continues to provide a basis for legislation and practices at national and international level.

In 2009, when we celebrated the 10th anniversary of the Oviedo Convention, Mr. Jean-Paul Costa, President of the ECtHR, referring to the principles laid down in that Convention talked about "a new generation of human rights".

Almost 20 years after its opening for signature, those principles remain relevant references to address the challenges raised by scientific and technological developments in the fast evolving field of biology and medicine.

More information is available on our website *www.coe.int/bioethics*.