

# The European Convention on bioethics

C Byk *Special Adviser on Bioethics to the Secretary General of the Council of Europe*

## Author's abstract

*Benefiting from a widely recognised experience of the field of bioethics, the Council of Europe which represents all the democratic countries of Europe, has embarked on the ambitious task of drafting a European Convention on bioethics. The purpose of this text is to set out fundamental values, such as respect for human dignity, free informed consent and non-commercialisation of the human body.*

*In addition to this task, protocols will provide specific standards for the different fields concerned with the application of biomedical sciences. The convention and the first two protocols (human experiments and organ transplants) are due to be ready for signature by mid 1994.*

Although diverse by their cultures, European nations have a common history. After World War II many of the European countries were aware that, in order to preserve peace, co-operation among them was essential. One example of such co-operation was the establishment of the Council of Europe which brings together all the democratic countries of Europe, ie presently 27 member states\*. It is active in many fields, ranging from law, human rights and health, to education, culture, the environment and the mass media.

The results of the council's action may take the form of multilateral treaties, ie binding instruments, or of recommendations setting out guidelines for the policy and legislation of the member states.

## Key words

Bioethics; convention; Council of Europe; human rights; biomedical sciences; organ transplants; human experimentation.

\* Austria, Belgium, Bulgaria, Cyprus, The Czech and Slovak Federal Republic (until January 1, 1993), Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, San Marino, Spain, Sweden, Switzerland, Turkey, United Kingdom.

Bioethics, which offers matter for reflection and a platform for debate, could not fail to attract the attention of our organisation.

It is therefore scarcely surprising that the Council of Europe already has longstanding and widely recognised experience in the field of bioethics, which provides the historical background to the European Convention on bioethics (I). Also various considerations have moved us to amplify our work and to prepare a European Convention on Bioethics (II).

## (I) The genesis of the convention

The activities of the Council of Europe in this field began at the very inception of our organisation in the sector of intergovernmental co-operation in the form of an ethical code for health, which was further developed, from the early 70s onwards, in the various sectors of bioethics.

During all this time, the results of the work of the Council of Europe were essentially recommendations to member states (A). The decision to elaborate a European Convention on Bioethics will now bring a new step in the European approach to biomedical issues because it will be the first treaty to be drafted in this field (B).

### A) RECOMMENDATIONS AS A FIRST STEP IN HARMONISING EUROPEAN LEGISLATION

Before quoting some of the work accomplished in the Council of Europe I would like to emphasise the role played by the committee of experts which deals with bioethics issues.

#### 1) *The committee of experts on bioethics*

Since 1983, the Council of Europe has charged a standing committee to prepare guidelines related to specific areas of biomedical research and technology. But the real impetus to this committee was given in 1985 when the European Ministerial Conference on Human Rights in Vienna, adopted Resolution No 3, asking that the Council of Europe become the focal point and clearing house for information, opinions and, where appropriate, joint international action with regard to biomedicine.

In response to this proposal, the committee of ministers decided to instruct the Ad Hoc Committee for Bioethics, the Comité Ad-Hoc de Bioéthique (CAHBI) to carry out the activities of the Council of Europe in this field.

The main object of this multidisciplinary body was to fill the political and legal gaps that could result from the rapid development of biomedical sciences.

The CAHBI was aware of the difficulty for the member states to arrive at a consensus on these extremely delicate problems. The committee therefore actively explores every means to promote constructive dialogue between the member states and to avoid deadlocks.

The texts of the CAHBI reaffirm the major principles and values which must guide any regulation on bioethics and also indicate which limits must at all cost be respected.

Since 1992, the committee has acquired the status of steering committee with the new title of Steering Committee for Bioethics, Comité Directeur de Bioéthique (CDBI).

Although the CDBI is the focus committee for bioethics, other committees such as the committee for public health or the parliamentary assembly, contributed to the work of the Council of Europe, to which I would now like to refer.

## 2) *Results of the work of the Council of Europe in the field of bioethics during this first period*

The Council of Europe's work in bioethics dealt with the life sciences and their applications. These concern the beginning of life, or access to life and quality of life.

Since 1978, when it began dealing with problems of biomedicine, the Council of Europe has adopted or published, among others, the following texts:

1978: Resolution (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances;

1983: Recommendation R (83) 2 on protection of persons suffering from mental disorders placed as involuntary patients;

1984: Recommendation R (84) 16 concerning notification of work involving recombinant deoxyribonucleic acid (DNA);

1989: Report on human artificial procreation;

1990: Recommendation R (90) 3 on medical research on human beings;

1990: Recommendation R (90) 13 on prenatal genetic screening, prenatal genetic diagnosis and associated genetic counselling;

1992: Recommendation R (92) 1 on the use of analysis of deoxyribonucleic acid (DNA) used within the framework of the criminal justice system; and

1992: Recommendation R (92) 3 on genetic testing and screening for health care purposes.

The assembly has also inspired and encouraged this work in particular by the following Recommendations:

Recommendation 934 (1982) on genetic engineering;

Recommendations 1046 (1986) and 1100 (1989) on the use of human embryos and fetuses.

The European approach to bioethics will now develop a second step: the European Convention on bioethics.

## B) A FURTHER STEP: THE EUROPEAN CONVENTION ON BIOETHICS

### 1) *The reasons for promoting a European Convention on bioethics*

It has long been suggested that national legislation will not be the most appropriate response to bioethics issues.

First, most of the questions raised are universal and reflect the European common values protected by the European Court of Human Rights.

Second, most of the scientific programmes with a potential for great impact on humanity imply international co-operation.

Third, a number of countries, in particular the former socialist countries, have no legislation at all in the field of bioethics.

Although other states have already adopted a position on one or more of the major themes of bioethics, this fact could also facilitate the necessary distinction between what can be harmonised at European level and what it is preferable to leave to be settled by the provisions of domestic law.

We therefore have a clearer view of the prospects and limitations for creating a European legal foundation in this matter.

Finally the process of initiating a convention received large support.

### 2) *The initiating process*

**a) Proposals were made within the Council of Europe quite early, if we consider both the work of the parliamentary assembly and that of the committee of ministers.**

The parliamentary assembly has repeatedly urged the governments of the member states to conclude a convention on biomedicine.

In its Recommendation 934 of 26 January 1982 on genetic engineering, the assembly stressed that the rights to life and to human dignity, guaranteed under articles 2 and 3 of the European Human Rights Convention, imply the right to inherit a genetic pattern which has not been artificially changed, and called on the committee of ministers to draw up a European agreement on what constitutes legitimate application to human beings of the techniques of genetic engineering.

The assembly came back to this matter in its Recommendation 1046 (1986) and 1100 (1989) on the use of human embryos and fetuses.

Finally, the assembly adopted Recommendation 1160 (1991) on the preparation of a convention on bioethics.

*The intergovernmental sector:* The question of what legal instruments could deal most effectively with bioethics was discussed during two conferences of specialised ministers: at the European Ministerial Conference on Human Rights which was held in 1985 in Vienna, as mentioned above, and at the Conference of Ministers of Justice held in Istanbul in June 1990, which approved the idea of examining the possibility of preparing a convention on bioethics. Finally, in September 1990 the committee of ministers instructed CAHBI to identify as soon as possible the questions to be dealt with as a matter of priority.

#### **b) The report on the possibility of preparing a convention on bioethics**

The CAHBI was of the opinion that it is not only necessary and urgent, but also possible to prepare international binding rules in the field of bioethics.

The CAHBI also considered that the Council of Europe is the most appropriate forum where this work can be undertaken because the Council of Europe guarantees the respect of the main fundamental values which should guide the convention.

*Format of the convention:* The main proposal submitted to the CAHBI was contained in a Secretary General's document proposing the adoption of a **framework convention** open to non-member states and setting out common general standards for the protection of the human person in the context of the development of the biomedical sciences. **The majority of the CAHBI declared itself in favour of this formula.**

*Questions to be dealt with within a possible convention:* Subject to the modalities of the legal instrument, the CAHBI agreed that the following two subjects should be dealt with as a matter of priority:

#### **Organ transplants and use of human substances**

The CAHBI considered the laying down of international rules on these questions a matter of urgency. It had had regard to serious abuses which had occurred in the recent past and which had shown that national regulations in this field could be circumvented at the international level as long as there were no corresponding international rules.

Finally CAHBI was instructed in September 1991 by the committee of ministers to elaborate a framework convention on bioethics incorporating the two suggested protocols.

## **(II) The elaboration process of the convention**

It is particularly important to look at the potential content of the convention (A) as well as at the

methodology chosen to elaborate this legal instrument (B).

### A) THE CONTENT OF THE CONVENTION

#### 1) *The general framework*

There is a link between the convention which is under preparation and the common heritage of values underlying the work of the Council of Europe encapsulated in the term 'human rights'.

This is because bioethics cannot be regarded as justifying the existence of any specific or separate right since the very aim of bioethics is to recognise certain fundamental principles safeguarding human beings.

The proposed draft text is therefore designed to provide more specific guidelines, while remaining as faithful as possible to a philosophy of fundamental rights, although the intention here is by no means to draw up an additional protocol to the European Human Rights Convention.

#### 2) *The principles integrated in the convention*

The convention will comprise a hard core of general principles, while certain specific aspects will be covered in a number of additional protocols.

The proposed fundamental principles are as follows: respect for human dignity; protection of individual integrity; assertion of public responsibility regarding the application of the biomedical sciences; prohibition of all commercial agreements concerning the human body and its organs, and a ban on all forms of discrimination.

a) In fact the chapter in which these principles will be encapsulated will present 3 sections.

*Section 1* will deal with the observance of the rule of law and provide the recognition of new rights for citizens. For example, in order to allow for public debate on basic issues, the creation of national ethics committees is to be encouraged; and the right of each citizen to make known her/his opinion to these committees on the questions raised shall be guaranteed.

*Section 2* will deal with the respect due to the human body. A specific provision will reassert the principle of the inviolability of the individual person. Another important provision will reassert the prohibition to establish proprietary right with regard to the human body or its components.

*Section 3* is entitled respect for private and family life and will specify, in particular, the conditions governing the use of personal data resulting from the processing of genetic tests. The right of a newborn child to enjoy a legal status from the moment of birth, irrespective of the manner in which he/she was procreated, will also be reaffirmed.

b. The first protocols, which are being drafted simultaneously, so far concern the ethics of experiments on human beings and organ transplants.

### **Organ transplants and the use of human substances**

The rules on this question will contain the necessary definitions and criteria, emphasise the requirement of consent of the persons concerned and prohibit commercial trafficking in organs.

### **Medical research on human beings**

The rules will largely follow those of Recommendation (90) 3 of the committee of ministers. The object is to strike a balance between the interests of society and those of the persons involved in research. While in some countries the matter is regulated by law in others by rules of professional conduct, the committee on bioethics considered that in both cases adequate and effective protection must be offered.

Such an ambitious project implies a clear view of the methodology to be applied.

#### **B) METHODOLOGY**

Much of it relies on the idea that European harmonisation can only be successful if it leaves some role to national authorities. It explains why the convention, as it has already been mentioned, will be a framework convention. It is also the reason for promoting co-operation between the parties to the convention.

#### *A framework convention*

What does this concept mean? In fact, it refers to two characteristics.

The convention will not be totally self-executing but each contracting party shall take those measures, in its domestic law and in accordance with its international undertakings, which are necessary to give effect to the principles set out in the convention.

#### *International co-operation is another important feature of this framework convention*

In addition to the obligations binding under their domestic law, parties to the convention will have to take into account the principles which they may have

accepted in the more general framework of international relations.

For this purpose, the fundamental principles set out in the convention and protocols will be regarded as public policy principles in terms of international law and each party will have to establish, in certain cases, sanctions with regard to persons coming within its jurisdiction who may, while abroad, have infringed them.

A final point concerning methodology is the calendar for the elaboration of the convention. The instruction is to have the convention and the first two protocols ready for signature in mid-1994. Time is very limited for such an objective and implies great and well-organised work. There is presently one working group for each text and the results of their endeavours must be approved by the plenary steering committee on bioethics. We hope that a first provisional document will be accepted in Spring 1993 so that we can proceed to consult the other interested steering committees as well as the Council of Europe's parliamentary assembly.

A second reading could then be accomplished before the committee of ministers decides if the proposed convention and its protocols could be passed for signature not only to member states but also to others.

Bioethics provides us with an excellent opportunity to reflect on law-making and methods of expressing democratic choices.

This is true, in the first instance, at national level. In equipping themselves with organs for analysing scientific choices, several national parliaments have, for example, made promising efforts to pave the way more effectively for the holding of political debates on such complex issues.

But it is also important at the same time that any European legislation should be preceded and informed by a rich and enlightened democratic debate in such matters.

It is hoped that the drafting of the European Convention on bioethics will contribute to such a debate.

*C Byk is the Special Adviser on Bioethics to the Secretary General of the Council of Europe.*