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Draft additional protocol to the Convention on Human Rights and Biomedicine, on genetic testing for health purposes

Report
Committee on Culture, Science and Education
Rapporteur: Mr Wolfgang WODARG, Germany

Summary

The draft additional protocol on genetic testing for health purposes builds on the principles embodied in the Convention on Human Rights and Biomedicine with a view to defining and safeguarding the fundamental rights of the persons concerned by genetic testing for health purposes. Protocols on genetic testing for other purposes than health, such as insurance, are being prepared.

While satisfied in general with the draft protocol, the Assembly recommends that the Committee of Ministers consider some amendments before opening it for signature.

The Assembly regrets that 26 out of the 47 member states of the Council of Europe have not yet ratified or acceded to the Convention on Human Rights and Biomedicine and urges them to do so as soon as possible.

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A. Draft opinion

1. The Additional Protocol to the Convention on Human Rights and Biomedicine on Genetic Testing for Health Purposes is the fourth in the series of additional protocols to the Convention, after those on the Prohibition of Cloning Human Beings (1997), on Transplantation of Organs and Tissues of Human Origin (2001) and on Biomedical Research (2004). The Parliamentary Assembly welcomes this further enrichment of the Convention.

2. The Assembly regrets that 26 out of the 47 member states of the Council of Europe have not yet ratified or acceded to the Bioethics Convention and urges them to do so as soon as possible.

3. Remarkable progress has been made in the field of human health thanks to research in biology and medicine. Knowledge of the human genome has been the source of considerable advances, in particular the development of genetic tests. These tests make it possible to identify genetic characteristics responsible for a disease or involved in its development.

4. Several hundred genetic tests are currently in use and more are being developed. Genetic testing is becoming more and more an integral part of medical practice, but at the same time a direct commercial offer for genetic tests outside any health system is developing. This may pose ethical problems.

5. The present Additional Protocol to the Convention on Human Rights and Biomedicine builds on the principles embodied in the convention with a view to defining and safeguarding the fundamental rights of the persons concerned by genetic testing for health purposes.

6. The Assembly notes that this protocol has been agreed unanimously by the Steering Committee on Bioethics (CDBI) following detailed examination.

7. It would point out that this is only the first in a series of protocols regarding genetic testing and will follow carefully the developing debate in this field.

8. The Assembly, while satisfied in general with the present draft protocol, feels however that it could be improved and in consequence recommends that the Committee of Ministers consider the following amendments:

8.1. in Article 2.1, add the word “only” after the words “which are”;

8.2. in Article 6, add the words “and medical indication” after the words “clinical utility”;

8.3. in Article 7.1, add at the end the words “of appropriately qualified physicians”;

8.4. in Article 8.2, add the words “or to exclude” after the word “detect”;

8.5. in Article 8.2, add the words “or to exclude” after the word “identify”;

8.6. change the first paragraph of Article 10 as follows “Subject to Article 13 of this protocol, a genetic test on a person who does not have the capacity to consent, may only be carried out for his or her direct benefit”.

B. Explanatory memorandum, by Mr Wolfgang Wodarg

1. The draft additional protocol to the Convention on Human Rights and Biomedicine, on genetic testing for health purposes is the fourth in the series of additional protocols to the convention, after those on the Prohibition of Cloning Human Beings (1997), on Transplantation of Organs and Tissues of Human Origin (2001) and on Biomedical Research (2004).

2. The Convention on Human Rights and Biomedicine was opened for signature in April 1997 and entered into force in December 1999. Altogether 34 member states have signed the convention and 21 have ratified (see appendix). There are 13 signatures still not followed by ratification (of which eight are more than ten years old), and 13 other member states have not yet signed.

3. In many countries ratification of the convention involves reviewing a number of laws in order to ensure that internal legislation is in full conformity with the convention. Some countries are in the process of revising their legislation in this field and have declared that they will ratify the convention at the conclusion of the process.

4. Some member states of the Council of Europe might not have signed or ratified the convention on the grounds that they already have more advanced legislation on this issue. The German Parliament felt that it should not relieve the government from doing its own analysis of the situation by simply relying on the convention. However, both the convention and its protocols clearly state that the parties may apply rules of a more protective nature.

5. The Protocol on the Prohibition of Cloning Human Beings was opened for signature in January 1998 and entered into force in March 2001. As of November 2007, 31 states have signed, of which 16 have ratified it (see appendix). This protocol is the only international legally binding instrument prohibiting the cloning of human beings and therefore should be ratified by as many member states as soon as possible in order both to prevent this unethical practice in our member states and to demonstrate Europe's consensus on this issue of worldwide importance.

6. The Protocol on Transplantation of Organs and Tissues of Human Origin was opened for signature in January 2002 and entered into force in May 2006. As of November 2007 it had been signed by 20 states and ratified by seven (see appendix).

7. The Protocol on Biomedical Research was opened for signature in January 2005 and entered into force in September 2007. As of November 2007, 21 states have signed of which five have ratified it (see appendix).

8. In its Recommendation 1160 (1991) on the preparation of a Convention on Bioethics, the Assembly had recommended that the Committee of Ministers "envisage a framework convention comprising a main text with general principles and additional protocols on specific aspects. The convention should provide a flexible formula with regard to its form, but must not constitute the lowest common denominator as to its content". It is worrying that in some countries the process of ratifying the convention has not been considered a priority on parliamentary and governmental agendas and it is to be hoped that those states that have not signed the convention and its protocols do so as soon as possible so as to remove doubt as to their commitment to the implementation of its principles. This is particularly crucial in the context of a worldwide debate on issues such as cloning where the impression of divided European opinion does not help the resolution of complex issues.

1. Genetic testing

9. Remarkable progress has been made in the field of human health thanks to research in biology and medicine. In that respect, genetics is one of the sciences seen as most promising. Knowledge of the human genome has been the source of considerable advances, in particular the development of genetic tests involving analysis enabling the identification of genetic characteristics responsible for a disease (monogenic diseases), or involved in its development (multifactorial diseases the development of which is also influenced by other factors). These tests make it possible to diagnose or to confirm the diagnosis in a person already presenting symptoms. But they also make possible the identification of genetic mutations responsible for a disease which may develop later in life or of a predisposition to a disease without any symptoms.

10. Early identification of genetic characteristics by a test can present a health benefit, if it makes it possible to take preventive measures or to limit the risks by modifying the behaviour, lifestyle or environment of the person concerned. However, for most genetic diseases, such possibilities are still very limited. Furthermore, the results of genetic analysis are often complex and a proper understanding of their implications is, in many cases, difficult for the persons concerned.

11. Several hundred genetic tests are currently in use and more are being developed. Genetic testing is becoming more and more an integral part of medical practice, but at the same time a direct commercial offer for genetic tests outside any health system is developing. This may pose ethical problems.

2. The additional protocol

12. This additional protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes builds on the principles embodied in the convention with a view to ensuring protection of people in the specific field of genetic testing for health purposes only.

13. The purpose of the protocol is to define and safeguard fundamental rights of the persons concerned by genetic testing for health purposes. Further additional protocols (or recommendations) will deal with genetic testing for purposes other than health (such as, for instance, insurance or recruitment).

14. Some of the most important principles laid down are:

– the prohibition of any discrimination, in particular based on genetic characteristics;

– equitable access to genetic services of appropriate quality;

– primacy of the human being;

– the clinical utility of the tests;

– individualised medical supervision;

– the right to information and genetic counselling;

– the requirement of free and informed consent, which may be withdrawn at any time;

– the protection of persons not able to consent;

– the respect for private life.

15. The purpose of genetic services, be they public or private, is to respond to the needs of individuals and families wishing to know whether they are at risk of developing or transmitting a disease or disorder with a genetic component, or who are faced with such a disease or disorder. This includes in particular providing information and, where appropriate, genetic counselling, carrying out genetic tests and interpreting their results, ensuring care for the persons concerned and their families, including preventive care, as well as training the persons involved in providing genetic services.

16. The draft protocol defines specific quality requirements at three different levels: the genetic test, the laboratory and the persons providing genetic services.

17. According to the draft protocol, it is the responsibility of the state to ensure the existence of a system that guarantees the reliability of a genetic test in respect of a determined disease, namely that its results with regard to the identification of particular genetic characteristics related to this disease are accurate and can be reproduced.

18. From the perspective of a medical professional, health tests must be medically indicated and be used for a medical therapy. They must also be carried out under the individualised supervision of medical professionals who are bound by the Hippocratic Oath. Genetic tests must respect certain other procedural requirements. They must be accompanied by medical advice and counselling, for instance about the consequences of test results. The right not to be informed must be respected.

19. The draft protocol allows, under certain conditions, exceptions to the rule of individualised medical supervision but such exceptions are limited to genetic tests without important implications for the health of the persons concerned or members of their family, and without important implications concerning procreation choices.

20. A problem may occur when persons are not able to consent to a test. The draft protocol sets the rules to be followed in order to ensure the protection of such persons.

21. Data protection is also an important aspect in this context as well as discrimination on genetic grounds. Most countries already have legal regulations dealing with a patient’s consent to medical acts, data protection and anti-discrimination. Therefore, existing standards on the protection of patients and other laws should also be applied to genetic tests.

22. Genetic screening may also pose problems: a single test could be used to analyse more than 200 potential medical conditions, whereas a patient could not usefully and adequately be advised about all those test results.

23. The draft protocol contains provisions which are relatively traditional, but they constitute, probably, the first legally binding formulation of the conditions for screening – not only genetic but any. A well-known example – and very successful in its results – was the screening carried out in Cyprus concerning the genetic test for beta-thalassaemia, an extremely serious disease prevalent in several islands of the Mediterranean, which occurs only if both parents (who could be healthy) transmit the anomaly. This test was proposed to all those who were getting married on the island. They could of course refuse. Once the screening routine was installed, the number of people being affected by this disease was reduced almost to zero (and so was the number of abortions caused to avoid the birth of a sick child).

3. Conclusion

24. The additional protocol under examination is not exhaustive but others will follow to cover the rest of the field. It provides for balanced and appropriate protection for those who take part in genetic testing for health purposes. It is therefore a useful complement to the series of legal texts produced by the Council of Europe in the field of biomedicine.

25. It could, however, be improved by some amendments.

Appendix – Chart of signatures and ratifications of the Convention on Human Rights and Biomedicine

This document is available on the Council of Europe website, at the following address: http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164.

Reporting committee: Committee on Culture, Science and Education.

Reference to committee: Doc. 11440 and Reference No. 3376 of 1 October 2007.

Draft resolution unanimously adopted by the committee on 10 December 2007.

Members of the committee: Mr Jacques **Legendre** (Chairperson), Baroness **Hooper** (Vice-Chairperson), Mr Wolfgang Wodarg (Vice-Chairperson), Mrs Anne **Brasseur** (Vice-Chairperson), Mr Hans Ager, Mr Kornél Almássy, Mrs Donka Banović, Mr Lars Barfoed, Mr Rony Bargetze, Mr Walter **Bartoš**, Mrs Marie-Louise Bemelmans-Videc, Mr Radu Mircea **Berceanu**, Mr Levan Berdzenishvili, Mrs Oksana Bilozir, Mrs Guðfinna Bjarnadóttir, Mrs Maria Luisa Boccia, Mrs Margherita Boniver, Mr Ivan Brajovic, Mr Osman Coşkunoğlu, Mr Vlad Cubreacov, Mr Ivica Dačić, Mr Joseph Debono Grech, Mr Ferdinand Devínsky, Mr Daniel Ducarme, Mrs Åse Gunhild Woie **Duesund**, Mr Detlef Dzembritzki, Mrs Anke Eymer, Mr Relu Fenechiu, Mrs Blanca Fernández-Capel, Mrs María Emelina Fernández Soriano, Mr Axel Fischer, Mr José **Freire Antunes**, Mr Ioannis Giannellis-Theodosiadis, Mr Stefan Glăvan, Mr Vladimir Grachev, Mr Andreas Gross, Mr Raffi **Hovannisian**, Mr Rafael Huseynov, Mr Fazail İbrahimlı, Mrs Halide İncekara, Mrs Evguenia Jivkova, Mr Morgan Johansson, Mrs Liana Kanelli, Mrs Cecilia **Keaveney**, Mr Ali Rashid Khalil, Mr József Kozma, Mr Jean-Pierre Kucheida, Mr Markku **Laukkanen**, Mr Yves Leterme, Mrs Jagoda Majska-Martinčević, Mrs Milica Marković, Mr Tomasz Markowski, Mrs Muriel Marland-Militello, Mr Andrew **McIntosh**, Mr Ivan Melnikov, Mrs Maria Manuela **Melo**, Mrs Assunta Meloni, Mr Paskal Milo, Mrs Christine **Muttonen**, Mrs Miroslava **Němcová**, Mr Edward **O'Hara**, Mr Kent Olsson, Mr Andrey Pantev, Mrs Antigoni Papadopoulos, Mr Azis **Pollozhani**, Mrs Majda Potrata, Mr Lluís Maria de Puig, Mr Zbigniew Rau, Mrs Anta Rugāte, Mr Indrek Saar, Mr André Schneider (alternate: Mr Philippe **Nachbar**), Mr Urs Schweitzer, Mr Vitaliy Shybko, Mrs Geraldine Smith (alternate: Mr Robert **Walter**), Mrs Albertina Soliani, Mr Yury Solonin, Mr Christophe Spiliotis-Saquet, Mr Valeriy Sudarenkov, Mr Petro Symonenko, Mr Mehmet **Tekelioğlu**, Mr Piotr **Wach**, Mr Emanuelis Zingeris.

NB: The names of those members present at the meeting are printed in bold.

See 8th Sitting, 24 January 2008 (adoption of the draft opinion, as amended); and Opinion No. 267.