



**Opinion 267 (2008)<sup>1</sup>**

## **Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on Genetic Testing for Health Purposes**

Parliamentary Assembly

1. The draft additional protocol to the Convention on Human Rights and Biomedicine (hereafter referred to as the Bioethics Convention, ETS No. 164) 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, ETS No. 168), on Transplantation of Organs and Tissues of Human Origin (2001, ETS No. 186) and on Biomedical Research (2004, CETS No. 195). 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 Convention on Bioethics 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 Bioethics 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 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 that it could be improved and, in consequence, recommends that the Committee of Ministers consider the following amendments:
  - 8.1. in Article 6, add the words “and medical indication” after the words “clinical utility”;
  - 8.2. in Article 7.1, add at the end the words “of appropriately qualified physicians”;
  - 8.3. in Article 8.2, add the words “or to exclude” after the word “detect”;
  - 8.4. in Article 8.2, add the words “or to exclude” after the word “identify”;
  - 8.5. 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”.

---

1. Assembly debate on 24 January 2008 (8th Sitting) (see [Doc.11466](#), report of the Committee on Culture, Science and Education, rapporteur: Mr Wodarg; and [Doc. 11506](#), opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Haibach). Text adopted by the Assembly on 24 January 2008 (8th Sitting).

