CDDH comments on the Parliamentary Assembly Recommendation 2115(2017) "The use of new genetic technologies in human beings"

88th meeting - 5/7 December 2017 - CDDH(2017)R88

1. The Steering Committee for Human Rights (CDDH) takes note of the Parliamentary Assembly Recommendation 2115(2017) - "*The use of new genetic technologies in human beings*" and commends to the Committee of Ministers the comments provided by the Committee on Bioethics (DH-BIO) on this subject. It considers that the ethical and legal implications of genetic technologies in human beings want an in-depth debate in light of the requirements of the European Convention on Human Rights and of the Oviedo Convention, and in accordance with the precautionary principle.

2. The CDDH welcomes the commitment made by the DH-BIO under paragraph 8 of its comments to continue its work in this field.

Comments of the DH-BIO[1] (for the information of the CDDH)

1. The Committee of Ministers agreed to communicate to the Committee on Bioethics (DH-BIO), as well as to the Steering Committee for Human Rights (CDDH), for information and possible comments, the Council of Europe Parliamentary Assembly (PACE) Recommendation 2115 (2017) – "The use of new genetic technologies in human beings".

2. The DH-BIO examined the Recommendation at its 12th plenary meeting (26-27 October 2017) and adopted these comments.

3. In its Recommendation, the PACE notes that "… recent discoveries related to the human genome have opened the door to new opportunities and unprecedented ethical concerns... this improved knowledge of our make-up as human beings brings with it welcome potential to diagnose, prevent and eventually cure diseases in the future. On the other hand, it raises complex ethical and human rights questions, including – but not limited to – unintended harm which may result from the techniques used, access and consent to such techniques, and their potential abuse for enhancement or eugenic purposes".

4. The DH-BIO welcomes the initiative taken by the PACE. Together with the latter it agrees with the "potential to diagnose, prevent and eventually cure diseases in the future" offered by new genetics technologies. But it also, shares the concerns expressed on the risks of certain technological developments and their possible applications to human beings. In this context, it recalls, as does the PACE, that Article 13 of the Convention on Human Rights and Biomedicine (Oviedo Convention) limits the purposes for which interventions on the human genome may be undertaken and prohibits intervention intending to introduce any modification in the genome of descendants.

5. The Statement on Genome Editing Technologies adopted by the DH-BIO in December 2015 underlines that the Oviedo Convention provides a framework and principles that could be used as reference for the debate called for at international level on the use of new genetic technologies in human beings. The DH-BIO therefore particularly welcomes the Assembly's recommendation to "urge member states which have not yet ratified the Oviedo Convention to do so without further delay, or, as a minimum, to put in place a national ban on establishing a pregnancy with germline cells or human embryos having undergone intentional genome editing."

[1] Adopted by the Bureau of the DH-BIO, by written procedure, on 27 November 2017.

6. The DH-BIO agrees with the Assembly that there is a need to "foster a broad and informed public debate on the medical potential and possible ethical and human rights consequences of the use of new genetic technologies in human beings". These considerations also find their expression in Article 28 of the Oviedo Convention, which calls to Parties to see to it that "the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation." In view of this undertaking and as part of its initiatives to address human rights challenges raised by emerging technologies, the DH-BIO has committed itself to develop guidance on how to promote public discussion and consultation on fundamental questions raised by the developments of biology and medicine.

7. The Assembly recommends that the Committee of Ministers "instruct[s] the DH-BIO to assess the ethical and legal challenges raised by emerging genome editing technologies, in the light of the principles laid down in the Oviedo Convention and the precautionary principle". The DH-BIO has already started to examine developments in this area, which has led to the adoption of the above-mentioned Statement on Genome Editing Technologies where it agreed, "as part of its mandate, to examine the ethical and legal challenges raised by these emerging genome editing technologies, in the light of the principles laid down in the Oviedo Convention."

8. The DH-BIO is committed to continue addressing human rights issues raised by genome editing technologies, and recalls in this respect that it intends to develop in the next biennium a Strategic Action Plan addressing human rights issues raised by emerging technologies and developments in the biomedical field. This Strategic Action Plan would be based on the outcome of the Conference organised by the DH-BIO on the occasion of 20th anniversary of the Oviedo Convention organised under the auspices of the Czech Chairmanship of the Committee of Ministers, which covered, *inter alia*, human rights challenges raised by new technological developments in the fields of genetics and genomics.

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Text of Recommendation 2115(2017)

The use of new genetic technologies in human beings

Parliamentary Assembly

1. Genetic engineering techniques have been applied in the medical field for several decades now. However, new technologies are developing very rapidly: recent discoveries related to the human genome have opened the door to new opportunities and unprecedented ethical concerns. On the one hand, this improved knowledge of our make-up as human beings brings with it welcome potential to diagnose, prevent and eventually cure diseases in the future. On the other hand, it raises complex ethical and human rights questions, including – but not limited to – unintended harm which may result from the techniques used, access and consent to such techniques, and their potential abuse for enhancement or eugenic purposes.

2. In particular, recent advances in genome editing are bound to result in germline interventions in human beings quite soon, for example with the birth of children whose genome has been altered with some unforeseeable consequences in such a way that their descendants are also affected. The scientific consensus is that these techniques are not "safe", leading to a *de facto* moratorium. However, other techniques, such as pronuclear transfer technology (the "three-parent" technique), which is used to avoid maternal inheritance of mitochondrial disease, have been used and resulted in the birth of two babies (one of them for reasons other than the treatment of mitochondrial disease), despite considerable ethical controversy and scientific uncertainty about the long-term effects.

3. Deliberate germline editing in human beings would cross a line viewed as ethically inviolable. Indeed, the 1997 Council of Europe Convention for the

Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164, “Oviedo Convention”), binding on the 29 member States which have ratified it, posits in its Article 13 that “an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modifications in the genome of any descendants”. The convention does, however, also establish a specific procedure for its amendment (Article 32), which should be read in conjunction with Article 28, which imposes on States Parties to see to it that “the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation”.

4. Numerous scientific and ethical bodies are starting to make recommendations to establish an appropriate regulatory framework for genome editing and germline interventions in human beings, including most recently the United States National Academy of Sciences and National Academy of Medicine, and the European Academies Science Advisory Council (EASAC). There is currently a prohibition on interventions aimed at modifying the germline in human beings in all European Union and many Council of Europe member States.

5. The Parliamentary Assembly thus recommends that the Committee of Ministers:

5.1. urge member States which have not yet ratified the Oviedo Convention to do so without further delay, or, as a minimum, to put in place a national ban on establishing a pregnancy with germline cells or human embryos having undergone intentional genome editing;

5.2. and, in addition, develop a common regulatory and legal framework which is able to balance the potential benefits and risks of these technologies aiming to treat serious diseases, while preventing abuse or adverse effects of genetic technology on human beings;

5.3. foster a broad and informed public debate on the medical potential and possible ethical and human rights consequences of the use of new genetic technologies in human beings;

5.4. instruct the Council of Europe Committee on Bioethics (DH-BIO) to assess the ethical and legal challenges raised by emerging genome editing technologies, in the light of the principles laid down in the Oviedo Convention and the precautionary principle;

5.5. recommend that member States, on the basis of the public debate, the DH-BIO assessment and the common regulatory and legal framework devised, develop a clear national position on the practical use of new genetic technologies, setting the limits and promoting good practices.