SEVENTH SESSION OF THE INTERGOVERNMENTAL BIOETHICS COMMITTEE (IGBC)
Paris, 5 – 6 September 2011
(UNESCO Headquarters, Room IV - Fontenoy Building)

Item 6 of the agenda – Progress report on the work carried out by IBC in 2010-2011 and the preliminary work programme of IBC for 2012-2013

I. INTRODUCTION

1. Based on the work programme of the International Bioethics Committee (IBC) fixed by its Bureau at the beginning of the biennium 2010-2011, the work of the Committee consisted of three thematic areas:

   1) the principle of respect for human vulnerability and personal integrity (Art. 8 of the Universal Declaration on Bioethics and Human Rights, hereafter “the Declaration”);
   2) the issue of human cloning and international governance; and
   3) the issue of traditional medicine and its ethical implications.

II. RESPECT FOR HUMAN VULNERABILITY AND PERSONAL INTEGRITY

2. The Report on the principle of respect for human vulnerability and personal integrity (Ref. SHS/EST/CIB-17/10/CONF.501/2 Rev 2 of 22 June 2011) (see item 7 of the agenda) is the result of a long reflection within IBC which began in 2008, was further developed at the 17th (ordinary) session of IBC and the joint session of IBC and IGBC (October 2010) and then finalized at the 18th session of IBC which took place in Baku, Azerbaijan, in May-June 2011.
III. TRADITIONAL MEDICINE AND ITS ETHICAL IMPLICATIONS

3. In so far as traditional medicine has been mentioned on several occasions as a topic of particular relevance for developing countries and their national bioethics committees the Bureau of IBC considered appropriate for the Committee to analyze the fundamental ethical questions raised by traditional medicine as part of its 2010-2011 work programme. Since the focus of this reflection was on the ethical implications of traditional health practices, it avoided duplication with works already carried out/or being carried out by other UN agencies (the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO) for example).

4. A small working group under the leadership of Dr (Mr) Emilio La Rosa was established with the aim of starting a reflection on the ethical implications of traditional health practices. The working group met in June 2010 and drew up a preliminary draft report (Ref: SHS/EST/CIB-17/10/CONF.501/3 of 29 September 2010) presented and discussed at the 17th (ordinary) session of IBC and at the joint session of IBC and IGBC held at UNESCO Headquarters in Paris in October 2010.

5. The preliminary draft report, as well as discussions during these sessions emphasized the fact that traditional medicine is an issue that directly concerns the lives of a major part of the world’s population, and that it is as such an important subject for an analysis from the ethical perspective.

6. The 17th session of IBC also gave the opportunity to hear from experts outside the Committee who brought their comments and constructive input to the reflection of the Committee. Specialists from the Natural Sciences Sector and the Culture Sector of UNESCO presented those programmes, reflections and activities within their Sector that were relevant for the work of IBC. In addition, a philosopher from Africa shared his knowledge about the ethical aspects of traditional medicine and its practice in his region. Eventually, Members States of IGBC committed themselves during the joint session of IBC and IGBC to provide data on the practices of traditional medicine specific to their country; but only few have effectively done so as of now.

7. Based on this preliminary work and on the discussions with Member States of IGBC at the October meetings, IBC considered appropriate, before proceeding further in the ethical reflection, to better clarify the scope of traditional medicine which encompasses a wide spectrum of very different activities that vary from one country to another. The Committee also highlighted the need to gather concrete information about the current practices of traditional medicine.

8. Two concrete actions were therefore carried out:

   1. A questionnaire was developed and sent to almost 100 specialized research institutes worldwide; it was designed to collect the needed practical information regarding practices of traditional medicine, as well as more specific data about the legal, institutional and ethical framework of these practices and their relation to conventional medicine.

   About 20 answers to the questionnaire were received, which analysis was presented during the 18th session of IBC held in Baku, Azerbaijan (31 May – 2 June 2011). Despite the small number of replies, their analysis revealed a relatively homogeneous overview of the present situation and of the current tendencies within traditional health practices specific to the countries in which the institutes having replied operate, and highlighted their present lack of regulations of traditional medicine as well as their lack of identified ethic codes specific to this type of medicine.

   2. Hearings with traditional health practitioners from China, India, Kenya and Peru were also organized on the occasion of the 18th session of IBC. Before participating in an exchange with the members of the Committee, the practitioners
were invited to present their activity from their own perspective by emphasizing the following issues: modalities and content of transmission of knowledge, strengths and weaknesses of their practice, criterions for establishment of efficacy, patient/practitioner relationship, risk assessment, ethical principles guiding their practice, mechanisms sanctioning/guaranteeing quality and expertise of traditional medical knowledge, networks of practitioners and differences and relationship between traditional and conventional medicines.

9. Members of the Committee expressed diverging opinions on the question whether IBC should pursue its reflection on this issue or not. These divergences partly stem from the difficulty of properly identifying the actual practices of traditional medicine that should be dealt with and isolating them from more harmful practices. However, due to lack of time during its 18th session, IBC was not able to go into an in-depth discussion on the results of the questionnaire and on the necessity and modalities of pursuing its work on this topic. The Committee therefore entrusted its Bureau, within the framework of establishing the work programme of IBC for 2012-2013 (see below) and based on opinions expressed by all members of IBC, to figure out the best way for moving forward in this respect.

IV. HUMAN CLONING AND ITS INTERNATIONAL GOVERNANCE

10. The issue of human cloning and its international governance is included to the work programme of IBC since 2008 with the specific mandate to explore whether there was any scientific, social or political change that would justify a new initiative at the international level.

11. Following the deliberations of the IBC working group established under the chairmanship of Professor (Mr) Toivo Maimets (Estonia), and based on the discussions held during the fifteenth session of IBC and the joint session of IBC and the Intergovernmental Bioethics Committee (IGBC) held in October 2008, IBC finalized its Report on Human Cloning and International Governance and transmitted it to the Director-General on 9 June 2009 (Ref. SHS/EST/CIB-16/09/CONF.503/2 Rev.2).

12. At its sixth session (Paris, July 2009), IGBC expressed its appreciation for the balanced and comprehensive Report and concurred with IBC that an international dialogue on the international governance of human cloning is needed and should be pursued. IGBC also supported the assessment of IBC that a review of the terminology used would be highly beneficial.

13. Based on this positive feedback and on an extensive discussion held at the 16th session of IBC (Mexico, November 2009) on the main issues raised during the preparation and finalization of the 2009 Report, IBC decided to pursue its reflexion on the issue of human cloning and international governance in 2010-2011. It should however be stressed that IBC did not initiate a new ethical analysis of the whole issue of human cloning as such during this period, but that it rather focused on three main areas:

- new scientific developments in the field of human cloning, the use of terminology and its ethical impact;
- legal developments and different options for legal regulation of human reproductive cloning (including the possibility of a moratorium); and
- options for activities designed to disseminate information and raise public awareness on the issue of human cloning and its governance.

14. Preliminary conclusions of the working group on these three topics were drawn up in a report (Ref. SHS/EST/CIB-17/10/CONF.501/4 of 7 October 2010) presented during the 17th session of IBC and the joint session of IBC and IGBC held in Paris in October 2010. Discussions on this occasion asserted the importance of studying the feasibility of implementing a binding international legal instrument prohibiting human cloning for
reproductive purposes. However, exchanges with Member States within IGBC suggested that the political hurdles that have prevented the realization of such an instrument in the past are still in place.

15. Within IBC itself, divergent positions exist among the members concerning the ethical implications of techniques of human cloning as well as the best option for international governance. Due to this, the working document (see annex II) containing a final draft statement on human cloning and international governance discussed among IBC members during the 18th session of IBC (Baku, May-June 2011) did not meet with a consensus. Consequently, the Bureau of IBC was entrusted to evaluate in the coming months if and how the draft document could be revised in order to accommodate the different positions expressed during the discussions.

V. PRELIMINARY REFLECTION OF THE WORK PROGRAMME OF IBC FOR 2012-2013

16. The 18th session of IBC (Baku, May-June 2011) was the occasion for a preliminary reflection on the Committee’s future work programme for 2012-2013 in accordance with Article 2 paragraph (2) of its Statutes. An initial exchange of ideas was thus launched on possible issues which would require special attention from IBC, including new areas of scientific and technological developments and the elaboration of other articles of the Declaration.

17. A number of possible issues have therefore been identified by IBC as possible relevant themes to be considered for the future work programme:

- biobanking;
- organs, tissues and cells transplantation (including trafficking);
- neuroscience;
- regenerative medicine,
- sharing of benefits (article 15 of the Declaration).

18. Moreover, the UNESCO Assistant Director-General for Social and Human Sciences indicated the strong interest of the Organization that the Committee embarks on an in-depth reflection on the principle of non-discrimination and non-stigmatization (article 11 of the Declaration).

19. IBC entrusted its Bureau to fix the work programme of IBC for 2012-2013 at a later stage by considering additional opinions of its members, as well as feedback from the seventh session of IGBC (5-6 September 2011), possible indications from the debate in the 36th session of the General Conference (October-November 2011) and possibly new requests from the Director-General of UNESCO.
Draft Final Statement of IBC on Human Cloning and International Governance

At this stage, this draft final statement constitutes a working document to be examined and finalized by IBC at its 18th (ordinary) session (Baku, Azerbaijan, 31 May – 2 June 2011).

As it stands, it does not necessarily represent the final opinion of IBC and it is subject to further modifications.

I. Historical Background

Since the birth of the first mammal clone – Dolly the sheep - - in 1997, the issue of human cloning and the appropriate international system of governance have been triggering off profound reflection and debates at national and international levels, including within the United Nations system. A number of norms have been elaborated at the international level which address directly or indirectly the issue of human cloning, in particular (in chronological order) the Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997); the World Health Organization resolutions WHA50.37 (1997) and WHA51.10 (1998); the Universal Declaration on Bioethics and Human Rights (UNESCO, 2005); and the United Nations Declaration on Human Cloning (2005).

A particularly intense debate took place in the UN General Assembly in regards to elaborating and voting for the United Nations Declaration on Human Cloning. While there was a unity in the commitment to uphold fundamental ethical principles that safeguard human dignity and human rights, the international community found itself divided in their approach to addressing the ethical challenges arising from advancement in cloning technologies.

In 2008, subsequent to the publication in 2007 of the report entitled Is Human Reproductive Cloning Inevitable: Future options for UN Governance by the Institute of Advanced Studies, United Nations University (UNU-IAS), the Director-General of UNESCO expressed his wish that the International Bioethics Committee (IBC) add the examination of this report to its agenda.

The issue of human cloning and international governance was therefore added to the work programme of IBC for 2008-2009 with the specific mandate to explore whether there was any scientific, social or political change that would justify a new initiative at the international level, and a working group was established under the chairmanship of Professor (Mr) Toivo MAIMETS (Estonia).

On the basis of the deliberations of the IBC working group, as well as the discussions held during the fifteenth session of IBC, and the joint session of IBC and the Intergovernmental Bioethics Committee (IGBC) in October 2008, IBC finalized its Report on Human Cloning and International Governance and transmitted it to the Director-General of UNESCO on 9 June 2009.

At its sixth session (Paris, July 2009), IGBC expressed its appreciation for the balance and the comprehensiveness of the Report of IBC and concurred with IBC that an international dialogue on the international governance of human cloning is needed and should be pursued. IGBC also supported the assessment of IBC that a review of the terminology used would be highly beneficial.
Based on this positive feedback from IGBC and on an extensive discussion held at the 16th session of IBC (Mexico, November 2009) on the main issues raised during the preparation and finalization of the 2009 Report, IBC decided to continue the work on the issue of human cloning and international governance in 2010-2011. It should be stressed that IBC did not initiate a new ethical analysis of the whole issue of human cloning as such during this period, but that it has rather focused on three main areas:

- new scientific developments in the field, the terminology used and its ethical impact;
- legal developments and different options for legal regulation of human reproductive cloning (including the possibility of a moratorium); and
- proposals for activities designed to disseminate information and raise public awareness on the issue of human cloning and its governance.

II. Final conclusions of IBC

After a four-year reflection that has benefited from the contribution of a broad spectrum of stakeholders from the scientific, political and ethics communities (in particular through hearings with scientific and legal specialists in the field, representatives of scientific associations and representatives of national bioethics committees), IBC has reached the following conclusions concerning international governance of human cloning:

**New scientific developments and the ethical dimension**

IBC recognizes the complexity of ethical questions arising from human cloning technologies and is aware of the differences in moral and cultural positions in this respect and the persisting difficulty in reconciling them. The cloning of a human being, whether for reproductive or research purposes, as well as other techniques of manipulation of human embryo, raise fundamental questions about dignity of life, the beginning of life and the status of the embryo.

From a scientific point of view, new scientific developments in cloning and related technologies, such as the use of induced pluripotent stem (iPS) cells and production of synthetic DNA, creates more technical possibilities for reproductive manipulation of human embryos and for the production of reproductive cells. It therefore brings new issues into the ethical debate which call for a reinvigorated international dialogue, involving all relevant stakeholders, i.e. intergovernmental organizations, national scientific bodies, bioethics institutions and the civil society.

**Terminology**

The terminology used in the bioethical and legal discourse is misleading and does not adequately describe the actual and potential technical procedures relevant to human cloning. The expression “human cloning” has so far been used to point at two very different purposes. On the one hand, the so-called “reproductive cloning” refers to the hypothetical possibility of creating a human embryo from the linear DNA nuclear sequence of one single human being in order to implant it into a womb, leading eventually to the birth of an identical human being. On the other hand, in the paradigm referred to as “therapeutic” or “research cloning”, the same technique of somatic cell nuclear transfer, as well as other related techniques (embryo splitting, iPS…) lead to the production of stem cells for research.

The International Bioethics Committee considers that a revision of the terminology is needed according to the new scientific developments, and proposes to restrict the use of the term “cloning” only to cases where “reproduction” is the intended purpose of the procedure. Indeed, the term is not perfectly correct from a scientific point of view, because it would in any case be impossible to produce an absolutely identical human being. However, as the term is deeply engrained in global discourse and already features in a number of national
legislation and international documents, the Committee thinks that it should be retained to encompass techniques (existing or potential) that would include but not be limited to somatic cell nuclear transfer aiming at creating a human baby whose genetic constitution is engineered to be identical (or virtually identical) to a preexisting person.

On the other hand, IBC proposes to dismiss the word “therapeutic” or “research” cloning. It would be more correct and easily understandable, also with regards to the ongoing developments of scientific knowledge and techniques, to speak of “derivation of pluripotent stem cells” through the means of nuclear transfer, together with the other procedures that make stem cells available. Of course, the difference between the procedures that entail the destruction of human embryos and those that are less ethically controversial – such as the research on “adult” stem cells – cannot be dismissed and should therefore always be made clear in the public debate.

**International governance**

IBC considers that the current non-binding international regulations cannot be considered sufficient in addressing the challenges posed by the contemporary scientific developments and to safeguard the interests of the developing countries that still lack specific regulations in this area.

The Committee, in its capacity as an advisory body of UNESCO, calls for a stronger international effort to take the necessary measures - including through a more robust international mechanism such as a moratorium or a convention - to ensure the prohibition of reproductive human cloning, meaning the use of any technique (existing or potential) aiming at creating a human baby whose genetic constitution is engineered to be identical (or virtually identical) to a preexisting person. The Committee considers that all other technical manipulations of human embryo, either for research or therapeutic purposes, remain controversial in a sense that their public recognition depends on the concrete social, religious and historical contexts of different countries and therefore should remain regulated nationally.

While hoping that the discussions and their outputs have provided guidance to policy makers and the scientific community in the complexity of ethical considerations behind human cloning, IBC also notes that existing differences amongst the Member States on the optimal way to regulate this issue internationally make it difficult to achieve a consensus on a binding international instrument that bans the practice of human cloning for reproductive purposes.

**Dissemination**

In order to promote the dissemination of information and to raise public awareness of the issues related to human cloning and its regulation, IBC considers UNESCO well-positioned to develop specific strategies and materials to promote international discourse on this topic and more actively encourage and support national research organizations, academies and national bioethics committees to foster debate on cloning issues. More specifically, two courses of action could significantly contribute to raising awareness and disseminating information concerning human cloning issues:

- Creation of a database within the framework of UNESCO’s Global Ethics Observatory (GEObs) databases to serve as a clearinghouse of information and to monitor new developments that affect the ethical aspects of human cloning debate; and
- Organization of a major Conference under the auspices of UNESCO dedicated to the theme of human cloning and international governance to target policy-makers, opinion leaders, and national and international regulators.