

**Meeting of Legal Experts for GEObs-Law Database
Division of Ethics of Science and Technology
UNESCO**

Meeting Report

Venue: UNESCO HQs, Bonvin Building
Room XVI
1, rue Miollis, 75015 Paris, France

Date: 14-15 September 2006

Attendance:

Members of Review Committee for GEObs-Law:

- Prof. Herman Nys, Belgium
- Prof. Judit Sandor, Hungary
- Prof. Monica Serra, Brazil
- Dr. Dirk Lanzerath, Germany
- Dr. Thomas Faunce, Australia
- Mr. John Hoff, U.S.A.

Legal experts (Group 1 – pilot phase)

- Dr. Omar Aljazy, Jordan
- Dr. Sylvie Bordet, Canada
- Dr. Thomas Faunce, Australia
- Prof. Judit Sandor, Hungary
- Prof. Monica Serra, Brazil
- Dr. Amha Tesfay Desta, Ethiopia
- Prof. Yuichiro Sato, Japan
- Prof. Mohsen El-Hazmi, Saudi Arabia

Members of the Secretariat:

- Mr. Henk ten Have, Director SHS/EST
- Mr. Tee Wee Ang, SHS/EST

Observer

- Prof. Amnon Carmi, Israel

Apologies

The following members of the Review Committee were not able to attend

- Prof. Carter Snead, U.S.A.
- Prof. Ryuichi Ida, Japan
- Prof. Cinzia Caporale, Italy
- Prof. Bartha Knoppers, Canada

- Dr. Genevieve Pinet, WHO

Discussion:

Mr. ten Have welcomed all participants and thanked them for their contributions thus far. Participants of the meeting consisted of members of the review committee and legal experts who have researched and prepared information for the pilot phase of the initiative. The following countries have been included in the pilot:

- Africa Region: Ethiopia
- Arab Region: Jordan and Saudi Arabia
- Asia Pacific Region: Australia and Japan
- Europe and North America Region: Canada and Hungary
- Latin America and Caribbean Region: Brazil

It was clarified that due to difficulties in finding suitable legal experts, not all the countries proposed by the Review Committee in December 2005 could be included in this phase. Furthermore, since this phase is meant to test the methodological approach proposed by the Review Committee, it involved only a limited number of bioethical themes and countries. It was stressed that the GEObs-Law database is a long-term initiative, and will gradually include more countries in subsequent phases.

Mr. ten Have emphasized that the objectives of this meeting include:

- Review and discuss the materials submitted by the legal experts.
- Decide whether the materials submitted are useful for the purpose of the database.
- Examine the methodological approach with the intent of adopting a revised methodological schedule that can be used for future expert contributions.

It was also pointed out that the GEObs-Law database is intended to provide Member States with a factual, standard, and useful representation of legal instruments within and across Member States related to the ethics declarations by:

- Promote and disseminate the principles of the UNESCO declarations
- Provide access to international, regional and domestic normative information
- Provide models to guide Member States in the formulation of their legislation, policies or other instruments in the field of bioethics

Participants were reminded that this exercise is meant to assist policy makers develop legislation in bioethics and to support Member States in their efforts to bring the ideas of the declarations into practice, and not so much for academic interest. The database is also meant to show the impact of the declarations, and to capture Member States' actions in relation to the declarations. A model of the GEObs-Law database, with possible screens, was also demonstrated to provide participants with a better idea of how the information could be presented on the website. Users

will be able to access the database through three primary search terms: themes, articles of the declarations, and types of legal instrument (other secondary search terms are also available).

In order to start the discussion on materials submitted, Prof. Nys provided a brief summary of the background of the methodological approach and overview of the information collected. The themes covered for this phase of the exercise were:

- Medical research with human beings.
- Access to health care and essential medicines.
- Genetic counseling.
- Protection of future generations.
- Freedom of scientific research.

Legal instruments considered by the experts included:

- Multilateral, regional, and bilateral treaties
- Constitutions
- Domestic laws
- Authoritative cases
- Regulations and guidelines

Prof. Nys made the following observations about materials submitted:

- Australia: Materials covered all five themes. Articles from the declarations were also approached from all types of legal instruments. Short academic commentaries were also provided.
- Brazil: Materials covered all five themes, primarily in the first two themes. References were made to the relevant articles in the declarations.
- Canada: Materials covered four themes, with no references to treaties. Sub-topics and comments were added.
- Ethiopia: Materials covered all five themes, with no references to treaties.
- Hungary: Materials covered all five themes. Background paper containing useful information, comments, and sources was also provided.
- Japan: Materials covered all five themes, but no clear link with articles in the declarations was made.
- Jordan: Materials covered two themes.
- Saudi Arabia: Materials covered four themes, but no clear link with articles in the declarations was made.

It was stressed that when discussing the methodological approach, participants need to keep in mind that the framework will be used for all Member States, and standardization is needed for comparison purposes within the database. From the discussion, the following concerns and changes were highlighted for the methodological approach and its related content:

- Concerns were raised that the database should not act like a report card or checklist of how Member States are “implementing” the declarations, but instead should provide

possible legal models related to the principles of the declarations. The database should also ensure that any “blanks” in the data or failure to take a particular action *not* be interpreted as a violation of the declarations (even if they are non-binding). Along this line, it was argued that directly relating the information provided to articles of the declarations could lead to such interpretations. In response, Mr. ten Have clarified that the database is definitely not meant to be a checklist or reporting tool of different countries, but rather an inspirational and educational tool. It was further observed that direct reference to articles of the declarations is necessary to provide a clearer picture of how the declarations are impacting the legal repertoire of Member States. This point will be clarified in an introductory note of the database on the website.

- It was emphasized that in order to accommodate the various legal systems around the world within the methodological framework, clear definitions of the terminologies used in the schedule are necessary.
- With regards to the legal instrument category of “regulations and guidelines,” it was decided that the term “regulations” will be dropped from the category. It was further clarified that all binding instruments that has a clear enforcement mechanism will be classified as “domestic laws,” and all non-binding instruments (including professional guidelines) will be classified as “guidelines.”
- With regards to the legal instrument category of “authoritative cases,” it was emphasized that only influential cases, preferably those of the highest court, should be included.
- With regards to the legal instrument category of “domestic laws,” it was clarified that generally, instruments at the federal level should be sufficient. However, further details at state or lower levels should also be included if it is deemed necessary by the expert (for example, in the case of a weak federal arrangement). In addition, web links to the instruments in their original language should be provided whenever available.
- With regards to all legal instruments, the legal hierarchy of these instruments should also be taken into consideration in case of contradictions.
- It was also decided that at this stage of research for the database, only the Universal Declaration of Bioethics and Human Rights (UDBHR) will be used in the methodological framework, unless otherwise stated.
- It was further clarified that under the short description of a particular legislation, only the articles or sections that are relevant to the bioethical theme in question should be quoted. Experts need to avoid interpretative commentaries when providing this short description.
- It was also recognized that commentaries are necessary to facilitate accurate and comprehensive understanding of the information presented in the database. However, it was emphasized that only general commentaries that seek to clarify the information provided in a neutral and objective manner will be included in the database (one-click access). Since general commentaries will have to be translated into the 6 official languages of UNESCO, they must be succinct and relatively short. Commentaries that are interpretative and critical will not be included in the database, but web links to these commentaries can be added if necessary (two-click access, and not residing within the UNESCO system). Wherever available, additional links to official websites explaining the legal system of a country will also be provided (two-click access). It was also suggested that links to religious and policy papers could also be included in this format. It was further recognized that although it would be interesting to capture the debate

surrounding certain policies, it is not feasible and sustainable to capture it in the database (monitoring, language, and political barriers).

- With regards to multilateral and regional treaties, such as those of the European Union or other UN conventions, instead of providing detailed descriptions related to each country, a web link to the official website of the instrument in question will be provided whenever available. The same should also be the case for religion-based legal systems which are applicable across borders. However, it should be noted that religion-based legal systems should only be included for countries where a secular system of government does not exist. Each expert should decide how relevant these trans-national instruments and systems are to their country.
- It was pointed out that since changes to legislation are very frequent in most countries, a sustainable method of updating the information in the database is necessary. It was suggested that the updating process can be used to build the capacity of young scholars in the area of health law and comparative legal studies if they were to be engaged for this purpose, under the supervision of the legal experts responsible for the initial entry. It was also suggested that each entry should have a “last updated” field in the database, as well as a log of all modifications made.
- With regards to intellectual property laws, it was clarified that these instruments should be included if they refer explicitly to the bioethical themes identified (such as human cloning, etc.).
- Referring to the “protection of future generations” theme, it was clarified that only legal instruments that explicitly mention this theme should be included in the database.
- In terms of the “access to health care and essential medicines” theme, it was pointed out that the UDBHR article states that “progress in science and technology should advance” access to quality health care and essential medicines. It was emphasized that the information presented should avoid any implications that this article created a right to health care. Experts were urged to focus on the spirit of the declaration, and the language of the declaration should be followed closely in defining what is to be presented. In this case, experts should list legal instruments that channel progress of science and technology towards advancing access to health care and essential medicines.
- With regards to the translation of listed legal instruments, it was clarified that only quoted articles or sections related to the theme in question should be translated (instead of the entire instrument). In translating this information, experts were urged to follow as closely as possible to the text of the law. Experts are also expected to make sure that their translation will not be contested by government authorities within their country. This point will also be clarified in the introductory note to the database on the website.
- It was further emphasized that in the introductory note to the database, clarification of how the different categories are defined and how they relate to each other is necessary to ensure its comprehensibility for users of the database.

Based upon the outcomes of the discussion above, Prof. Nys and Mr. ten Have will revise the methodological schedule and all related documents for the database. It was also suggested that a style guide on how the information is to be formatted (font, size, etc.) would be useful.

It was pointed out that the work submitted thus far is considered as for Phase 1 of Group 1, and revised materials should be submitted by 1 December 2006. After further review and validation,

these materials will be entered into the database, which is expected to be launched by early 2007. During this time, Group 1 will start on Phase 2 of the work, expanding its research into new themes. The deadline for submission of Phase 2 materials is 1 February 2007. New experts for Group 2 will also be identified to expand the number of countries represented for Phase 1 data.

The themes for Phase 2 have been identified as follow:

- Human cloning.
- Transplantation.
- Bio-banking (genetic and health data).
- Non-discrimination.
- Ethics committees.
- Protection of genetic resources.

The next meeting, which will include both Group 1 and Group 2, is tentatively set for 28-30 March 2007. This will be confirmed by the secretariat once logistical details are clearer.