

Seventh European Commission Forum of National Ethics Councils 9-10 March 2006 Minutes

The Forum of National Ethics Councils (NEC) is an independent informal platform for exchange of information, experience and best practices on issues of major significance or interest in the field of ethics and science.

25 EU countries were represented at the 7th NEC Forum Meeting which took place in Vienna on March 9-10, 2006. Romania joined the Forum for the first time as an invited guest. The European Group on Ethics (EGE) was represented by **Prof. Hermeren**, President of the EGE. The Council of Europe (COMETH) was represented by Dr Lwoff and Prof. Tarchys (President COMETH). The European Commission (DG RTD) was represented by **Dr J-M Baer** (Director of Science and Society), **Dr P. Zilgalvis** (Head of Unit Ethics and Science) and **Dr Salvi** (Secretary of the NEC Forum and deputy head of Unit Ethics and Science). Austrian political personalities included: **Elisabeth Gehrler**, **Austrian Federal Minister of Education, Science and Culture** and **Franz Morak**, **State Secretary for Arts and Media**, representing the Austrian Federal Chancellor **Dr. Wolfgang Schüssel** (as President of the Council of the European Union). The Chairs of the International Bioethics Committee of UNESCO (IBC), **Prof. Nouzha Guessous-Idrissi**; the Chairs of the USA President's Council on Bioethics, **Prof. Edmund J. Pellegrino** attended.

The Forum was opened by Prof. **Johannes C. Huber**, Chair of the Austrian Bioethics Commission.

Minister Gehrler underlined the heterogeneous nature of the debate on ethics and science across the EU and underlined the importance of research to safeguard the protection of human dignity. She underlined the important role the Forum plays in pan-European debates on ethics and technology and stressed the need of promoting dialogue to identify communalities across EU countries while respecting cultural identities. Minister Gehrler also advocated the need for policy makers to be aware of issues of major significance on ethics when approaching debates on science and technology. She welcomed participants at the Forum, indicated as the expression of an authentic dialogue across EU countries.

Dr Baer spoke about the role of the next framework programme with regard to the Lisbon strategy. He underlined the importance of endorsing scientific policies that promote both innovation and social acceptance of science and technology. He underlined the need to respect integrity in scientific practices while valuing the potential of new scientific discoveries and their impact for EU social welfare. Dr Baer stated that the EU is a community of shared values, in which research and innovation can be developed and incorporated as the next EU Framework Programme intends to do.

Dr Zilgalvis, reported on actions taken in the Unit ethics and science since the last Forum meeting in London. In particular, he focused on EC initiatives in international cooperation on ethics and research, both in terms of financing research projects on ELSA at the international level and promoting pro-active actions in capacity building on ethics in developing countries. Dr. Zilgalvis reported on two major events in this respect being organised by the Commission services: a workshop on ethics and pandemics and infectious diseases (HIV, Birth flue and SARS) which will take place in Brussels in May 2006, and a EC conference on research ethics in developing and emerging countries (India, Brazil, Chine, South Africa) which is scheduled at the end of January 2007. He underlined the international dimension and developing countries is becoming key policy priorities for the EU.

Prof. Hermeren, reported on the activities of the EGE. The EGE is currently working on an opinion on ethics and nanomedicine. Future opinions of the Group may include ethics and stem cell research and ethics and agriculture.

The first session was then opened by **Dr Lwoff**. She reported on the current work of the Council of Europe in the fields of bioethics and announced the approval of the Recommendation on research on biological material foreseen the second week of March. Dr Lwoff also underlined the need to establish strong cooperation on ethics and bioethics between the Council of Europe and the Commission, in the respect of the mutual competence and powers.

Prof. Nouzha Guessous-Idrissi summarised the main steps taken for both the preparation and approval of the UN Declaration on Bioethics and Human Rights adopted by the General Conference of UNESCO at its 33rd session in October 2006. She explained the complex mechanism established by UNESCO to safeguard the democratic discussion of the Declaration and its capacity to reflect the cultural variety of positions that characterises the UN world. Prof. Guessous-Idrissi also stressed on the fact that the Declaration brought at least two important innovations that were not stated in previous Declarations of the UNESCO. One is the definition of the principle of Social responsibility and health as a universal principle stating that since the enjoyment of the highest attainable standard of health is one of the fundamental human rights, the promotion of health and social development is a central purpose of governments that all sectors of societies shares. The second innovation of the Declaration is related to the principle of benefit sharing since Article 15 gives some concrete examples of actions to give effect to this principle. Finally, Prof. Guessous-Idrissi confirmed that IBC will concentrate its efforts on the implementation of the principles set out in the Declaration at a world level, and that two groups of experts from the IBC will work one on the principle of Social responsibility and health, and the second on the problematic of consent.

Prof. Edmund J. Pellegrino then reported, by adopting a descriptive non analytical approach, on the main axes of discussions on bioethics in the USA. He underlined the key role of bioethics with regard policy design/discussion in USA, in particular on issues of major significance on research. Such issues include, inter alia, euthanasia, abortion, stem cells, the moral status of the embryo and its use in research (including the debate on alternatives), cloning, human enhancement (cognitive or behavioural applications and doping in sport) including regenerative medicine. Prof. Pellegrino made an historical overview of bioethics and reported on current and future approaches being taken in USA, where major efforts in terms of education and embedding are carried out. Prof. Pellegrino also underlined the dialective and global role of bioethics and underlined that the use of bioethics for policy matters is filtered by political factors; he therefore advocated the need of making a distinction between bioethics as a scientific discipline and its use in a political context.

Prof. Hermeren made a presentation on European bioethics, following the same descriptive approach of the previous speaker. He underlined the cultural complexity and variety that characterises the European debate, and then he reported on the main approaches being used across the EU (principles, virtues, rights and consequentialism). Prof. Hermeren illustrated the main principles being debated and applied to the European debate on ethics of science, namely: human dignity, autonomy, justice, privacy, proportionality –assessment of objectives and their implications in a value system balance–, precaution. He underlined the need to relate ethics values to other value systems of different kind and nature, such as economic growth and social welfare. Prof. Hermeren then stressed the global stand of the values above but advocated the existing difference in terms of ranking in different cultures and appealed for the need of finding balances which are respective of ethics pluralism while promoting communalities and standards; a balance, he advocated, which is complex and needs debates and tolerance. He underlined the work of the EGE in that context and advocated the need of fully endorsing the notion of social solidarity in health systems and global discussion on science and technology. He also stated the need the EU to endorse global approaches and dialogues on ethics and science within the EU countries and with other regions of the world.

Prof. Harris made then an intervention on issues to consider when ethics is approached at a global level. He underlined paradoxical situations in which researchers who carry out research in a jurisdiction where it is legal, may find themselves in a situation of legal uncertainty if they travel to a jurisdiction where that same research is prohibited. He reported on the case of human embryonic stem cells and researchers travelling from EU countries having different legal systems in force (DE and UK for example or California and more conservative States such as Michigan). He therefore advocated the need to face the situations above by endorsing, in a consistent way, the notion of pluralism and freedom of research. He made reference to some projects on ethics and stem cells he has coordinated and expressed his personal position on this debate which has a high relevance at a global level.

Debate

- The difficulty of clarifying the notion of human dignity and its relevance for embryo research was stressed.
- The difficulty of relating the notion of autonomy with regard to several expressions of paternalism embodied in the medical practice was also stressed. The difficulty was equally underlined of endorsing the notion of autonomy in cultures far from western cultural roots.
- The role of NECs was also stressed in the international debate on ethics and science. Such a dialogue should not be only characterised by political and religious matters but should respect the central role of ethics in debates on science and technology at a global level. The need of keeping a credible balance in the composition of NECs, with regard to pluralism of views and expertises was also stressed.

The second session of the Forum was then introduced by **Dr. Robert Gmeiner**, Head of the Secretariat, Austrian Bioethics Commission. Dr Gmeiner underlined the main intention of such a session which was to analyse and discuss actions taken in several MS to involve and stimulate the participation of the public in discussions associated to science and technology. He reported on a survey of initiatives taken by NECs and introduced the 3 cases: NL, **Dr. Sara Heesterbeek**, Rathenau Institute; IRL **Dr. Siobhán O'Sullivan**, Head of the Secretariat of the Irish Council for Bioethics; **Dr. Ursula Hunger**, dialog \diamond gentechnik, Austria.

Dr. Sara Heesterbeek reported on the technology festival she organised in 2005. The Festival intended to raise public awareness on science and society, including ethics and in particular addressing nanotechnologies, genetic testing and human enhancement and converging technology. The initiative also intended to stress the daily implications/applications of the aforementioned technology for users of different kind and nature. Debates, exposition and art were the tools used to favour such a public awareness.

Dr. Siobhán O'Sullivan reported on the actions taken by the IRL NEC. She explained that the public engagement is a goal and a target objective of IRL NEC. The tools used to accomplish this objective are, web-fora (attractive for young generation but not used by other age and socio-cultural groups of the population); interviews (500 people randomly chosen). From the survey above it appeared that the level of knowledge and involvement on bioethics is extremely variegated and socio-culturally characterised. Main interest sector for the contacted people was the application of science that affects the daily life of the population, for example abortion, embryo, organ donation, forensic databases etc.). She also reported on other tools used to involve the public such as radio broadcast, and, eventually in a future, television programmes that may amplify the access to different kind of users than the one so far contacted or involved in the debate.

Dr. Ursula Hunger, then reported on an initiative on stem cells and public engagement and information being taken in Austria. She underlined that the aim of such an effort was to sensitise students on issues surrounding the debate on ethics and cloning, including somatic nuclear cell transfer. 11 teams have then launched the initiative involving more than 2000 pupils across the country. The effort was positive for encouraging an early awareness of students on ethics and science.

Debate:

Several initiatives aimed to increase the public participation were reported, for example, film and theatre festivals in UK, future efforts planned by Unesco to facilitate and help public awareness across the world on the basis of the Universal declaration on bioethics and human rights.

It was also noticed that effective communication on innovative developments is a main issue of a responsible promotion of science & policy. Policy stakeholders should give more priority and invest skills in communicating openly and clearly on what is known and not known, possible advantages and risks, and perspectives, and should invite the public to share views, pose questions, and give suggestions for how to proceed.

Prior to introduce the session on research ethics and developing countries, the representatives of the FI NEC took the fore and gave indications on the next meeting hosted by the FI Presidency.

The **Finish Presidency** said the next meeting of the NEC Forum will take place in Helsinki on **September 20-21**. It was pre-announced that the issues that would be of interest for the Presidency include: bioterrorism, prevention of pandemics, impact assessment of the Helsinki declaration (1964-2006) or biotechnology and ethics. The Secretariat of the NEC Forum will collect additional proposals from the Forum members and define the agenda. See also <http://www.tenk.fi/nechelsinki>

The 3rd session of the meeting was introduced by **Prof. Didier Sicard**, President of the National Consultative Ethics Committee for Health and Life Sciences (F). Prof. Sicard underlined the need to address the discussion on research ethics with special attention to developing countries, a key factor for research practices that have global role and outcomes.

Dr. Marc Guerrier, Espace Ethique/AP-HP, reported on results from a research project on capacity building in research ethics in Africa (15 African countries involved) financed by the commission services -NEBRA. He explained that, according results from the project above, the integration of ethics in the regulatory systems in francophone Africa is still far to be fully effective, also for regulations involving clinical trials with human subjects. However, main efforts are being taken by local regulators and International Organisations (WHO in particular) to help such a process which is complex and varied and involves the active role of local research ethics committees -RECs, NGOs, local organisations –e.g. PABIN- and pressures from the different sponsors of the trials being implemented in that region of the world. He underlined that there is a general need for clarification of what research ethics is, to promote the establishment of platforms of RECs and facilitate efforts in terms of education and vocational training.

Dr. Harald Schmidt, Assistant Director, Nuffield Council on Bioethics, presented the main conclusions of the report on ethics and clinical trials in developing countries published by the Nuffield Council in 2002. He reported on the production of a high number of reports on research ethics and developing countries (from WHO (2002) to EGE (2004), from CIOMS (2004) to WHO -ongoing), a phenomenon which shows not only the complexity of this issue but also its relevance for global governance of science. Dr. Schmidt underlined the difficulty in addressing issues related to the follow up of completed trials in regard to subsequent medical treatments for the patients involved in the research trials. He mentioned the EDCTP, Global Forum on Research Bioethics and other target initiatives oriented to promote a dialogue on the issues above as well as a mechanism of implementation of ethics guidelines in research practices being carried out in developing countries. Dr Schmidt also reported on the need to properly address the balance between institutionalised moral agencies and local actors, a balance which is complex not only because of socio-economic considerations but also because are to face risk and emergency situations (epidemics e.g.)

Debate:

From the debate the following items were stressed and discussed:

- Some pro-active role may be taken by scientific journals by refusing the publication of papers reporting results of trials non-ethically sound developing internationally collaborative editorial guidelines for researchers/authors to comply with.
- The link between ethics standards and local values is hard to find however, the existence of local values systems should not justify the lack of full respect of minimal ethics standards and human rights protection.
- A mechanism of using developing countries to escape rules and standards of developed countries must be avoided and opposed by all means.
- It was also noted that as far as international dimension on ethics is concerned an open and creative dialogue on diversity has a central role and an adequate space for own

development for those countries with less established frameworks is essential for both progress and mutual learning.

The Forum session was closed by a first intervention of **Prof. Holger Baumgartner**, Medical University Innsbruck, Austrian Bioethics Commission. Prof. Baumgartner reported on an ongoing proposal to establish a UN prize on ethics and science. He also appealed to the EC to consider this option as a tool to favour the integration of ethics into scientific practices globally and to give attention to the developing world.

The Forum was then closed by **Prof. Christine Mannhalter**, Medical University Vienna, Vice-Chair Austrian Bioethics Commission and **Dr P. Zilgalvis**, Head of unit Ethics and Science, European Commission who thanked particularly the participants and the Austrian hosts for all their work and active engagement to make the Forum a success.



Maurizio SALVI (Secretary of the NEC Forum)