Oviedo Convention in Central and Eastern Europe
Overview of the Country Reports Presented and the Conference Conclusions

Jozef Glasa

Institute of Medical Ethics and Bioethics n. f.; Institute of Pharmacology and Clinical Pharmacology of the Slovak Medical University; Bratislava, Slovak Republic

Introduction

Delegates from 13 CEE countries took part in the International Bioethics Conference – Oviedo Convention in Central and Eastern European Countries, which was held in Bratislava (Slovakia) on September 24 – 25, 2009 (details at www.bioethics.sk). The meeting was prepared by the Secretariat of the Steering Committee on Bioethics (CDBI) of the Council of Europe (CoE), in collaboration with the Slovak Ministry of Health, Slovak Medical Association and the Institute of Medical Ethics and Bioethics n. f. in Bratislava as a regional international conference under the CoE’s Program DEBRA.

The delegates were considering the characteristic traits of the situation and major challenges these countries face with regard to the area of biomedicine and health care and to the striking transition processes in these sectors and in general. Furthermore, they were looking into possible contributions and impact Oviedo Convention and its Additional Protocols may have had on the development of a novel biomedical and health care legislation, as well as on the promotion and observance of the good practices in their respective countries. Moreover, in preparation for the conference, Secretariat of CDBI undertook a special questionnaire survey on the relevant situations present in the CEE countries. The delegates were also looking into the possible ways forward in the processes of ratification and implementation of the Convention and its Protocols in their respective countries.

Situation in CEE Countries

In reporting and considering their respective countries’ situations, the delegates noted that there were both striking differences and similarities/common traits present. Importance of a country non/membership in the European Union was also pointed out (it provides for many of the said differences – economical, social, cultural, and political). The similarities and differences were observed also with regard to the signing/ratification processes of the Convention and its Protocols in CEE countries.

Most of the countries experienced, or are still experiencing complex transitions with regard to their political, economical and cultural lives. The transition is present in the countries in its various phases (early, medium, late, ‘soon after’). It may also work in different phases in different sectors of a particular country. Those transitions were (and still may be) marked by unprecedented changes (social, cultural, economical, moral) that include/d also serious attempts in bringing about successful health care reforms (with varying degree of success/failure). There was (and still is) a strong need to introduce, develop, or improve the good practices, as well as the perceived necessity of a legal support of the reforms – past and ongoing. It is seen as a pressing necessity in re/drafting the various national legislations, and also to re/develop the national ‘soft law’ documents (guidelines, recommendations, codes of practice, standard procedures, etc.).
In struggling with the enormous demands posed by the novelty of processes and tasks of their complex transition efforts, the CEE countries were offered and provided with a lot of professional/expert help. It was coming from various international sources (e.g. European Commission, Council of Europe, World Health Organization, World Medical Association, various international organizations, university centres – European and overseas (USA), and international NGOs). In this, the legal expertise help provided by the existence and subsequent development of the Oviedo Convention and its Additional Protocols was of a special importance.

**Contribution of Oviedo Convention and its Additional Protocols**

The delegates noted that the Oviedo Convention and its Protocols had been an important resource in re/drafting their own national health care and biomedical legislation. This resource should be seen not only in the texts of the Convention and its Protocols, but equally important have been the texts of Explanatory memoranda, recommendations, working and “white” papers, reviews, invited papers, survey results and other materials prepared by CDBI and its Secretariat. The regular and sometimes personal continuous participation of the country representatives in CDBI (CAHBI) work, especially in deliberations and consultations during the preparatory processes of CDBI materials and documents was pointed out as a very useful education and information opportunity.

The value of various activities (especially bilateral and multilateral seminars and conferences) organised within the CoE’s DEBRA Program was particularly emphasised. It was also noted that several countries that had originally benefitted from the DEBRA Program activities were able, later on, take part in DEBRA activities in other CoE member states.

The information and principles of the legal solutions contained in the Convention, its Protocols, in recommendations and various other materials prepared by CDBI, its Secretariat and Working Parties have been used by the CEE states in several modes, e.g. by: a) taking up the formulations of the principles contained in the Convention/Protocols and their re/formulation into the country’s own legal language, b) taking portions of the texts translated (almost unchanged) into the new national legislation, c) using as a help in defining novel legal notions/terms.

Interestingly, the existence of a feedback mechanism was pointed out by some delegates: the CEE countries’ delegations contributions to CDBI (CAHBI) debates, including the presentations of the countries’ legal solutions, influencing the CDBI debates on the newly prepared texts.

The delegates identified as the most important issues, i.e. those, where the Convention and its Protocols contribution was probably most substantive the following items: protection of human dignity, human rights – rights of the patient, informed consent, protection of persons not able to consent, ethics of biomedical research, transplantation, genetics – genetic tests for health purposes. They also pin-pointed some important issues still missing in, or dealt with insufficiently by the existing Convention and its Protocols texts (especially at the legally binding level): protection of the embryo, assisted reproduction, end-of-life decisions, mental health, and also long list of the newest or ‘emerging issues’ (e.g. nano-medicine, regenerative medicine, IT implants, human enhancement, etc.).
CEE Countries’ Needs

The delegates discussed also the more-less specific needs of CEE countries in the area of biomedical and health care legislation and good practices development and implementation. The need to catch up with ‘the delays’ in their respective legislation developments and filling in the gaps in drafting the legislation still missing was underlined. Here, the Convention and its Protocols texts, as well as the information in the explanatory memoranda and preparatory materials and information may be especially helpful. Several delegates stressed the urgency to develop the national legislations (legislation and/or the ‘soft law’) on the newer or ‘emerging’ issues in biomedicine and health care (see above).

The successful implementation of the existing biomedical and health legislation in practice (i.e. developing and implementing of the good practices, standard procedures, ‘know how’, ‘producing’ well educated professionals, education of public – ‘professional’ and general, education of journalists, media, politicians, etc.) was seen as an equally important and pressing need (in several countries the problems in this respect were pointed out: “…the existing legislation does not work…”).

In increasing the effectiveness of the national development processes, sharing of the national experiences and previously elaborated solutions (ethical/legal) was identified as another strong need. Several possibilities for the CEE countries to work together were pin-pointed (e.g. various forms of networking; development and sharing of the databases of the relevant ‘know how’ and information; meetings of experts/professionals; exchange of students (including doctoral – postgraduate) and professionals, etc.).

Suggestions for the Future CDBI Work

In conclusion of their deliberations the countries’ delegations tried to identify and formulate some suggestions for future work of the Council of Europe – in particular of the Steering Committee on Bioethics – in the biomedical and health area. In this respect, continuation of the standard setting work of CDBI – especially on the ‘missing issues’ and ‘newer/newest issues’ – was strongly advocated. Also CDBI continuation in the guidance producing activities to enhance the implementation of already existing legal texts and recommendations was supported (such as e.g. the CoE’s Guide for Research Ethics Committees). Further support for DEBRA program or for similar CoE supported (and funded) regular activities was seen as necessary (possible room for improvements was indicated).

Delegates also advocated the need for a concrete support of information activities aimed both at the professionals, politicians, and at the general public – development of novel approaches and use of contemporary and emerging information technologies was strongly recommended. The already conducted collection of relevant documentation and information in the field was applauded, but the need for further improvements was also articulated – including the need of providing for the necessary logistical and institutional support. This may possibly be done more effectively by developing and increasing collaboration with other partners in the field, to avoid duplicities and waste of precious resources (e.g. CoE and EU collaboration within dedicated FP projects).

The idea of providing a better institutional support for the research on bioethical/bio-law issues, especially with participation of young investigators and with enhanced possibilities for them to work at CoE and/or EU institutions and at the leading European academic and research institutions was supported by all delegations. The need for better and increased
abilities and opportunities of working together/networking at the bilateral/multilateral, regional levels, EU and CoE and Global level was understood as basic pre-requisite for future work and development.

The most important common goal in this area, i.e. in the biomedical ethics and bio-law, should be the development of a possible ‘common European ethical space/area’, enabling all European countries to face the ‘upcoming new’ and ‘persisting old’ ethical challenges in the biomedicine and health sectors together.

About the Author

Assoc. Prof. Jozef Glasa, M.D., PhD., PhD. – physician and clinical researcher, teaches clinical pharmacology, therapeutics, hepatology and bioethics at the Slovak Medical University (SMU), Bratislava. Deputy head, Institute of Pharmacology and Clinical Pharmacology SMU; director, Institute of Medical Ethics and Bioethics n. f.; editor, Medical Ethics & Bioethics; past chairman, member, Ethics Committee, Ministry of Health, Slovak Republic (SR); president, Slovak Society of Clinical Pharmacology; scientific secretary, Slovak Society of Hepatology; member, Council of Europe Steering Committee on Bioethics (CDBI), past Bureau member of CDBI and of COMETH; member, European Group on Ethics in Science and New Technologies (EGE); Board member of the European Forum of Good Clinical Practice (EF GCP).

Correspondence to: Assoc. Prof. Jozef Glasa, MD, PhD., PhD., Institute of Medical Ethics and Bioethics n. f., Vysoká 32, 81106 Bratislava, Slovak Republic, e-mail: jozef.glasa@szu.sk