MEDICÍNSKA ETIKA & BIOETIKA

MEDICAL ETHICS & BIOETHICS

ČASOPIS PRE MEDICÍNSKU ETIKU A BIOETIKU

■

JOURNAL FOR MEDICAL ETHICS AND BIOETHICS

ISSN 1335-0560

BRATISLAVA, SLOVAK REPUBLIC
Spring – Summer 2002 Vol. 9 No. 1 – 2

OBSAH / CONTENTS

OD REDAKCIE / EDITORIAL

COLLABORATION AND NETWORKING IN BIOETHICS IN CENTRAL AND EASTERN EUROPEAN COUNTRIES

The countries of Central and Eastern Europe (CEE) - that have emerged from behind the sadly known „Iron Curtain“ after more or less turbulent ‘revolutionary’ events of the early nineties of the former century - are striving to catch up the lost history train of economical, technological and social development enjoyed by their, so far, ‘more fortunate siblings’ inhabiting the ‘big European House’. Though the goals seem to be clear, the ways or paths of the necessary transformations are far from being simple, safe, or easy-to-walk. The transformations of health care systems, for example, have brought in a lot of problems and instabilities, followed by serious drops in health parameters in several of these countries. Though apparently stable health care systems of the previous totalitarian period had already reached the edges of their sustainability long before the eager ‘democracy-fuelled’ transitions started - having been weakened substantially by the years of corruption, insufficient funding (especially concerning the necessary investments into the new technologies, instruments, infrastructure and modernisation), as well as by the mismanagement and wastage of their material, technological and manpower resources - the reforms undertaken have sometimes brought in new, unexpected problems, fears, and even some nostalgia after the ‘Uncle State’, especially in members of the older generations.

In these challenging situations, in many of the CEE countries, a new scientific discipline has been born - sometimes as an imported baby from the USA or the ‘West’, and - because she has been rooted strongly both in the life sciences (esp. (molecular) biology, medicine and environment) and in ‘practical’ philosophy (ethics) - she started her life bearing the ‘nick name’ BIOETHICS (bio-medical ethics). For the decade to come after her (re-)birth in the nineties, bioethics in CEE countries was looking both around (mostly to the ‘West’ or even overseas) and into her own respective country for the necessary nourishment, help and inspiration, and also for the reliable people to lay herself upon in her later years of life. Nowadays, ‘new bioethics’ in CEE countries slowly approaches her „adolescence“. This phase of her ‘life’ seems to be marked, among other nice ‘developmental’ signs of growth and maturation, also by her coming out to find friends and a ‘good company’, both in CEE and beyond.

In August 2000, for example, the Central and East European Association of Bioethics (CEEAB) was officially found, following the efforts of Prof. Béla Blasszauer (Pécs, Hungary) and a group of devoted bioethics scholars and friends from several CEE countries. Though the Association has not inherited money or any material property, its members share an optimistic common vision, broad spectrum of multidisciplinary experience, and also ‘great expectations’ believed to become true in fostering the CEEAB’s aims and goals.

(continued at p. 9)

Reklama

Advertisement

ETHICAL AND JURIDICAL FOUNDATIONS OF CONSCIENTIOUS OBJECTION FOR HEALTH CARE WORKERS

Gabriella Gambino, Antonio G. Spagnolo

Institute of Bioethics, Catholic University of the Sacred Heart, School of Medicine, Rome, Italy

Abstract

In front of the evolution of medicine and biotechnology, health care workers are called upon to take part within new biomedical practices, that may overcome the limit of acceptability, as it is perceived by their moral conscience. Issues as abortion, euthanasia, assisted suicide, artificial fertilisation, experimentation on human embryos and prescription of contraceptives and abortifacients call into play the *right to conscientious objection* of health care personnel, and in some cases, perhaps of physicians and pharmacists too. This recall - already present in many codes of professional conduct and medical ethics - sounds today as a necessity, which asks for a serious deepening of the content, the applicability and the new hypothesis of conscientious objection, in the light of bioethics and law. In particular, the self-determination and often exasperated autonomy of the patient within these practices makes a new principle of *professional integrity* arise, to protect the physician's conscientious convictions, if the request of the patient or society seem to violate some fundamental human values.

Key-words: conscientious objection, right to, professional integrity, codes of ethics, patient's autonomy, health care workers.

The continuous evolution of science and technology within medicine and biology, if on one side makes possible always bolder interventions on human life, from conception to death, on the other side puts more and more relevant ethical questions to the conscience of health care personnel. Physicians, in fact are called upon to take part within biomedical practices, that even when normatively legitimated, often overcome the limit of acceptability, as it is perceived by moral conscience.

It is commonly experienced the charge of ethical questionability caused by issues as abortion, euthanasia, artificial fertilization, experimentation on human embryos, prescription of contraceptives and abortifacients and assisted suicide. These issues, in fact, call into play the respect of fundamental values of human person, first of all the value of life and of its dignity.

In front of them, the assertion of the *right to conscientious objection* of health care personnel by the legislator appears as an essential element of professional conduct and medical ethics for the integrity and for the responsible practice of medical professions.

The codes of professional conduct and medical ethics after Nuremberg have only partially asserted the *right to conscientious objection*, even if the importance of conscience in the field of law had been underlined by the International Tribunal of Nuremberg, which stated the insufficiency of the written law and the superiority of the moral law, as it is normally perceived by human conscience. The complexity of this clause is proved by the International Code of Medical Ethics (WMA, 1983), in which the original statement «therapeutic abortion may only be performed if the conscience of the doctors and the national laws permit» was deleted from the adopted version, because of its controversial nature.

Recently, the European Convention on Human Rights and Biomedicine rejected the recall to conscientious objection proposed by the Italian delegates, in the name of an exasperated self-determination of the patient, which exposes the physician to the risk of being transformed in a passive executor of his or her will. In Europe, this rejection will bring to a normative unlikeness concerning one of the fundamental rights of human person.

But what is it exactly conscientious objection? The subjective right to conscientious objection is the faculty - of health care personnel - to refuse a rule laid by an authority because of its contrast with another fundamental rule of human life, as it is perceived by conscience, which prevents from acting as it is prescribed.

The content of objection develops in a two-fold direction: a negative one, of rejecting a rule, and a positive one, of proposing a value or a system of values, which the subject joins. The objection is founded on the respect of the individual's conscience and it develops in the difficult balance among three elements: „bindingness" of law, so that law must be respected; coherence between civil norm and moral value, so that a law that violates the moral value is not a law and may be transgressed; dignity of person and of his conscience, a value that civil orders must respect.

A specific characteristic of an objector, in fact, is that he does not refuse the whole right, but only the particular norm, with the intent of not making law clashing with right, saying «no» to the law because and only when he considers it a bad determination of right. As a reply to the call of the duty that makes its way in the conscience, objection is founded on the idea that the *truth of right* does not take origin from the political activity, but it is a premise of it. In this sense, objection is always on the part of the legislator, calling him to be faithful to the correct use of power, and revealing itself as a moment of mediation between the truth of right and the concrete historical processes.

The objector, in fact, «do not refuse the principle *auctoritas, non veritas facit legem*», but puts besides it the principle «*veritas, non auctoritas facit ius*».

Objection does not refer to strength, but can be witness of truth, based on the research of common good and of common knowledge (*cum-scientia*).

It means that in democratic states, conscientious objection may bring to light the constitutive link between politics and truth, between the „ontic" and ontological level, among which there is a distinction but also a necessary communicability.

Referring to health care personnel, conscientious objection has a two-fold worth: as right and as duty. As a duty of conscience, objection is based on the first moral principle *bonum faciendum, malum vitandum*, that compels the health care personnel to avoid any form of direct or indirect cooperation with actions aiming to the repression of human life. «Doctors and nurses are obliged to be conscientious objectors. The great, fundamental value of life makes this obligation a grave moral duty for medical personnel, encouraged by the law to carry out abortions or to cooperate in it. Naturally, it is not always easy to follow one's conscience in obedience to God's law. It may entail sacrifice and disadvantages [.], sometimes heroism. Nevertheless, it must be clearly stated that the road of genuine progress for the human person passes through

this constant fidelity to a conscience upholding rectitude and truth».

As a right, the statement of objection is more recent and it is based on the respect of the individual's freedom of conscience, expressed in the constitutions of civil nations and in the art. 18 of the «Universal Declaration of Human Rights».

Moreover, the Declaration of Geneva (1948-1983) says that the physician has to «practice his profession with conscience and dignity» and the Guide of the Canadian Catholic Health Association (1991) states «the exercise of conscientious objection in order to protect individual freedom».

Nevertheless, this right is not undisputed: if on one side, the freedom of conscience allows to respect the moral option of health care personnel, on the other side it can appear as a violation of the patient's autonomy, who asks the physician a specific treatment.

Undoubtedly, in the last century the physician-patient relationship has changed its structure. It has moved from the classical relationship based on the subjection and obedience of the patient to the physician - often degenerating in paternalism - to a relationship mainly based on the patient's autonomy, conceived as the expression of his right of self-determination and of his individual freedom.

However, recently, the principle of *deontological integrity of health care professions* is going to be stated as a limit to the patient's autonomy, as it is asserted in the Preamble of the *Canadian Code of ethics for nursing* (1985-1991), in the *American Pharmaceutical Code of ethics* (1969-1981), and in the *Code of ethics of the physician assistant profession* (1983-1990). Moreover, in the case of conscientious objection, it could be hypothesized an obligation to refer or to transfer the patient to another physician. This questionable obligation is stated, for example, into many recent natural «death acts», which do not mandate coercion of physician's conscience in carrying out a patient's advance directives, and do require physicians to make a reasonable effort to transfer the patient to another doctor. The same principle, and the duty of informing the patient, are established in the *Canadian and New Zealand guides to the ethical behavior of physicians* (1990), the *Code of medical ethics of Brazil (*1988*), the Codes of Ethics of Chile* (1983) *and Norway* (1992)*, the European Code of Medical Ethics* (1987) and *the Declaration of Oslo on Therapeutic Abortion (1970).*

Anyway, the physician's conscientious convictions should always be respected, if the patient's request or refusals seem morally repugnant. In this case the physician can withdraw, assuming that the requested actions are not among the responsibilities one generally accepts in agreeing to be someone's physician. A patient's right of autonomy, in fact, should not be purchased at the price of the physician's parallel right.

For this reason it is important to recover the *intersubjective* relationship of the therapeutic dynamics, which characterizes man's structure, and that is expressed in the *respect for others life* in itself, as a necessary condition for any other existential relationship. The typical cases that arise in the conscience of health care personnel are those directly linked to the principle *not to kill*, supreme transgression of human relationship. This relationship constitutes the essence of medicine, in which each ethical problem becomes a dialogical question between physician and patient, contemplated in all the deontological rules concerning conscientious objection, , provided that there is not any serious and immediate risk for the patient's life.

As to the rules that contemplate the possibility of conscientious objection, the main reference is to the laws that the most of the European countries have promulgated concerning abortion and to the European Code of Medical Ethics (art. 18, 1987). In some of this rules, the physician's refusal of practicing abortion does not contrast with the woman's right to abortion, since many laws that decriminalize abortion - as the Italian one- do not state a *right,* but only the possibility for an exception to the general principle of the protection of human life. The legislator himself, recognizing in particular cases the primacy of the mother as to the fetus, tried to transform himself in the source of a «woman's right», giving her an ontological and axiological primacy as to the unborn child. That's why the legislator himself, realizing of having violated a fundamental value of civil orders - as it is the protection of human life - chose to reestablish the axiological balance, foreseeing conscientious objection for the health care worker who perceived the immorality of the abortifacient intervention.

However, other biomedical practices are now under the attention of the legislator for their evident ethical implications, and regarding which we propose to enclose the possibility of conscientious objection. Relating to some of these issues, there are particular deontological indications. Conscientious objection to euthanasia and assisted suicide is contemplated in the Current Opinions of the American Medical Association. Referring to these two issues, in the case of some recent national deontological codes, as the Italian one, it appears particularly questionable the introduction of norms, which oblige the physician to give juridical relevance to the manifestation of will, previously expressed by the patient, who is in danger of life (art.34). This kind of norm, which introduces the debated principles of the «living will», is deeply in conflict with the norm, stated in the same code (art.36), which prevents euthanasia (also passive euthanasia); but also with the respect of human person, as it gives juridical strength not to an actual will, but to the foregoing will of a still living person. It is probable that many physicians will have difficulties in sharing a norm in conflict with their science and conscience, that upsets their fundamental task of safeguarding the psycho-physical objectivity of the individual. Shouldn't we arrive to propose conscientious objection to the deontological code?

Moreover, as the Canadian Health Care Ethics Guide of the Catholic Health Association suggests, the clause of conscience appears necessary also relating to artificial fertilization and to genetic manipulations, to research on human embryos and prenatal diagnosis, which violate the principle «not to kill», as they end with the death of the embryo.

The position of physicians and pharmacists is also delicate, concerning the possibility of prescribing abortifacient drugs. In these cases the pharmacist, in particular, has to take decisions, which can affect the beginning and the ending of life, and is allowed to make conscientious objection, as the drugs he can prescribe are clearly directed to the breakdown of pregnancy. The problem arises also for contraception: in this case, the bases for conscientious objection to the promotion, elaboration and distribution of contraceptives are founded on the respect of the truth of the sexual act as the expression of conjugal love, in both its unitive and procreative meanings. Contraception, in fact, is contrary to the generative possibility as to the unity of the couple too, and so to the good of the conjugal act.

In such a way, the extension of the *right to conscientious objection* to these matters will allow the health care worker to respect the truth of his conscience, within a therapeutic process which is able to «give voice» to all the parties of the physician-patient's relationship: even when this «giving voice» involves a *meta-physical* effort for those who prefer staying within the narrow borders of *physicality.*

References

1. Blustein J., *Doing what the patient orders: maintaining integrity in the doctor-patient relationship*, Bioethics, vol. 7, n. 4, 1993, pp. 289-314. The possibility of a conflict between a juridical norm and deontological directives is explicitly considered in some deontological codes, as the Italian one (1998), that in the art. 1states that principles and deontological rules must be observed, whatever the ambit and the juridical state, in which the physician works, could be. (Italian Code of Professional Ethics, 1998.) **2.** Araujo Oliver, *La objeción de conciencia al servicio militar*, Madrid, Civitas, 1993, p. 31. **3.** Bompiani A., *Una valutazione della «Convenzione sui diritti dell'uomo e la biomedicina» del Consiglio d'Europa*, in Medicina e Morale, 1997/1, pp. 37-57. Particularly significant is also that in the new version of the Italian deontological code (1998) any reference to the expression «conscientious objection» has disappeared, and has been replaced by the expression «refusal of professional performance» (art. 19). **4.** Serrat Moré D., Bernad Perez L., *Las profesiones sanitarias ante la objecion de conciencia*, in Cuadernos de Bioetica, vol. VIII, n. 30-II, 1997, pagg. 855, ss. Ciccone L., *I problemi etici dell'aborto nell'Enciclica Evangelium Vitae*, in Medicina e Morale, 1995-4, pagg. 701-718; Ferasin E., *Obiezione di coscienza crocevia tra obbedienza e disobbedienza,* Editrice Elle Di Ci, Torino, 1994. **5.** Miglietta G.M., «*Evangelium Vitae*» *tra coscienza professionale e obiezione di coscienza. Il tema dell'obiezione nel Magistero recente*, in *Evangelium Vitae and Law*, Acta Symposii internationalis in Civitate Vaticana celebrati, 23-25 maii 1996, Libreria Editrice Vaticana, 1997, pag. 407-415; Possenti V., *L'obiezione di coscienza oggi: elementi di analisi,* in Perrone B. (a cura di), *Realta e prospettive dell'obiezione di coscienza*, I conflitti degli ordinamenti, Atti del Seminario nazionale di studio, Milano, 9-11 aprile 1992, Giuffre Editore, Milano, 1992. **6.** Benjamin Martin, *Conscience*, in W.T. Reich, Encyclopedia of Bioethics, Georgetown University, Washington, D.C., 1995, 1, pp. 469-472. **7.** Evangelium Vitae, n. 71. **8.** D'Agostino F., *Il diritto come problema teologico*, G. Giappichelli Editore, Torino, 1995, pp. 185-208. **9.** D'Agostino F., *Il diritto come problema teologico,* cit., pp. 202, ss. **10.** Pontifical Council for pastoral assistance to health care workers, *Charter for health care workers,* Vatican City, 1995, n. 143. **11.** See: López Guzmán J., *Objeción de consiencia farmacéutica*, Ediciones Internacionales Universitarias, Barcelona, 1997, pp. 64-65. **12.** Other international documents, which state the freedom of conscience, are the art. 9 of the Convention of Rome for the protection of the rights of human kind and fundamental freedom (1950) and the art. 18 of the International Agreement of Civil and Political Rights of New York (1966). Within the European Community, we have to remember the Resolution n. 337 of the Consultative Assembly of the European Council and the Resolution of the European Parliament, February 7, 1983. **13.** Beauchamp T.L-Childress J.F., *Principles of biomedical ethics*, Fourth Edition, Oxford University Press, New York, Oxford, 1994, pag.479-480. Against the right to conscientious objection some authors speak about Physician's value neutrality, see: Peppin J.F., *The Christian physician in the non-Christian institution: objections of conscience and physician value neutrality*, Christian Bioethics, vol. 3, n. 1, 1997, pp. 39-54. **14.** Cotta S., *Coscienza e obiezione di coscienza, in Realta e prospettive dell'obiezione di coscienza*, cit., pp. 207-221. **15.** D'Agostino F., *Bioetica*, Giappichelli Ed., Torino, 1996, p. 38. **16.** Deontological Italian Code, 1998, art. 19; Deontological Italian Code of professional nursing, art. 11; Codigo de Deontología médica, Espana, cap. VI, art. 27.1 y 27.2; Codigo de Enfermería, Espana, cap. III, art. 22; Codigo de Veterinaria, Espana, cap. I, art.5 y 8; English Pharmaceutical Code, 1992. **17.** Dalla Torre G., *Bioetica e diritto*, Giappichelli Ed., Torino, 1993, p. 131, ss; Benciolini P., *Deontologia e obiezione di coscienza,* in Bompiani A., *Bioetica in medicina*, CIC Edizioni Internazionali, Roma, 1996, pagg. 366, ss. **18.** Paul VI, *Encyclical «Humanae Vitae»*, n. 14; López Guzmán J., *Objeción de conciencia farmacéutica*, pag. 110; **19.** D'Agostino F., *Bioetica*, cit., p. 38.

Abstrakt

Gabriella Gambino, G., Spagnolo, A. G.: Ethical and juridical foundations of conscientious objection for health care workers. [Etické a právne základy výhrady svedomia u zdravotníckych pracovníkov.] Med. Eth. Bioet., 9, 2002, No. 1 - 2, p. 3 - 5. Vzhľadom na rozvoj medicíny a moderných biotechnológií sú zdravotnícki pracovníci neraz vyzvaní, aby sa podieľali na nových biomedicínskych postupoch, ktoré môžu prekračovať prijateľné hranice, vnímané ich svedomím. Prípady ako sú umelý potrat, eutanázia, asistovaná samovražda, umelé oplodnenie, experimenty na ľudských zárodkoch a predpisovanie kontraceptív a abortívnych prípravkov nastoľujú *právo na výhradu svedomia* zdravotníckych pracovníkov, vrátane lekárov a farmaceutov. Odvolanie sa na toto právo sa nachádza v mnohých profesijných kódexoch a v kódexoch medicínskej etiky. V súčasnosti sa tento koncept javí azda ešte potrebnejší ako v minulosti, a žiada si prehĺbenie svojho obsahu a štúdium jeho uplatnenia v kontexte súčasnej bioetiky a práva. Najmä princíp samourčenia a prehnané zdôrazňovanie autonómie pacienta vo vyššie spomínaných prípadoch vedie k zdôrazneniu princípu *profesionálnej integrity,* ktorý má chrániť morálne presvedčenie lekára, pokiaľ požiadavky pacienta alebo spoločnosti narušujú niektoré základné ľudské hodnoty. *Kľúčové slová*: výhrada svedomia, právo, zdravotnícky pracovník, pacient, profesionálna integrita, etické kódexy, autonómia pacienta.

Correspondence to: Prof. A. G. Spagnolo, Centro di bioetica, UCSC, Largo F. Vitto 1, Rome, Italy.

K DISKUZI O EUTANAZII V ČESKÉ REPUBLICE

Květoslav Šipr

Univerzita Palackého, Olomouc, ČR

Abstrakt

Otázky eutanazie se stávají častým předmětem veřejných diskuzí, postoje k eutanazii bývají ovlivněny náboženským přesvědčením. U souboru 364 mladých lidí, kteří konkrétním projevem vyjádřili svůj pozitivní postoj ke katolické církvi, se sledovaly jejich názory na eutanazii. S obecnou legalizací eutanazie souhlasilo méně než jedno procento dotázaných, avšak téměř čtvrtina projevila souhlas s umožněním eutanazie ve zcela výjimečných případech. Podrobnější rozbor prokázal, že liberálnější přístup souvisel především s nedostatečným poučením a s neschopností podat přesnou definice eutanazie. Ukazuje se potřeba věnovat pozornost postojům k eutanazii také u osob věřících.

Klíčová slova: eutanazie, situace v České republice, názory mladých lidí, vliv náboženského přesvědčení.

Úvod

V minulosti byla eutanazie v České republice obecně považována za nemorální a právně nepřijatelnou. Usmrcení z útrpnosti je dosud chápáno jako úmyslné zabití a podle trestního zákona klasifikováno jako vražda. [1] Také etický kodex České lékařské komory z roku 1995 hovoří jednoznačně: Eutanazie a asistované suicidium není přípustné. [2]

Pozoruhodnou iniciativu vyvinul v roce 1996 tehdejší ministr spravedlnosti České republiky Jiří Novák, když prohlásil: „Lékaři by neměli být trestáni, pomohou-li zemřít nemocným lidem, kteří si přejí smrt."[3] Stanovisko ministra spravedlnosti podpořil Miroslav Mitlöhner z Ústavu státu a práva Akademie věd České republiky: vyjmenoval pět situací, ve kterých by se mělo uvažovat o eutanazii. [4] Výčet ovšem zahrnoval také nemocné, kteří by se k případnému návrhu eutanazie kompetentně vyjádřit vůbec nemohli. Doporučoval totiž rozšířit úvahy o eutanazii též na „velice staré, fyzicky a psychicky otupělé lidi, kteří již ničím nepřipomínají svoji bývalou osobnost" a na „těžce psychicky a fyzicky poškozené novorozence, u nichž není reálná vyhlídka na sebemenší zlepšení zdravotního stavu". Autoři převážné většiny příspěvků otištěných v odborných časopisech se ovšem k předkládanému návrhu vyslovovaly negativně. [5] Ani sonda zaměřená na poznání postojů studentů medicíny k eutanazii nevyzněla v její prospěch. [6]

Diskuze k otázkám eutanazie se znovu oživila v letech 2000 a 2001 v souvislosti s přijetím návrhu na legalizaci eutanazie dolní i horní komorou holandského parlamentu. [7] Odborná veřejnost je ovšem i nadále k možnosti legalizace eutanazie značně zdrženlivá. [8]

Zahraniční studie potvrdily i teoreticky odůvodněný předpoklad, že názory na eutanazii jsou do značné míry ovlivněny náboženským přesvědčením. Jevilo se proto užitečným zjistit postoje k eutanazii u osob, které konkrétním vnějším projevem vyjádřily pozitivní vztah ke katolické církvi, ke které se podle výsledků sčítání lidu dosud stále hlásí nejvíce obyvatel České republiky.

Vlastní soubor a metodika

Studie se uskutečnila v době od 15.10.2000 do 15.12. 2000 a byla zaměřena na mladé lidi - věřící katolíky nebo

osoby s katolickou církví sympatizující. Kritériem bylo studium na církevní škole, na katolické teologické fakultě, anebo účast ve společenstvích mladých lidí ve farnostech. Náhodným výběrem byla vytvořena skupina 392 osob, studentů Cyrilometodějské teologické fakulty v Olomouci, církevního gymnázia v Hradci Králové, biskupského gymnázia v Brně a účastníků setkání společenství rodin a neformálních skupin mladých lidí ve farnostech v Brně a ve Zlíně.

Všichni byli seznámeni s cílem studie a vyzváni k vyplnění dotazníku, který obsahoval otevřené, polootevřené i zavřené otázky. Z celkového počtu 392 dotázaných vrátilo vyplněný dotazník 364 respondentů (návratnost 93 %), kteří pak tvořili vlastní zkoumaný soubor. Bylo v něm zastoupeno 134 gymnaziálních studentů (79 studentů církevního gymnázia v Hradci Králové a 55 studentů biskupského gymnázia v Brně), 161 studentů Cyrilometodějské teologické fakulty v Olomouci (103 studenti denního studia oboru teologie a 58 studentů kombinovaného studia oboru charitativně sociální práce a oboru křesťanská výchova) a 69 účastníků neformálních farních společenství mladých lidí v Brně a ve Zlíně. Nejmladšímu členu souboru bylo 17 a nejstaršímu 35 let.

Otázky obsažené v dotazníku se týkaly názoru na vhodnost legalizace eutanazie, na přednosti a rizika eutanazie i na důvody, které vedou nebo mohou vést k vyslovení žádosti o eutanazii. Respondenti byli rovněž vyzváni k napsání definice eutanazie. Poslední otázka pak byla zaměřena na prevenci žádosti o eutanazii.

Za správnou definici eutanazie byla modelově považována formulace: „Eutanazie je úmyslné ukončení života těžce nemocného na jeho žádost, a to lékařem: ať již jeho aktivním jednáním nebo vynecháním indikované léčby."

Úplná definice eutanazie tedy měla obsahovat čtyři znaky: 1. úmysl způsobit smrt, 2. přítomnost těžké choroby, 3. žádost vyslovená kompetentním pacientem 4. uskutečnění zákroku lékařem. Odpověď obsahující všechny čtyři rysy byla označena jako přesná, při chybění jednoho znaku jako přibližně správná, při chybění dvou znaků jako nedostačující a při chybění tří nebo čtyř znaků jako odpověď zcela špatná.

Všechny odpovědi byly statisticky dvoustupňově zpracovány a významnost výsledků byla posouzena pomocí Cramerova ukazatele.

Výsledky

Názory na legalizaci eutanazie

Pro obecné povolení eutanazie se vyslovili pouze 3 respondenti, čtvrtina považovala za vhodné povolit eutanazii ve výjimečných případech a dvě třetiny s povolením eutanazie nesouhlasily. Více než devět desetin studentů teologie eutanazii odmítlo, mezi gymnaziálními studenty však mírně převažovali zastánci výjimečného povolení eutanazie (**tab. 1**).

Tab. 1
Názory na vhodnost legalizace eutanazie

Povolit eutanazii ?	Ano		Zcela výjimečně		Ne		Neví		Celkem	
	N	%	N	%	N	%	N	%	N	%
Studenti gymnázií	2	1,5	56	41,8	52	38,8	24	17,9	134	100,0
TF - denní studium	1	1	6	5,8	94	91,3	2	1,9	103	100,0
TF - kombinované studium	0	0	13	22,4	39	67,2	6	10,4	58	100,0
Společenství	0	0	10	14,5	48	69,6	11	15,9	69	100,0
Celkem	3	0,8	85	23,6	233	64,0	43	11,8	364	100,0

Tab. 2
Přesnost definice eutanazie

Definice eutanazie	Přesná		Přibližně správná		Nedostačující		Zcela špatná		Celkem	
	N	%	N	%	N	%	N	%	N	%
Studenti gymnázií	24	17,9	53	39,6	39	29,1	18	13,4	134	100,0
TF - denní studium	60	58,2	31	30,1	10	9,7	2	2,0	103	100,0
TF - kombinované studium	27	46,6	21	36,2	6	10,3	4	6,9	58	100,0
Společenství	30	43,5	23	33,3	10	14,5	6	8,7	69	100,0
Celkem	141	38,7	128	35,2	65	17,9	30	8,2	364	100,0

Tab. 3
Přesnost definice eutanazie - podle postoje k její legalizaci

Definice eutanazie	Povolit eutanazii?									
	Ano		Zcela výjimečně		Ne		Nevím nebo bez odpovědi		Celkem	
	N	%	N	%	N	%	N	%	N	%
Přesná	0	0,0	11	7,8	127	90,1	3	2,1	141	100,0
Přibližně správná	1	0,8	35	27,3	78	61,0	14	10,9	128	100,0
Nedostačující	2	3,1	26	40,0	22	33,8	15	23,1	65	100,0
Zcela špatná	0	0,0	13	43,3	6	20,0	11	36,7	30	100,0
Celkem	3	0,8	85	23,4	233	64,0	43	11,8	364	100,0

Pozitivní stanovisko (odpovědi ano a zcela výjimečně) bylo odůvodňováno zejména odstraněním utrpení nemocných (36,6% kladných odpovědí) a právem člověka rozhodovat o své smrti (22,1%). Odpůrci eutanazie argumentovali především tím, že nikdo nemá právo brát, co sám nedal (45,9% záporných odpovědí) a že žádný důvod neospravedlňuje k zabití nevinného (32,6%). Některou z obou těch odpovědí uvedlo jako hlavní důvod negativního stanoviska k legalizaci eutanazie dohromady 78% respondentů. Třetím uváděným důvodem bylo riziko zneužití eutanazie (18,3%).

Znalost obsahu pojmu eutanazie

Podle hodnotící škály popsané v kapitole o použité bylo možno tři čtvrtiny odpovědí hodnotit jako přesné nebo přibližně správné a jen 8% odpovědí bylo zcela špatných. Podíl přesných odpovědí byl nejvyšší u studentů teologie a nejnižší u gymnaziálních studentů (**tab. 2**).

Podstatně lépe eutanazii definovali respondenti legalizaci odmítající, než respondenti, kteří s legalizací eutanazie souhlasili - ať již obecně nebo pro výjimečné případy (**tab. 3**). Do skupiny zcela špatných odpovědí byly přitom zařazeny i dva případy, ve kterých odpověď nebyla uvedena vůbec.

Předpokládané výhody legalizace eutanazie

Téměř polovina respondentů neshledávala na případném povolení eutanazie žádnou přednost, čtvrtina hodnotila kladně především odstranění utrpení. Desetina dotázaných uvedla jako hlavní výhodu případné legalizace eutanazie ušetření finančních nákladů, zbylé prostředky pak bude možno věnovat na léčbu perspektivnějších nemocných (**tab. 4**). Žádné přednosti na případné legalizaci eutanazie nespatřovaly dvě třetiny studentů teologie a více než polovina respondentů ze společenství ve farnostech.

Rizika případné legalizace eutanazie

Pouze 2 procenta respondentů se neobávala možnosti zneužití eutanazie, téměř pětina členů souboru uvedla jako hlavní riziko odstraňování nepohodlných osob. Převážně studenti gymnázií vyjadřovali obavy z možné snahy uspíšit smrt příbuzných pro získání dědictví. Studenti kombinovaného studia teologické fakulty projevovali obavu zvláště ze špatného stanovení prognózy (**tab. 5**).

Okolnosti, které vedou nebo mohou vést k vyžadování eutanazie

Za nejčastější důvod vyžadování eutanazie se považovala bolest a bezmocnost, mezi přepokládanými důvody se však často vyskytoval také pocit beznaděje a opuštěnost (**tab. 6,** s. 8).

Jak předcházet žádostem o eutanazii

Čtyři desetiny respondentů považovaly za nejdůležitější spirituální podporu nemocných: přispívat k chápání smyslu utrpení, podporovat křesťanskou naději a porozumění pro transcedenci. Čtvrtina dotázaných zdůrazňovala nezbytnost psychologické podpory: potřebu nemocné v jejich chorobě doprovázet a přispívat k uchování jejich vědomí užitečnosti. Pětina respondentů kladla důraz především na vysokou úroveň zdravotní péče, byli mezi nimi zvláště studenty gymnázií. (**tab. 7,** s. 8).

Diskuze a závěry

Letmý pohled do historie napovídá, že mnohé autority starého Řecka i Říma považovali zabití nevyléčitelně

Tab. 4
Výhody případné legalizace eutanazie

Výhody	Odstraní se utrpení		Ušetří se peníze		Beztrestnost lékaře		Odstraní se utrpení a ušetří se peníze		Autonomie pacienta		Žádné		Celkem	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Studenti gymnázií	48	35,9	16	11,9	10	7,5	8	5,9	12	8,9	40	29,9	134	100,0
TF - denní studium	15	14,8	9	9,0	4	4,0	6	4,9	1	1,0	68	66,3	103	100,0
TF - kombinované studium	7	12,2	4	6,9	5	8,6	10	17,2	3	5,1	29	50,0	58	100,0
Společenství	20	29,4	6	8,8	2	2,9	3	4,4	1	1,5	37	53,0	69	100,0
Celkem	90	24,7	35	9,6	21	5,7	27	7,4	17	4,6	174	48,0	364	100,0

Tab. 5
Rizika legalizace eutanazie

Rizika eutanazie	Možnost zneužití		Získat dědictví		Častěji provádět		Rozhodování v nesvobodě		Odstranit nepohodlné		Mylná prognóza		Nespravedlivé zabití		Žádné		celkem	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Studenti gymnázií	29	21,5	24	17,8	10	7,5	13	9,8	28	21,2	24	17,8	1	0,7	5	3,7	134	100
TF - denní studium	17	16,5	12	11,7	9	8,7	11	10,7	12	11,7	19	18,4	22	21,3	1	1,0	103	100
TF - kombinované studium	5	8,6	6	10,4	6	10,4	6	10,4	10	17,2	16	27,6	9	15,4	0	0	58	100
Společenství	20	29,0	7	10,2	3	4,4	3	4,4	19	27,4	6	10,2	9	13,0	1	1,4	69	100
Celkem	71	19,0	49	13,5	28	7,7	33	9,1	69	19,0	66	18,1	41	11,3	7	1,9	364	100

Tab. 6
Které okolnosti se považují za rozhodující pro vyžadování eutanazie * (*respodenti mohli uvést více než jednu odpověď)

Důvod pro vyžádání eutanazie	Bolest		Beznaděj		Bezmocnost		Zatěžování		Opuštěnost		Počet respondentů	
	N	%	N	%	N	%	N	%	N	%	N	%
Studenti gymnázií	82	61,0	58	43,3	83	61,9	32	23,9	38	28,3	134	100,0
TF - denní studium	78	75,7	37	35,9	75	72,8	55	53,4	55	53,4	103	100,0
TF - kombinované studium	46	79,3	27	46,6	37	63,8	26	44,8	19	32,8	58	100,0
Společenství	45	65,2	40	58,0	49	71,0	22	31,9	31	44,9	69	100,0
Kolikrát byly jednotlivé odpovědi uvedeny	251	68,9	162	44,5	244	67,0	135	37,1	143	39,3	364	100,0

Tab. 7
Jak předcházet žádostem o eutanazii

	Zdravotní péče		Psychologická podpora		Spirituální podpora		Nepovolit eutanazii		Nelze nic dělat		Celkem	
	N	%	N	%	N	%	N	%	N	%	N	%
Studenti gymnázií	35	26,0	25	18,7	43	32,1	8	6,0	23	17,2	134	100,0
TF - denní studium	14	13,6	33	32,0	50	48,6	6	5,8	0	0	103	100,0
TF - kombinované studium	13	22,4	10	17,3	31	53,4	4	6,9	0	0	58	100,0
Společenství	12	17,4	23	33,3	24	34,8	2	2,9	8	11,6	69	100,0
Celkem	74	20,3	91	25,0	148	40,7	20	5,5	31	8,5	364	100,0

nemocného za akt milosrdenství. Mezi stoupence jednání, které dnes považujeme za eutanazii, lze nepochybně zařadit Pythagora, Platona, Sofokla, Cicerona i Senecu. [9] Změny v nazírání na hodnotu lidského života i na smysl utrpení přineslo křesťanství. Od starověku až po začátek 20. století pak patřila eutanazie mezi tabuizovaná témata. Teprve začátkem čtyřicátých let minulého století se k eutanazii přihlásilo nacistické Německo a od osmdesátých let je eutanazie praktikována v Holandsku. [10]

Jen málo bioetiků dnes eutanazii obhajuje, a naopak čelní přestavitelé renomovaných bioetických ústavů ji jednoznačně odmítají [11], stejně jako zastánci tradičního křesťanského učení. [12] Spíše k výjimkám patří někteří protestantští a anglikánští myslitelé [13], „proti proudu" se ovšem zařadil i katolík William Curran. [14]

Jednoznačně negativní stanovisko magisteria katolické církve k eutanazii bylo opakovaně deklarováno v obecně známých dokumentech. [15] V novějších textech se upouští od dříve používaných termínů řádné a mimořádné prostředky léčby a hovoří spíše o prostředcích přiměřených a nepřiměřených (proporciálních a disproporcionálních). Eutanazie se také již nerozděluje na „aktivní" a „pasivní". Pokud se termín „aktivní euthanazie" objeví, potom především k jednoznačnějšímu odlišení nedovolených prostředků od oprávněného upuštění od nepřiměřených (příliš zatěžujících nebo neúčinných) léčebných postupů. Není nutno udržovat život za každou cenu, zejména když proces umírání již začal.

Studií o postoji katolických věřících k eutanazii je málo. V roce 1997 uskutečnil Jan Dziedzic výzkum u skupiny 242 studentů Lékařské fakulty Jagelonské univerzity v Krakově. [16] Zjistil, že nižší sebehodnocení znalostí pravd víry a menší sebeidentifikace s církví zvyšuje inklinaci k pozitivnímu postoji vůči eutanazii.

Výsledky naší studie jsou s nálezy J. Dziedzice konformní. Nejkritičtější postoj k eutanazii zaujímali studenti denního studia oboru teologie a nejsmířlivější byli studenti gymnázia. V obecné rovině přitom s legalizací eutanazie souhlasilo méně než jedno procento respondentů, avšak ve „zcela výjimečných případech" ji připouštěla téměř čtvrtina.

Významný byl vztah mezi znalostí definice eutanazie a negativním postojem k její legalizaci. Z těch kteří dokázali předložit přesnou definici eutanazie, devět desetin její legalizaci jednoznačně odmítlo. Mezi respondenty, kteří podali definici chybnou, odmítala legalizaci pouze pětina.

Dosti pestré byly názory na hypotetické výhody případné legalizace eutanazie. Čtvrtina dotázaných uvedla jako hlavní výhodu legalizace odstranění utrpení a desetina finanční úspory. Avšak téměř polovina respondentů neviděla v legalizaci eutanazie vůbec žádnou přednost. Ve všech skupinách respondentů přitom panovaly obavy z možných rizik legalizace, jen méně než dvě procenta dotázaných rizika popíralo.

Metodika předložené studie se ovšem lišila od postupu zvoleného při šetření uskutečněném J. Dziedicem. Z obou prací je však zřejmé, že náboženská víra zmenšuje pravděpodobnost vidět v eutanazii přijatelné řešení problému utrpení působeného těžkou nemocí. Obě práce však prokázaly, že i mezi osobami s kladným vztahem ke katolické církvi jsou názory na eutanazii velmi diferencované. S ohledem na očekávaný tlak na legalizaci eutanazie je potřeba již nyní na národní i mezinárodní rovině otázkou eutanazie se šířeji zabývat a při osvětovém působení neopomíjet ani skupinu věřících.

Literatura

1. „Naše právní úprava nedovoluje lékaři záměrně ukončit život pacienta ani nezná speciální (privilegovaný) trestný čin eutanazie, resp. usmrcení z útrpnosti. Úmyslné zabití je podle trestního zákona kvalifikováno jako vražda." STOLÍNOVÁ J. *Etika a právo v* lékařské *praxi.* Praha: Avicenum, 1990. ISBN 80-201-0090-3. **2.** Cit.podle HAŠKOVCOVÁ, H. *Lékařská etika.* Praha: Galén, 1997. ISBN 80-85824-54-X **3.** Uvedené prohlášení J. Nováka

uveřejnila v květnu 1996 většina českých deníků. **4.** MITLÖHNER, M. Pro a proti legalizaci eutanazie. *Svobodné slovo,* 88, 1996, č. 137, s. 5. **5.** MUNZAROVÁ M. Eutanazie: Dosáhne Evropa konsensu? *Praktický lékař,* 76,1996,č. 2, s. 95-97 - ŠIPR K. Aktuální problematika eutanazie. *Scripta bioethica.*1997, č.14, s.11-18 **6.** KOŘENEK J. Postoje mediků k eutanazii. *Praktický lékař,* 80, 2000, č. 4, s. 226-228 **7.** BRODSKÝ Š. Na eutanazii nejsme zralí. *Lidové noviny* 20.4.2001 - FREIOVÁ M. Lékař má chránit život, ne usmrcovat. *Lidové noviny* 24.1.2001 - FREIOVÁ M. Budeme vybíjet slabé? *Lidové noviny,* 17. 4. 2001 - HACH P., Eutanazie. *Praktický lékař,* 80, 2000, č. 4, s. 222-225. - HOLÁŇ V. Projev lidské svobody, nebo pýchy? *Lidové noviny 24.1.2001.* - KABELA, M. Být svým pánem až do smrti. *Lidové noviny, 24.1.2001.* MUMZAROVÁ M. Eutanazie je legalizací zabíjení. *Lidové noviny* 5.12.2000 - ŠIMEK J. Umírající nemají co nabídnout. *Lidové noviny,* 18. 4. 2001 - Šipr K.: Závažná choroba a Kevorkian. *Světlo,* 9, 2001, č. 19, s. 13. **8.** HAŠKOVCOVÁ H. Umírání a smrt. In: VORLÍČEK J., ADAM Z. et al., *Paliativní medicína.* Praha: GRADDA Publishing, 1998. ISBN 80-7169-437-1. - HAŠKOVCOVÁ H., *Thanatologie.* Praha: Galén, 2000, ISBN 80-7264-034-7. - HONZÁK R. Eutanazie není řešením, paliativní péče ano. *JAMA-CS,* 9, 2001, Č. 4, S. 314. **9.** Podrobněji viz ZIMMERMANN-ACKLIN, M. *Euthanasie.* Freiburg: Herder, 1997. ISBN 3-451-26554-0 **10.** KEOWN J. *Euthanasia examined.* Cambridge: Gambridge University Press, 1995. ISBN 0-521-58613-5. **11.** CALLAHAN, D. When Doctors Run Amoc. *The Hastings Center Report,* 22, 1992, 2, s. 55. **12.** ASHLEY B., OjROURKE K. *Health Care Etics.* Washington: Georgetown University Press, 1997. ISBN 0-87840-640-1. **13.** Smith D. *Life and Morality.* Dublin: Gill and Macmillan, 1996. ISBN: 0-7171-2172-0. **14.** Názory tohoto autora si lze přiblížit například z CURRAN W.: Defining Appropriate Medical Care. in: SHANNON T.: *Bioetics.* Mahwah: Paulist Press, 1987. ISBN: 0-808912805-5 **15.** Připomeňme alespoň: Gaudium et spes, 1965, Deklarace o eutanazii, 1980, Donum vitae, 1987, Evangelium vitae, 1995. **16.** DZIEDZIC J. *Euthanazija a religijnonosc.* Krakow: Wydwnictwo naukowe Papieskiej akademii teologicznej, 1999 ISBN-87681-26-1

Abstract

Šipr, K.: K diskuzi o eutanazii v České republice. [To the euthanasia debate in the Czech Republic.] Medicínska etika & Bioetika / Medical Ethics & Bioethics, 8, 2001, No. 3 - 4, p. 5 - 9. Problem of euthanasia is frequently tackled upon in contemporary public debate. The attitudes to euthanasia are usually strongly influenced by religious backgrounds of the respondents questioned. These attitudes were studied in the series of 364 young people, who, by a concrete action, had expressed their positive attitudes to the Catholic Church. An anonymous questionaire method was used. The general legalisation of euthanasia was supported by less than 1% of respondents, while the legalisation of the procedure to be used in strictly exceptional cases was supported by almost 25% of the subjects. The analysis of data revealed that a more permissive attitudes to euthanasia legalisation were associated with an inferior level of information on the issue and inability of subjects to give an appropriate definition of euthanasia. The attitudes to euthanasia in religious people should be given due attention. *Key words*: euthanasia, situation in the Czech Republic, attitudes of young people, influence of religion.

Correspondence to: Prof. MUDr. Květoslav Šipr, Míčkova 59, 614 00 Brno, ČR.

(continued from p. 1)

Among those, the bi- and multilateral collaboration and networking of bioethicists in CEE countries is of utmost importance. This should be enhanced and promoted also by the establishment of the „Bioethics Information and Documentation Centre“ and „CEEAB Liaison Office“ in Bratislava in March 2002.

Our journal, dear readers and friends, shall be closely following, reporting and reflecting these exciting developments.

Jozef Glasa, ME&B Editor, Acting President CEEAB

ESTABLISHMENT AND WORK OF ETHICS COMMITTEES IN CENTRAL AND EASTERN EUROPEAN COUNTRIES

Jozef Glasa

Slovak Postgraduate Academy of Medicine, Bratislava, Slovak Republic

Abstract

The genuine reform efforts in medicine and health care in Central and East European (CEE) countries have continued to pose important and thought-provoking challenges to the newly reborn disciplines of medical ethics (or bioethics). They are embodied in the bulk of new ethical problems, concepts and quandaries brought about by the developments, changes, clashes, and „real life“ issues of the CEE countries' health care systems and biomedical sciences. Certain part, quite variable from country to country, of this bio-ethical endeavour has been confined to the work and activities of ethics committees (ECs) or similar bodies. They have emerged in varying number, shape, composition, competence, legal status, responsibility and time of appearance, in almost all transition countries of CEE. They may be considered as a kind of „field workplaces“ of medical ethics/ bioethics within the countries' HCSs or biomedical re-search structures. Despite some shortcomings and drawbacks, a lot has already been achieved. In some countries the progress made has been quick and systematic. The major pitfalls were mostly due to the missing, weak or unclear legal backing of ECs' establishment and work; lack of education and training of their members; insufficient support from health care administrators; misconceptions concerning their mission, procedures, scope of responsibility, and reporting; insufficient or missing funding; low profile societal esteem for ECs' work; but some drawbacks were due also to the underdeveloped 'dialogic' culture of the impartial discussion and democratic discourse in the 'post-totalitarian' CEE transition countries. The future of ECs in CEE will be connected to the countries' integration and harmonization efforts towards research, health systems, and other international structures in Europe and beyond. This should need an extensive and non-discriminatory international partnership, exchange and co-operation.

Key words: ethics committees, transition countries, Central and East Europe, establishment and work, biomedical research, integration efforts.

Introduction - challenges of transition

Since early nineties of the 20th century, the countries in Central and Eastern Europe (CEE) have entered difficult paths of unprecedented political, economical, social and cultural transitions. [1, 6] The changes needed are complex and difficult to achieve. The countries while facing various problems inherited from the past struggle badly with scarcities of the available financial, manpower, technical - technological, infrastructure, and other necessary resources. The „old guard“ retaining or regaining the power, the „populists“ outplaying the conceptual reformers in the public, corruption, „black/grey economy“ interests, together with a considerable „brain drain“ towards the more fortunate parts of the „Western World“, make the reformation attempts in CEE difficult, and sometimes a bit frustrating endeavours.

This holds even more, as far as the health care systems (HCSs) reforms are concerned. [4] Removing „the walls" has been accompanied by unmerciful intrusions of the market, the industry (pharmaceutical and other), new businesses, new health insurance companies, „high-tech" (at all costs), new drugs, new diagnostics, new treatments, „new" patients (such as the very wealthy and very poor ones, drug addicts, HIV-positives or those with AIDS) and other factors into the already shattering and largely unprepared HCSs. Moreover, those HCSs are still lacking the necessary infrastructure, funds, and sometimes also managerial skills and competence. Partly hypocritical, fee-free „health care for all" (which was neither „for all", nor free, effective or sustainable) has been aimed to be replaced by various HCS models borrowed from abroad, or developed somehow by eager domestic reformers. (Sometimes HCS models have been changing abruptly after each personal change at the post of the minister of health, or, „jokingly", following each „study tour" of a ministerial „establishment" abroad.)

Resulting crisis of the health care systems, which took place in many of the CEE transition countries, together with other unfavourable factors with negative impact on public health, led to considerable deterioration of health indicators in many of these countries. (E.g. dropping of the life expectancy; new rise of some serious infectious diseases (combated successfully in these countries already decades ago); increase of infant mortality, mental diseases, cancers, cardiovascular morbidity and mortality, etc.) An unprecedented fall in live births, the s. c. „second demographic revolution", has hit the CEE countries totally unprepared to handle its worrisome consequences. (E. g. public health - the quickly ageing populations' health needs; economical - growing tax burden, increasing price of the manpower, etc.; social - collapsing pension and social security systems, etc.)

On the other hand, the genuine reform efforts in medicine and health care in CEE countries have continued to pose important and thought-provoking challenges to the newly re-born disciplines of medical ethics or (as a mostly US-imported concept) bioethics. [2] They are embodied in the bulk of new ethical problems, concepts and quandaries brought about by the developments, changes, clashes, and „real life" issues of the CEE countries' HCSs and biomedical sciences.

Certain part, quite variable from country to country, of this bio-ethical endeavour has been confined to the work and activities of ethics committees (ECs) or similar bodies. They have emerged in varying number, shape, composition, competence, legal status, responsibility and time of appearance, in almost all transition countries of CEE. [5] They may be considered as a kind of „field workplaces" of medical ethics/bioethics within the countries' HCSs or biomedical research structures.

Variability of „traditions" to start with

Medical ethics/bioethics scholars, available for the „thought or action" in CEE countries, usually came to this field from various professional, cultural and ideological backgrounds. [6] At the beginning, mostly three groups of medical ethicists/bioethicists could have been distinguished:

a) people coming out from the underground resistance structures, usually independently thinking, selfeducated intellectuals, or members of formerly oppressed religious orders, or other underground spiritual/intellectual resistance groups;

b) university teachers and other representatives of the „scientific disciplines" of late Marxism - Leninism, educated in abundance during the previous period and seeking to preserve their positions within the universities and academia by quickly becoming proponents of various schools of secular (or even religious) philosophical thought;

c) new „domestic" pupils and „imported" proponents of different interest groups, schools, ideologies, and value systems present within the contemporary global bioethics scene.

These have been continuously, but quite slowly joined by a „new blood" - young scholars entering the field after graduation, many of them having benefited from studies at the universities and academia institutions abroad.

This situation has contributed to a rather broad variability of expertise, education, competence, personal experience, and also to the plurality of opinions and visions within the slowly growing group of „bioethics experts" available for the ECs' work in CEE countries.

Establishment of ethics committees (or similar bodies) in CEE transition countries

In transition CEE countries, similarly to the situation in Western Europe (WE) and elsewhere, usually 3 or 4 types of ECs (or similar bodies) have been introduced [5]:

a) Central (or National) Ethics Committees (CECs): established at the ministries of health, or at other central state institutions to give opinions or recommendations on ethical aspects of a more general nature, health legislation proposals, and also to do some conceptual work and enter into „official" international networks and collaboration (e.g. within COMETH - European Council sponsored network of national ECs).

b) Research Ethics Committees (RECs): founded at institutional, regional, or even national level to review projects or protocols of biomedical research, including clinical trials. In the later area, these bodies usually aimed to ensure compliance with requirements of Good Clinical Practice (GCP) and other relevant international standards.

c) Hospital/Institutional Ethics Committees (HECs): established at major teaching hospitals or specialised health care institutions to deal with ethical problems related to the health care provision within the hospital/institution. These are still pretty rare bodies in CEE settings.

d) Ethics Committees for Animal Research: set up at highly specialised research institutes to comply with international standards in the field.

Besides the ECs mentioned above, also „ethics working groups" founded by scientific or professional societies or associations of various medical disciplines, and the „ethics boards" of professional associations (such as medical chambers, or other health professionals' associations) exist in many, if not all CEE countries.

Interestingly, the reasons for establishing ECs have been rather different in the cases of different committees types, and also in different periods of the health care transformation process. Both domestic („internal"), as well as international („external") driving forces have been active in ECs' founding efforts. [5, 7]

At the very beginning, in what I would describe as the ***„period of enthusiasm"***, ECs or similar bodies have been established at the „grass-root" level, as more-less informal working groups of physicians and other concerned individuals, aiming at „humanisation" of the health care or HCS, remaining in crisis after disruption of the previous totalitarian system of planning and management. The other groups, especially the members of scientific socie-

ties or organisations of health professionals, enjoying possibilities of the newly regained freedom, entered eagerly the suddenly opened space of a free scientific debate concerning also various ethical aspects of the newest developments in life sciences. The „enthusiastic period" in some countries was marked by the establishment of „self-designed" CECs (e.g. Czech Republic, Slovakia, Hungary, etc.).

Once established, the CECs usually took on the initiative in the field helping to move it forward - sometimes even through a ***„period of disillusion"*** (when original enthusiasm vanished facing difficulties of financially and „politically" not rewarding work) - into the next ***„period of institutionalisation"***. Within this period, besides the ECs establishment and work, also the first teaching institutions of medical ethics/bioethics have gradually been called into the existence (university or postgraduate institutes or chairs of medical ethics or bioethics), starting the undergraduate and even postgraduate programmes for medical students, students of nursing, and other health care professionals. Some of the original „ethics working/discussion groups" developed themselves into various types of associations on a „scientific", professional or confessional basis (e.g. medial ethics or bioethics societies, charities, associations of christian physicians and health professionals, pro-life associations, hospice promotion groups, etc.).

Help from abroad – the pharmaceutical industry, international organisations

Interestingly, the international inspiration and influence have been of utmost importance in the promotion of ECs (predominantly or solely of REC type) in CEE countries. In this respect, the ***pharmaceutical industry*** has played a major role, mostly at the local level, requiring the principles of Good Clinical Practice (GCP) and Helsinki Declaration (HD) be respected in clinical trials' preparation, conduct, evaluation and reporting. [3] At the beginning, it did a lot for the education of researchers, members of ECs, and even - of the state authorities. The international corporations were followed closely by domestic firms. All parties involved in the „clinical trials business" were concerned to have the „GCP job" done properly, at least from the formal point of view.

In parallel, the activities and initiatives of international organisations and agencies, such as the ***Council of Europe*** (especially its Steering Committee on Bioethics, the COMETH network of CECs, the specialised DEBRA Program), the ***World Health Organisation*** (Target No. 38 of its „Health for All till the Year 2000" Programme), later on also the ***European Commission*** (especially its activities directed towards the „pre-accession countries") were aiming to bring changes at the governmental and legislation level.

At the same time, several internationally respected institutions or charities, such as The Hastings Center (Garrison, N.Y., USA; through its Eastern European Programme), Albert Schweitzer Institute for Humanities (Hamden, CT, USA; through international conferences and workshops in CEE countries), the Open Society Funds (numerous activities sponsored by Mr. George Soros), as well as many pro-life and liberal international associations have been active in medical ethics/bioethics in CEE region.

These activities contributed substantially to the legal developments, and also boosted the education and personal growth of new scholars and professionals to enter medical ethics/bioethics field, including ECs. [5]

Outlook for the future: possibly more ethics despite drawbacks

Despite some shortcomings and drawbacks, a lot has already been achieved in CEE countries as far as ECs' establishment and work is concerned. In some countries the progress made has been surprisingly swift and systematic (e.g. Hungary, Czech Republic, Slovakia, Slovenia (in this country, building on a unique tradition already present for decades), and others). The major pitfalls were mostly due to the missing, weak or unclear legal backing of ECs' establishment and work; lack of education and training of their members; insufficient support from health care administrators; misconceptions concerning their mission, procedures, scope of responsibility, and reporting; insufficient or missing funding; low profile societal esteem for ECs' work; but some drawbacks were due also to the underdeveloped 'dialogic' culture of the impartial discussion and democratic discourse in the 'post-totalitarian' CEE transition countries. [7, 8]

The future of ECs in CEE transition countries could be seen as bound to the countries' integration and harmonization efforts towards research, health systems, and other international structures in Europe and beyond. Those are, hopefully, heading towards more unity, cooperation and exchange, while respecting differences and national or local traditions and concerns. After passing through various 'childhood diseases' of their institutionalization, as briefly outlined above, I am convinced, ECs in CEE transition countries may turn from struggling with 'procedurals' and different shortcomings, towards dealing with 'the ethical' problems and quandaries brought to them by the very life of the communities, where they have been established. Hopefully, they may also serve as a dialogue promoting and enhancing points: mediating between the professionals - be these physicians, researchers, nurses, health administrators, or others - and the patients, their relatives, and also the worried or ignorant public. The achievements of ECs in this respect will be directly dependent on the success or failure in building of the overall free, democratic, open, dialogic and tolerant culture in their respective countries. [8] The promotion of the culture of life for the new century and millenium recently entered. This would need, as a must, an extensive and non-discriminatory international partnership, exchange and co-operation.

References*

1. Glasa, J. (Ed.): Contemporary Problems of Medical Ethics in Central Europe. Charis, Bratislava, 1993 (book, 128 pgs). **2.** Glasa, J.: Attuali controversie e future prospettive della bioetica: un 'analisi dell'Europa centrale. In: Comitato Nazionale per la Bioetica (Roma): Bioetiche a Confronto. Presidenza del Consiglio dei Ministri, Dipartimento per L'Informazione e L'Editoria, Roma, 1995, p. 61 - 70. **3.** Glasa J., Holomáň J., Klepanec J., Šoltés L.: Ethics commitees and achievement of good clinical practice. Thérapie, 51, 1996, s. 369 - 372. **4.** Glasa, J., Klepanec, J. R. (Eds.): Health Care under Stress. Charis - IMEB Fdn., Bratislava, 1998 (book, 147 pgs). **5.** Glasa, J. (Ed.): Ethics Committees in Central & Eastern Europe. Council of Europe - Charis - IMEB Fdn., Bratislava, 2000 (book, 266 pgs). **6.** Glasa, J.: Bioethics and challenges of a society in transition: The birth and development of bioethics in post - totalitarian Slovakia. Kennedy Institute of Ethics Journal, 10, 2000, č. 2, s. 165 - 170. **7.** Glasa, J., Bielik, J., Ďačok, J., Glasová, M., Porubský, J.: Ethics committees (HECs/IRBs) and health care reform in the Slovak Republic: 1990 - 2000. HEC Forum, 12, 2000, č. 4, s. 358 - 366. **8.** Glasa, J., Glasová, M.: Ethics committees and consensus in the post-totalitarian society. Med. Eth. Bioet., 8, 2001, No. 1 - 2, p. 5 - 9.

***** Selected papers of the author containing references to other relevant literature.

Abstrakt

Glasa, J.: Establishment and work of ethics committees in Central and Eastern European countries. [Založenie a činnosť etických komisií v krajinách strednej a východnej Európy.] Med. Eth. Bioet., 9, 2002, No. 1 - 2, p. 9 - 12. Skutočné reformné úsilie v oblasti medicíny a zdravotníckej starostlivosti v krajinách strednej a východnej Európy (SVE) neustále prináša významné a provokujúce problémy pre nanovo zrodené disciplíny medicínskej etiky (alebo bioetiky). Sú vtelené v rastúcom množstve nových etických otázok, pojmov, koncepcií a debát, ktoré prináša vývoj, konflikty a „skutočný život" zdravotníckych systémov (ZS) a biomedicínskych vied v týchto krajinách. Určitá časť tohto etického úsilia, rozdielna z krajiny na krajinu, sa viaže na založenie a aktivity etických komisií (EK) alebo podobných útvarov. Objavili sa v rozličnom počte, zložení a čase, s rozdielnymi kompetenciami, postupmi práce, legislatívnym zaistením a zodpovednosťou takmer vo všetkých krajinách SVE. Možno ich považovať za „terénne pracovné miesta" medicínskej etiky/bioetiky v rámci ZS a štruktúr bio-medicínskeho výskumu v týchto krajinách. Napriek mnohým ťažkostiam a problémom sa už mnoho v tejto oblasti dosiahlo. V niektorých krajinách bol pokrok v práci EK zvlášť rýchly a systematický. Hlavné problémy boli zapríčinené chýbajúcim, nedostatočným alebo nejasným právnym zakotvením EK; nedostatkom vzdelania a skúseností členov EK; nedostatočnou podporou zo strany riadiacich štruktúr zdravotníctva; nedorozumeniami ohľadom poslania, pracovných postupov, miery zodpovednosti EK; nízkym ohodnotením práce EK zo strany verejnosti; avšak niektoré ťažkosti vyplývali aj z nedostatočne rozvinutej „kultúry dialógu" v mnohých „posttotalitných" krajinách SVE. Budúcnosť EK v krajinách SVE je spojená s pokračujúcimi integračnými a harmonizačnými snahami týchto krajín voči výskumným, zdravotníckym a iným medzinárodným štruktúram v Európe i za jej hranicami. To si vyžiada rozsiahlu, nediskriminujúcu medzinárodnú spoluprácu a živú výmenu odborných skúseností. *Kľúčové slová*: etické komisie, transformujúce sa krajiny, stredná a východná Európa, založenie a činnosť, biomedicínsky výskum, zdravotnícke systémy, integračné úsilie.

Correspondence to / Adresa: Assoc. Prof. Jozef Glasa, M.D., PhD., Slovak Postgraduate Academy of Medicine, Institute of Medical Ethics and Bioethics Foundation, Limbová 12, 833 03 Bratislava, Slovak Republic, e-mail: glasa@upkm.sk

DOKUMENTY / DOCUMENTS

DIRECTIVE 2001/20/EC

of the European Parliament and of the Council of 4 April 2001

on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,Having regard to the proposal from the Commission (1)
Having regard to the opinion of the Economic and Social Committee (2)
Acting in accordance with the procedure laid down in Article 251 of the Treaty (3)
Whereas:

(1) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (4) requires that applications for authorisation to place a medicinal product on the market should be accompanied by a dossier containing particulars and documents relating to the results of tests and clinical trials carried out on the product. Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products (5) lays down uniform rules on the compilation of dossiers including their presentation.

(2) The accepted basis for the conduct of clinical trials in humans is founded in the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as for instance reflected in the 1996 version of the Helsinki Declaration. The clinical trial subject's protection is safeguarded through risk assessment based on the results of toxicological experiments prior to any clinical trial, screening by ethics committees and Member States' competent authorities, and rules on the protection of personal data.

(3) Persons who are incapable of giving legal consent to clinical trials should be given special protection. It is incumbent on the Member States to lay down rules to this effect. Such persons may not be included in clinical trials if the same results can be obtained using persons capable of giving consent. Normally these persons should be included in clinical trials only when there are grounds for expecting that the administering of the medicinal product would be of direct benefit to the patient, thereby outweighing the risks. However, there is a need for clinical trials involving children to improve the treatment available to them. Children represent a vulnerable population with developmental, physiological and psychological differences from adults, which make age- and development- related research important for their benefit. Medicinal products, including vaccines, for children need to be tested scientifically before widespread use. This can only be achieved by ensuring that medicinal products which are likely to be of significant clinical value for children are fully studied. The clinical trials required for this purpose should be carried out under conditions affording the best possible protection for the subjects. Criteria for the protection of children in clinical trials therefore need to be laid down.

(4) In the case of other persons incapable of giving their consent, such as persons with dementia, psychiatric patients, etc., inclusion in clinical trials in such cases should be on an even more restrictive basis. Medicinal products for trial may be administered to all such individuals only when there are grounds for assuming that the direct benefit to the patient outweighs the risks. Moreover, in such cases the written consent of the patient's legal representative, given in cooperation with the treating doctor, is necessary before participation in any such clinical trial.

(5) The notion of legal representative refers back to existing national law and consequently may include natural or legal persons, an authority and/or a body provided for by national law.

(6) In order to achieve optimum protection of health, obsolete or repetitive tests will not be carried out, whether within the Community or in third countries. The harmonisation of technical requirements for the development of medicinal products should therefore be pursued through the appropriate fora, in particular the International Conference on Harmonisation.

(7) For medicinal products falling within the scope of Part A of the Annex to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Pro-

ducts (6), which include products intended for gene therapy or cell therapy, prior scientific evaluation by the European Agency for the Evaluation of Medicinal Products (hereinafter referred to as the „Agency"), assisted by the Committee for Proprietary Medicinal Products, is mandatory before the Commission grants marketing authorisation. In the course of this evaluation, the said Committee may request full details of the results of the clinical trials on which the application for marketing authorisation is based and, consequently, on the manner in which these trials were conducted and the same Committee may go so far as to require the applicant for such authorisation to conduct further clinical trials. Provision must therefore be made to allow the Agency to have full information on the conduct of any clinical trial for such medicinal products.

(8) A single opinion for each Member State concerned reduces delay in the commencement of a trial without jeopardising the well-being of the people participating in the trial or excluding the possibility of rejecting it in specific sites.

(9) Information on the content, commencement and termination of a clinical trial should be available to the Member States where the trial takes place and all the other Member States should have access to the same information. A European database bringing together this information should therefore be set up, with due regard for the rules of confidentiality.

(10) Clinical trials are a complex operation, generally lasting one or more years, usually involving numerous participants and several trial sites, often in different Member States. Member States' current practices diverge considerably on the rules on commencement and conduct of the clinical trials and the requirements for carrying them out vary widely. This therefore results in delays and complications detrimental to effective conduct of such trials in the Community. It is therefore necessary to simplify and harmonise the administrative provisions governing such trials by establishing a clear, transparent procedure and creating conditions conducive to effective coordination of such clinical trials in the Community by the authorities concerned.

(11) As a rule, authorisation should be implicit, i.e. if there has been a vote in favour by the Ethics Committee and the competent authority has not objected within a given period, it should be possible to begin the clinical trials. In exceptional cases raising especially complex problems, explicit written authorisation should, however, be required.

(12) The principles of good manufacturing practice should be applied to investigational medicinal products.

(13) Special provisions should be laid down for the labelling of these products.

(14) Non-commercial clinical trials conducted by researchers without the participation of the pharmaceuticals industry may be of great benefit to the patients concerned. The Directive should therefore take account of the special position of trials whose planning does not require particular manufacturing or packaging processes, if these trials are carried out with medicinal products with a marketing authorisation within the meaning of Directive 65/65/EEC, manufactured or imported in accordance with the provisions of Directives 75/319/EEC and 91/356/EEC, and on patients with the same characteristics as those covered by the indication specified in this marketing authorisation. Labelling of the investigational medicinal products intended for trials of this nature should be subject to simplified provisions laid down in the good manufacturing practice guidelines on investigational products and in Directive 91/356/EEC.

(15) The verification of compliance with the standards of good clinical practice and the need to subject data, information and documents to inspection in order to confirm that they have been properly generated, recorded and reported are essential in order to justify the involvement of human subjects in clinical trials.

(16) The person participating in a trial must consent to the scrutiny of personal information during inspection by competent authorities and properly authorised persons, provided that such personal information is treated as strictly confidential and is not made publicly available.

(17) This Directive is to apply without prejudice to Directive 95/46/EEC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (7).

(18) It is also necessary to make provision for the monitoring of adverse reactions occurring in clinical trials using Community surveillance (pharmacovigilance) procedures in order to ensure the immediate cessation of any clinical trial in which there is an unacceptable level of risk.

(19) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission(8),

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Scope

1. This Directive establishes specific provisions regarding the conduct of clinical trials, including multicentre trials, on human subjects involving medicinal products as defined in Article 1 of Directive 65/65/EEC, in particular relating to the implementation of good clinical practice. This Directive does not apply to non-interventional trials.

2. Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible.

3. The principles of good clinical practice and detailed guidelines in line with those principles shall be adopted and, if necessary, revised to take account of technical and scientific progress in accordance with the procedure referred to in Article 21(2).These detailed guidelines shall be published by the Commission.

4. All clinical trials, including bioavailability and bioequivalence studies, shall be designed, conducted and reported in accordance with the principles of good clinical practice.

Article 2

Definitions

For the purposes of this Directive the following definitions shall apply:

(a) „clinical trial": any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy;

This includes clinical trials carried out in either one site or multiple sites, whether in one or more than one Member State;

(b) „multi-centre clinical trial“: a clinical trial conducted according to a single protocol but at more than one site, and therefore by more than one investigator, in which the trial sites may be located in a single Member State, in a number of Member States and/or in Member States and third countries;

(c) „non-interventional trial“: a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data;

(d) „investigational medicinal product“: a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form;

(e) „sponsor“: an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial;

(f) „investigator“: a doctor or a person following a profession agreed in the Member State for investigations because of the scientific background and the experience in patient care it requires. The investigator is responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the leader responsible for the team and may be called the principal investigator;

(g) „investigator's brochure“: a compilation of the clinical and non-clinical data on the investigational medicinal product or products which are relevant to the study of the product or products in human subjects;

(h) „protocol“: a document that describes the objective(s), design, methodology, statistical considerations and organisation of a trial. The term protocol refers to the protocol, successive versions of the protocol and protocol amendments;

(i) „subject“: an individual who participates in a clinical trial as either a recipient of the investigational medicinal product or a control;

(j) „informed consent“: decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.

(k) „ethics committee“: an independent body in a Member State, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent;

(l) „inspection“: the act by a competent authority of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;

(m) „adverse event“: any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment;

(n) „adverse reaction“: all untoward and unintended responses to an investigational medicinal product related to any dose administered;

(o) „serious adverse event or serious adverse reaction“: any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect;

(p) „unexpected adverse reaction“: an adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. investigator's brochure for an unauthorised investigational product or summary of product characteristics for an authorised product).

Article 3

Protection of clinical trial subjects

1. This Directive shall apply without prejudice to the national provisions on the protection of clinical trial subjects if they are more comprehensive than the provisions of this Directive and consistent with the procedures and time-scales specified therein. Member States shall, insofar as they have not already done so, adopt detailed rules to protect from abuse individuals who are incapable of giving their informed consent.

2. A clinical trial may be undertaken only if, in particular:

(a) the foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A clinical trial may be initiated only if the Ethics Committee and/or the competent authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored;

(b) the trial subject or, when the person is not able to give informed consent, his legal representative has had the opportunity, in a prior interview with the investigator or a member of the investigating team, to understand the objectives, risks and inconveniences of the trial, and the conditions under which it is to be conducted and has also been informed of his right to withdraw from the trial at any time;

(c) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with Directive 95/46/EC are safeguarded;

(d) the trial subject or, when the person is not able to give informed consent, his legal representative has given his written consent after being informed of the nature, significance, implications and risks of the clinical trial; if the individual is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation;

(e) the subject may without any resulting detriment withdraw from the clinical trial at any time by revoking his informed consent;

(f) provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor.

3. The medical care given to, and medical decisions made on behalf of, subjects shall be the responsibility of an appropriately qualified doctor or, where appropriate, of a qualified dentist.

4. The subject shall be provided with a contact point where he may obtain further information.

Article 4

Clinical trials on minors

In addition to any other relevant restriction, a clinical trial on minors may be undertaken only if:

(a) the informed consent of the parents or legal representative has been obtained; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor;

(b) the minor has received information according to its capacity of understanding, from staff with experience with minors, regarding the trial, the risks and the benefits;

(c) the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation or to be withdrawn from the clinical trial at any time is considered by the investigator or where appropriate the principal investigator;

(d) no incentives or financial inducements are given except compensation;

(e) some direct benefit for the group of patients is obtained from the clinical trial and only where such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods; additionally, such research should either relate directly to a clinical condition from which the minor concerned suffers or be of such a nature that it can only be carried out on minors;

(f) the corresponding scientific guidelines of the Agency have been followed;

(g) clinical trials have been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage; both the risk threshold and the degree of distress have to be specially defined and constantly monitored;

(h) the Ethics Committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol; and

(i) the interests of the patient always prevail over those of science and society.

Article 5

Clinical trials on incapacitated adults not able to give informed legal consent

In the case of other persons incapable of giving informed legal consent, all relevant requirements listed for persons capable of giving such consent shall apply. In addition to these requirements, inclusion in clinical trials of incapacitated adults who have not given or not refused informed consent before the onset of their incapacity shall be allowed only if:

(a) the informed consent of the legal representative has been obtained; consent must represent the subject's presumed will and may be revoked at any time, without detriment to the subject;

(b) the person not able to give informed legal consent has received information according to his/her capacity of understanding regarding the trial, the risks and the benefits;

(c) the explicit wish of a subject who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator or where appropriate the principal investigator;

(d) no incentives or financial inducements are given except compensation;

(e) such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods and relates directly to a life-threatening or debilitating clinical condition from which the incapacitated adult concerned suffers;

(f) clinical trials have been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage; both the risk threshold and the degree of distress shall be specially defined and constantly monitored;

(g) the Ethics Committee, with expertise in the relevant disease and the patient population concerned or after taking advice in clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;

(h) the interests of the patient always prevail over those of science and society; and

(i) there are grounds for expecting that administering the medicinal product to be tested will produce a benefit to the patient outweighing the risks or produce no risk at all.

Article 6

Ethics Committee

1. For the purposes of implementation of the clinical trials, Member States shall take the measures necessary for establishment and operation of Ethics Committees.

2. The Ethics Committee shall give its opinion, before a clinical trial commences, on any issue requested.

3. In preparing its opinion, the Ethics Committee shall consider, in particular:

(a) the relevance of the clinical trial and the trial design;

(b) whether the evaluation of the anticipated benefits and risks as required under Article 3(2)(a) is satisfactory and whether the conclusions are justified;

(c) the protocol;

(d) the suitability of the investigator and supporting staff;

(e) the investigator's brochure;

(f) the quality of the facilities;

(g) the adequacy and completeness of the written information to be given and the procedure to be followed for the purpose of obtaining informed consent and the justification for the research on persons incapable of giving informed consent as regards the specific restrictions laid down in Article 3;

(h) provision for indemnity or compensation in the event of injury or death attributable to a clinical trial;

(i) any insurance or indemnity to cover the liability of the investigator and sponsor;

(j) the amounts and, where appropriate, the arrangements for rewarding or compensating investigators and trial subjects and the relevant aspects of any agreement between the sponsor and the site;

(k) the arrangements for the recruitment of subjects.

4. Notwithstanding the provisions of this Article, a Member State may decide that the competent authority it has designated for the purpose of Article 9 shall be responsible for the consideration of, and the giving of an opinion on, the matters referred to in paragraph 3(h), (i) and (j) of this Article.When a Member State avails itself of this provision, it shall notify the Commission, the other Member States and the Agency.

5. The Ethics Committee shall have a maximum of 60 days from the date of receipt of a valid application to give its reasoned opinion to the applicant and the competent authority in the Member State concerned.

6. Within the period of examination of the application for an opinion, the Ethics Committee may send a single request for information supplementary to that already supplied by the applicant. The period laid down in paragraph 5 shall be suspended until receipt of the supplementary information.

7. No extension to the 60-day period referred to in paragraph 5 shall be permissible except in the case of trials involving medicinal products for gene therapy or somatic cell therapy or medicinal products containing geneti-

cally modified organisms. In this case, an extension of a maximum of 30 days shall be permitted. For these products, this 90-day period may be extended by a further 90 days in the event of consultation of a group or a committee in accordance with the regulations and procedures of the Member States concerned. In the case of xenogenic cell therapy, there shall be no time limit to the authorisation period.

Article 7

Single opinion

For multi-centre clinical trials limited to the territory of a single Member State, Member States shall establish a procedure providing, notwithstanding the number of Ethics Committees, for the adoption of a single opinion for that Member State.

In the case of multi-centre clinical trials carried out in more than one Member State simultaneously, a single opinion shall be given for each Member State concerned by the clinical trial.

Article 8

Detailed guidance

The Commission, in consultation with Member States and interested parties, shall draw up and publish detailed guidance on the application format and documentation to be submitted in an application for an ethics committee opinion, in particular regarding the information that is given to subjects, and on the appropriate safeguards for the protection of personal data.

Article 9

Commencement of a clinical trial

1. Member States shall take the measures necessary to ensure that the procedure described in this Article is followed for commencement of a clinical trial. The sponsor may not start a clinical trial until the Ethics Committee has issued a favourable opinion and inasmuch as the competent authority of the Member State concerned has not informed the sponsor of any grounds for non-acceptance. The procedures to reach these decisions can be run in parallel or not, depending on the sponsor.

2. Before commencing any clinical trial, the sponsor shall be required to submit a valid request for authorisation to the competent authority of the Member State in which the sponsor plans to conduct the clinical trial.

3. If the competent authority of the Member State notifies the sponsor of grounds for non-acceptance, the sponsor may, on one occasion only, amend the content of the request referred to in paragraph 2 in order to take due account of the grounds given. If the sponsor fails to amend the request accordingly, the request shall be considered rejected and the clinical trial may not commence.

4. Consideration of a valid request for authorisation by the competent authority as stated in paragraph 2 shall be carried out as rapidly as possible and may not exceed 60 days. The Member States may lay down a shorter period than 60 days within their area of responsibility if that is in compliance with current practice. The competent authority can nevertheless notify the sponsor before the end of this period that it has no grounds for non-acceptance. No further extensions to the period referred to in the first subparagraph shall be permissible except in the case of trials involving the medicinal products listed in paragraph 6, for which an extension of a maximum of 30 days shall be permitted. For these products, this 90-day period may be extended by a further 90 days in the event of consultation of a group or a committee in accordance with the regulations and procedures of the Member States concerned. In the case of xenogenic cell therapy there shall be no time limit to the authorisation period.

5. Without prejudice to paragraph 6, written authorisation may be required before the commencement of clinical trials for such trials on medicinal products which do not have a marketing authorisation within the meaning of Directive 65/65/EEC and are referred to in Part A of the Annex to Regulation (EEC) No 2309/93, and other medicinal products with special characteristics, such as medicinal products the active ingredient or active ingredients of which is or are a biological product or biological products of human or animal origin, or contains biological components of human or animal origin, or the manufacturing of which requires such components.

6. Written authorisation shall be required before commencing clinical trials involving medicinal products for gene therapy, somatic cell therapy including xenogenic cell therapy and all medicinal products containing genetically modified organisms. No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity.

7. This authorisation shall be issued without prejudice to the application of Council Directives 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms(9) and 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms(10).

8. In consultation with Member States, the Commission shall draw up and publish detailed guidance on:

(a) the format and contents of the request referred to in paragraph 2 as well as the documentation to be submitted to support that request, on the quality and manufacture of the investigational medicinal product, any toxicological and pharmacological tests, the protocol and clinical information on the investigational medicinal product including the investigator's brochure;

(b) the presentation and content of the proposed amendment referred to in point (a) of Article 10 on substantial amendments made to the protocol;

(c) the declaration of the end of the clinical trial.

Article 10

Conduct of a clinical trial

Amendments may be made to the conduct of a clinical trial following the procedure described hereinafter:

(a) after the commencement of the clinical trial, the sponsor may make amendments to the protocol. If those amendments are substantial and are likely to have an impact on the safety of the trial subjects or to change the interpretation of the scientific documents in support of the conduct of the trial, or if they are otherwise significant, the sponsor shall notify the competent authorities of the Member State or Member States concerned of the reasons for, and content of, these amendments and shall inform the ethics committee or committees concerned in accordance with Articles 6 and 9.

On the basis of the details referred to in Article 6(3) and in accordance with Article 7, the Ethics Committee shall give an opinion within a maximum of 35 days of the date of receipt of the proposed amendment in good and due form. If this opinion is unfavourable, the sponsor may not implement the amendment to the protocol. If the opinion of the Ethics Committee is favourable and the competent authorities of the Member States have raised no grounds for non-acceptance of the abovementioned substantial amendments, the sponsor shall proceed to conduct the clinical trial following the amended protocol. Should this not be the case, the sponsor shall either take account of the grounds for non-acceptance and adapt the proposed amendment to the protocol accordingly or withdraw the proposed amendment;

(b) without prejudice to point (a), in the light of the circumstances, notably the occurrence of any new event

relating to the conduct of the trial or the development of the investigational medicinal product where that new event is likely to affect the safety of the subjects, the sponsor and the investigator shall take appropriate urgent safety measures to protect the subjects against any immediate hazard. The sponsor shall forthwith inform the competent authorities of those new events and the measures taken and shall ensure that the Ethics Committee is notified at the same time;

(c) within 90 days of the end of a clinical trial the sponsor shall notify the competent authorities of the Member State or Member States concerned and the Ethics Committee that the clinical trial has ended. If the trial has to be terminated early, this period shall be reduced to 15 days and the reasons clearly explained.

Article 11

Exchange of information

1. Member States in whose territory the clinical trial takes place shall enter in a European database, accessible only to the competent authorities of the Member States, the Agency and the Commission:

(a) extracts from the request for authorisation referred to in Article 9(2);

(b) any amendments made to the request, as provided for in Article 9(3);

(c) any amendments made to the protocol, as provided for in point a of Article 10;

(d) the favourable opinion of the Ethics Committee;

(e) the declaration of the end of the clinical trial; and

(f) a reference to the inspections carried out on conformity with good clinical practice.

2. At the substantiated request of any Member State, the Agency or the Commission, the competent authority to which the request for authorisation was submitted shall supply all further information concerning the clinical trial in question other than the data already in the European database.

3. In consultation with the Member States, the Commission shall draw up and publish detailed guidance on the relevant data to be included in this European database, which it operates with the assistance of the Agency, as well as the methods for electronic communication of the data. The detailed guidance thus drawn up shall ensure that the confidentiality of the data is strictly observed.

Article 12

Suspension of the trial or infringements

1. Where a Member State has objective grounds for considering that the conditions in the request for authorisation referred to in Article 9(2) are no longer met or has information raising doubts about the safety or scientific validity of the clinical trial, it may suspend or prohibit the clinical trial and shall notify the sponsor thereof.

Before the Member State reaches its decision it shall, except where there is imminent risk, ask the sponsor and/or the investigator for their opinion, to be delivered within one week.

In this case, the competent authority concerned shall forthwith inform the other competent authorities, the Ethics Committee concerned, the Agency and the Commission of its decision to suspend or prohibit the trial and of the reasons for the decision.

2. Where a competent authority has objective grounds for considering that the sponsor or the investigator or any other person involved in the conduct of the trial no longer meets the obligations laid down, it shall forthwith inform him thereof, indicating the course of action which he must take to remedy this state of affairs. The competent authority concerned shall forthwith inform the Ethics Committee, the other competent authorities and the Commission of this course of action.

Article 13

Manufacture and import of investigational medicinal products

1. Member States shall take all appropriate measures to ensure that the manufacture or importation of investigational medicinal products is subject to the holding of authorisation. In order to obtain the authorisation, the applicant and, subsequently, the holder of the authorisation, shall meet at least the requirements defined in accordance with the procedure referred to in Article 21(2).

2. Member States shall take all appropriate measures to ensure that the holder of the authorisation referred to in paragraph 1 has permanently and continuously at his disposal the services of at least one qualified person who, in accordance with the conditions laid down in Article 23 of the second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products(11), is responsible in particular for carrying out the duties specified in paragraph 3 of this Article.

3. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 21 of Directive 75/319/EEC, without prejudice to his relationship with the manufacturer or importer, is responsible, in the context of the procedures referred to in Article 25 of the said Directive, for ensuring:

(a) in the case of investigational medicinal products manufactured in the Member State concerned, that each batch of medicinal products has been manufactured and checked in compliance with the requirements of Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use(12), the product specification file and the information notified pursuant to Article 9(2) of this Directive;

(b) in the case of investigational medicinal products manufactured in a third country, that each production batch has been manufactured and checked in accordance with standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/356/EEC, in accordance with the product specification file, and that each production batch has been checked in accordance with the information notified pursuant to Article 9(2) of this Directive;

(c) in the case of an investigational medicinal product which is a comparator product from a third country, and which has a marketing authorisation, where the documentation certifying that each production batch has been manufactured in conditions at least equivalent to the standards of good manufacturing practice referred to above cannot be obtained, that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality in accordance with the information notified pursuant to Article 9(2) of this Directive.

Detailed guidance on the elements to be taken into account when evaluating products with the object of releasing batches within the Community shall be drawn up pursuant to the good manufacturing practice guidelines, and in particular Annex 13 to the said guidelines. Such guidelines will be adopted in accordance with the procedure referred to in Article 21(2) of this Directive and published in accordance with Article 19a of Directive 75/319/EEC.

Insofar as the provisions laid down in (a), (b) or (c) are complied with, investigational medicinal products shall not have to undergo any further checks if they are imported into another Member State together with batch release certification signed by the qualified person.

4. In all cases, the qualified person must certify in a register or equivalent document that each production batch satisfies the provisions of this Article. The said register or equivalent document shall be kept up to date as

operations are carried out and shall remain at the disposal of the agents of the competent authority for the period specified in the provisions of the Member States concerned. This period shall in any event be not less than five years.

5. Any person engaging in activities as the qualified person referred to in Article 21 of Directive 75/319/EEC as regards investigational medicinal products at the time when this Directive is applied in the Member State where that person is, but without complying with the conditions laid down in Articles 23 and 24 of that Directive, shall be authorised to continue those activities in the Member State concerned.

Article 14

Labelling

The particulars to appear in at least the official language(s) of the Member State on the outer packaging of investigational medicinal products or, where there is no outer packaging, on the immediate packaging, shall be published by the Commission in the good manufacturing practice guidelines on investigational medicinal products adopted in accordance with Article 19a of Directive 75/319/EEC.

In addition, these guidelines shall lay down adapted provisions relating to labelling for investigational medicinal products intended for clinical trials with the following characteristics:

– the planning of the trial does not require particular manufacturing or packaging processes;

– the trial is conducted with medicinal products with, in the Member States concerned by the study, a marketing authorisation within the meaning of Directive 65/65/EEC, manufactured or imported in accordance with the provisions of Directive 75/319/EEC;

– the patients participating in the trial have the same characteristics as those covered by the indication specified in the abovementioned authorisation.

Article 15

Verification of compliance of investigational medicinal products with good clinical and manufacturing practice

1. To verify compliance with the provisions on good clinical and manufacturing practice, Member States shall appoint inspectors to inspect the sites concerned by any clinical trial conducted, particularly the trial site or sites, the manufacturing site of the investigational medicinal product, any laboratory used for analyses in the clinical trial and/or the sponsor's premises.

The inspections shall be conducted by the competent authority of the Member State concerned, which shall inform the Agency; they shall be carried out on behalf of the Community and the results shall be recognised by all the other Member States. These inspections shall be coordinated by the Agency, within the framework of its powers as provided for in Regulation (EEC) No 2309/93. A Member State may request assistance from another Member State in this matter.

2. Following inspection, an inspection report shall be prepared. It must be made available to the sponsor while safeguarding confidential aspects. It may be made available to the other Member States, to the Ethics Committee and to the Agency, at their reasoned request.

3. At the request of the Agency, within the framework of its powers as provided for in Regulation (EEC) No 2309/93, or of one of the Member States concerned, and following consultation with the Member States concerned, the Commission may request a new inspection should verification of compliance with this Directive reveal differences between Member States.

4. Subject to any arrangements which may have been concluded between the Community and third countries, the Commission, upon receipt of a reasoned request from a Member State or on its own initiative, or a Member State may propose that the trial site and/or the sponsor's premises and/or the manufacturer established in a third country undergo an inspection. The inspection shall be carried out by duly qualified Community inspectors.

5. The detailed guidelines on the documentation relating to the clinical trial, which shall constitute the master file on the trial, archiving, qualifications of inspectors and inspection procedures to verify compliance of the clinical trial in question with this Directive shall be adopted and revised in accordance with the procedure referred to in Article 21(2).

Article 16

Notification of adverse events

1. The investigator shall report all serious adverse events immediately to the sponsor except for those that the protocol or investigator's brochure identifies as not requiring immediate reporting. The immediate report shall be followed by detailed, written reports. The immediate and follow-up reports shall identify subjects by unique code numbers assigned to the latter.

2. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations shall be reported to the sponsor according to the reporting requirements and within the time periods specified in the protocol.

3. For reported deaths of a subject, the investigator shall supply the sponsor and the Ethics Committee with any additional information requested.

4. The sponsor shall keep detailed records of all adverse events which are reported to him by the investigator or investigators. These records shall be submitted to the Member States in whose territory the clinical trial is being conducted, if they so request.

Article 17

Notification of serious adverse reactions

1. (a) The sponsor shall ensure that all relevant information about suspected serious unexpected adverse reactions that are fatal or life-threatening is recorded and reported as soon as possible to the competent authorities in all the Member States concerned, and to the Ethics Committee, and in any case no later than seven days after knowledge by the sponsor of such a case, and that relevant follow-up information is subsequently communicated within an additional eight days.

(b) All other suspected serious unexpected adverse reactions shall be reported to the competent authorities concerned and to the Ethics Committee concerned as soon as possible but within a maximum of fifteen days of first knowledge by the sponsor.

(c) Each Member State shall ensure that all suspected unexpected serious adverse reactions to an investigational medicinal product which are brought to its attention are recorded.

(d) The sponsor shall also inform all investigators.

2. Once a year throughout the clinical trial, the sponsor shall provide the Member States in whose territory the clinical trial is being conducted and the Ethics Committee with a listing of all suspected serious adverse reactions which have occurred over this period and a report of the subjects' safety.

3. (a) Each Member State shall see to it that all suspected unexpected serious adverse reactions to an investigational medicinal product which are brought to its attention are immediately entered in a European database to which, in accordance with Article 11(1), only the competent authorities of the Member States, the Agency and the Commission shall have access.

(b) The Agency shall make the information notified by the sponsor available to the competent authorities of the Member States.

Article 18

Guidance concerning reports

The Commission, in consultation with the Agency, Member States and interested parties, shall draw up and publish detailed guidance on the collection, verification and presentation of adverse event/reaction reports, together with decoding procedures for unexpected serious adverse reactions.

Article 19

General provisions

This Directive is without prejudice to the civil and criminal liability of the sponsor or the investigator. To this end, the sponsor or a legal representative of the sponsor must be established in the Community.

Unless Member States have established precise conditions for exceptional circumstances, investigational medicinal products and, as the case may be, the devices used for their administration shall be made available free of charge by the sponsor.

The Member States shall inform the Commission of such conditions.

Article 20

Adaptation to scientific and technical progress

This Directive shall be adapted to take account of scientific and technical progress in accordance with the procedure referred to in Article 21(2).

Article 21

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use, set up by Article 2b of Directive 75/318/EEC (hereinafter referred to as the Committee).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 22

Application

1. Member States shall adopt and publish before 1 May 2003 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply these provisions at the latest with effect from 1 May 2004.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive.

Article 23

Entry into force

This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 24

Addressees

This Directive is addressed to the Member States.

Done at Luxembourg, 4 April 2001.

For the European Parliament	For the Council
The President	The President
N. Fontaine	B. Rosengren

(1) OJ C 306, 8.10.1997, p. 9 andOJ C 161, 8.6.1999, p. 5. **(2)** OJ C 95, 30.3.1998, p. 1. **(3)** Opinion of the European Parliament of 17 November 1998 (OJ C 379, 7. 12. 1998, p. 27). Council Common Position of 20 July 2000 (OJ C 300, 20.10.2000, p. 32) and Decision of the European Parliament of 12 December 2000. Council Decision of 26 February 2001. **(4)** OJ 22, 9.2.1965, p. 1/65. Directive as last amended by Council Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22). **(5)** OJ L 147, 9.6.1975, p. 1. Directive as last amended by Commission Directive 1999/83/EC (OJ L 243, 15.9.1999, p. 9). **(6)** OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7) **(7)** OJ L 281, 23.11.1995, p. 31. **(8)** OJ L 184, 17.7.1999, p. 23. **(9)** OJ L 117, 8.5.1990, p. 1. Directive as last amended by Directive 98/81/EC (OJ L 330, 5.12.1998, p. 13). **(10)** OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72). **(11)** OJ L 147, 9.6.1975, p. 13. Directive as last amended by Council Directive 93/39/EC (OJ L 214, 24.8.1993, p. 22). **(12)** OJ L 193, 17.7.1991, p. 30.

Editorial note: The text taken from the Eur-Lex website - officially published by EC in the *Official Journal L 121, 01/05/2001 P. 0034 - 0044.*

Medicínska etika & bioetika - Medical Ethics & Bioethics, založený ako časopis Ústavu medicínskej etiky a bioetiky v Bratislave, spoločného pracoviska Lekárskej fakulty Univerzity Komenského a Inštitútu pre ďalšie vzdelávanie zdravotníckych pracovníkov v Bratislave. Je určený pracovníkom etických komisií v Slovenskej republike, ako aj najširšej medicínskej a zdravotníckej verejnosti. Má tiež za cieľ napomáhať medzinárodnú výmenu informácií na poli medicínskej etiky a bioetiky. Prináša informácie o aktuálnych podujatiach a udalostiach v oblasti medicínskej etiky a bioetiky, pôvodné práce, prehľady, reprinty legislatívnych materiálov a smerníc pre oblasť bioetiky, listy redakcii a recenzie. Príspevky a materiály uverejňuje v slovenskom alebo anglickom jazyku. Vybrané materiály vychádzajú dvojjazyčne. Vedecké práce publikované v časopise musia zodpovedať obvyklým medzinárodným kritériám (pozri Pokyny prispievateľom - ME&B 2/94, s. 10).

Medicínska etika & bioetika - Medical Ethics & Bioethics, founded as the journal of the Institute of Medical Ethics & Bioethics (Bratislava), a joint facility of the Medical Faculty of the Comenius University and the Postgraduate Medical Institute in Bratislava (Slovak Republic). It aims to serve the informational and educational needs of the members of ethics committees in the Slovak Republic and the broadest medical and health audience as well. It aims also to enhance the international exchange of information in the field of medical ethics and bioethics. The information published comprises news, original papers, review articles, reprints of national and international regulatory materials, letters, reviews. Contributions and materials are published in Slovak or English. Choosen materials are published in both languages. Scientific papers published in ME&B must respect the usual international standards (see Instructions for authors - ME&B 2/94, p. 10)

ISSN 1335–0560 **http: //www.elis.sk/etika/etika.html** **PRINTED IN SLOVAKIA**

POKYNY PRE AUTOROV

1. Rukopisy majú byť napísané v spisovnom slovenskom alebo anglickom jazyku na kvalitnom papieri formátu A4 (60 znakov, 30 riadkov na jednu stranu), najlepšie elektrickým písacím strojom alebo laserovou tlačiarňou počítača.

2. Pokiaľ možno prosíme dodať rukopisy napísané aj v niektorom z bežných textových editorov (napr. T602, Word Perfect, MS Word, atď.) na diskete s uvedením mena autora, názvu príslušného súboru a použitého textového programu.

3. Rozsah príspevkov: a) pôvodné práce a prehľady: do 10 strán textu (vrátane zoznamu literatúry) a najviac 5 príloh (obrázky, grafy, tabuľky, a pod.), b) listy redakcii, recenzie, správy z kongresov a konferencií, a pod.: do 4 strán textu a 2 prílohy.

4. Titulná strana rukopisu má obsahovať názov práce, mená a priezviská všetkých autorov príspevku (vrátane ich akademických titulov), názov pracoviska (pracovísk) autora (autorov) s uvedením mena a priezviska vedúceho pracoviska (vrátane titulov). Pôvodná ako aj prehľadová práca má byť doplnená výstižným súhrnom, napísaným v rozsahu cca 10 - 20 riadkov, a zoznamom kľúčových slov (v slovenčine aj v angličtine). (Redakcia zabezpečí preklady súhrnov iba v osobitných prípadoch.)

5. Citovaná literatúra sa usporadúva abecedne podľa priezviska a skratky krstného mena (prvého) autora. V texte sa odvolanie na citovanú prácu označí uvedením poradového čísla citovaného literárneho prameňa [v zátvorkách].

Citácie prác z časopisov: (poradové číslo citácie), priezvisko autora, skratka jeho krstného mena (najviac 4 autori, ak je autorov 5 a viac, uvedú sa len prví traja a po čiarke "a spol." alebo "et al."), dvojbodka, plný názov citovanej práce (bodka), oficiálna skratka názvu časopisu, ročník, rok vydania, číslo, prvá strana, pomlčka, posledná strana citovaného príspevku, bodka. Pred číslo uviesť skratku "č", pred prvú stranu skratku "s". (Príklad (vymyslený): 1. Mašura, J., Kopáč, L., Sedlák, V., a spol.: Problém parenterálnej výživy u pacientov v perzistujúcom vegetatívnom stave - etické aspekty. ME&B, 1, 1994, č. 2, s. 12 - 14.)

Citácia knihy: priezvisko autora (autorov), skratka krstného mena, dvojbodka, plný názov knihy (bodka), vydavateľ, miesto, rok vydania, počet strán, citovaná/é strana/y. Citácia knižnej kapitoly: priezvisko autora (autorov), skratka krstného mena, dvojbodka, plný názov knihy (bodka), In: Citovaná kniha, prvá strana, pomlčka, posledná strana citovanej kapitoly. Pred prvú stranu uviesť skratku "s".

6. Dokumentácia príspevku môže obsahovať obrázky (ev. kvalitné ČB fotografie, prípadne negatívy), grafy a tabulky. Každú prílohu uviesť samostatne na zvláštnom liste papiera v kvalitnom vyhotovení. Označiť na zadnej strane menom (prvého) autora, druhom prílohy (obr., tab., graf) a jej poradovým číslom.

7. Rukopisy sa zasielajú v dvoch kompletných exemplároch (vrátane dokumentácie) na adresu redakcie. V sprievodnom liste je potrebné uviesť presnú adresu autora pre korešpondenciu (vrátane telefónneho prípadne faxového čísla), úplný zoznam spoluautorov s názvom ich pracoviska a presnou adresou, ako aj prehlásenie o tom, že rukopis dosiaľ nebol uverejnený alebo poslaný na uverejnenie v inom medicínskom periodiku.

8. Zaslané rukopisy majú byť formulované definitívne. Pôvodné práce a prehľady sú pred prijatím na uverejnenie recenzované.

9. Redakcia si vyhradzuje právo vykonať na rukopise (vrátane jeho názvu) nevyhnutné redakčné úpravy, skrátiť ho, alebo po pripomienkach recenzenta vrátiť autorovi na upravenie.

10. Redakcia si vyhradzuje právo určiť poradie a konečnú úpravu rukopisu do tlače.

11. Rukopisy, ktoré nezodpovedajú celkovej koncepcii časopisu, alebo neboli upravené v súlade s pokynmi pre autorov a pripomienkami recenzentov, nemôžu byť uverejnené.

12. Vzhľadom na neziskový charakter časopisu uverejnené príspevky nie sú honorované.

INSTRUCTIONS FOR AUTHORS

1. Manuscripts submitted for publishing in "Medical Ethics & Bioethics" should be written in standard Slovak or English on a good quality white paper - format A4 (60 characters per line, 30 lines per page). Electric typewriter or PC laser (not matrix) printer should preferably be used.

2. Authors are encouraged to submit manuscripts also written on a diskette by using a common PC text editor (e.g. T602, Word Perfect, MS Word, etc.) - the name of the author, text file and the text editor used should be indicated on the label of the diskette.

3. Size of contributions: a) original articles and reviews: up to 10 text pages (including the list of references) and 5 pieces of enclosures (pictures, figures, tables), b) letters to the editor, book reviews, news, reports from scientific meetings, etc.: up to 4 text pages and 2 pieces of enclosures.

4. Title page of the manuscript should indicate the title of the contribution, names (incl. academic titles), institutions and addresses of all authors. Original as well as a review article should be accompanied by an abstract (size about 10 - 20 lines) and a list of key words in Slovak and English. (In some cases the translation of the abstract could be provided by the Editorial Office.)

5. References should be given in an alphabetical order according to the surname and initial(s) of other name(s) of the first author. Quotations in the text should be made by indicating the order number of the reference [in the brackets].

Individual references should be given according to the tentative examples given here:

a) journal articles: 1. Mašura, J., Kopáč, L., Sedlák, V., et al.: Problém parenterálnej výživy u pacientov v perzistujúcom vegetatívnom stave - etické aspekty. ME&B, Vol. 1, 1994, No. 2, p. 12 - 14.

b) articles in the book: Johnson, V.: Persistent vegetative state - medical aspects. In: Shaw, T. S. (ed.): Persistent vegetative state. Irwin Books Ltd., Bratislava, 1994, 386 pages, p. 31 - 49.

6. Documentation of the manuscript could comprise pictures (ev. good quality photos, or negatives), figures and tables. Every item should be enclosed on a separate sheet of paper (not included in the text), made up in a good quality. Author's name, type of documentation (picture, table, figure) and its order number should be indicated overleaf.

7. Manuscripts should be mailed as two complete copies (including documentation) to the address of the editor. In the accompanying letter the address of author to whom the correspondence should be directed (incl. telephone, or fax numbers), as well as a complete list of other authors together with the names of institutions and authors'addresses should be indicated.

The letter should contain also the statement on the originality of submitted manuscript (i. e. that it has not yet been published or submitted for publication elsewhere).

8. Manuscripts submitted should be formulated in a final form. Original papers as well as review articles are subjected to the peer review process before their acceptance for publication.

9. Editorial Board reserves itself the right to make necessary editorial changes of the manuscript (including its title), to shorten the original text, or returning the manuscript to the author for adjustments according to the recommendations of the reviewers.

10. Editorial Board reserves itself the right to determine the order and final adjustment of the manuscripts for the publication.

11. Manuscripts that do not meet the overall conception of the journal, or those not prepared according to the Instructions for Authors and recommendations of reviewers cannot be accepted for the publication.

12. According to the non-profit character of the journal the authors of manuscripts published are not entitled to any financial honorarium.