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OBSAH / CONTENTS

Thomas Percival
(1740-1804)

Born in Warrington in 1740, the son of a local merchant, Thomas Percival chose to follow the profession of his grandfather and uncles - that of a physician. Both of his parents died when he was a very young boy, and he was raised by a sister. He was educated at Warrington Grammar School and at Warrington Academy. Later he followed by studying Medicine at Edinburgh University, where he came into contact with several Scottish intellectuals, including David Hume.

On graduation, Percival returned to Warrington, where he married and established a medical practice, though in 1767 he moved the practice to Manchester. He was a prolific author, and apart from several childrens' stories, he published two volumes of essays: "Essays, Medical and Experimental" in 1767, and "Essays, Medical, Philosophical and Experimental" in 1773 - both books found popular praise from the critics. In 1770, concerned by the high rate of mortality in Manchester, he began to study death records in an attempt to discover the causes.

He isolated several now self-evident causes - poverty, malnourishment and lack of public hygiene. He made specific proposals for the more detailed and accurate keeping of official death records. His work caused him to develop a great deal of sympathy for the poor of Manchester, and he became more involved in reforms aimed at correcting the worst effects of poverty - these included reforming the conditions of work in factories.

Percival was instrumental in 1781 in setting up the Manchester Literary and Philosophical Society, which he started in his own home. It grew so large that another meeting place had soon to be found. Percival was President of the Society for the most part of his life.

In 1803, Percival published a document on medical ethics; this laid down strict rules of conduct for medical practitioners. His Code was the basis of the "Code of Ethics of the American Medical Association" drawn up in 1849. A man of great charisma, Percival numbered Voltaire and Diderot amongst his friends. Thomas Percival died in 1804.

A monument to his memory stands in Warrington Parish Church, and an inscribed tablet can be found in the rooms of the Literary & Philosophical Society in Manchester.

Text taken from: A Virtual Encyclopaedia of Greater Manchester in the Third Millennium, http://raq2168.uk2net.com/celebs/scientists1.html

WHY IS THE ETHICS OF EUTHANASIA WRONG?

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Introduction

The culture of death embodies a total misunderstan ding of the nature of the human person, a denial of the innate dignity of persons. The denial of this truth causes a crisis in ethics. Sometimes there are very good reasons why we have the right even the obligation to allow the dying to die their own death. But there is a world of difference between allowing or permitting death and deliberately setting out to bring death about. So it is very important to show the real nature of euthanasia in order to avoid confusing terminology.

We will try to show why euthanasia is wrong by showing, first, how seriously false its anthropology is; second, how its consequentialist/proportionalist methodology is simply unworkable; and third, later on we will show the consequences that follow from accepting the presuppositions of pro-euthanasia leaders (developing the "slippery slope" argument).

I. False Anthropology

The defence of euthanasia presupposes that there is such a thing as a life not worth living and that it is morally right to bring death about if this is necessary to protect the higher good of human dignity. For proponents of euthanasia, human bodily life is of itself not an intrinsic good ***of*** the person but merely an instrumental good ***for*** the person, i.e., the consciously experiencing subject. The ethics of euthanasia holds that all human lives are not of equal value but only lives of a certain "quality." It is "maintained that a human being must possess a number of presently exercisable capacities in order to be counted as a person. Somebody lacking those abilities also lacks the rights which properly belong to persons – including the 'right to life.'" (1) Moreover, they are defending a person's right "to determine the manner of their dying, since persons are entitled to dignity, and certain conditions of dying are incompatible with dignity and worth, and that lives lived under certain conditions are lives which cannot be respected, are lives which lack dignity." (2)

For proponents of euthanasia, it seems crucial that one should be able to judge certain human beings' lack of dignity and worth. For them, to kill these people is to do them a benefit: "it is to terminate pathetic existences; such killings are said to be merciful." (3) The Christian understanding of persons includes the truth that man is also spirit and in life differs from the life of the other animals. The proponents of euthanasia define the word "person" wrongly in terms of characteristics which may come and go, and which are a matter of degree.

A Working Party Report contains such comparison: "A piece of iron gets magnetised and so ***becomes*** a magnet; later it may get demagnetised and ***stops*** being a magnet, though it is still the same piece of iron. If indeed you explain the word 'person' as meaning someone e.g. who can talk (has self-consciousness) and lead a social life (have inter-personal relations), you may say that someone can be the same human being but no longer a person. It does not come so easy to say 'since he can no longer do such-and-such, he no longer has rights, and it is in order to kill him.'" (4)

It is clear that you cannot be killing a human being and not be killing a person. The dignity, which belongs to humans, is not because of 'good condition' but simply because of the kind of beings they are: spirit as well as flesh. And "because man is spirit, talk of the quality of his life is not an adequate basis for deciding to suppress his existence." Therefore, "the full meaning of any part of anyone's existence eludes our understanding; judgements about that meaning cannot reasonably provide the basis for a decision to move someone from existence to non-existence in this world." (5)

The ethics of euthanasia, according to May, "involves the weighing or commensurating of human goods and choosing some, for instance, dignity or personal integrity, and rejecting or repudiating others, namely, life itself – and he continues, saying: "But no created human good is the ***summum bonum***, the absolute good, and no created human good is an evil. Those who justify suicide and mercy killing claim that we can rightfully choose death – an evil that is privative of the good of life – for the sake of the 'higher' or 'greater' good of dignity or integrity. They thus maintain that life as such is not a good that is worthy of human choice, and they erect the goods of dignity and personal integrity into absolute goods, that is, goods whose protection and preservation is so important that they can justify our repudiation of other basic human goods. (6)

It is clear that these goods are not comparable and cannot be weighed one against the other. All our goods, including life itself, merit our love and respect. We can say that euthanasia itself is dehumanising, and it is not at all "dying with dignity."

We have to say that on the one hand we reject those 'quality of life' judgements which are intended to identify death itself as a good to be pursued, but on the other hand we do not deny that judgements which can (but need not) be called 'quality of life' judgements do enter into the process of medical decision making. In the latter case, the doctor makes some sort of comparison between the benefits and the risks and burdens for the patient that will or may accrue from the specific treatment under consideration. And this comparison is inevitably made against the background of the patient's present and likely condition and prognosis. It focuses, and must be kept focused, on the advantages and disadvantages of specific possible treatments, given their effects, side effects, and outcome. But it does not inquire about the worthwhileness of the patient's being alive at all. (7)

A Working Party Report makes a distinction in the decision resulting from the non-euthanasiast and euthanasiast practical reflection: "The decision resulting from the non-euthanasiast practical reflection may be that ***no*** possible specific treatment is now, for this patient, worthwhile. And that decision may be arrived at in the knowledge that untreated, the patient will probably die somewhat earlier than he would if treated. And indeed that consequence of the decision may be accepted without regret, and with the feeling, expressed or unexpressed, that death will bring relief to that patient. Still, such a decision can be ***perfectly reasonable and morally proper***. But it would be euthanasiast, and so ***morally improper***, if it used the judgement that death would bring relief, or that the patient's life was no longer worth living, or that the patient's prospective quality of life was too poor, as the basis for a decision to regard death as the objective, or an objective, of the treatments to be decided on." (8)

The other big problem of the ethics of euthanasia is in a false understanding of the human person. As May says: "For them, man is not an indissoluble union of body and soul; he is the Cartesian ghost in a machine, for they regard man's humanity as exhausted by his consciousness and rationality, and his body and biological life as a subpersonal, subhuman component, part of a 'world of nature' over which the rational and conscious agent has complete dominion." (9) We see that this view of man is incompatible with the biblical and Christian understanding of the human person.

Here it is worthwhile to take a deeper look at dualism and what influence it makes to morality. According to Christian faith and sound philosophy, human beings are ***animals***, but they are animals who are radically different in kind from other kinds of animals. They are different because they can do things that other animals cannot do at all, i.e., speak in propositional sentences, judge the truth or falsity of propositions, and make free choices. And in order to account for their capacity to do these things, it is absolutely necessary to infer that there is present, within the entitative or ontological make-up of the human animal something utterly lacking in the entitative make-up of other animals, i.e., a spiritual or nonmaterial principle – the soul. They are, in other words, ***persons.***

But human persons, insofar as they are in truth animals, are not spirit persons. Rather, they are body persons, sexually differentiated into male and female. When God created man, he did not create a conscious subject aware of itself and capable of relating to other selves, to whom he then gave a "body structure." Rather, when God created man to his own image, "male and female he created them." (10) He created man as living flesh, and when his only-begotten Son became man in order to show the depths of the Father's love for this special creature, he became flesh. (11)

We are not selves having and using bodies. According to Grisez, "***we are bodies*** – we are rational, sentient, organic bodies," and "the fact remains that the human person is a certain, special kind of body." But dualistic theory "would frankly state that a person owns and uses a body, but that a person is ***not*** a body." (12)

Moreover, he says: "In the light of the teaching of faith that the human person becomes by adoption a member of the divine family (cf. Rom. 8:14-17) and a participant in divinity (cf. II Pet. 1:4), we also can conclude that the organic life and the biological process of the human body belong to divine life. Moreover, 'belong to' here means inclusion, not merely possession. Human biological processes are not possessions and instruments of the person. And as dogma of the Assumption makes clear, the person as body is destined for heavenly glory." (13)

According to St. Thomas Aquinas, the human person is a unity and the body is the person who is to be saved. Germain Grisez gives a synthetic treatise of St. Thomas on this matter in his ***Summa Theologica***, I, q.78: "The human soul, which is the person's intellectual principle, is united to the body as form. As form of the body, the soul is not merely a moving principle of the body. Nor is the soul an agent of which the body is instrument. Rather, the soul is an intrinsic principle of the human person. The soul makes the person be the body he or she is. Nor is there any other form, which makes the body be body than the soul by which the person has the capacities of intellect and free choice. Each person has his own soul; substantial unity excludes many individuals having the same soul. Since the soul and the body are not distinct entities, no link is needed to unite soul and body. The human soul, as a formal part of the body, makes the entire human body be a person; the entire soul is present in every part of the body." (14)

But we see the separation of the unity of body and soul in classical philosophy. The atheistic or humanistic worldview sees people as autonomous self-ruling biological entities whose life's purpose is pleasure, and whose end is complete extinction. This view logically results in a self-centred hedonism that sees life as utilitarian, i.e., valuable only for what it offers. The logical conclusion of this perspective, generally denied by most people who hold this view, is nihilism – "is that all there is?"

According to this perspective, life should not be continued unless it is a wanted life. This dualism is the basis of contemporary evaluations of human actions and attitudes regarding organic human life and sexuality. If the person really is not his body, then the destruction of the life of the body is not directly and in itself an attack on a value intrinsic to the human person. It leads to very sad consequences when the lives of the unborn, the hopelessly insane, the "vegetating" senile, and the lives of those who no longer can engage in praxis or problem solving become lives no longer meaningful, no longer valueable, no longer inviolable. (15) For proponents of dualistic theory, the body and its members, our organs and their functions belong to physical nature, and they consider that physical nature is not the person. Everything of moral significance for them is exclusively located within the person. From this statement follows an erroneous understanding of superiority of intelligent abilities over physical nature, and namely bodily life itself. It opens the door to such crimes as abortion, euthanasia, etc.

Thus, human bodily life is not something subhuman or subpersonal, part of the world of nature over which man, the person, has been given dominion. Rather, the human body and human bodily life are integral to the human person; they are ***goods of the person, not merely goods for the person***. A human person comes into being when a living human body comes into being and remains a being until that living human body ceases to exist.

II. False Methods of Moral Judgement

The proponents of euthanasia give a very false dualistic anthropology using the consequentialist/proportionalist method. We call this ethics "consequentialism" because it focuses upon states of affairs consequent upon choices and their execution. This theory is also called "proportionalism" because what is the most central to it is its appeal to the proportion of good and bad as a basis for moral judgement. (16) The proponents of this method of moral judgement use a comparative evaluation of the benefits (goods or values) and harms (bads or disvalues) promised by the various alternatives of choice. According to them, one ought to choose the possibility, which offers the best proportion of good to bad.

Grisez notes that "the human goods (and bads) whose proportions are to be compared exist for proportionalists only in the sum total of their concrete instances." (17) By this he means that proportionalists focus attention on the actual realisation of these goods in definite states of affairs. They look upon them as goals to be achieved. Grisez criticises this understanding of the human goods because it fails to appreciate the truth that "all of the basic human goods have a certain reality – they determine persons existentially – simply in being chosen." (18)

This understanding, in other words, fails to take seriously the self-determining character of free choice. According to May, "a proportionate reason or good is needed to justify doing deeds that effect evil, but the proportionate good that serves as the end to be achieved does not suffice to render deeds good and right" and "if we take the significance of our deeds seriously, as revelatory of our being and as shaping our identity, we must conclude that if we directly will or intend an evil, such as

death, we show that we are willing to take on as part of our moral identity the identity of evildoers, for ***evil is what we do*** if it is an evil that cannot be intended." (19) In the case of euthanasia, no redescription ("showing compassion," "preserving human dignity," etc.) can conceal the reality of killing because this evil (death) is brought about directly intended or willed.

For they deny moral absolutes, some acts which are intrinsically evil; in some moral dilemmas they accept these acts which are normally prohibited as morally acceptable in the presence of a proportionate good. (20) But how can a moral theory, which claims to be a coherent one, condone the doing of evil to achieve good? Moreover, "judging the moral character of an action principally on the basis of hoped-for results is, at best, ambiguous and, at worst, an exercise in futility," and our daily human experience "proves how difficult it is to accurately predict the results or consequences that will flow from our actions, especially in the context of moral dilemmatic situations." (21)

That the theory is absurd and incoherent Grisez shows by proving that two conditions to be met which proportionalism requires are simply not compatible. What are these conditions? The first is "that a moral judgement is to be made, which means both that a choice must be made and a morally wrong option could be chosen." The second is "that the option which promises the definitely superior proportion of good to bad be knowable." (22)

Grisez puts it this way: "If the first condition is met and the morally wrong option could be chosen, then its morally acceptable alternative must be known. Otherwise one could not choose wrongly, for one chooses wrongly only when one knows which option one ought to choose and chooses a different option. But when the first condition is met, the second cannot be. A person who chooses an alternative, which promises less, cannot know the option, which promises the definitely superior proportion of good to bad. If the superior option were known as superior, its inferior alternative simply could not be chosen. Any reason for choosing it would be a better reason for choosing the superior option. Whenever one really knows that one possibility is definitely superior in terms of the proportion of good to bad it promises, any alternative simply falls away." (23)

In other words, to choose, alternatives must be available alternatives; however, they exist only when the goods promised by them are incommensurable. Were they commensurable, one alternative would be known to be definitely superior, and the attraction of the other alternatives would disappear, and they would no longer remain as alternatives.

III. Slippery Slope Argument

In order to show the danger, which follows from the theories carried out by proponents of euthanasia, here it is worthwhile to examine a principal argument used years ago against euthanasia. This argument has different metaphorical expressions, namely, "thin edge of the wedge," "the first step on the slippery slope," "the foot in the door," "the camel's nose under the tent." This argument forces us to consider whether unacceptable harms may result from attractive and apparently innocent first steps. It means that legitimisation of some forms of action will lead to other acts or practices that are morally objectionable. (24) The first step down the "slippery slope" is the hardest, but it will find itself moving so quickly that it will be very difficult to stop or turn back.

In other words, the "slippery slope" affects us in subtle increments, which in themselves seem not only harmless but often as helpful individual steps. Yet once we take the first step, we may be half way down the slope to the next step. We can end up at the bottom of tragic immorality without even realising how we got to a place that would have shocked us at first. (25) The sad example of how "slippery slope" operates in reality is the history of abortion. If technology can help actually abort a foetus easily and safely, then why not do it for women facing a life-threatening pregnancy? Next, the victims of rape and incest were included: why should these victims have to endure the trauma of bearing an unwanted child? Supporting arguments soon focused on the problem of other "unwanted pregnancies." Abortions became common during the second and even third trimester (as partial birth abortions). (26) The technology today enables us to prolong life in different ways. But some fear that there is a possibility of being forced to endure an unnatural, lingering dying process and/or have our bodies kept functioning longer after we die.

Usually a typical picture is drawn of an old man tied down in bed, in constant pain, clearly dying. He has tubes in every natural body orifice and in several artificial ones. The doctor is keeping him alive, perhaps to obtain a larger fee, perhaps because the doctor does not want to admit that he is losing the battle for this man's life. This is echoed commonly in retirement communities where senior citizens can be heard to say, 'I don't want you to keep me alive with all those tubes. When my time comes, let me go.' (27)

And here proponents of euthanasia find good soil to sow their deadly seeds. Here it is worth noticing that patients who are dying will go on to die regardless of whether treatment is given or not, but dying patients are really not the ones whom the proponents of "assisted suicide" and euthanasia have in their sights. They are looking for people who are not in pain, on life support systems, but are by their judgements a burden. It could be people who have had strokes, multiple sclerosis, Alzheimer's disease. These are people who someone thinks ought to die but who won't. The proponents of euthanasia want them to get dead. (28) Many euthanasia activists consider the "Living Will" just the first step on the road to all kinds of euthanasia. (29) They know that if they can get society to make the first critical step, all of the subsequent steps – no matter how many or how long they are – will be ***much*** easier. Once a society accepts the "Living Will," it completely changes the measuring of human worth. "The quality of life" ethic changes the focus from the ***spiritual*** to the ***physical, mental, emotional***. A person's usefulness to society, to his family, and even to himself is measured by the condition of his body and his mind. Once the proponents of euthanasia make this transformation from the "sanctity of life" ethic to the "quality of life" ethic, they can justify anything behind the masks of "compassion" and "altruism." (30) After a "Living Will" as the first step in the pro-euthanasia strategy follows the other – passive euthanasia – followed by assisted suicide and active voluntary euthanasia. The last step would be on the very bottom – involuntary euthanasia. The other steps became a reality when Dr. Jack Kevorkian had assisted in the suicides of scores of people. The goal of pro-euthanasia activists is a world – wide "right to die." But as Brian Clowes says: "As we learned with contraception and abortion, when the courts extend a new 'fundamental human right' to one group of people, it is unconstitutional to deny it to ***other*** groups of people. This means that if incurably ill people receive a 'right' to euthanasia, it is inevitable that the courts will quickly expand the 'right' to include every citizen in the United States. Anti-lifers first justified the contraception and abortion 'rights' under the 'hard cases' ... and within 5 years expanded them to include any reason whatever and at any time during preg-

nancy. Right now, they are justifying euthanasia for the 'hard cases' of terminally ill and comatose people and those suffering unbearable pain. The anti-lifers will inevitably expand the 'right' to euthanasia, just as they did with abortion, so that anyone of any age will be able to kill themselves with the 'aid' of a 'Doctor Death' for any reason whatsoever." (31)

The authorising of killing patients for their own benefit (according to proponents of euthanasia) when they are suffering excruciating pain or have a bleak future could open the door to a policy of killing patients for the sake of social benefits such as reducing financial burdens. Voluntary euthanasia might open the door to non-voluntary and perhaps involuntary euthanasia. The danger in permitting some killing is that it would habituate people to doing and to accepting killing in general. (32)

If direct killing of a competent individual at his or her own request becomes a legal right, the simple application of these now accepted legal principles might well legalise direct killing of those who have made no such request. This will occur without any further policy decision by voters or legislators – simply by the action of the courts when an appropriate case is heard. (33) Legalisation of voluntary active euthanasia will directly bring about legalisation of non-voluntary euthanasia.

Society might gradually move in the form of killing handicapped new – born to avoid social and familial burdens. There could be a general reduction of respect for human life as a result of the official removal of barriers to killing. Unfortunately, the principle is formulated in terms of quality of life or meaningful life. Sometimes it is formulated in terms of the naturalness and goodness of death. Sometimes it is formulated negatively and brutally by talking about certain non-competent persons as vegetables or cabbages. (34)

The holocaust under Nazi rule continues to serve as a powerful vision of the bottom of the slippery slope for a society that adopts mercy killing. The Nazis started by accepting euthanasia for the incurably ill and then moved on to their policies of genocide: "Whatever proportions [the Nazi] crimes finally assumed, it became evident to all who investigated them that they had started from small beginnings. The beginnings at first were merely a subtle shift in emphasis in the basic attitude of the physicians. It started with the acceptance of the attitude, basic in the euthanasia movement, that there is such a thing as life not worthy to be lived. This attitude in its early stages concerned itself merely with the severely and chronically sick. Gradually the sphere of those to be included in this category was enlarged to encompass the socially unproductive, the ideologically unwanted, the racially unwanted, and finally all non-Germans. But it is important to realise that the infinitely small wedged-in lever from which this entire trend of mind received its impetus was the attitude toward the unrehabilitable sick." (35)

The Nazi program did not begin with voluntary euthanasia. The Nazis did proceed from more to less restricted non-voluntary euthanasia, and they proceeded from non-voluntary euthanasia to genocide. Although this program was called euthanasia, the term simply camouflaged mass murder. Non voluntary euthanasia involves a very serious injustice right from the beginning. (36)

"As the euthanasia movement rolls on in many Western countries," Brian Clowes stresses, "those who combat the 'culture of death' must learn from those who made grievous mistakes regarding the value of human life." (37)

As we see, the "slippery slope" danger is real; "The camel's nose does get under the tent; once opened, the movement of the door to death by human choice may be constantly widening, and likely a never narrowing movement." (38) And it does not matter how we will call certain action – voluntary, non-voluntary, or involuntary euthanasia, or physician-assisted suicide – we see that what connects them is homicide. Beginning with an exceptional permission of euthanasia out of pity for a terminally ill person who requests it, there is a move towards granting power to euthanise anyone whose life is deemed unworthy of being lived. Once it has been agreed to violate the principle of the absolute respect for life, once its sacredness and unmanipulability have been repudiated, then somebody else has power over the life and death of disabled people. It could even become a "duty" to take the moral responsibility for putting an end to such "useless" and burdensome lives. It is a great injustice "when certain people, such as physicians or legislators, arrogate to themselves the power to decide who ought to live and who ought to die". Moreover, "the act of euthanasia appears all the more perverse if it is carried out by those, like relatives, who are supposed to treat a family member with patience and love, or by those, such as doctors, who by virtue of their specific profession are supposed to care for the sick person even in the most painful terminal stages." (39)

Conclusion

We see "in the earthly life of each individual human being, however damaged, a weight and significance such that the termination of that life can never rightly be chosen as a means of advancing overall human welfare – not even the welfare of that damaged individual himself." (40) For Christians, life is God's gift, and its end is to be determined by Him. God is sovereign over life and death: we have no jurisdiction in this area; therefore, we have no mandate to end lives.

God's dominion includes all of life, which means that suffering is a part of God's providence. Therefore, suffering that cannot be relieved by modern medical means is to be accepted as from the hand of a loving God who knows what he is doing, even when we do not understand. In looking at suffering and impending death, the Christian should see God's sovereign hand and purpose, as well as the opportunity for ministering to the weak and vulnerable.

Notes

1. A Working Party Report, "Euthanasia and Clinical Practice: Trends, Principles and Alternatives" in *Euthanasia, Clinical Practice and the Law*, ed. Luke Gormally (London: The Linacre Center for Health Care Ethics, 1994), 29. **2.** Ibid., 31. **3.** Cf. Ibid., 31. **4.** Ibid., 41. **5.** Ibid., 44. **6.** May, *Human Existence, Medicine and Ethics*, 141. **7.** Cf. A Working Party Report, "Euthanasia and Clinical Practice: Trends, Principles and Alternatives," 33. **8.** Ibid., 44. **9.** May, *Human Existence, Medicine and Ethics*, 142. **10.** Gen. 1:28. **11.** Cf. John 1:14. **12.** Germain Grisez, "Suicide and Euthanasia" in *Death, Dying and Euthanasia*, ed. Dennis J. Horan and David Mall (Frederick, Maryland: University Publications of America, Inc., 1980), 767. **13.** Germain Grisez, "Dualism and the New Morality" in *Atti Del Cong-resso Internazionale: Tommaso D'Aquino Nel Suo Settimo Centenario*, Vol. 5 (Napoli: Edizioni Domenicane Italiane, 1977), 131-132. **14.** Ibid., 131. **15.** Ibid., 141. **16.** Cf. Germain Grisez, *The Way of the Lord Jesus: Christian Moral Principles* (Chicago, Illinois: Franciscan Herald Press, 1983), 141. **17.** Ibid., 143. **18.** Ibid., 144. **19.** May, *Human Existence, Medicine and Ethics*, 140. **20.** Cf. Renee Mirkes, "Selective Termination: Doing Evil to Achieve Good?" in *Abortion: A New Generation of Catholic Responses*, ed. Stephen J. Heaney (Braintree, Massachusetts: The Pope John Center, 1992), 183. **21.** Ibid., 183. **22.** Grisez, *Christian Moral Principles*, 152. **23.** Ibid., 152. **24.** Cf. Beauchamp and Childress, *Principles of Biomedical Ethics* (New York: Oxford University Press, 1989), 139. **25.** Cf. Kenneth E. Schemmer, Dave and Neta Jackson, *Between Life and Death: The Life-Support Dilemma* (Wheaton, IL: Victor Books, 1988), 120. **26.** Ibid., 121. **27.** John C. Willke et al, *Assisted Suicide & Euthanasia: Past & Present*, 2. **28.** Ibid., 4. **29.** Living will' is a term used in the United States to refer to a document in which a person, while still competent, requests and directs that certain measures (which may be variously specified) should not be used to preserve him if and when he becomes seriously ill (as variously defined) and incapable of consenting to or refusing treatment. Beginning with the Natural Death Act 1976 (California), a number of American States have made laws to give legal effect to such documents. Some of these laws are quite ambiguous and may amount to partial authorisation of euthanasia, even involuntary euthanasia. For example, the Arkansas statute of 1977 authorises either parent of a child, or the guardian of a mentally incompetent person, to execute a document 'on his be-

half' denying him not only 'extraordinary,' 'extreme,' or 'radical' treatment but also all '*artificial* medical or surgical means calculated to prolong his life'; such a document is effective provided it contains 'a signed statement by two physicians that extraordinary means would have to be utilised to prolong life.' The movement to popularise and give legal effect to living wills has been particularly promoted by an organisation describing itself as 'a successor of the Euthanasia Society of America.' In England, Exit, which campaigns for euthanasia, has distributed a living will under the description 'Advance Declaration.' Broadly similar documents have been distributed by persons who have no euthanasiast intent and who are concerned only to prevent the unreasonable prolongation of dying. In every case the precise wording of the document or law must be studied closely to discern whether it has euthanasiast intent or effect." A Working Party Report, *Euthanasia and Clinical Practice: Trends, Principles and Alternatives*, 26. **30.** Cf. Brian Clowes, *The Facts of Life: An Authoritative Guide to Life and Family Issues* (Front Royal, Virginia: Human Life International, 1997), 141-142. **31.** Ibid., 142-143. **32.** Cf. Grisez and Boyle, *Life and Death with Liberty and Justice*, 172. **33.** Cf. Robert Powell, "They Sent Me Home to Die" in *Life Cycle* 114 (April 1992):1. **34.** Cf. Grisez and Boyle, *Life and Death with Liberty and Justice*, 172-173. **35.** Leo Alexander, "Medical Science under Dictatorship" in *Death, Dying and Euthanasia*, ed. Dennis J. Horan and David Mall (Frederick, Maryland: University Publications of America Inc., 1980), 584. **36.** Cf. Grisez and Boyle, *Life and Death with Liberty and Justice*, 242. **37.** Brian Clowes, *The Facts of Life: An Authoritative Guide to Life and Family Issues*, 144. **38.** David W. Louisell, "Euthanasia and Biathanasia: On Dying and Killing" in *Death, Dying and Euthanasia,* ed. Dennis J. Horan and David Mall (Frederick, Maryland: Aletheia Books, University Publications of America, Inc., 1980), 389. **39.** John Paul II, *Evangelium Vitae*, 66. **40.** A Working Party Report, "Euthanasia and Clinical Practice: Trends, Principles and Alternatives,"45.

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Abstract

Human beings are made in the image and likeness of God and are therefore of intrinsic worth or value, beyond all prices. Almost all Christian pro-life arguments spring from the fountain of personal dignity. Euthanasia would make moral sense only if it were possible to say, morally, that this dignity had vanished. To commit euthanasia is to act with the specific intention that somebody should be nobody. This is the fundamental error of all immorality in human relations. To commit euthanasia is to fail to see the intrinsic worth or dignity of the person. The judgement that what *has* worth, intrinsically, somehow does *not* have worth, is both logically and morally wrong. The ethics of euthanasia is based on dualistic anthropology and wrong moral presuppositions underlying the defence of euthanasia, namely, proportionalism and consequentialism. The basic claim of proponents of the ethics of euthanasia is that human persons are consciously experiencing subjects whose dignity consists of their ability to make choices and to determine their own lives. Bodily life, according to them, is a *condition* for personal life because without bodily life one cannot be a consciously experiencing subject. It means that bodily life is distinct from personal life. Thus, the body and bodily life are *instrumental goods*, goods *for* the person, not goods *of* the person. It thus follows that there can be such a thing as a life not worth living — one can judge that bodily life itself is useless or burdensome, and when it is, the person, i.e., the consciously experiencing subject, is at liberty to free himself of this useless burden. Today a key in fighting euthanasia and assisted suicide is better care for the sick and dying. The dignity of the sick cannot be erased by illness and suffering. Such procedures are not private decisions; they affect the who-le society. Death with dignity, in the end, is the realisation that human beings are also spiritual beings. We have to promote the way of caring for the dying in which mercy is extended to the patients without inducing death.

Key words: euthanasia, physician – assisted suicide, anthropology, proportionalism/ consequentialism, morality, slippery slope, palliative care.

Abstrakt

Ľudské bytosti sú stvorené na obraz a podobu Božiu, a preto majú vlastnú vnútornú (intrinsic) hodnotu, ktorá je presahuje každé bežné ocenenie. Temer všetky kresťanské 'pro-life' argumenty vyvierajú z prameňa dôstojnosti človeka. Eutanázia by mohla nadobudnúť morálny zmysel iba vtedy, ak by bolo možné tvrdiť, morálne, že táto dôstojnosť sa pominula. Spáchať eutanáziu znamená konať v špecifickom úmysle, aby sa 'niekto' stal 'nikým'. Toto je základný omyl každej nemorálnosti v ľudských vzťahoch. Vykonať eutanáziu znamená poprieť vnútornú hodnotu a dôstojnosť danej ľudskej osoby. Úsudok, že niečo, čo *má* hodnotu, ju zároveň aj *nemá*, je logicky aj morálne chybný. Etika eutanázie sa zakladá na dualistickej antropológii a chybných morálnych predpokladoch, poskytujúcich základ pre obhajobu eutanázie, t.j. na proporcionalizme a konzekvencionalizme. Základné tvrdenie zástancov etiky eutanázie je, že ľudské osoby sú vedome vnímajúce subjekty, ktorých dôstojnosť spočíva v schopnosti rozhodovať sa a ovplyvňovať svoj vlastný život. Telesný život, podľa nich, je *podmienkou* osobného života, pretože bez telesného života niekto nemôže byť vedome vnímajúcim subjektom. To znamená, že telesný život je odlišný od života osoby. Potom telo a telesný život sú *inštrumentálne* dobrá, dobrá pre osobu, nie dobrá osoby. Z toho vyplýva, že môže existovať "život, ktorý nemá hodnotu, aby sa žil". Potom možno tvrdiť, že telesný život je zbytočný alebo zaťažujúci, a keď je to tak, potom osoba, t.j. vedome vnímajúci subjekt, je slobodná v tom, aby sa 'oslobodila' od tohoto od tejto zbytočnej záťaže. Kľúčovou vecou odporu voči eutanázii a asistovanej samovražde v súčasnosti je zlepšenie starostlivosti o chorých a umierajúcich. Dôstojnosť chorého nemôže byť zmazaná chorobou a utrpením. Takýto postup (eutanázia, asistovaná samovražda, pozn. red.) nie je len súkromným rozhodnutím; ovplyvňuje celú spoločnosť. Umrieť dôstojne, napokon, znamená pochopiť, že ľudské bytosti sú aj duchovnými bytosťami. Musíme presadzovať takú starostlivosť o umierajúcich, pri ktorej sa pacientom preukazuje milosrdenstvo bez toho, aby sa spôsobovala smrť.

Kľúčové slová: eutanázia, asistovaná samovražda, antropológia, proporcionalizmus/ konzekvencionalizmus, morálka, klzká plocha, paliatívna starostlivosť.

BRIEF COMMUNICATIONS

EUTHANASIA: THE CONCEPT AND THE SITUATION IN TURKEY

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Introduction

As a coined word **euthanasia** – 'good and gentle death', originates from Greek "eu" meaning good and "thanatos" meaning death. It refers to the deliberate cessation or forgoing of the life-saving procedures or treatment, administration of a lethal substances, or using any other means by a physician that result in the death of a patient. The request of the patient for his/her life to be terminated by the physician is considered being an indispensable part of the notion ("voluntary euthanasia"). Euthanasia is usually believed to be performed for not to let a terminally ill patient to suffer any longer ("merciful death"). [1]

Sometimes, two 'categories' of euthanasia are outlined: 1. Active euthanasia – the physician performs a concrete act, which brings about the death of the patient (e.g. administration of a lethal dose of a drug), 2. Passive euthanasia – cessation or forgoing of the life-saving procedures by a physician, with an aim to bring about the death of the patient.

Other categorisation distinguishes: a) voluntary euthanasia (patient asks for it), b) non-voluntary euthanasia (patient does not ask for it), c) forced euthanasia (patient does not want it).

Historical Remarks

In antiquity, the terminally ill would not be allowed to enter Asklepieion. Hanging in the entrance of the temple, there was an inscription stating, "According to the will of Gods, death is prohibited to enter to a holy site."(1) *Plato* (427 – 347 BC) argued that Asklepios should dedicate the art of medicine to those patients, who had the likelihood of getting well with the treatment. Physicians ought not to maintain treating the terminally ill, since it would neither be to the patient's nor to the public's benefit (2). *Aristotle* (384 – 322 BC) agreed with his master Plato and stated that medical treatment should be ceased for the terminally ill, and it would be to the benefit both of the physician and the patient.

Spartans, citizens of the Greek city-state Sparta, threw their newborn babies with visible somatic defects to the depths of a declivity. As a similar pattern, Indians left the terminally ill to the flow of the Ganj River (2).

Hippokrates' Oath, on the other hand, strongly opposes euthanasia. In *Corpus Hippokraticum*, Hippokrates argues: "The physician is responsible for completely restoring patients' health as well as stopping their suffering," and "He is also charged with the duty to carry out the treatment of the terminally ill."

Meaning gentle and good death in Greek, the word "euthanasia" was commonly used during the Roman period. Historian *Suetonius* (120 BC) recorded, that when Emperor Augustus heard about the quick and painless death of a patient, he used the word and wished 'euthanasia' for himself and his family." (3)

Galenos (129 – 199 AC) treated the pain in his patients with opium. Hospices for the care of terminally ill patients began to appear early in the Middle Age.

Ambroise Paré (1510 – 1590), the pioneer of modern surgery, who lived in the 16th century, argued that the choice between life and death belonged only to God; since the suffering of a patient or recovering of his/her health was within the boundaries of the God's will. (4)

Francis Bacon (1561-1626) used the term "euthanasia exterior" to describe the act's aim to end the life of the terminally patient, not to waste the time and effort with the treatment.

In the 19th century, however, *Thomas Percival (1740-1804)* discussed the physician-patient relationship in his book *Medical Ethics* (1803). It was a period when euthanasia was strongly opposed. (5)

In the beginning of the 20th century, *Émile Durkheim (1857-1917),* as a sociologist, argued that ethical views dominant during the ancient periods and the middle ages were static, but on the other side, ethical codes connected and developing with the public were dynamic. (6)

Early Attempts of Euthanasia Legislation

Euthanasia was first legalised in 1906 upon the proposed bill by Miss *Ann Hall (1875-1943)* to the New York Medical Academy. The proposal included the following crucial idea: "A patient suffering from an incurable disease causing intolerable pain is to have the right to ask an authorisation to end his/her suffering from a commission including four members."

The Parliament of Iowa passed the proposal providing the permission for death of congenitally defect, disabled and mentally retarded children. But the congress convened in Washington strongly refused to pass the draft law (7).

The issue was also discussed at the International Tuberculosis Congress in 1907, in the German Parliament in 1913, and in the House of Lords in 1936 (8).

Situation in Some Countries

Active euthanasia is illegal in the **US**. However, the patient may demand cessation of particular medication or surgery, and the physician should act according to the expressed wishes of the patient.

In the **Netherlands**, both 'passive' and 'active' euthanasia is legal. The law regulates the 'right to die' as follows (9): 1. The patient is to demand the application of euthanasia. 2. The suffering of the patient is to be at an intolerable level. 3. Every medical mean is to be applied first. 4. The patient is to be fully informed about euthanasia. 5. The physician in charge is to consult two other physicians capable of taking decisions independently.

Euthanasia is illegal also in almost all **EU countries** – a recent exception being **Belgium.** In some regions of **Australia**, there were attempts to make euthanasia legal, but the law was later struck down by the parliament.

It was stated in the declaration of the World Medical Association (**WMA**; Madrid, 1987) that to perform the assisted suicide or euthanasia is not ethical, even when the patient gives his/her relatives permission to act in this regard. (12)

Turkey

Similarly to many countries in the world, euthanasia has not been legalised in **Turkey**. The Article 13/3 of *Me-*

dical Deontology Regulation, that has been in effect since January 3, 1960 does not allow even the 'passive euthanasia'. According to the Regulation: "The physician and dentist are not authorised by law to conduct any action having any other reason than restoring the health of the patient." The Article 14/1 of the Regulation states: "The dentist and physician act in line with requirements of the patient's situation. If it is not possible to keep the patient alive or restore his/her health, they are still responsible for seeking remedies to decrease the amount of pain."(10) According to Article 448 of the *Turkish Penal Code*, any action opposing these articles are deemed the same as a murder.

Following are the views of some Turkish physicians regarding euthanasia. *Dr. Cengiz Aslan* (brain surgeon) argues: "There is no point in trying to keep a patient alive, whose brain is already dead. Because, all your deeds are in vain. However, the organs of the patient in question may be used and transplanted to those in need. As doctors, we demand to have the right to cease medication and stop the machines of patients, who maintain their 'lives' connected to a machine with their brains being already dead." Similarly, *Prof. Dr. Kutay Akpir* from the Department of Anaesthesiology and Reanimation puts forth his opinion, saying: "Transplanting the patient's organs, whose brain has already died, should not be regarded as euthanasia." (11)

Performing euthanasia is also deemed illegal in the *Patient's Rights Regulation* of the Ministry of Health. According to the Regulation: "The right to survive shall not be abandoned in any circumstances. No lives are allowed to be terminated."

"Right to die" movement

There are several organizations in various countries demanding the legal right for patients to commit assisted suicide. 27 'euthanasia associations' are known to exist as of 1988 in the following countries: Austria, Germany, Belgium, Denmark, England, France, Holland, India, Italy, Japan, Canada, Colombia, New Zealand, Switzerland, Sweden, Spain, South Africa, the US, and Zimbabwe. The oldest of these is the "Voluntary Euthanasia Society". (13)

The goals of euthanasia societies can be delineated in three groups:

1. Decriminalisation of 'mercy killing'. It is already 'achieved' by the specific laws in Holland (more recently also in children), and in Belgium. There are strong pressures from 'liberal' circles in Europe and beyond to have this list speedily extended.

2. 'Self deliverance' through euthanasia or assisted suicide: there are already several associations or institutions operating in some countries (usually on the border of law) offering as a special service to end the lives of individuals suffering of an incurable disease.

3. Pushing for 'passive euthanasia': picking up so-called 'hard cases', and discouragement of medical treatments in people with incurable diseases, persistent vegetative state (PVS), coma, or babies born with severe disabilities; pushing to regard "food and water" a medical treatment that should be stopped in such patients ("removing the tube").

Conclusion

Although the problem of euthanasia started to gain a widespread attention throughout the world, becoming a relatively frequent topic for legislative initiatives and public media campaigns, at present, it is neither accepted nor authorised in Turkey. This is due both to the deontological and legal reasons. The surveys concerning the public opinion on the issue have shown that euthanasia is not regarded positively by the Turkish population. i

Notes

[1] Euthanasia is sometimes compared with what happens at the cellular level within the process of *apoptosis* – physiologically programmed death of the cell. The cells that reach the end of their life span, or those genetically or otherwise damaged, undergo this cascade of events that are pre-programmed in their genome (genes for apoptosis). The result of these processes is the cell 'suicide'. A cell has to leap this process in order to become malignant. (15).

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Abstract

The paper gives a brief conceptual and historical overview of euthanasia. These are supplemented by considerations of the attitudes to euthanasia and assisted suicide in Turkey. At present, euthanasia is neither accepted nor authorised in Turkey. This is due both to deontological and legal reasons. It is also not regarded positively by the general public.

Key words: euthanasia, assisted suicide, conceptual and historical issues, situation in Turkey

Abstrakt

Práca podáva stručný konceptuálny a historický prehľad problematiky eutanázie, ktorý dopĺňa informáciami o postojoch k eutanázii a asistovanej samovražde v Turecku. Ani eutanázia, ani asistovaná samovražda nie sú v súčasnosti v Turecku akceptované, ani povolené, a to tak z deontologických, ako aj z legislatívnych dôvodov. Ani široká verejnosť eutanáziu v Turecku neakceptuje.

Kľúčové slová: eutanázia, asistovaná samovražda, koncepčné a historické aspekty, situácia v Turecku.

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RELATIONSHIPS BETWEEN THE CENTRAL ("NATIONAL") ETHICS COMMITTEE AND LOCAL ETHICS COMMITTEES IN THE SLOVAK REPUBLIC (1)

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Legal situation concerning ethics committees in Slovakia

The first document devoted to ethics committees (ECs) was published by the Ministry of Health of the Slovak Republic (MH SR) in June **1992**, entitled "Guidelines for the establishment and work of ECs in health care facilities and research institutions" **(2)**. These guidelines, which at the time of their publication were quite progressive and comprehensive, will soon be replaced by the specific and detailed regulations of the MH SR to be issued under the new health legislation, which comes to force on Jan. 1, 2005 (see below).

At present, from the legal point of view, ECs in the Slovakia Republic are established according to the requirements of either:

a) §40 par. (4) of the Law No. 277/**1994** Coll. on health care – for ECs to review biomedical research projects (this will be completely replaced by the law No. 576/2004 Coll. on health care, see below); or

b) §16 par. (2) sub-paragraph j) of the Law No. 140/**1998** Coll. on drugs and health equipment – for ECs to review protocols of drug clinical trials.

The requirements set in the above mentioned laws are rather general and simple. Local ECs themselves, however, and the health care facilities and research institutions, when establishing and developing these bodies, have been respecting, still on a voluntary basis, the relevant international requirements and standards (especially those of the GCP) as reflected in the ECs'' statutes and standard ope-rating procedures (SOPs) **(3)**.

New health legislation – Law No. 576/**2004** Coll. on health care (to be in force since January 1, 2005) pays a considerable attention to the problem of ECs. It provides for 3 types of ECs:

a) Central Ethics Committee (CEC) of the Ministry of Health, established by the minister of health; to advise the minister, other ministries and top state institutions (government, president,...) on bioethical issues, and to perform other tasks of a „national bioethics body",

b) Ethics Committees (ECs), established by directors of health care facilities or biomedical research institutions to:

– review protocols of clinical trials or biomedical research projects planned to be performed in that facility/institution, and to provide a follow up of the research protocol approved ("***research ethics committee***"), and/or

– advice the director of health care facility or of biomedical research institution providing also health care on ethical aspects of health care provided by the facility/institution ("***clinical ethics committee***"),

c) Regional Ethics Committees (RECs) to review and follow up multicentre clinical trials and multicentre biomedical research projects (with the exception of the review of the 'local aspects' of research projects).

The law requires the Ministry of Health to issue the comprehensive regulation on ECs. It is being elaborated just now by a task force sponsored by CEC.

Relationships between Central Ethics Committee and Ethics Committees

CEC, according to its statutes issued by the minister of health (June 2002), is expected, among its other duties, to **provide guidance to** (local) **ECs** in the health care facilities and biomedical research institutions in whole country. (In the near future, when RECs are established, they will be expected to serve with guidance to ECs at their territory.)

In practice, representatives of ECs (usually their chairs or secretaries) approach CEC members (usually the chair), or CEC as such, with ***requests for clarification, or guidance*** on more difficult, new, or unclear cases they meet in their review or consultation work, or – so far quite rarely – in the clinical practice of ‚their' health care facilities. These requests are either posed in writing – then the CEC's chair responds in writing, consulting, if necessary, other members of CEC (and informing CEC on its subsequent plenary meeting), or seeking advice from the whole CEC on its next scheduled plenary meeting; or the requests are posed during informal ***telephone consultations*** that are usually given by the CEC chair.

Since 2002, the ‚tradition' of ***regular meetings of ECs*** representatives and members with CEC presidium and members has been re-established (going back to the early phase of CEC work in years 1990 – 1992). Usually, these meetings are connected either with an international bioethics conference held in Bratislava, or with a specially organized course on actual ethical issues (up till now those were predominantly research ethics issues).

The **web page** for ECs is being established within the web page of CEC hosted by the server of the Ministry of Health (www.health.gov.sk). It should be operational by the end of January 2005.

Exceptionally, upon a specific request from the (local) EC, CEC is taking upon itself an **ethics review** of the research project, which is felt by the EC to exceed its competence and the competence of any other EC (or REC) in the country (e.g. unprecedented research projects utilizing newest (bio)technologies, stem cells, gene therapies, etc.).**(4)**

Conclusion

Systematic efforts have been present in the Slovak Republic since early 90-ties of the last century, to build a functioning system of ethics committees (ECs) in the health care facilities ("clinical ECs") and institutions of biomedical research ("research ECs"). During the latest years, these efforts are being tranformed into substantial legislative improvements. Also, concrete means of mutual communication and support between CEC and LECs in the country are being developed and introduced gradually. The main aim of these activities is to improve the situation concerning the application of ethics in health care and in biomedical research. To provide a better protection of the patients, and of subjects of research studies – including those involved in the clinical trials of new drugs, and, ultimately, to enhance favourable conditions for the practice of medicine and provision of health care in Slovakia.

Notes

1. Based on the text prepared for the 4th National Ethics Councils Forum meeting, December 21 – 22, 2004, Amsterdam (NL). **2.** Ministry of Health, Bratislava (Slovakia): Guidelines for

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Glasa, J.: Relationships between the Central ("National") Ethics Committee and Local Ethics Committees in the Slovak Republic. [Vzťahy medzi Centrálnou („Národnou") etickou komisiou a lokálnymi etickými komisiami v Slovenskej republike.] Med. Eth. Bioet., 11, 2004, No. 3 – 4, p. 9 – 10.

Abstract

A brief outline about the present relationships between Central ("National") Ethics Committee at the Ministry of Health of the Slovak Republic, and the local ethics committees in Slovakia is given. The planned improvements concerning the function of the system of ethics committees in the Slovak Republic are also outlined.

Key words: ethics committees, local, national; communication

Abstrakt

Článok podáva krátky prehľad o aktuálnych vzťahoch medzi Centrálnou ("Národnou") Etickou Komisiou Ministerstva zdravotníctva Slovenskej republiky a miestnymi (lokálnymi) etickými komisiami na Slovensku. Uvádza aj plánované opatrenia na zlepšenie fungovania systému etických komisií v Slovenskej republike.

Kľúčové slová: etické komisie, miestne, národné; komunikácia

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DOKUMENTY / DOCUMENTS

CLINICAL TRIAL REGISTRATION A Statement from the International Committee of Medical Journal Editors

Altruism and trust lie at the heart of research on human subjects. Altruistic individuals volunteer for research because they trust that their participation will contribute to improved health for others and that researchers will minimize risks to participants. In return for the altruism and trust that make clinical research possible, the research enterprise has an obligation to conduct research ethically and to report it honestly. Honest reporting begins with revealing the existence of all clinical studies, even those that reflect unfavorably on a research sponsor's product.

Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision-making. Researchers (and journal editors) are generally most enthusiastic about the publication of trials that show either a large effect of a new treatment (positive trials) or equivalence of two approaches to treatment (non-inferiority trials). Researchers (and journals) typically are less excited about trials that show that a new treatment is inferior to standard treatment (negative trials) and even less interested in trials that are neither clearly positive nor clearly negative, since inconclusive trials will not in themselves change practice. Irrespective of their scientific interest, trial results that place financial interests at risk are particularly likely to remain unpublished and hidden from public view. The interests of the sponsor or authors notwithstanding, anyone should be able to learn of any trial's existence and its important characteristics.

The case against selective reporting is particularly compelling for research that tests interventions that could enter mainstream clinical practice. Rather than a single trial, it is usually a body of evidence, consisting of many studies, that changes medical practice. When research sponsors or investigators conceal the presence of selected trials, these studies cannot influence the thinking of patients, clinicians, other researchers, and experts who write practice guidelines or decide on insurance-coverage policy. If all trials are registered in a public repository at their inception, every trial's existence is part of the public record and the many stakeholders in clinical research can explore the full range of clinical evidence. We are far from this ideal at present, since trial registration is largely voluntary, registry data sets and public access to them varies, and registries contain only a small proportion of trials. In this editorial, published simultaneously in all member journals, the International Committee of Medical Journal Editors (ICMJE) proposes comprehensive trials registration as a solution to the problem of selective awareness and announces that all eleven ICMJE member journals will adopt a trials-registration policy to promote this goal.

The ICMJE member journals will require, as a condition of consideration for publication, registration in a public trials registry. Trials must register at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after July 1, 2005. For trials that began enrollment before this date, the ICMJE member journals will require registration by September 13, 2005, before considering the trial for publication. We speak only for ourselves, but we encourage editors of other biomedical journals to adopt similar policies. For this purpose, the ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g., phase 1 trials), would be exempt.

The ICMJE does not advocate one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not-for-profit organization. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable. An acceptable registry must include at minimum the following information: a unique identifying number, a statement of the intervention (or interventions) and comparison (or comparisons) studied, a statement of the study hypothesis, definitions of the primary and secondary outcome measures, eligibility criteria, key trial dates (registration date, anticipated or actual start date, anticipated or actual

date of last follow-up, planned or actual date of closure to data entry, and date trial data considered complete), target number of subjects, funding source, and contact information for the principal investigator. To our knowledge, at present, only *www.clinicaltrials.gov*, sponsored by the United States National Library of Medicine, meets these requirements; there may be other registries, now or in the future, that meet all these requirements.

Registration is only part of the means to an end; that end is full transparency with respect to performance and reporting of clinical trials. Research sponsors may argue that public registration of clinical trials will result in unnecessary bureaucratic delays and destroy their competitive edge by allowing competitors full access to their research plans. We argue that enhanced public confidence in the research enterprise will compensate for the costs of full disclosure. Patients who volunteer to participate in clinical trials deserve to know that their contribution to improving human health will be available to inform health care decisions. The knowledge made possible by their collective altruism must be accessible to everyone. Required trial registration will advance this goal.

Catherine De Angelis, M.D., M.P.H.
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Hal C. Sox, M.D.
Editor, Annals of Internal Medicine

Martin B. Van Der Weyden, M.D.
Editor, The Medical Journal of Australia

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Poznámka redakcie: Všetky štúdie klinického skúšania liečiv v Slovenskej republike, rovnako ako takéto štúdie vo všetkých členských krajinách Európskej únie, podliehajú povinnej registrácii v Európskej databáze klinických štúdií (EudraCT), ktorú spravuje Európska agentúra pre liečivá (EMEA) so sídlom v Londýne.

Dr. Jozef Glasa

ETHICAL CODE OF THE PHARMACEUTICAL INDUSTRY IN SLOVAKIA
(Excerpts)

Contents

Excerpts

Preface

The pharmaceutical industry* promotes the concept of good health, and a positive, health-oriented approach to daily living. Recognising that medicines play a vital role in the prevention, amelioration and treatment of disease states, the industry undertakes:

- to provide medicines that conform to the highest standards of safety, efficacy and quality;
- to ensure that medicines are supported by compre hensive technical and informational services in accordance with currently accepted medical and scientific knowledge and experience;
- to use professionalism in dealing with healthcare professionals*, public health officials and the general public.

The industry is committed to the quality use of medicines and rationale prescribing, and supports that its products be used in accordance with the directions and advice of healthcare professionals. To ensure that the information* is available upon which to make informed prescribing decisions, it is necessary for the manufacturer* to disseminate to healthcare professionals the specialised product information gained during the research and development process, and from experience gained in clinical use. In doing so, the manufacturer draws attention to the existence and nature of a particular product* by appropriate educative and promotional measures.

With the full cooperation of the industry, there is now adequate legislation designed to safeguard the public by ensuring that all products marketed meet standards of quality, effectiveness and safety which are acceptable in the view of present knowledge and experience.

While it is possible to legislate satisfactorily for the testing, manufacture and control of medical products, appropriate standards of marketing conduct cannot be defined by the same means. For this reason, responsible manufacturers have concurred in the promulgation of the Code of Conduct and submitted to its constraints.

A Member* of the ADL, GENAS and SAFS (**see Editorial note**) undertakes to comply with the SAFS Statutes and the Code of Conduct of Pharmaceutical Industry in Slovakia.

Complaints against any activity of a member company should be made to the Ethical Committee of Pharmaceutical Industry in Slovakia as provided for in the Code (Operating procedures).

Note: A glossary of terms is provided. The first inclusion in the Code of a term defined by the glossary is denoted by asterisk (*).

Preamble

(a) This Code of Conduct sets out standards of conduct for the activities of companies when engaged in the marketing of prescription products used under medical supervision as permitted by Slovak legislation. The Code owes its origin to the determination of the ADL, GENAS and SAFS to secure universal acceptance and adoption of high standards in the marketing of prescription products for human use.

(b) Acceptance and observance of the Code is a condition of membership of the ADL, GENAS and SAFS, and a Member must comply with both the letter and the spirit of the Code. Members should ensure that all agents acting on their behalf are fully conversant with the provisions of this Code. Pharmaceutical companies outside the associations are invited to accept and observe this Code.

The Code shall be supervised and administered by the Ethical Committee. The Committee may issue determinations from time to time for the purpose of interpretation of certain sections of the Code. Complaints concerning alleged breaches of the Code should be reported to the Ethical Committee.

(c) A major guiding principle of the Code is that, whenever a promotional claim* is made for a product, it shall be accompanied by Slovak Product Information.*

(d) Failure to comply with the Code will result in sanctions being applied under the provisions of operating procedures. Adherence to this Code in no way reduces Members' responsibilities to comply with the Slovak legislation and Codes, including the IFPMA Code. Promotion* of prescription-only products to the general public is prohibited by law.

PROVISIONS OF THE CODE

1. Nature and availability of information and claims

1. 1. Responsibility

It is the responsibility of Members, their employees and their medical/technical advisers to ensure that medical content* included in all promotional material* is correct*, fully supported by the product information, literature* or „Data on File"*, where the latter do not conflict with the former. Activities of company representatives* must comply with the Code at all times.

1. 2. Provision of Substantiating Data

Further to the information supplied or generally available, the manufacturer will, upon reasonable request, provide healthcare professionals with additional accurate and relevant information about products which it markets.

Substantiating information must not rely solely on data on file.

Data cited in promotional material in support of a claim, including "data on file" or "in press" must be made available to healthcare professionals and industry companies upon request.

1. 3. False or Misleading Claims

Information, medical claims* and graphical representations about products must be current, accurate, balanced and must not mislead either directly, by implication, or by omission.

Information, claims and graphics* must be capable of substantiation*, such substantiation being provided without delay at the request of health professionals.

1. 3. 1. Unapproved products and indications. Products that have not been approved for registration by ŠÚKL must not be promoted. However, samples of unapproved products may be displayed and educational material* made available at International Congresses* and local Congresses in accordance with Section 6. This restriction also applies to unapproved indications for registered products.

1. 4. Good Taste

Promotional material (including graphics and other visual representations) should conform to generally accepted standards of good taste and recognise the professional standing of the recipients.

1.5. Unqualified Superlatives

Unqualified superlatives must not be used. Claims must not imply that a product or an active ingredient is unique* or has some special merit, quality or property unless this can be substantiated. The word "safe" must not be used without qualification.

1.6. New Products

The word "new" must not be used to describe any

product, presentation, or therapeutic indication which has been available and generally promoted for more than 12 months in Slovak Republic.

1. 7. Comparative Statements

Comparison of products must not be disparaging, but must be factual, fair and capable of substantiation and referenced to its source. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis or in any other way. „Hanging" comparatives - those which merely claim that a product is better, stronger, more widely prescribed etc must not be used.

„Data on file" when used to substantiate comparative statements must comply with the requirement of Section 1.2.

1. 8. Imitation

Promotional information should not imitate the devices, copy, slogans or general layout adopted by other manufacturers in a way that is likely to mislead or confuse.

1. 9. Medical Ethics

Doctors' names or photographs must not be used in any way that is contrary to medical ethics.

1. 10. Distinction of Promotional Material

Promotional material must be clearly distinguishable as such.

2. Product Information

Certain types of promotional material described in Section 3 must be accompanied by either full or abridged product information. Wherever required, product information must appear in a type size of not less than 2 mm on a background sufficiently contrasting for legibility. Major headings should be easily identifiable. Product information must not be overprinted or interspersed with promotional phrases or graphics and must clearly identify any recent change of clinical significance*.

2. 1. Full or abridged product information must accompany all promotional material in the Slovak Republic.

2. 2. Abridged Product Information may be used in medical publications.

2. 2. 1. Abridged Product Information must accurately reflect the full Product Information but may be a paraphrase or précis of the full Product Information.

2. 2. 2. Under the heading "Abridged Product Information", the following shall appear:

(a) Approved indications for use, (b) Contra-indications, (c) Clinically significant warnings, (d) Clinically significant precautions for use, (e) Clinically significant adverse effects and interactions, (f) Available dosage forms, (g) Dosage regimens and routes of administration, (h) Dependence potential of clinical significance, (i) Reference to special groups of patients.

Where the full Product Information does not include items under these headings, such headings are not required to be included in the document.

2. 3. Changes of Clinical Significance

2. 3. 1. Where a change of clinical significance relating to product safety is incorporated into the Product Information, it should be indicated in all representations of the Product Information for a period of 12 months from the date of change by an asterisk(s) to a footnote in type size of not less than 2 mm: Please, note change(s) in product information.

2. 3. 2. The full text of the changed section should be included in any abridged Product Information during this period.

2. 3. 3. Where a Member is not actively promoting the product, written advice of the change to product information should be forwarded to the appropriate healthcare professionals.

3. Promotional Material*

3. 1. Journal Advertising

Journal Advertising must conform with the requirements of one or other of the following categories. The information required shall appear in each publication in a type size of not less than 2 mm, and should appear on a background sufficiently contrasting for legibility.

3. 1. 1. Full advertisement*

3. 1. 1. 1. A full advertisement must contain the following within the body of the advertisement: (a) The brand name of the product, (b) The INN* of the active ingredient(s), (c) The name of the registration holder and its mailing address in Slovak Republic, (d) The full or abridged Product Information.

3. 1. 1. 2. A full advertisement is mandatory for the advertising of all new chemical entities* or the advertising of new indications for 12 months from the date of first advertising in medical publications, or longer at the discretion of the advertiser.

3. 1. 1. 3. The Product Information should be placed adjacent to the body of the advertisement. Where it is not practicable to do so, the advertisement must carry a statement in type size not less than 2 mm to the effect of the following statement: „Please review Product Information before prescribing. In this publication, product information can be found ...." At the point ..., insert the page number in the publication where the information can be found or reference to an adequately referenced product information section or advertisers index. Product Information should form a fixed part of the journal.

3. 1. 1. 4. The use of an abridged advertisement is permitted after 12 months from first advertising of a new chemical in medical publications.

3. 1. 1. 5. The abridged Product Information should be placed adjacent to the body of the advertisement. Where it is not practicable to do so, the advertisement will carry a statement in not less than 2 mm type size, to the effect of the following statement: "Please review product information before prescribing. In this publication, product information can be found ..." At the point ..., insert the page number in the publication where the information can be found or reference to an adequately referenced product information section or advertisers index. Product Information should form a fixed part of the journal.

3. 1. 2. Short advertisement

3. 1. 2. 1. A short advertisement is designed to remind a prescriber of a product's existence, and must not contain promotional claims. The sole use of a short advertisement within any one issue of a publication is not permitted before 12 months from first advertising of a new chemical entity or before 12 months following a change of clinical significance made to the Product Information.

3. 1. 2. 2. A short advertisement must contain: (a) The brand name of the product, (b) The INN of the active ingredient(s), (c) The name of the registration holder and its mailing address, (d) A statement to the effect that further information is available on request from the supplier.

3. 1. 2. 3. A short advertisement may contain: (a) up to 5 words describing therapeutic class*, but without the use of promotional phrases, (b) graphics, (c) a statement of available dosage forms, (d) a statement referring to the location of product information in a reference manual.

No other material is permitted.

3. 1. 3. Company Commissioned Articles

3. 1. 3. 1. Company Commissioned Articles must be

identified as such in a type size of not less than 2 mm.

3. 1. 3. 2. The Member which is responsible for the insertion of the Company Commissioned Article must be clearly identified at either the top or the bottom of the Company Commissioned Article in a type size of not less than 2 mm.

3. 1. 3. 3. Company Commissioned Articles must conform to all relevant provisions of Section 1 of this Code.

3. 1. 3. 4. Commissioned Articles shall also conform to the requirements of sections 3.1.1. and 3.1.2. of the Code of Conduct.

3. 2. Materials for use by Medical Representatives*

A major guiding principle of the Code is that, whenever a promotional claim is made for a product, it shall be accompanied by product information Where multiple forms of promotion items are intended to be distributed at one time, the product information must appear at least once.

3. 2. 1. Printed promotional material

3. 2. 1. 1. All Member printed promotional material must include the following information: (a) The brand name of the product, (b) The INN of the active ingredient(s), (c) The name of the registration holder and its mailing address in Slovak Republic, (d) Full or abridged Product Information, (e) The date of the issuing or of the revision.

3. 2. 1. 2. Where it is impractical to print the Product Information on the body of the promotional material, the promotional material will carry a statement to the effect of the following in a type size of not less than 2 mm: „Please review Product Information before prescribing. Product Information accompanies this item." The item is then to be accompanied by a full or abridged Product Information document.

3. 2. 2. Audio-visual promotional material

3. 2. 2. 1. All audio-visual promotional material must be accompanied by a document which contains the following information: (a) The brand name of the product, (b) The INN of the active ingredient(s), (c) The name of the registration holder and its mailing address in Slovak Republic, (d) Full or abridged Product Information.

3. 2. 2. 2. Where an audio-visual item is demonstrated, the product information document must be given to the individual reviewing the promotional material, or offered to the audience in a group situation on completion of the presentation.

3. 2. 3. Brand name reminders*

Brand name reminders or promotional items of insignificant value, provided free of charge, are permissible as long as they are related to the health care provider's work and/or entail a benefit to patients.

3. 2. 3. 1. Brand Name Reminders or Promotional Items must include the following information: (a) The brand name of the product, (b) The INN of the active ingredient(s).

3. 2. 3. 2. Brand Name Reminders or Promotional Items are not to contain any promotional claims/and or statements.

3. 2. 3. 3. Where the nature of a Brand Name Reminder or Promotional Item is such that it is demonstrably and obviously impractical to display legibly the brand name of the product and the INN of the active ingredient(s) as required in Section 3.2.3.1, the Brand Name Reminder or Promotional Item must be accompanied by a document containing the information specified in Section 3. 2. 3. 1.

3. 2. 3. 4. Where the nature of a Brand Name Reminder or Promotional Item is such that it is demonstrably and obviously impractical to display legibly the notation "See Warning" as required in Section 2.3.1 a Brand Name Reminder or Promotional Item must not be used for that product.

3. 2. 4. Medical literature/reprints

3. 2. 4. 1. The general tenor of any reprints of journal articles, proceedings of symposia* or summaries of literature used in promotion must be consistent with the Product Information.

3. 2. 4. 2. Quotations from medical literature or from personal communications must accurately reflect the meaning of the author and significance of the study.

3. 2. 5. Computer Based Promotional Material

3. 2. 5. 1. Computer based promotional material must comply with all relevant provisions of this Code.

3. 2. 5. 2. Where an individual product is being promoted the appropriate Product Information must be given to an individual reviewing the promotional material, readily accessible via the computer based material or offered to an audience in a group situation on completion of the presentation.

3. 2. 5. 3. Where the Product Information is included in interactive data system, instructions for accessing it must be clearly displayed.

3. 3. Mailings*

3. 3. 1. Mailings must comply will all relevant provisions of Section 1 of this Code.

3. 3. 2. The full or abridged Product Information as applicable must be included in all mailings where promotional claims are made.

3. 3. 3. Mailings should only be sent to those categories of health professionals whose need for, or interest in, the particular information can be reasonably assumed. Requests to be removed from promotional mailing lists must be complied with promptly and no name restored except at specific request or with written permission.

3. 3. 4. Exposed mailings including postcards, envelopes or wrappers must not carry matter which might be regarded as advertising to the general public or which could be considered unsuitable for public view.

3. 4. Document Transfer Media

Unsolicited telegrams, telexes and electronic transmissions, or replicas thereof, must not be used for promotional purposes.

3. 5. Promotional Competitions

3. 5. 1. Promotional competitions must fulfil all of the following criteria:

(i) The competition is based on medical knowledge or the acquisition of medical knowledge.

(ii) The prize is directly relevant to the practice of medicine or pharmacy.

(iii) Individual prizes offered are to be of low monetary value or be an item of educational material.

3. 5. 2. Entry into a competition must not be dependent upon prescribing or recommending of a product and no such condition shall be made or implied.

3. 5. 3. The conduct of competitions shall comply in all respects with relevant Slovak regulations.

4. Medical representatives

4. 1. Medical representatives must only use promotional material which conforms to the provisions of Section 3 of this Code. Verbal statements made about a product must comply with the provisions of Section 1 of this Code.

4. 2. Members have a responsibility to maintain high standards of ongoing training for representatives.

4. 3. Medical representatives should possess sufficient medical and technical knowledge to present information on the company's products in an accurate current and balanced manner and should be cognisant of all provisions of this Code.

4. 4. Medical representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties.

4. 5. Medical representatives must not employ any deception to gain an interview.

4. 6. Medical representatives should ensure that the frequency, timing and duration of calls, together with the manner in which they are made, are such as not to cause inconvenience. The wishes of an individual doctor, or the arrangements in force at any particular establishment, must be observed by medical representatives.

4. 7. Medical representatives must not use the telephone to promote products to the medical profession unless the agreement of the doctor has been obtained.

4. 8. Wherever a promotional claim is made, the medical representative will provide product information.

4. 9. Under no circumstances shall representatives pay a fee in order to gain access to a healthcare professional.

5. Product Samples

Care should be exercised by Members that the distribution of Samples is carried out in a reasonable manner.

5. 1. Samples may only be supplied to physicians for going familiarisation with products. Product information and Consumer Product Information, when available, should be offered at the time of distribution or included in the product pack.

5. 2. Sample packs should be clearly identified as such and must be labelled in such a way that it is clear expressed they are medical samples and not for sale.

5. 3. Representatives must take adequate precautions to ensure the security of samples in their possession. Members should develop an appropriate recording system so that, if a product recall is necessary, relevant samples will be included in the recall.

5.4. Drug donation to hospital should be at the reasonable level and should be of public knowledge.

5.5. On request, Members must promptly accept the return of samples of their products.

6. Trade displays

General Principle: Trade displays are important for the dissemination of knowledge and experience to the healthcare professions. The prime objective in organising such displays should be the enhancement of medical knowledge. Where hospitality is associated with symposia and congresses, it should always be secondary to the main purpose of the meeting.

6. 1. Trade displays must only be directed to healthcare professionals.

6. 2. A trade display must include, in a prominent position, the name of the sponsoring company.

6. 3. Exhibitors must comply with all requirements of the sponsoring institution when mounting and conducting an exhibit.

6. 4. Product information for products being promoted must be available from the display stand.

6. 5. Samples must not be made available for collection from unattended stands, nor be supplied to unauthorised or non-qualified persons.

6. 6. Competitions that are held as part of a Trade Display must be consistent with the requirements of Section 3.7 of this Code.

6. 7. All promotional materials used at Trade Displays must be consistent with the requirements of Sections 1.3.1 and 3.2 of this Code.

7. Travel and sponsorship

7. 1. The following applies to Members sponsoring delegates travelling from or within Slovak Republic to symposia and/or congresses:

- Travel may be subsidised provided the meeting is directly related to the healthcare professional's area of expertise.
- A reasonable level of accommodation expenses may be covered.
- Expenses for family or travelling companion(s) should not be paid by the sponsoring Member.
- Travel agenda and programme should be approved by company General Manager.
- At least 60 % of working hours* (at the place without travelling time) should be dedicated to work.
- Participation should not be made dependent on request to prescribe determined amount of certain drug.

7. 2. Where attendees are being sponsored to attend symposia, meetings are to be held in appropriate centres and geographically adequate locations.

7. 3. The symposia's focus should be on scientific and medical matters and hospitality should be secondary to the main purpose of the event.

8. Research

The following provisions apply to Market Research* and Post-Marketing Surveillance Studies*, whether the research is carried out directly by the manufacturer or by an organisation acting under its direction.

General: Clinical trials of products approved for registration are not covered by the above categories.

8. 1. Post Marketing Surveillance (PMS) Studies

8. 1. 1. Post-Marketing Surveillance Studies should have scientific or medical merit and not be designed for, or conducted as, a promotional exercise.

8. 1. 2. Post-Marketing Surveillance Studies must have a formal protocol, a requirement for data collection and generation of a report. Report should be suitable for publication on medical journals or for presentation at a conference.

8. 1. 3. Only patients being treated for approved indications of the product are to be included in the Post-Marketing Surveillance Study.

8. 1. 4. Decisions by the medical profession to prescribe the product should be based on their clinical judgement.

8. 1. 5. No starter packs or free trade packs* should be distributed as part of the Post-Marketing Surveillance Study.

8. 1. 6. Any payment to the medical profession must be commensurate with the work involved.

8. 2. Market Research

8. 2. 1. Market Research studies must be clearly identified as such when the initial approach is made.

8. 2. 2. Any payment must be kept to a minimum and should not exceed a level commensurate with the work involved.

8. 2. 3. Promotion should not be represented as Market Research or research of any type.

9. Relations with healthcare professionals

Members may choose to support professional activities, by financial or other means. Such support must be able to successfully withstand public and professional scrutiny, and conform to professional standards of ethics and of good taste.

9. 1. Entertainment. Entertainment or other hospitality offered to healthcare professionals should be appropriate, secondary to the educational content and in proportion to the occasion.

9. 2. Medical Educational Material

9. 2. 1. Materials supplied for medical education must include the name of the manufacturer and its mailing address in the Slovak Republic.

9. 2. 2. Material supplied for medical education may include promotional claims and/or statements, but must comply with Section 3 of the Code of Conduct.

9. 3. General Remuneration.

Any remuneration for services rendered should not exceed that which is commensurate with the services supplied. The remuneration must not be dependent upon prescribing of a determined amount of certain product and no such condition shall be made or implied.

10. Public and media relations

Information delivered to public has to be used exclusively for improvement of public knowledge from medical and healthcare area only. Such information about new chemical entities, new drugs and ways of treatment delivered to public and media has to be:

- truthful, verified, full, clear and understandable;
- would not contain any unproved assumptions and expectations;
- would not create an false illusion for patients about treatment efficacy or unverified hope for certain improvement of his health status;
- would not have intention to cheat journalist or patient or intention to damage competitor.

No pressure has to be created to media professionals to publish delivered information. They have to have freedom for their own decision how they will use information according to their professional opinion and reader's interests.

Media have to be not financially motivated by advertising or other barters to publish certain information about prescription drugs. In this case it is advertising which is prohibited by law.

10. 1. Press releases. Press release has to follow all rules stated under point 10. Content of press release has to use proved facts without advertising messages.

10. 2. Press Conferences. Information delivered to journalists has to follow all rules stated under point 10. It is recommended to use as speakers for medical information, methods of treatment and drug related information preferably medical professionals which are not company employees. Entertainment or other hospitality have to be appropriate and in proportion to the occasion.

The standard part of press conference has to be press release.

10. 3. Radio and TV. Radio and TV broadcasts have to follow all rules stated under point 10.

10. 4. Entertainment and incentives. Entertainment or other hospitality offered to journalists should be appropriate and in proportion to the occasion and must not motivate or oblige journalists to publish information delivered by company in wished manner. The journalists would be invited by company for foreign trips or trips within Slovakia for educational or expert purpose only and hospitality should be secondary to the main purpose of event.

11. Marketing of pharmaceutical products on Internet

Generally:

- Whole Internet communication of Members and their products has to be in accordance with other regulations described in the Ethical Code.
- For the purpose of marketing and promotion activities Internet is considered to be an public information and advertising medium.
- Advisory/educational web page or company web page must clearly state who is the orderer and who is the guarantor of the web page content.

11. 1 Advisory/ Educational Web Page

- It is dedicated and used by wide public.
- It can contain information about diseases, principals of treatment, prevention but trade /brand names of products cannot be used (names of substances can be used).
- It must contain recommendation that if the disease is suspected or problems with treatment appear it is necessary to contact medical doctor.
- The web page content must not urge laic public to use a treatment if it is not necessary.
- "Advisor" which acts on web page must be a medical doctor and his full name, specialisation and working place must be published.
- All questions and answers discussed on web page have to be archived for one year.
- It can not contain visualisation of concrete drug package with the name of drug and also can not contain any other visualisation of drug or drug form which could help to recognise it (for example the picture of pill with the name of the drug).
- Illustrative visualisation of drug could be only general picture, which will not indicate concrete product.
- If graphic design contains features taken from drug visual, than product name can not be used.

11. 2 Company web page

- It contains information about company and its activities.
- Company web page can contain portfolio with the product brand names with complete SPC and package insert leaflet.
- Before the specialist will enter the page with the product information he has to passed through the page with claim: following information is for medical specialists only (for medical doctors and pharmacists) and if the laic will read them misunderstanding of content can seriously damage his health although he will not act according them.
- Additionally, to enter web page with these product information it is necessary actively (by click) to mark an answer that person is specialist as it is described.
- If the company web page contains list of company products (portfolio with brand names) it can not be advertised to wide public and marketing and adverting activities which support the sales of new product can not be supported by advertising tend to company web page.
- Company page can contain information about product prices and reimbursement. Web page provider is obliged to update these data after every change.

Note of the Editor

The code has been approved by all three associations of pharmaceutical companies and medicinal drugs distrubuting companies in Slovakia, namely by the ***Slovak Association of Research based Pharmaceutical Industry in Slovakia*** (**SAFS**), ***Association of Producers of Generic Drugs*** (**GENAS**) and ***Association of Distributors of Drugs*** (**ADL**), and has been made valid for all member companies since October 1, 2004. „Explanatory Notes" (ommitted in this excerpts) form an integral and important part of the Code. They elaborate further the principles set out in the Code and provide more detailed guidance for their application. The full text of the Code in PDF can be downloaded at e.g. http://www.safs.sk

ETICKÝ KODEX FARMACEUTICKÉHO PRIEMYSLU NA SLOVENSKU

(Výňatky)

Obsah

Výňatky

Predslov

Farmaceutický priemysel* propaguje koncepciu dobrého zdravia a pozitívneho, na zdravie orientovaného prístupu ku každodennému životu. Uznávajúc, že lieky zohrávajú dôležitú úlohu v prevencii, zlepšení a liečbe ochorení, sa farmaceutický priemysel zaväzuje:

- zabezpečovať lieky, ktoré spĺňajú najvyššie štandardy bezpečnosti, účinnosti a kvality;
- zabezpečovať, aby lieky sprevádzali komplexné technické a informačné služby v súlade s aktuálne uznávaným medicínskym a vedeckým poznaním a skúsenosťami;
- preukazovať profesionalitu pri styku so zdravotníckymi pracovníkmi*, predstaviteľmi verejného zdravotníctva a verejnosťou.

Priemysel sa angažuje za kvalitné využívanie liekov a racionálne predpisovanie a podporuje, aby sa jeho produkty využívali v súlade s pokynmi a radami zdravotníckych odborných pracovníkov. Aby sa zabezpečila dostupnosť informácií*, na základe ktorých je možné robiť kvalifikované rozhodnutia pri predpisovaní liekov, je potrebné, aby výrobca* rozširoval medzi zdravotníckymi odborníkmi odborné informácie o produkte, ktoré získal počas výskumného a vývojového procesu, a skúsenosti získané v klinickom používaní. Touto činnosťou výrobca upriamuje pozornosť na existenciu a vlastnosti príslušného produktu* vhodnými vzdelávacími a propagačnými prostriedkami.

S plnou podporou priemyslu vznikla v súčasnosti dostatočná legislatíva, ktorej cieľom je chrániť verejnosť tým, že zaručuje, aby všetky produkty ponúkané na trhu spĺňali štandardy kvality, efektívnosti a bezpečnosti, ktoré sú prijateľné z pohľadu súčasných poznatkov a skúseností.

Kým skúšanie, výrobu a kontrolu je možné legislatívne uspokojivo uzákoniť, nemožno tými istými prostriedkami definovať vhodné štandardy marketingového správania. Preto sa zodpovední výrobcovia zhodli na zverejnení etického kódexu a podriadili sa jeho obmedzeniam.

Člen* ADL, GENAS a SAFS (viď Poznámku editora) sa zaväzuje dodržiavať Štatút, Postupy pri podávaní sťažností a Etický kódex farmaceutického priemyslu na Slovensku. Sťažnosti proti akejkoľvek činnosti niektorej členskej spoločnosti by sa mali podávať Etickej komisii farmaceutického priemyslu na Slovensku tak, ako to ustanovuje Etický kódex a Postupy pri podávaní sťažností.

Poznámka: Pripojený je glosár odborných termínov. Prvé uvedenie termínu, ktorého definícia je v glosári, je označené hviezdičkou (*).

Úvod

(a) Tento etický kódex stanovuje štandardy správania spoločností pri marketingu produktov na predpis, používaných pod dozorom lekára, tak ako to umožňujú slovenské právne predpisy. Kódex má pôvod v odhodlaní ADL, GENAS a SAFS zabezpečiť všeobecné prijatie a dodržiavanie vysokých štandardov v marketingu produktov na predpis na ľudské použitie.

(b) Prijatie a dodržiavanie kódexu je podmienkou členstva v ADL, GENAS a SAFS a člen sa musí podriadiť slovu a duchu tohto kódexu. Členovia musia zaistiť, aby všetci pracovníci konajúci v ich mene boli zbehlí v ustanoveniach tohto kódexu. Farmaceutické spoločnosti, ktoré nie sú členmi asociácií, vyzývame na to, aby prijali a dodržiavali tento kódex.

Dohľad nad uplatňovaním kódexu bude vykonávať Etická komisia farmaceutického priemyslu. Etická komisia môže z času na čas vydávať výklady, ktorých cieľom je interpretovať určité časti kódexu. Sťažnosti v prípade podozrenia z porušenia kódexu by sa mali hlásiť Etickej komisii .

(c) Základným riadiacim princípom kódexu je to, že kedykoľvek sa o produkte urobí propagačné tvrdenie* , musí ho sprevádzať slovenská informácia o produkte*.

(d) Nedodržanie kódexu bude mať za následok sankcie, ktoré sa budú udeľovať podľa ustanovení postupov pri podávaní sťažností. Dodržiavanie tohto kódexu nijakým spôsobom neznižuje povinnosti členov dodržiavať slovenské právne predpisy a kódexy vrátane Kódexu IFPMA. Zákon zakazuje propagáciu* produktov, ktoré sú iba na predpis, ktorá je určená širokej verejnosti.

USTANOVENIA KÓDEXU

1. Povaha a dostupnosť informácií a tvrdení

1. 1. Zodpovednosť

Členovia, ich zamestnanci a zdravotnícki/technickí poradcovia sú zodpovední za zabezpečenie toho, aby bol medicínsky obsah* zaradený do všetkých propagačných materiálov* korektný* , plne doložený informáciami o produkte, literatúrou* alebo "archivovanými údajmi"*, pričom tieto neprotirečia obsahu. Aktivity zástupcov* spoločnosti musia byť neustále v súlade s kódexom.

1. 2. Poskytovanie preukazných údajov

Okrem dodaných informácií alebo informácií všeobecne dostupných musí výrobca na odôvodnené vyžiadanie poskytnúť zdravotníckym odborným pracovníkom ďalšie presné a relevantné informácie o produktoch, ktoré ponúka na trh.

Preukazné informácie nesmú spočívať iba v archivovaných údajoch.

Údaje, ktoré sú citované v propagačných materiáloch na doloženie tvrdení vrátane "archivovaných údajov" alebo údajov "v tlači", musia byť na požiadanie sprístupnené zdravotníckym pracovníkom a spoločnostiam.

1. 3. Nepravdivé alebo zavádzajúce tvrdenia

Informácie, medicínske tvrdenia* a grafické stvárnenia o produktoch musia byť správne, presné a vyvážené a nesmú zavádzať priamo alebo implikovane alebo zamlčaním.

Informácie, tvrdenia a názorné grafické prostriedky* sa musia dať preukázať*, pričom takého preukázanie sa poskytne bezodkladne na požiadanie zdravotníckych pracovníkov.

1. 3. 1. Neschválené produkty a indikácie. Produkty, ktorým ŠUKL neschválil registráciu, sa nesmú propagovať. Avšak na medzinárodných kongresoch* a domácich kongresoch* sa môžu vystavovať vzorky neschválených produktov a vzdelávacích materiálov v súlade s časťou 6. Toto obmedzenie sa vzťahuje aj na neschválené indikácie pri registrovaných produktoch.

1. 4. Dobrý vkus

Propagačný materiál (vrátane grafických a iných vizuálnych prezentácií) by sa mal podriadiť všeobecne uznávaným normám dobrého vkusu a rešpektovať profesionálne postavenie príjemcov.

1. 5. Neoprávnené superlatívy

Neoprávnené superlatívy sa nesmú používať. Tvrdenia nesmú implikovať, že produkt alebo jeho aktívna zložka sú unikátne* alebo majú nejakú zvláštnu prednosť ,kvalitu alebo vlastnosť, pokiaľ táto nie je preukázaná. Slovo "bezpečný" sa nesmie používať neoprávnene.

1. 6. Nové produkty

Slovo "nový" sa nesmie použiť na opis žiadneho produktu, prezentácie alebo terapeutickej indikácie, ktoré boli dostupné a všeobecne propagované na trhu v Slovenskej republike viac ako 12 mesiacov.

1. 7. Porovnávacie tvrdenia

Porovnávanie produktov nesmie byť znevažujúce, musí byť vecné, poctivé a musí sa dať preukázať alebo doložiť odkazom na zdroj. Pri uvádzaní porovnania je potrebná opatrnosť a je potrebné zaistiť, aby porovnávanie nezavádzalo skresľovaním, nenáležitým dôrazom alebo inak. Nesmú sa používať také komparatívne prirovnania, ktoré iba tvrdia, že produkt je lepší, silnejší, častejšie predpisovaný a pod. Ak sa používajú na zdôvodňovanie porovnávacích tvrdení "archivované údaje", musia v byť v súlade s požiadavkou časti 1.2.

1. 8. Napodobňovanie

Propagačné informácie by nemali napodobňovať prostriedky, kopírovať slogany alebo všeobecnú grafickú úpravu, ktorú si zvolili iní výrobcovia, spôsobom, ktorý by ľahko mohol zavádzať alebo pomýliť.

1. 9. Lekárska etika

Mená lekárov alebo fotografie sa nesmú používať spôsobom, ktorý by odporoval lekárskej etike.

1.10. Rozlíšenie propagačného materiálu

Propagačný materiál ako taký sa musí dať zreteľne odlíšiť.

2. Informácia o produkte

Určité typy propagačného materiálu opisované v časti 3 musí sprevádzať úplná alebo skrátená informácia o produkte.

Vždy, keď je to potrebné, musí sa informácia o produkte objaviť tlačená veľkosťou písma nie menšou ako 2 mm a dostatočne kontrastne odlíšená od pozadia tak, aby bola čitateľná. Hlavné titulky sa musia dať ľahko identifikovať.

Informácia o produkte nesmie byť pretlačená alebo prekladaná propagačnými frázami alebo grafickými prostriedkami a musí zreteľne označiť každú najnovšiu klinicky významnú zmenu* .

2. 1. Úplná informácia o produkte

Úplná alebo skrátená informácia o produkte musí byť priložená ku všetkým propagačným materiálom v Slovenskej republike.

2. 2. Skrátená informácia o produkte

V lekárskych publikáciách sa môže používať skrátená informácia o produkte.

2. 2. 1. Skrátená informácia o produkte musí presne zodpovedať úplnej informácii o produkte, pričom môže byť parafrázou alebo zhrnutím úplnej informácie o produkte.

2. 2. 2. Pod označením "skrátená informácia o produkte", sa musí objaviť nasledovné: (a) Schválené indikácie použitia, (b) Kontraindikácie, (c) Klinicky významné varovania, (d) Klinicky významné upozornenia na použitie, (e) Klinicky významné nežiaduce účinky a interakcie, (f) Dostupné formy dávkovania, (g) Režimy dávkovania a spôsoby podávania, (h) Klinicky významný potenciál na možnú liekovú závislosť, (i) Odkaz na špeciálnu skupinu pacientov.

Ak úplná informácia o produkte neobsahuje položky pod týmito titulkami, nie je potrebné uvádzať takéto titulky ani v tomto dokumente.

2. 3. Klinicky významné zmeny

2. 3. 1. Ak sa uvádza klinicky významná zmena týkajúca sa bezpečnosti produktu do informácie o produkte, musí sa označovať vo všetkých prezentáciách informácie o produkte po dobu 12 mesiacov s hviezdičkou (hviezdičkami) k poznámke pod čiarou, veľkosťou písma nie menšou ako 2 mm textom: Všimnite si láskavo zmenu(y) v informácii o produkte.

2. 3. 2. Úplné znenie zmenenej časti sa musí uvádzať počas tohto obdobia v každej informácii o produkte.

2. 3. 3. Ak člen aktívne nepropaguje produkt, musí sa zmena informácie o produkte písomne oznámiť príslušným zdravotníckym odborníkom.

3. Propagačný materiál*

3. 1. Reklama v časopisoch

Reklama v časopisoch musí byť v súlade s požiadavkami jednej z nasledujúcich kategórií. Požadovaná informácia sa musí objaviť v každej publikácii vytlačená veľkosťou písma nie menšou ako 2 mm a musí byť z dôvodov čitateľnosti dostatočne odlíšená od pozadia.

3. 1. 1. Úplná reklama*

3. 1. 1. 1. Úplná reklama musí obsahovať v rámci reklamného útvaru nasledovné: (a) Obchodnú značku produktu, (b) INN* aktívnych látok (látky), (c) Meno držiteľa registrácie a jeho poštovú adresu v Slovenskej republike, (d) Úplnú alebo skrátenú informáciu o produkte.

3. 1. 1. 2. Úplná reklama je povinná pre reklamu všetkých nových chemických látok* alebo nových indikácií počas 12 mesiacov od dátumu prvej reklamy v lekárskych časopisoch alebo dlhšie, podľa rozhodnutia zadávateľa reklamy.

3. 1. 1. 3. Informácia o produkte musí byť umiestnená vedľa útvaru reklamy. Ak to nie je prakticky uskutočniteľné, musí reklama obsahovať o tom vetu, vytlačenú aspoň 2 mm veľkosťou písma nasledovného obsahu: "Pred predpisovaním prezrite si láskavo informáciu o produkte. V tejto publikácii informáciu o produkte nájdete..." V tomto bode ..., vložte číslo strany v publikácii, kde sa informácia nachádza, alebo odkaz na príslušne odporučenú časť s informáciou o produkte alebo index inzerentov. Informácia o produkte musí byť pevnou súčasťou časopisu.

3. 1. 1. 4. Použitie skrátenej reklamy je dovolené po 12 mesiacoch od uvedenia prvej reklamy novej chemikálie v lekárskych publikáciách.

3. 1. 1. 5. Skrátená informácia o produkte by mala byť umiestnená vedľa útvaru reklamy. Ak to nie je prakticky uskutočniteľné, musí reklama obsahovať o tom vetu, vytlačenú aspoň 2 mm veľkosťou písma nasledovného obsahu: "Pred predpisovaním prezrite si láskavo informáciu o produkte. V tejto publikácii informáciu o produkte nájdete..." V tomto bode ..., vložte číslo strany v publikácii, kde sa informácia nachádza, alebo odkaz na príslušne doporučenú časť s informáciou o produkte alebo index inzerentov. Informácia o produkte musí byť pevnou súčasťou časopisu.

3. 1. 2. Krátka reklama

3. 1. 2. 1. Krátka reklama má pripomenúť predpisujúcemu existenciu produktu a nesmie obsahovať propagačné tvrdenia. Použitie iba krátkej reklamy v rámci jedného čísla publikácie nie je dovolené pred uplynutím 12 mesiacov od prvého uverejnenia reklamy na nový chemickú látku alebo pred uplynutím 12 mesiacov po významnej klinickej zmene zaznamenanej v informácii o produkte.

3.1.2.2. Krátka reklama musí obsahovať: (a) Obchodnú značku produktu, (b) INN aktívnych látok (látky), (c) Názov držiteľa rozhodnutia o registrácii a jeho poštovú adresu, (d) Formuláciu o tom, že je možné získať na požiadanie ďalšie informácie od dodávateľa.

3. 1. 2. 3. Krátka reklama môže obsahovať: (a) do 5 slov opisujúcich terapeutickú triedu*, avšak bez použitia propagačných fráz, (b) grafické prostriedky, (c) vetu o dostupných formách dávkovania, (d) vetu odkazujúcu na umiestnenie informácie o produkte v referenčnom manuáli.

Žiaden iný materiál nie je dovolený.

3. 1. 3. Články zadané spoločnosťou

3. 1. 3. 1. Články zadané spoločnosťou je potrebné označiť ako také veľkosťou písma nie menšou ako 2 mm.

3. 1. 3. 2. Členská spoločnosť, ktorá je zodpovedná za zaradenie článku zadaného spoločnosťou, musí byť zreteľne identifikovaná, buď nad článkom zadaným spoločnosťou, alebo pod ním, veľkosťou písma najmenej 2 mm.

3. 1. 3. 3. Články zadané spoločnosťou musia byť v súlade so všetkými relevantnými ustanoveniami časti 1 tohto kódexu.

3. 1. 3. 4. Články zadané spoločnosťou musia byť v súlade aj so všetkými relevantnými ustanoveniami častí 3.1.1. a 3.1.2. tohto etického kódexu.

3. 2. Materiály na použitie lekárskymi zástupcami*

Hlavnými usmerňujúcim princípom tohto kódexu je, že kedykoľvek sa urobí propagačné tvrdenie pre nejaký produkt, musí ho sprevádzať informácia o produkte. Ak je úmysel distribuovať viaceré formy propagačných predmetov zároveň, musí sa informácia o produkte objaviť aspoň raz.

3. 2. 1. Tlačený propagačný materiál

3. 2. 1. 1. Všetky propagačné materiály člena musia obsahovať nasledovnú informáciu: (a) obchodnú značku produktu, (b) INN aktívnych látok (látky), (c) meno držiteľa rozhodnutia o registrácii a jeho poštovú adresu v Slovenskej republike, (c) úplnú alebo skrátenú informáciu o produkte, (e) dátum vydania alebo revízie.

3. 2. 1. 2. Ak je nepraktické vytlačiť informáciu o produkte na útvar propagačného materiálu, musí tento propagačný materiál obsahovať vetu v zmysle nasledovného, vytlačenú najmenej 2 mm veľkosťou písma: "Pred predpisovaním, si láskavo prezrite informáciu o produkte. Informácia o produkte je priložená k tomuto predmetu."

K predmetu potom musí byť priložený dokument úplnej alebo skrátenej informácie o produkte.

3. 2. 2. Audiovizuálny propagačný materiál

3. 2. 2. 1. Každý audiovizuálny materiál musí sprevádzať dokument, ktorý obsahuje nasledovné informácie: (a) značku produktu, (b) INN aktívnych látok (látky), (c) meno držiteľa rozhodnutia o registrácii a jeho poštovnú adresu v Slovenskej republike, (d) úplnú alebo skrátenú informáciu o produkte.

3. 2. 2. 2. Ak sa audiovizuálny útvar predvádza, musí byť po skončení prezentácie odovzdaná informácia o produkte jednotlivcovi, ktorý sledoval propagačný materiál, alebo ponúknutá publiku, ak prezentáciu sleduje skupina divákov.

3. 2. 3. Upomienky na značky*

Upomienky na značky alebo propagačné predmety malej hodnoty poskytované zadarmo sú dovolené, pokiaľ súvisia s prácou poskytovateľa zdravotnej starostlivosti alebo sú užitočné pre pacientov.

3. 2. 3. 1. Upomienky na značky alebo propagačné predmety musia obsahovať nasledovné informácie: (a) značku produktu, (b) INN aktívnych látok (látky).

3. 2. 3. 2. Upomienky na značky alebo propagačné predmety nesmú obsahovať žiadne propagačné tvrdenia alebo formulácie.

3. 2. 3. 3. Ak povaha upomienky na značku alebo propagačného predmetu je taká, že je očividne zrejmé, že je nepraktické zobraziť čitateľne značku produktu alebo INN aktívnych látok (látky) tak, ako sa to požaduje v 3.2.3.1., musí byť k upomienke na značku alebo propagačnému predmetu priložený dokument obsahujúci informácie, ktoré špecifikuje časť 3.2.3.1.

3. 2. 3. 4. Ak je povaha upomienky na značku alebo propagačného predmetu taká, že je zrejmé, že je nepraktické zobraziť čitateľne označenie "Pozri upozornenie" tak, ako sa to požaduje v časti 2.3.1, nesmie sa táto upomienka na značku alebo propagačný predmet pre tento produkt používať.

3. 2. 4. Lekárska literatúra / autorské výtlačky

3. 2. 4. 1. Hlavná myšlienka každého autorského výtlačku časopiseckého článku, zborníka zo sympózia* alebo

súhrnu literatúry použitej v propagácii musí byť v súlade s informáciou o produkte.

3. 2. 4. 2. Citácie z lekárskej literatúry alebo osobných výpovedí musia presne vyjadrovať názor autora a význam štúdie.

3. 2. 5. Počítačový propagačný materiál

3. 2. 5. 1. Počítačové propagačné materiály musia dodržiavať všetky príslušné ustanovenia tohto kódexu.

3. 2. 5. 2. Pri propagácii individuálneho produktu musí dostať jednotlivec prezerajúci si propagačný materiál ľahko dostupný cez počítač alebo ponúkaný publiku v skupinovej situácii po skončení prezentácie príslušnú informáciu o produkte.

3. 2. 5. 3. Ak je informácia o produkte vložená do interaktívneho systému, musia byť inštrukcie na jej sprístupnenie jasne znázornené.

3. 3 Poštové zásielky*

3. 3. 1. Poštové zásielky musia dodržiavať všetky relevantné ustanovenia časti 1 tohto kódexu.

3. 3. 2. Podľa potreby musí byť zaradená do všetkých poštových zásielok, v ktorých sú uvedené propagačné tvrdenia, úplná alebo skrátená informácia o produkte.

3. 3. 3. Poštové zásielky sa môžu posielať iba tým kategóriám zdravotníckych pracovníkov, u ktorých možno primerane predpokladať ich potrebu alebo záujem. Žiadostiam o vyradenie z reklamného adresára je potrebné promptne vyhovieť a žiadne meno sa nesmie obnoviť bez osobitnej žiadosti alebo písomného súhlasu.

3. 3. 4. Obnažené zásielky vrátane pohľadníc, obálok, prebalov nesmú mať na sebe obsah, ktorý by sa mohol považovať za reklamu pre širokú verejnosť alebo ktorý by sa mohol považovať za nevhodný pre zrak verejnosti.

3. 4. Médiá používané na prenos dokumentov

Nevyžiadané telegramy, telexy a elektronické prenosy alebo repliky na ne sa nesmú využívať na propagačné účely.

3. 5. Propagačné súťaže

3. 5. 1. Propagačné súťaže musia spĺňať všetky nasledujúce kritériá:

(i) Súťaž sa zakladá na medicínskych znalostiach alebo na ich získaní.

(ii) Cena priamo súvisí s praxou medicíny alebo farmácie.

(iii) Jednotlivé ponúknuté ceny majú byť nízkej peňažnej hodnoty alebo mať vzdelávací charakter.

3. 5. 2. Zapojenie sa do súťaže nesmie závisieť od predpisovania alebo odporúčania určitého produktu a nesmie byť použitá ani naznačená žiadna takáto podmienka.

3. 5. 3. Organizovanie takýchto súťaží musí byť vo všetkých ohľadoch v súlade s príslušnými slovenskými predpismi.

4. Lekárski zástupcovia

4. 1. Lekárski zástupcovia musia používať iba propagačný materiál, ktorý vyhovuje ustanoveniam časti 3 tohto kódexu. Slovné vyhlásenia o produkte musia byť v súlade s ustanoveniami časti 1 tohto kódexu.

4. 2. Členovia sú zodpovední za udržiavanie vysokých štandardov a sústavné školenie zástupcov.

4. 3. Lekárski zástupcovia musia mať dostatočné lekárske a technické vedomosti, aby prezentovali informácie o produktoch spoločnosti presne, aktuálne a vyvážene, a mali by byť oboznámení so všetkými ustanoveniami tohto kódexu.

4. 4. Lekárski zástupcovia musia vždy udržiavať vysoký štandard etického správania pri výkone svojich povinností.

4. 5. Lekárski zástupcovia nesmú používať žiadne podvodné triky s cieľom dosiahnuť tak stretnutie so zákazníkom.

4. 6. Lekárski zástupcovia sa musia postarať o to, aby frekvencia, načasovanie a dĺžka návštev, ako aj spôsob, akým sú robené, neobťažovali. Lekárski zástupcovia musia dodržiavať priania jednotlivého lekára alebo organizačné predpisy platné v konkrétnom zariadení.

4. 7. Lekárski zástupcovia nesmú využívať na propagáciu produktov medzi lekármi telefón, ak na to nezískali súhlas lekára.

4. 8. Kedykoľvek sa robí propagačné tvrdenie, poskytne lekársky zástupca informáciu o produkte.

4. 9. Za žiadnych okolností nebude lekársky zástupca platiť za to, aby získal prístup k zdravotníckemu pracovníkovi.

5. Vzorky produktov

Členovia musia dohliadnuť, aby sa distribúcia vzoriek robila primeraným spôsobom.

5. 1. Vzorky sa môžu lekárom dávať iba na dokonalé oboznámenie sa s produktmi. V čase distribúcie musí byť ponúknutá alebo do balíčka produktov zaradená informácia o produkte, a ak je k dispozícii, aj informácia o produkte pre spotrebiteľa.

5. 2. Balíčky vzoriek musia byť ako také zreteľne identifikovateľné a musia byť označené takým spôsobom, aby bolo jasné, že ide o lekárske vzorky a že nie sú určené na predaj.

5. 3. Zástupcovia musia urobiť príslušné bezpečnostné opatrenia na to, aby zaistili bezpečnosť vzoriek, ktoré prechovávajú. Členovia by mali vytvoriť vhodný evidenčný systém tak, aby ak je potrebné produkt stiahnuť, boli stiahnuté aj relevantné vzorky.

5. 4. Dary liekov pre nemocnice majú byť primerané a informácia o poskytnutom dare je vec verejná.

5. 5. Na požiadanie musia členovia promptne prijať vrátené vzorky svojich produktov.

6. Obchodné výstavy

Všeobecný princíp. Obchodné výstavy sú pri šírení poznatkov a skúseností medzi zdravotníckymi pracovníkmi dôležité. Hlavným cieľom pri organizovaní takýchto výstav musí byť zvyšovanie lekárskych vedomostí. Ak je pridružená k sympóziám a kongresom pohostinnosť, musí byť vždy sekundárna vzhľadom na hlavný účel stretnutia.

6. 1. Obchodné výstavy musia byť určené iba pre zdravotníckych pracovníkov.

6. 2. Obchodná výstava musí mať na prominentnom mieste uvedené meno sponzorujúcej spoločnosti.

6. 3. Vystavovatelia musia rešpektovať všetky požiadavky sponzorujúcej inštitúcie pri inštalovaní a vedení výstavy.

6. 4. Informácie o produktoch, ktoré sú propagované, musia byť k dispozícii v stánku výstavy.

6. 5. Nesmie sa umožniť brať vzorky zo stánku bez dozoru ani ich dávať neoprávneným alebo nekvalifikovaným osobám.

6. 6. Súťaže, ktoré sa uskutočňujú ako súčasť obchodnej výstavy, musia byť v súlade s požiadavkami časti 3.7 tohto kódexu.

6. 7. Všetky propagačné materiály používané pri obchodných výstavách musia byť v súlade s požiadavkami častí 1.3.1 a 3.2 tohto kódexu.

7. Cestovanie a sponzorstvo

7. 1. Na členov sponzorujúcich delegátov cestujúcich zo Slovenskej republiky alebo v rámci Slovenskej republiky na sympóziá a kongresy sa vzťahuje nasledovné:

• Cestovné možno dotovať za podmienky, že stretnutie priamo súvisí s oblasťou odbornej kvalifikácie zdravotníckeho pracovníka. • Možno hradiť primeranú úroveň

ubytovacích výdavkov. • Sponzorujúci člen nemá hradiť výdavky za rodinu alebo spolucestujúcu/e osobu/y. • Cestovný poriadok a program majú byť schválené generálnym riaditeľom spoločnosti. • Najmenej 60 % pracovného času* (na mieste určenia bez dopravy) má byť venované práci. • Účasť nesmie byť podmienená žiadosťou o predpisovanie stanoveného množstva určitého lieku.

7. 2. Ak sú účastníci sponzorovaní, aby sa zúčastnili na sympóziách, stretnutia sa majú uskutočňovať vo vhodných centrách a geograficky adekvátnych lokalitách.

7. 3. Cieľom sympózia by mali byť vedecké a medicínske záležitosti a pohostinnosť by mala byť druhoradou k hlavnému účelu podujatia.

8. Výskum

Nasledovné ustanovenia sa vzťahujú na prieskum trhu* a postmarketingové pozorovacie štúdie* bez ohľadu na to, či ich vykonáva výrobca alebo organizácia konajúca podľa jeho inštrukcií.

Všeobecne: Vyššie uvedené kategórie nezahŕňajú klinické skúšky produktov schválených na registráciu.

8. 1. Postmarketingové pozorovacie štúdie (PMS)

8. 1. 1. Postmarketingové pozorovacie štúdie by mali mať vedeckú alebo lekársku hodnotu a nemali by byť zostavované alebo uskutočňované ako nejaké propagačné cvičenie.

8. 1. 2. Postmarketingové pozorovacie štúdie musia mať formálny protokol, čo je požiadavkou na zber údajov a vyhotovenie správy. Správa má byť vhodná na publikovanie v medicínskom časopise alebo prezentáciu na konferencii.

8. 1. 3. Do postmarketingovej pozorovacej štúdie možno zaradiť iba pacientov liečených na schválené indikácie produktu.

8. 1. 4. Rozhodnutia lekárov predpisovať produkt by sa mali zakladať na ich klinickom úsudku.

8. 1. 5. Ako súčasť postmarketingovej pozorovacej štúdie by sa nemali distribuovať žiadne nábehové alebo komerčné balenia*.

8. 1. 6. Každá platba lekárom musí zodpovedať práci, ktorej sa týka.

8. 2. Prieskum trhu

8. 2. 1. Štúdie prieskumu trhu musia byť ako také zreteľne identifikované pri úvodnom kontakte.

8. 2. 2. Každú platbu je potrebné udržiavať na minime a nemala by prevyšovať úroveň zodpovedajúcu vykonanej práci.

8. 2. 3. Propagácia by sa nemala vydávať za prieskum trhu ani za výskum žiadneho typu.

9. Vzťahy so zdravotníckymi pracovníkmi

Členovia si môžu zvoliť, že budú finančne alebo inak podporovať odborné aktivity. Takáto podpora musí úspešne obstáť pred podrobným skúmaním zo strany verejnosti a odborníkov a musí byť v súlade s profesionálnymi štandardmi etiky a vkusu.

9. 1. Zábava

Zábava alebo pohostinnosť venovaná zdravotníckym odborným pracovníkom by mala byť vhodná, sekundárna k vzdelávaciemu obsahu a zodpovedajúca danej príležitosti.

9. 2. Vzdelávacie materiály pre lekárov

9. 2. 1. Materiály poskytované na vzdelávanie lekárov musia obsahovať meno výrobcu a jeho poštovú adresu v Slovenskej republike.

9. 2. 2. Materiál poskytnutý na vzdelávanie lekárov môže obsahovať propagačné tvrdenia a vyhlásenia, ale musí byť v súlade s časťou 3 etického kódexu.

9. 3. Všeobecné odmeňovanie

Každé odmeňovanie za poskytnuté služby nesmie prevýšiť to, čo je primerané za dodané služby. Odmeňovanie nesmie závisieť od predpisovania stanoveného množstva niektorého produktu a žiadna takáto podmienka sa nesmie dať ani implikovať.

10. Vzťahy s verejnosťou a médiami

Informácie, ktoré sú verejnosti poskytované, musia byť výlučne použité na zlepšenie informovanosti verejnosti v lekárskej a zdravotníckej oblasti. Takéto informácie o nových chemických látkach, nových liekoch a spôsoboch liečby odovzdávané verejnosti a médiám musia byť:

• pravdivé, overené, úplné, jasné a zrozumiteľné; • nesmú obsahovať žiadne nepodložené predpoklady a očakávania; • nesmú vytvárať u pacienta falošnú ilúziu o účinnosti liečby alebo neoverenú nádej na určité zlepšenie jeho zdravotného stavu; • nesmú mať zámer oklamať novinára alebo pacienta alebo zámerne poškodiť konkurenta.

Na predstaviteľov médií sa nesmie vyvíjať tlak, aby uverejnili dodané informácie. Musia sa slobodne rozhodovať, ako využijú informácie, podľa svojho profesionálneho názoru a záujmov čitateľa. Médiá nemajú byť finančne motivované reklamou alebo výmenným obchodom, aby uverejňovali určité informácie o liekoch na predpis. V tomto prípade je to práve reklama, ktorú zákon zakazuje.

10. 1. Oznámenia pre tlač

Oznámenia pre tlač musia dodržiavať všetky pravidlá uvedené v bode 10. Obsah tlačových oznámení musí využívať dokázané fakty bez reklamných výpovedí.

10. 2. Tlačové konferencie

Informácie poskytované novinárom musia dodržiavať všetky pravidlá uvedené v bode 10. Odporúča sa, aby sa pri lekárskych informáciách, metódach liečby a informáciách týkajúcich sa liekov ako informujúci využívali radšej lekárski odborníci, ktorí nie sú zamestnancami spoločnosti.

Zábava a iné prejavy pohostinnosti musia byť vhodné a primerané danej príležitosti. Štandardnou súčasťou tlačových konferencií musí byť oznámenie pre tlač.

10. 3. Rozhlas a televízia

Rozhlasové a televízne vysielania musia dodržiavať všetky pravidlá uvedené v bode 10.

10. 4. Zábava a prostriedky motivovania

Zábava a iné prejavy pohostinnosti poskytované novinárom by mali byť vhodné a primerané danej príležitosti a nesmú motivovať ani zaväzovať novinárov, aby uverejnili informácie dodané spoločnosťou jej želateľným spôsobom.

Novinári bývajú pozývaní spoločnosťou na pobyty do zahraničia alebo pobyty v rámci Slovenska iba za účelom vzdelávania alebo z odborných dôvodov a pohostinnosť by mala byť druhoradou k hlavnému účelu podujatia.

11. Marketing farmaceutických výrobkov na Internete

Všeobecne:

• Všetka internetová komunikácia týkajúca sa prezentácie členov a ich produktov na Internete musí byť v súlade s ustanoveniami Etického Kódexu. • Internet považujeme v súvislosti s marketingovými a propagačnými aktivitami za informačné a reklamné médium pre širokú verejnosť. • Na poradenskej (vzdelávacej) internetovej stránke ako aj firemnej internetovej stránke musí byť zreteľne uvedený zadávateľ a garant obsahu internetovej stránky.

11. 1. Poradenská (vzdelávacia) stránka

• Je určená preč širokú laickú verejnosť. • Môže obsa-

hovať informácie o ochoreniach, princípy liečby ochorenia a jeho prevencie, ale bez udania konkrétnych (obchodných) názvov liekov. • Musí obsahovať odporučenie, že v prípade podozrenia z ochorenia a ťažkostí s liečbou treba kontaktovať lekára. • Obsah stránky nebude laickú verejnosť nabádať k liečbe. • "Poradca", ktorý pôsobí na stránke musí byť konkrétny lekár a musí byť uvedené jeho plné meno a adresa. • Všetky otázky a odpovede v rámci "poradne" treba archivovať po dobu jedného roka. • Vizuál krabičky konkrétneho lieku s názvom lieku nesmie byť umiestnený na edukačnej stránke a takisto žiadne iné zobrazenie lieku a liekovej formy, ktoré by ho mohlo identifikovať (napríklad tabletky s názvom lieku). • Ilustračná snímka lieku môže zobrazovať len všeobecný obrázok, ktorý nebude navodzovať konkrétny produkt. • Ak sú pri grafickom riešení stránky použité prvky vizuálu konkrétneho lieku, nesmú obsahovať názov lieku.

11. 2. Firemná stránka

• Firemná stránka obsahuje informácie o výrobcovi, jeho aktivitách. • Firemná stránka môže obsahovať aj portfólio liekov s kompletným znením SPC a príbalovej informácie. • Predtým, ako sa odborník k týmto informáciám dostane, musí prejsť cez stránku, na ktorej bude upozornenie o tom, že "nasledujúce informácie sú určené len odbornej verejnosti t.j. lekárom a farmaceutom, a v prípade, že ich bude čítať laik, môže nesprávne porozumenie nasledujúcich textov vážne poškodiť jeho zdravie aj vtedy ak nebude podľa nich konať". • Okrem toho k ďalším týmto informáciám sa odborník dostane len vtedy, keď aktívne (kliknutím) označí odpoveď, že odborníkom v horeuvedenom slova zmysle je. • Ak firemná stránka obsahuje zoznam liekov (portfólio), tak stránka nesmie byť propagovaná smerom k laickej verejnosti a takisto reklamné aktivity na podporu predaja nového produktu nesmú byť podporované reklamou smerovanou na firemnú stránku. • Firemná stránka môže obsahovať informácie o cenách liekov a ich hradení zo ZP. Prevádzkovateľ stránky je povinný tieto údaje aktualizovať pri každej zmene.

Poznámka editora

Kódex bol prijatý všetkými troma asociáciami farmaceutických spoločností a distribútorov liekov na Slovensku, t.j. ***Slovenskou asociáciou farmaceutických spoločností orientovaných na výskum*** (**SAFS**), ***Asociáciou výrobcov generických liekov*** (**GENAS**) a ***Asociáciou distribútorov liekov*** (**ADL**), a uvedený do platnosti od 1. októbra 2004. „Vysvetlivky" (vynechané v týchto výňatkoch) tvoria integrálnu a dôležitú súčasť Kódexu. Rozvíjajú ďalej princípy ustanovené v Kódexe a poskytujú podrobnejšie usmernenie pre ich aplikáciu. Úlný text Kódexu vo formáte PDF možno získať napr. na internetovej adrese http://www.safs.sk

STATEMENT ON EUTHANASIA IN CHILDREN

International Federation of Associations of Catholic Physicians (FIAMC)

The recent decision of permitting euthanasia on children under the age of 12 years in Holland is another violent laceration of the very fundaments of our social living together.

Officially aimed to put an end to "unbearable suffering" it actually permits the killing of human persons without their consent. This happens in a society, like the Dutch one, in which euthanasia on adults has been legally performed even in depressed persons and where, as documented by official studies, there is already an illegal, but tolerated, euthanasia performed by physicians on non consentient patients [1, 2]. Once again, the decision proposes a death solution in situations, which could be afforded by modern palliative care. In addition, the decision raises the suspicion of a financial interest of public authorities, since it decreases the "burden" of a prolonged and expensive care in clinical conditions for which any extension of life duration is considered meaningless.

More importantly, it opens the door, on a national scale, to the "mercy" killing of other mentally incompetent persons, to be eliminated, without their consent, for reasons based on an external appreciation of their quality of life.

In the same direction goes a decision issued on August 26th by the Kentucky Supreme Court, granting legal authority to the state of Kentucky to end the life of a citizen of the state. The case involved a mildly retarded black male, Matthew Woods, who was placed on a ventilator after suffering cardiac arrest at the age of 54. The state requested permission to remove his life support, contrary to the wishes of Woods' guardian *ad litem*.

Although Woods died of natural causes during the litigation process, the Court agreed to rule on the legality of the state's request, because of the legal questions involved. Prior to his natural death, Woods had never expressed whether he wanted life-supporting measures removed.

Catholic doctors call all their colleagues, medical doctors still committed to the Hippocratic Oath, to feel the moral imperative to contrast the slippery slope that, step by step, is permitting the public authorities to take decisions on which lives are worthy to be lived. The next steps will be the Mental Capacity Bill under scrutiny by the British Parliament [3] and the attempt to change the Ethical Code of Belgian Doctors made by local authorities [4]. The risks of such an attitude, in terms of violence and discrimination, should be evident for physicians and call them to resist and fight.

Udine, 2 September 2004 — Prof. Gian Luigi Gigli, MD, President of FIAMC

Notes

[1] B.D. Onwuteaka-Philipsen, et. Al. Euthanasia and other end-of-life decisions in the Netherlands in 1990, 1995, and 2001, **362** *Lancet* (2003), 395-9. **[2]** Rietjens JA, et Al. Physician reports of terminal sedation without hydration or nutrition for patients nearing death in the Netherlands. *Annals of Internal Medicine*, **141** (2004), 178-85. **[3]** Parliament of the United Kingdom, The Mental Capacity Bill, Presented on 17th June 2004 http://www.-publications.parliament.uk/pa/cm200304/cmbills/120/2004120 .htm **[4]** Conseil national de l'Ordre des médecins (Belgium), Avis relatif aux soins palliatifs, l'euthanasie et d'autres décisions médicales concernant la fin de vie, http://195.234.184.64/web-Fr/fr/a100/ a100006f.htm

KONFERENCIE / CONFERENCES

PODPORA ETIKY V KLINICKEJ PRAXI – SÚČASNÝ STAV A PERSPEKTÍVY V EURÓPE
Multilaterálna konzultatívna konferencia
Bratislava, 18. – 19. novembra 2004

V dňoch 18. – 19. novembra 2004 sa v priestoroch Ministerstva zdravotníctva Slovenskej republiky (MZ SR) v Bratislave uskutočnila Multilaterálna konzultatívna konferencia na tému „***Podpora etiky v klinickej praxi – Súčasný stav a perspektívy v Európe***" (angl. *Ethics Support in Clinical Practice – Status Quo and Perspectives in Europe*). **(1)** Podujatie sa konalo v rámci Programu DEBRA Rady Európy (RE), v spolupráci s Riadiacim výborom pre bioetiku (CDBI) RE so sídlom v Štrasburgu. Na konferen-

cii sa zúčastnili delegáti z 22 členských krajín RE. Slovenskú republiku reprezentovali členovia Centrálnej etickej komisie MZ SR. Spoluorganizátorom podujatia bol Ústav medicínskej etiky a bioetiky (ÚMEB) v Bratislave.

Cieľom konferencie bolo zhodnotiť súčasný stav problematiky etickej podpory medicínskeho (prípadne ošetrovateľského) rozhodovania v klinickej praxi v európskom pohľade a načrtnúť perspektívy jej riešenia na pôde Rady Európy. Bezprostredným podnetom pre usporiadanie tejto konferencie boli závery Konferencie národných etických komisií (a podobných inštitúcií) – COMETH, ktorá sa konala v decembri 2003 v Štrasburgu, ako aj iniciatíva a pozvanie Centrálnej etickej komisie MZ SR.

Zvýšený záujem o túto súčasne tradičnú, ale aj relatívne novú oblasť podnietil akcelerovaný rozvoj moderných diagnostických a liečebných metód súčasnej medicíny. Ich aplikácia v praxi nezriedka prináša nové, dosiaľ neriešené etické problémy pri rozhodovaní o primeranom (najlepšom?) postupe diagnostiky a liečby u konkrétneho pacienta. Okrem lekára a zdravotníckeho pracovníka sa na rozhodovaní v týchto situáciách čoraz viac podieľa aj samotný pacient, jeho príbuzní, či iné blízke osoby – „nezdravotníci". Prijaté rozhodnutia majú často význam aj pre ďalšie zúčastnené osoby, vrátane príbuzných pacienta, ba i pre celú spoločnosť (napr. aplikácia moderných biotechnológií, vývoj génovej a bunkovej terapie ai.).

V európskych krajinách i v zámorí sa rozvíjajú rôzne formy interdisciplinárne, resp. dialogicky budovanej „etickej podpory" pre rozhodovanie lekárov, sestier a ostatných zúčastnených osôb v eticky náročných prípadoch klinickej praxe. Ide napr. o etické komisie, etické konzultácie poskytované odborníkmi na bioetiku, „etickú konzultačnú službu" bioetikov alebo osôb poskytujúcich duchovnú službu pacientom (kňazi alebo duchovní rôznych náboženských denominácií), kurzy a workshopy klinickej bioetiky, klinicko-etické semináre a analýzy konkrétnych prípadov, apod. Na celoeurópskej úrovni zatiaľ chýba týmto rozličným aktivitám vhodné zastrešenie, vzájomná komunikácia, prípadne primeraná „harmonizácia" v tých oblastiach, kde by to bolo vzhľadom na akcentovaný európsky názorový pluralizmus možné, resp. žiadúce.

Odborné rokovania jednotlivých programových blokov konferencie uviedli prehľadové prednášky pozvaných prednášateľov: Dr. A. – M. Slowther (Oxford, Veľká Británia): *Aktuálne etické dilemy v klinickej praxi v Európe*, Prof. G. Le Beer (Leuven, Belgicko): *Služby etickej podpory v klinickej praxi* a Prof. R. Pegoraro (Padova, Taliansko): *Vzdelávanie v klinickej bioetike v Európe*. Podkladom rokovaní bola analýza výsledkov celoeurópskeho dotazníkového prieskumu, uskutočneného v rámci príprav konferencie Sekretariátom CDBI (referovala Dr. E. Gadd, bývalá predsedajúca CDBI).

Podstatou multilaterálnej konzultačnej konferencie bola však predovšetkým výmena informácií o situácii v jednotlivých zúčastnených krajinách – a tiež spoločná diskusia, zameraná na hľadanie modelov pre riešenie tejto závažnej problematiky v budúcnosti. Rokovania boli zaujímavé a konštruktívne. Priniesli konkrétne **závery a odporúčania**, najmä pre smerovanie ďalších aktivít v tejto oblasti na pôde RE.

Účastníci sa zhodli na jednoznačnej potrebe vytvárania štruktúr etickej podpory pre klinickú prax – predovšetkým etických komisií (komisií pre klinickú bioetiku, „nemocničných" etických komisií), a primeraného zabezpečenia ich činnosti po stránke odbornej (výchova a ďalšie vzdelávanie (potenciálnych) členov, tvorba a dostupnosť vhodných odborných usmernení pre oblasť klinickej bioetiky (smernice – *angl. guidelines*), legislatívnej (zákonné normy a vhodné vykonávacie predpisy) a organizačnej (vytváranie potrebných podmienok v rámci zdravotníckych zariadení). Zdôraznili význam kontinuálneho vzdelávania zdravotníckych pracovníkov v oblasti klinickej bioetiky – a to i vzhľadom na dosiaľ nedostatočný priestor na získavanie týchto poznatkov a schopností v rámci pre-graduálnej výuky na lekárskych fakultách, ako aj vzhľadom na rýchly rozvoj medicíny a ošetrovateľstva s nárastom počtu eticky náročných prípadov v každodennej klinickej praxi.

Na pôde RE účastníci odporučili venovať tejto oblasti konkrétnu a špecifickú pozornosť. CDBI pravdepodobne navrhne vypracovanie prehľadného informatívneho materiálu (*angl. position paper*) o situácii v Európe a o aktuálnych možnostiach jej riešenia. V ďalšom kroku zváži iniciatívu na vypracovanie medzinárodného odporúčania (*angl. recommendation*), ktoré by bolo už konsenzuálnym medzinárodným dokumentom so závažným významom pre riešenú oblasť (podobné odporúčania CDBI vypracovalo napr. pre oblasť psychiatrickej starostlivosti, xenotransplantácií; v súčasnosti sa pripravuje odporúčanie pre oblasť výskumného využitia biologických materiálov ľudského pôvodu atď.). Delegáti podčiarkli význam vzdelávacích a 'osvetových' aktivít, ktoré by pod záštitou RE mohli mať celoeurópsky rozmer – a boli by zamerané nielen na zdravotníckych pracovníkov, ale usilovali by sa osloviť aj ďalších odborníkov zasahujúcich do oblasti zdravotnej starostlivosti, zdravotnej politiky a programov verejného zdravotníctva, vrátane politikov a pracovníkov médií – a v neposlednom rade i širšiu verejnosť.

Závažný význam by i v budúcnosti mala mať medzinárodná spolupráca, výmena informácií, 'know-how', a riešenie spoločných výskumných, prípadne vzdelávacích projektov. V tomto smere by bolo možné nadviazať na niektoré už existujúce aktivity prebiehajúce v rámci výskumných projektov Európskej komisie (napr. EURETHNET, EHBP, PRIVIREAL ai.). Delegáti krajín strednej a východnej Európy zdôraznili aj pozitívny význam aktivít Programu DEBRA – a potrebu jeho ďalšieho pokračovania, a to zvlášť vzhľadom na pomoc, ktorú aktivity tohoto programu predstavujú pre zúčastnené krajiny pri príprave špecifickej 'národnej' legislatívy v oblasti biomedicíny v duchu medzinárodne záväzných právnych dokumentov a odporúčaní RE.

Slovenskí delegáti prezentovali výsledky, ktoré sa dosiahli v SR v diskutovanej oblasti v uplynulom období (napr. viac než 10-ročná existencia etických komisií, aktivity Centrálnej etickej komisie MZ SR (od r. 1990), pravidelné celoštátne stretnutia členov etických komisií (opäť od r. 2002), existencia špecializovaného odborného pracoviska – ÚMEB (od r. 1992) a medzinárodného odborného časopisu – *Medicínska etika & Bioetika* [*Medical Ethics & Bioethics*] (od r. 1994); výuka medicínskej etiky na lekárskych fakultách a ošetrovateľskej etiky na zdravotníckych školách a v rámci štúdia ošetrovateľstva, atď.). Pozornosť vzbudila aj informácia o nedávno prijatej novej zdravotníckej legislatíve, ktorá obsahuje aj nové ustanovenia o zriadení a činnosti etických komisií v zdravotníckych zariadeniach a predpokladá v blízkej budúcnosti vydanie príslušných vykonávacích predpisov (vyhlášky, prípadne odborného usmernenia).

Konanie už štvrtej konferencie bioetiky Programu DEBRA Rady Európy v hlavnom meste Slovenskej republiky (prvá sa uskutočnila v roku 1991) dôstojne nadviazalo na úspešnú tradíciu predchádzajúcich medzinárodných odborných podujatí, ako aj na početné medzinárodné odborné a vedecké aktivity slovenských odborníkov v tejto rýchlo sa rozvíjajúcej oblasti. Konkrétne závery rokovaní konferencie majú potenciál pozitívne ovplyvniť riešenie problematiky klinickej bioetiky v celoeurópskom meradle a budú obsiahnuté v zborníku podujatia, ktorý by mal pod záštitou RE vyjsť už začiatkom budúceho roka (ako suplementum 1/2004 časopisu Medicínska etika & Bioetika).

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(**1.**) Predchádzajúca, skrátená verzia tejto správy bola zaslaná na uverejnenie do periodika Zdravotnícke noviny, vydávaného v Bratislave.

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Medicínska etika & bioetika - Medical Ethics & Bioethics, founded as the journal of the Institute of Medical Ethics & Bioethics in Bratislava. 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)