

HARMONISATION OF THE POLISH LAW WITH THE EU DIRECTIVES IN THE FIELD OF BIOMEDICINE

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S u m m a r y

The article consists of four parts. The first one in a short way presents the notion of biomedical law. In the second part the author points out the main ways of harmonisation of the internal law of the Member States of EU by directives. The next part is dedicated to the Polish laws connected with the biomedical law. The author analyses two EU directives: the first one about the principles of *Good Clinical Practice* – the document which is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects and the second one about patenting biomedical inventions, comparing them to Polish legal solutions in this field. The last part – conclusions – presents the opinion of the author about the concordance of Polish and EU law in the field of biomedicine.

1. Introduction to the problem. The notion of biomedical law

The biomedical law is the relatively new branch of law. It has come into being as a result of expansive development of new medical techniques as well as inventions in this field. The task of this branch of law is to regulate the human rights and duties in the relationships between medicine and biotechnology along with the genetics. In view of, that progress in medicine to a considerable degree depends on the investigations on human organism, the protection of subject of these experiments in civilized society seems to be obvious thing. Equally essential is the range of this protection, especially in aspect of international co-operation as well as among the Member States of European Union. Effectiveness of this protection is conditioned first of all by international and national suitable level of protection of human rights. In more far order the essential way to protect human being is to take the common minimum standard in the largest number of states, and if it is possible to detail regulations connected with the protection of the human as a subject of medical experiments, both therapeutic and investigative. Equally important is the assumption of legal provisions about the possibility of use biomedical inventions and patenting them.

The duty of implementation of the EC law (*acquis communautaires*) – according to the requirements defined in treaties - is the consequence of accession of Poland to the European Union. This results both from the Founding Treaties and with suitable rules of the Treaty of Accession. Art. 2 of the Act relating the conditions of accession foresees, that: "Since the day of accession new Membership States are bound by the regulations of the Founding Treaties and acts passed by the institutions of European Community and the European Central Bank before the day of accession (...) "[1].

2. The harmonisation by directives

Directives play a very important role in the legal system of EC law, particularly as an effective instrument of approximation of laws within the European Community.

The scope of the obligation to implement properly the EC law into the national legal systems is defined in the Article 249 (3) of the EC Treaty, which states that a directive shall be binding as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. Moreover, following the principle of the solidarity stemming from the Article 10 of the EC Treaty, Member States shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Treaty or resulting from action taken by the institutions of the Community [10: 14].

The directive is binding by virtue of Article 249 (3), which entails that every instance of incorrect or belated implementation will amount to a breach of this article. The requirement that directives must be implemented in due time and correctly is based on the fundamental necessity of uniform and simultaneous application of the Community law [9: 107]. All the provisions contained in a directive constitute an entity that should work properly in practice; it must be possible to monitor permanently the operation of the directive and where necessary to adjust the directive to the developments within the Member States, in accordance with the objectives pursued by the Community. Considered in its entirety, a directive may lay down a complex system of rights and duties for a variety of subjects of Community law [9: 109].

3. Evaluation of accordance of polish and EU law

Evaluating the accordance of Polish legal regulations relating to the *Good Clinical Practice* (the GCP) with regulations of the European Community, it is necessary to analyse the correctness of implementation of the Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [6]. Clinical trials and GCP are regulated in Poland in several legislative acts, like:

- a) Act of doctor's profession of 5 December 1996 r., in detail regulations of the 4th Capital about medical experiment,
- b) Act of the Pharmaceutical Law of 6 September 2001 r., in detail the regulations of the 2nd Capital about clinical trials of the healing products,
- c) the Health Minister Order in matter of the Central Records of Clinical Trials of 29 November 2002 r.,
- d) the Health Minister Order in matter of requirements of Good Clinical Practice of Producing of 3 December 2002 r.,
- e) the Health Minister Order in matter of way and range of inspection of clinical trials in range of accordance these trial with requirements of Good Clinical Practice of 10 December 2002 r.,
- f) the Health Minister Order in matter of determination of detailed requirements of Good Clinical Practice of 10 December 2002 r.,
- g) the Health Minister Order in matter of detailed principles of appointing and financing a bioethical commission of 11 May 1999 r.,
- h) the Health Minister Order in matter of way of conduct clinical trials with part of juveniles of 30 April 2004 year.

The Directive establishes specific provisions concerning the conduct of clinical trials, including multi- centre trials, on human subjects involving medicinal products, in particular relating to the implementation of good clinical practice. The main scope of this document is to define and assure the minimal standard of the protection of the subjects of clinical trials [4]. *Good Clinical Practice* is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects [5]. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of clinical trials are credible. The nature of a directive as a source of the secondary community law permits the national authorities of Member States to choose the form and methods of implementation, on the stipulation of adopting and maintaining the minimal standard of the protection.

This standard provides for:

1. A clinical trial may be initiated only if the Ethics Committee and/or the competent authority

comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored,

2. The trial subject or, when the person is not able to give informed consent, his legal representative has had the opportunity, in a prior interview with the investigator or a member of the investigating team, to understand the objectives, risks and inconveniences of the trial, and the conditions under which it is to be conducted and has also been informed of his right to withdraw from the trial at any time,
3. The rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him are safeguarded,
4. The trial subject or, when the person is not able to give informed consent, his legal representative has given his written consent after being informed of the nature, significance, implications and risks of the clinical trial; if the individual is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation,
5. The subject may without any resulting detriment withdraw from the clinical trial at any time by revoking his informed consent,
6. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor.

The medical care given to, and medical decisions made on behalf of subjects shall be the responsibility of an appropriately qualified doctor (Art. 3 of the Directive).

Generally, taking in consideration Polish provisions in this field, it should be pointed out that in the effect of an amendment of medical law in laws and regulations, the valid regulations of Polish law concerning *Good Clinical Practice* correspond to the requirements of community regulations in considerable degree. On the one hand, this accordance is based on the framework of notions implemented in the correct way. On the second one, Polish authorities adopted the proper measures to protect the rights of the subject of clinical trial. However it must be said, that in the Polish regulations in comparison with the Directive there are some divergences and legal loopholes.

The basic inconvenience is that the relevant rules are dispersed in several legal documents. This causes, more than once, the incoherency of the legal system and the lack of transparency.

The implementation of the legal provisions about the protection of clinical trials subjects should be evaluated in a positive way. Specially it should be stressed that the Polish law in a very detailed way protects juvenile, handicapped as well as adult incapable to expression informed consent, what means a conscious and voluntary consent for taking part in experiment. However it should be noticed, that the Polish laws, going out over the Directive standard, set up the special protection of pregnant women, breastfeeding mothers, the conceived children, soldiers of the principle service as well as imprisonment persons, establishing that these persons' categories can not be the subject of investigative clinical trials (and so such, which the main aim is the widening the medical knowledge, and not the therapy in a strict sense).

The Polish laws, in accordance with the Directive predict the necessity of obtainment of positive opinion of the Ethical Committee as a *conditio sine qua* to begin the clinical trial. The way of appointing and establishing the Committee, as well as the range of cognition of committee is in accordance with the standards of Directive.

In accordance with Directive, the Polish laws predict, that apart from obtainment the positive opinion of Ethical Committee, it is required for beginning the trials the permission of the Health Minister in form of administrative decision.

Differently than in the Directive, there is lack in Polish law the regulations connected with the duty to exchange the information. According to the Art. 11 of the Directive: "Member States in whose territory the clinical trials takes place shall enter in a European database, accessible only to the competent authorities of the Member States, the Agency and the Commission". Partly, but not sufficiently, this duty is carrying out by the Polish Central Records of Clinical Trials.

In the scope of suspension of trials or the defiance of the law, the Polish regulations are, in principle, in accordance with Directive. However there is lack of the rule, that apart from situation of occurrence of direct threat of life, proper powers at the state before they will suspect or pause the trial, they should turn about opinion to sponsor or conductor of trial on possessed information, which then the opinion should be delivered in one week.

In range of notifying serious adverse events Polish laws are, to a great extent, in accordance with Directive.

Generally the implementation of the Directive was done correctly. However it could be indicated a serious problem connected with the duty to the obligatory insurance of the investigator and the sponsor.

According to the Art. 3 par. 2 point f of the Directive: "A clinical trial may be undertaken only if (...) provisions has been made for insurance or indemnity to cover the liability of the investigator and sponsor" This provision explicitly demands that the main obligation of the authorities of the Member States is to implement the legal duty in the range of insurance.

Some states have already issued the proper acts. In other Member States the legislative works are in realisation. Because of the accession of Poland to the EU, there were adopted proper laws. According to the Art. 37 j of the Act of Pharmaceutical law: " For damages done in relationship with the conducting of clinical trials the investigator and sponsor are responsible" This regulation is replenished by the Order of the Ministry of Finance in matter of obligatory insurance of civil liability of investigator and sponsor of 30 April 2004. The paragraph 2 of this document explains, that: "The insurance of civile liability of the investigator and the sponsor provides damages done as an effect of actiting or abandoning, resulting in period of duration of insurance protection" The order requires the minimum guarantee sum of insurance OC to carry out equivalent 500.000 euro in zloties with reference to investigator and with reference to sponsor (§ 4. 1.). The content of the order, especially in range of financial decisions, is the prosecution of vagueness and doubt. The problem of double insurance is the most frequent demurrer to the legislator, especially, that his substantive dimension can in practice make impossible conducting the clinical trials investigations.

The important event in evolution of position of European Community in the face of biotechnology should be treated the adoption by the European Parliament and the Council the Directive No. 98/44 of 6 July 1998 on the legal protection of biotechnological inventions. The act was adopted on the ground of the Art. 95 of the Treaty establishing the European Community as the act harmonizing the law of the Member States for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

In Directive it was adopted the principle, expressed in the Art. 5, that: The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions" However the same article in point 2 predicts that: "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element" [7].

The provisions of the Directive, on the base of Art. 95, 308, 157 and 163 of the Treaty establishing the European Community and the obligations of the Member States resulting from their international undertakings was questioned by Holland in the case C-377/98 against the European Parliament and the Council about the aanulment of the Directive [2: I-07079]. From the content of the application it implies that the Directive violetes the Community obligation of respecting fundamental rights, because „the patentability of isolated parts of human body provided by Article 5 (2) of the Directive reduces living human matter to a means to an end, undermining human dignity" [2: 07079, point 69]. It is for the Court of Justice, in its review of the compatibility of acts of the institutions with the general principles of Community law, to ensure that the fundamental right to human dignity and integrity is observed 2: I-07079, point 70]. The similar point of view presented in his opinion Mr Advocate General Jacobs [8: I-07079].

Polish legislator, harmonizing the national legislation with the community one, made an amendment of the Act of the law of industrial property introducing to this document some changes which came into force of 18 October 2002 year. As a result of amendment it was added the new chapter 9 to the previous law entitled: "Special provision relating to the biotechnological inventions" [3].

In range of the definition of the biotechnological invention and the biological material the provisions of Polish law are in accordance with the Directive (see: Art. 2 of the Directive and Art. 931 of the Act of the law of industrial property).

Also the range of biotechnological inventions, which can be subject of patenting is in general way in accordance with the community provisions (the Art. 3 of the Directive and Art. 932 of polish industrial property law). The difference is because the Directive admits patenting the inventions of the genetic structure of the human body, however the Polish law predicts the opposite solution - excluding the possibility of patenting the elements of human body. It seems that the contradiction of Polish law just in this range does not deny the aim of the Directive because, as it was noticed earlier, the Directive in this matter has an internal inconsistency and contradiction once illegalizing the patenting of elements of human body and once admitting to receive such possibility. It illustrates then quotation with Art. 5: "The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, **including the sequence or partial sequence of a gene**, [the emphasis of the author], cannot constitute patentable inventions". Paragraph 2 of Art. 5 predicts that: "An element isolated from

the human body or otherwise produced by means of a technical process, **including the sequence or partial sequence of a gene**, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”[the emphasis of the author].

According to the Directive: “Inventions shall be considered unpatentable where their commercial exploitation would be contrary to order public or morality (...). In particular, shall be considered unpatentable: processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes”. Polish law, in this range repeats the provisions of the Directive in exact way (Art. 93).

Similarly, the Polish regulations about the range of legal protection of biotechnological inventions, are in accordance with community law.

Thus generally the implementation of the Directive on the legal protection of biotechnological inventions in the formal and substantive respect seems to be correct. It would like to say even more, that in contrast to the provisions of the Directive in range of the patentability of human body elements, it was worked out logically and lucidly. The demurrer in relation to contradiction of the provisions of the Directive in the case of Polish law it can not take place.

4. Conclusions

Taking into consideration the fundamental rules of implementation of the community law into the internal law, the attention should be paid to the methods of implementation and the duties of the Member States connected with the proper realisation of directives.

In the formal respect it is possible to distinguish four principle approaches. It seems, that in this catalogue the most correct form of implementation is this one, which depends on the non literal transposition of the directive’s provisions, but on the adaptation in positive and negative aspect the national law. Second approach is the lack of transposition near simultaneous fulfilment of the formal requirements of implementation. Such a situation takes place in case of pre-existence national provisions in accordance with provisions of directive. Third method depends on literal “rewriting ” the directive and dressing her into the suitable name of national implementing instrument. The last but not least method is the implementation by reference, what means, that the national act refers to the community act published in the Official Journal of European Union. Taking all the above mentioned, it is possible to say that the formal implementation of directives with range of biomedical law by Polish authorities was made correctly and even according to the highest standard.

As regards about substantive implementing requirements, then it would to pay attention to the following principles. First of all it should be stressed, that it is not enough for the proper implementation to transpose directives formally into national legal system, but also to ensure the proper and effective application of the national implementing measures in practice [10: 14-15]. Moreover a very important condition of correct implementation of directives is clearness and uniqueness expressions, which from the beginning excludes the potential possibility of conflict between national and community law.

The key meaning in realization of the provisions of community directives has the principle of efficiency. In implementation of community law it is not sufficient to do any legal action, but only such, which will assure the possibility of effective application and effective controlment of warnings of norms of this law. Efficiency in this sense, hugs not only achievement of lodged result, but also achievement it in appropriate (eg. what to time) way.

This rules are confirmed in the judicature. The European Court of Justice has constantly expressed its view that it is not enough for the proper implementation to transpose directives formally into national legal system, but also to ensure the proper and effective application of the national implementing measures in practice. In consequence it became essential to define the term “proper implementation” Regarding the fact that nor the Treaty provisions neither the directives contain sufficient definitions or merely indications as to what the proper implementation is, the role of ECJ in this respect is difficult to overestimate. In its case-law, by setting the conditions and requirements concerning the legislation and executive practice of the Member States, it defined the scope and limits of proper implementation [10: 14-15; see the judgments discussed therein].

Making the evaluation of correctness of implementation directives with range of biomedical law to the Polish legal system, it should be affirmed, that also under substantive regard it became accomplished correctly. The earlier comparative considerations confirmed it. Obviously, as it was noted above, it is possible to show some shortcomings and lacks. But they are not as serious as could have a negative influence on the high evaluation of the work of Polish legislator. It should be only underlined, that the problem of obligatory insurance of investigator and sponsor demands more attention of the

legislator to make this regulation more clear and proper. It would be noticed that the problem of obligatory investigator's and sponsor's insurance is not solved in a perfect way on the community level. It seems to be not clear in community law the need to stretching over the insurance on the subject of clinical trial. Leading out therefore conclusion with present legal status, it would belong to postulate monitoring systematically the legal status of the subject of clinical trials and initiating actual and adequate solutions in the range of human rights in the field of biomedicine, both on community level, and the national.



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Lenkijos Respublikos teisės aktų derinimas su Europos Sąjungos direktyvomis bioteisės srityje

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SANTRAUKA

Bioteisė yra labai nauja teisės šaka. Jos formavimąsi skatina spartus medicinos mokslo ir technologijų vystymasis. Pagrindinis bioteisės, kartais vadinamos biomedicinos teise, uždavinys yra užtikrinti žmogaus teises ir pareigas biomedicinoje reglamentuojant genų technologijas ir biomedicininius tyrimus. Šiame straipsnyje pabrėžiama tarptautinio bendradarbiavimo svarba ir ES teisės aktų adaptacija valstybėse narėse siekiant garantuoti bendrus minimalius standartus bioteisės srityje.

Daugiausia dėmesio skiriama ES teisyno ir Lenkijos Respublikos teisės aktų analizei. Visų pirma nagrinėjamas nacionalinių teisės aktų derinimo su ES direktyvomis procesas remiantis Bendrijos steigiamosios sutarties ir Lenkijos Respublikos stojimo sutarties nuostatomis. Trečioji ir pati svarbiausia straipsnio dalis skirta Lenkijos teisės ir ES teisės aktų atitikties klausimams. Tuo tikslu išsamiai analizuojami pagrindiniai Lenkijos įstatymai ir poįstatyminiai aktai, reglamentuojantys biomedicininius ir genetinius tyrimus, medikų etiką, asmens orumo apsaugą.

Išvadosse konstatuojama, kad yra keturi galimi direktyvų įgyvendinimo nacionalinėje teisėje variantai. Tačiau vien perkelti direktyvas nepakanka, itin svarbu, kad valstybė narė sugebėtų užtikrinti tinkamą ir efektyvų perkeltų direktyvų įgyvendinimą. Ši nuostata grindžiama ES teisės efektyvumo principu, išplėtotu Europos Teisingumo Teismo jurisprudencijoje.