# HEALTH LAW. SELECTED ISSUES

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# FOREWORD

Health is a special area of interest of legislation and legal environment, as it has a special meaning for the entire community and includes most of the disciplines of knowledge. Thus, its proper legal regulation is a very difficult and responsible task, as consequences of legal loopholes or careless regulations affect the highest value, which is a human life.

At this point it is worth emphasizing that the term 'health law' is not commonly used in Poland. Polish legal nomenclature concentrates on such terms as: medical law, health protection law, public health law. Meanwhile, health law is a term commonly used in international publications, and it includes all regulations referring to health protection of community, both in the field of private and legal law. Deciding on using the term 'health law' in the title of publication the authors wanted to emphasize multitude of aspects included in this publication, unlimited to the field of medical law, and contribute to propagation of international terminology also on the ground of Polish science.

The 'Health law. Selected issues' book was prepared as a result of scientific lectures and discussions held at an international conference, International Focus Programme Final Conference Health Law, organised in Gdańsk by the European Law Students' Association ELSA Gdańsk. The discussions opened during the conference had a great impact on a decision to present the legal research in a scientific monograph. In this place, I would like to thank to all ELSA Gdańsk members, especially Mr. Jakub Puszkarski and Mr. Adam Kowalewski, for their hard work and priceless support during the publishing procedure.

The volume includes studies presenting the chosen aspects of health law. Fourteen lawyers, representatives of science and legal practice, have shared the results of their research. The collective study has been divided into three parts: pharmaceutical law, medical malpractice and varia. All of them are innovative and the aim is to present a broad area of health law interests.

The first part of the book focuses on pharmaceutical law, which is most changeable part of the health law. It includes the European Union norms and their particular impact (both direct and indirect) on the national health law. The papers in second part of the book are concentrated on a malpractice issue. The authors have mostly focused on criminal aspects of Polish medical law, however, it also includes two papers on international law issues. The third part, called Varia, shows different perspectives of health law – its connection with the environmental law, human rights and bioethics.

Gathering so many experts around one book is an honour for its editor. I would like to thanks the authors for their acceptance of my invitation. I hope that this collection of works written by the experts of health law will contribute to popularisation and development of health law.

The work has no ambition of achieving a comprehensive approach to the subject. I venture to suggest that this monograph is just the beginning of health law exploration. Many aspects of this fascinating part of law have been presented only briefly. It is worth knowing that the health law includes all aspect of health care.

The book is written for health lawyers, medical personnel, public health specialists, members of academic community, including students and those, who practise in the field of health, both private and public.

I sincerely hope that the presented monograph will contribute to further discussion on shape and direction of health law development.

I wish to show my great appreciation for prof. Jacek Barcik and dr. Anna Jacek for reviewing the book. Their valuable comments and suggestions had a great influence on the final text.

dr. Emilia Sarnacka

# PHARMACEUTICAL LAW

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# I. GOOD CLINICAL PRACTICE (GCP). EUROPEAN HEALTH LAW NORM

## 1. Introduction

The process of health globalization generate the necessity to create the global management system in health area to protect the highest values like human rights in relation to global market. Such a system is based on proper legal regulations in international public health law[1]. Regulations of international pharmaceutical law related to pharmaceutical industry, involved in clinical trials and distribution of medicinal products all over the world[2] are included in these regulations. The global market is a stimulus to pharmaceutical industry to develop over the individual rights. The individual rights are in opposition to business and public interests. It is a challenge for professionals to regulate it appropriately[3]. One of the most important regulations in European health law, worked out by professionals, is ethical and pharmaceutical standard Good Clinical Practice. But it is not only a standard. Studying the European health law and the history of Good Clinical Practice, we can understand, it evaluated as the European health law norm.

## 2. Origin of GCP

The origin of GCP ethical principles for medical research is the Declaration of Helsinki provided by the World Medical Association. Official name of the act is the *World Medical Association Declaration of Helsinki,* adopted by the 18th World Medical Assembly, Helsinki, Finland, in June 1964. The last revision was done by WMA in 2013, in Brazil. The objective of this Declaration was safety of human subjects involved in any medical research.

In this Declaration we can notice the primacy of human rights in every point of the principles, e.g. the principle of 'concern for the interests of the subjects shall always

[1] For more information see: Barcik, J. 'Międzynarodowe prawo zdrowia publicznego', C.H. Beck, Warszawa, 2013, p 14-17.

[2] B. Tag, 'Intrnationale Medizin. Nationale Standardbildung? Möglichkeiten und Grenzen eine globalen Medizinrechts' in 'Standardiesirung in der Medizin als Rechtsproblem' (ed.) H.Lilie, E.Bernat, H.Rosenau, Nomos, Baden-Baden 2009, pp.163-169.

[3] Bennett, B., Tomossy, G.F. 'Globalization and Health. Challenges for Health Law and Bioethics', Berlin 2006, p. VIII.

prevail over the interest of science and society', repeated in later European acts (see attachment 1).

### 3. International Conference on Harmonization(ICH)

International Conference on Harmonization (ICH) is an international body that defines standards, which governments can transpose into regulations on clinical trials involving human subjects. The full name of ICH is the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. This is a project that brings together the regulatory authorities of Europe, Japan and USA and experts from the pharmaceutical industry. It is worth mentioning the history of ICH. In the 1980's the European Community began to harmonize regulatory requirements for the medicinal products market. In 1989, Europe, Japan and USA began to prepare plans for harmonization. ICH was established in April 1990 at the meeting in Brussels. ICH worked out the standard of GCP. In that way GCP arose as an international standard and a frame for clinical trials. If we would like to understand what GCP of ICH is, we shall familiarize ourselves with its objective and principles. The objective of ICH GCP guideline is to provide a unified standard for the European Union, Japan and USA to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. The guideline was developed with consideration of the current Good Clinical Practices of EU, Japan and USA, as well as those of Australia, Canada, the Nordic Countries and the World Health Organization (WHO)[4]. The guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities. The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects. Studying the principles of ICH GCP (see attachement nr. 2), the main idea refers to respecting human rights.

All the principles of ICH GCP are intended to determine responsibility of every subject involved in organizing clinical trials, like a sponsor, investigator, ethics committee and state authorities. I have selected these points from ICH documentation: 'ICH Harmonized Tripartite Guideline for Good Clinical Practice E6(R1)' Current Step Version dated 10 June 1966, to compare with the main principles of the Declaration of Helsinki and EU GCP.

### 4. European Union GCP

EU GCP is an international standard, very important as a legal norm of European health law, especially in the field of pharmaceutical law due to the fact that clinical

[4] 'ICH Harmonized Tripartite Guideline for Good Clinical Practice E6(R1)', Current Step Version dated 10 June 1996, p.1.

trials involve human subjects. Standardisation in health law[5] is one of the points where medicine meets law, particularly because of ethical problems. Thus, this standard is an idea to protect human rights and established ethical rules. However, firstly we need to analyze its meaning. The definition of GCP given by the European Medicines Agency says that it is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.[6] The Declaration of Helsinki was the first step, made by the World Medical Association, to create such international standard by making guidelines for biomedical[7] research, including clinical trials.

In fact, we can find two kinds of GCPs like GCP of the International Conference on Harmonization (ICH GCP) and GCP of the European Union (EU GCP). ICH GCP is not completely different from the European GCP. Studying history of GCP creation at the beginning of this article, we can understand that both GCPs stem from the Declaration of Helsinki. An international agreement of ICH, initiated by the European Community in order to harmonize regulations for clinical trials, developed an international standard of pharmaceutical law – ICH GCP, which refers to EEC Directives. Main principles of each GCP relate to quality, safety and efficacy. The reason for applying the principles is that human subjects are used as subjects of clinical trials and medicinal products distribution. Nowadays, everyone in the European Union, starting clinical trials against medicinal products, shall conduct them respecting the legal framework for GCP coming from the EU Directives. According to the Bradford Institute for Health Research, EU GCP is a higher and more restrictive standard than ICH GCP because of more precise and restrictive regulations[8]. Unfortunately the EU regulations cause too much bureaucracy and they produce negative results, reducing the number of clinical trials.[9] Another problem refers to ethical committees[10] – regulations

[5] Standardisation in medicine is also a part of health law because of the invoking standards by the provisions of legal acts and liability of medical professions according to them.

[6] Guidelines for Industry E6 Good Clinical Practice:Consolidated Guidance ICH CPMP/ICH135/95 July 2002 www.emea.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf (28.12.2013).

[7] Biomedical research is a medical research, using available knowledge in biomedicine. Biomedicine is a field of medicine, using science (biology, biotechnology, biochemistry, biophysics) development. Medical research can be divided into two general categories: evaluation of new treatments in terms of safety and efficacy in clinical trials, and other researches that contribute to the development of new treatments.

[8] www.bradfordresearch.nhs.uk/governance/what-is-gcp (8.04.2013).

[9] Report of PwC in 2010 www.http://bio-etyka.blogspot.com/2010/12/raport-pwc-dotyczy-badan-linicznych_12.html (7.04.2013).

[10] There are differences in terms of ethics committee, in Directive 2001/20/EC it is 'commission', in

related to them are not unified for every member of EU, thus, e.g.: in Poland there are 53 committees and in Hungary, only one[11], but it is impossible to regulate everything in the Directives[12]. Although there is the Proposal of the European Parliament and the Council for regulation of clinical trials over medicinal products for human use, and repeal of Directive 2001/20/EC Proposal for regulation of the European Parliament and the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, to unify clinical trials as biomedical research by allowing to experiment on human beings[13].

## 5. European Directives about GCP

First European regulations on the directive to GCP were: *Council Directive 65/65/EEC of January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of testing of medicinal products.*

The next step to EU GCP was the international agreement – ICH GCP – implemented into European law. Nowadays, two European Directives constitute the framework for EU GCP: *DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 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 and COMMISSION DIRECTIVE 2005/28/EC of April 2005 laying down principles and detailed guidelines of good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products*. They imposed GCP in every country in EU as a binding norm that must be implemented. These two Directives must be taken into account by anyone, who conducts clinical trials over medicinal products. EU GCP is the guaranty of credibility and precision of the data obtained from clinical trials and published results. The guidelines of EU GCP precisely allocated and determined responsibility for subjects

GB 'ethics committee', in Poland 'bioethics committee' and in USA 'Institutional Review Boards'. For more information see: Czarkowski, M. 'Rola Komisji Bioetycznych w badaniach klinicznych' [in] 'Prawo badań klinicznych w zarysie' ed. Śliwka, M., Dom Organizatora, Toruń 2013, pp.55-56.

[11] www.bio-etyka.spot.com/2012/07/badania-kliniczne-europejskie-dyrektywy.html (7 April 2013).

[12] See more information: www.http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

[13] Bosek, L., Olejniczak, D.'Opinie w sprawie projektu rozporządzenia Parlamentu Europejskiego i Rady w sprawie badań klinicznych produktów leczniczych stosowanych u ludzi oraz o uchyleniu Dyrektywy 2001/20/WE in Zeszyty Prawnicze, Biuro Analiz Sejmowych Kancelarii Sejmu, No. 4(36)/2012, p.119.

arranged. In Directive 2001/20/EC [Article 1.2] we can find definition of GCP, also mentioned in the first paragraph announced by the European Medicines Agency[14].

In Directive 2005/28/EC there are presented the main rules of EU GCP [Chapter 2, section 1, articles 2-5]:

– The rights, safety and wellbeing of the trial subjects shall prevail over the interests of science and society,
– Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his tasks,
– Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects,
– The necessary procedures to secure the quality of every aspect the trials shall be complied with,
– The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial,
– Clinical trials shall be conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the General Assembly of the World Medical Association (1996),
– The protocol referred to in point (h) of Article 2 of Directive 2001/20/EC shall provide the definition of inclusion and exclusion of subjects participating in clinical trial, monitoring and publication policy,
– The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial,
– All clinical trial information shall be recorded, handled, and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.

I'd like to emphasize point 1 of the introduction of Directive 2005/28/EC and point 14 of the introduction of Directive 2001/20/EC promoting non-commercial investigations without participation of pharmaceutical industry due to the great benefits for patients.

Good Clinical Practice of the European Union is closely connected with guidelines for other good practices, important in terms of pharmaceutical law, and the most important is: ***Good Manufacturing Practice*** (GMP) guidelines for production and testing practice that helps to ensure a good quality product. Many countries have

[14] The European Medicines Agency is the European Union Agency (London). It plays an important role in the harmonization and co-ordination of GCP – related activities at the EU level. It is involved in: co-ordinating GCP inspections for the centralised procedure; preparing guidance on GCP topics through the work of the GCP Inspectors Working Group; co-ordinating advice on the interpretation of EU GCP requirements and related technical issues; developing of EU-wide guidelines on GCP inspections and related procedures for the centralised procedure. For more information see: www.ema.europa.eu

approved that pharmaceutical and medical equipment companies must follow GMP procedures[15].

Good Manufacturing Practice is connected with other good practices:

**Good Laboratory Practice** (GLP) guidelines for laboratories conducting non-clinical studies (toxicological and pharmacological studies on animals)[16],

**Good Regulatory Practice**(GRP) guidelines for the management of regulatory commitments, procedures and documentations[17], **Good Documentation Practice** (GDP) instructions and procedures shall be written in clear and unambiguous language[18],

**Good Distribution Practice** (GDP) guidelines for the proper distribution of medicinal products for human use[19], **Good Transportation Practice** (GTP) guidelines for proper domestic and international transportation of medicinal products for human use[20].

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[15] Directive 2001/20/EC introduction point (12): 'The principles of good manufacturing practice should be applied to investigational medicinal products.

[16] The European regulation for GLP:
1. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances. This directive lays down the obligation of the Member States to designate the authorities responsible for GLP inspections in their territory. It also comprises requirements for reporting and for the internal market (i.e., mutual acceptance of data).
2. Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP). The Directive requires that the OECD Revised Guides for Compliance Monitoring Procedures for GLP and the OECD Guidance for the Conduct of Test Facility Inspections and Study Audits must be followed during laboratory inspections and study audits.
3. 89/569/EEC Council Decision of 28 July 1989 on the acceptance by the European Economic Community of an OECD decision / recommendation on compliance with principles of good laboratory practice.

[17] Good Regulatory Practice helps in international trade, for more information see in: Directive 2010/63/EU (EC,2010), www.trade.ec.europa.eu/doclib/docs/2008/january/tradoc_137564.pdf – document of Committee on Technical Barriers to Trade „Good Regulatory Practice" GT/TBT/W/254 (14 June 2005).

[18] Good documentation constitutes an essential part of the quality assurance system and it is a key to operating in compliance with GMP requirements. For more information see the Document of the European Commission, Brussels, SANCO/C8/AM/sl/areas(2010)1064587, link: www.ec.europa.eu/health/files/eudralex/vd-4/chapter4_01-2011.en.pdf

[19] The present guidelines are based on Articles 84 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ('Directive 2001/83/EC'), see more information: 'Guidelines on Good Distribution Practice of Medicinal Products for human use' (94/C63/03), link: www.ec.europa.eu/health/human-use/good_distribiution_practice/index_en.htm

[20] For more information see the document of European Commission, Directorate – General for Energy and Transportation 'European Best Practice Guidelines on Cargo Securing for Road Transport' link: www.ec.europa.eu/transport/road_safety/vehicle/doc/cargo_securing_guidelines_en.pdf

Obviously, Good Clinical Practice would not have any sense in relation to safety of medical products without other good practices. At this point, the complexity of EU GCP appears.

### 6. GCP – the European legal norm

It was not my aim to precisely describe GCP in this article. I wanted to prove that European GCP is not only an international ethical or pharmaceutical standard but also a European health law norm for a few reasons:

– First of all, it is more restrictive and better described than ICH GCP, not only in case of one act of law, and it has a long history dating back to 1965;

– it has a legal definition;

– a legal norm is complicated and connected with many other rules and standards (like guidelines for every step in producing and distributing medical products) of pharmaceutical and medical law;

– European GCP has its own legal institutions, like the Ethics Committee, the European Medicines Agency or the Standing Committee for Medical Products for Human Use[21]

– the main rules of GCP consist in implementation of natural law, international law and ethics;

– according to the EU Treaty, EU GCP implements EU policies supporting the high level of health care;

– the implementation of human rights by EU GCP is the most important value that is above legal rules;

– EU GCP is compatible with international agreements and legal acts on human rights like the Convention for the Protection of Human Rights and dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine, Oviedo, April 4,1997)

– very important for Europe.

I think that EU GCP is a special legal norm that expresses ideological, political and ethical principles, which shall also be respected by the state authorities of each Member State of the European Union. It defines a notion used in the process of law enforcement and is a binding rule determining duties of legal subjects. I would like to show the significance of this European legal norm by presenting the hierarchy of EU norms. EU law is based on primary legislation and secondary legislation. The primary legislation consists of the Treaties, general principles established by the Court of Justice of the European Union (CJEU) and international agreements. The secondary

[21] Their role and objectives are defined in Directives 2001/20/EC and 2005/28/EC.

legislation consists of all acts that enable the Union to exercise its powers. The hierarchy is introduced by the Treaty of Lisbon and establishes primary and secondary legislation. It appears in distinction between:

– legislative acts (Article 289 TFEU). These are legal acts adopted by an ordinary or special legislative procedure;

– delegated acts (Article 290 TFEU). These are non-legislative acts of general application which supplement or amend certain non-essential elements of the legislative acts. The power to adopt this type of act may be delegated to the Commission by the European Parliament or the Council;

– implementing acts (Article 291 TFEU). These acts are generally adopted by the Commission which is conferred with implementing powers; in certain cases the Council may also be called upon to adopt implementing acts[22].

If we present EU law as a 'pyramid' – a triangle to analyse the hierarchy of EU law (see attachment 3). we will find the GCP norm on its top. The top will also include primary law like Treaties, provisions concerning European policies (like health policy), social conditions and, most of all, human rights ( Article 6 point 1 of TEU) and high level of health protection (Article 3 point p of TFEU). In the Charter of Fundamental Rights (CFR), from the Preamble, mentioning moral inheritance and common values, to Articles: on Dignity (Article 1), on the right to life (Article 2), on the right to safe integrity (Article 3), on the right to respect private life (Article 7), on the right to safe personal data (Article 8), on the right to high level of health protection (Article 35) and also on good administration (Article 41) relating to Good Practice in Documentation and Good Practice in Regulation, and binding rules for legal subjects of EU and the state authorities of the Member States of EU; these are rules for Good Clinical Practice, which must be respected[23].

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical for Human Use is an international agreement (worked out by ICH GCP) which establishes the beginning of European GCP – which is the next level of the hierarchy triangle but it is also primary law. Secondary law consists in legislative acts of the European Parliament and the Council and delegated acts (delegated to European Parliament and the Council). Obviously, such acts include Directives 2001/20/EC, 2005/28/EC and the Proposal of the European Parliament and the Council for regulation on clinical trials over medicinal products for human use, and repealing Directive 2001/20/EC. Implementing acts are regulations of state authorities of every Member State of EU on Good Clinical Practice according to the two European Directives.

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[22] www.europaeu/legislation-summaries/glossary/norms_hierarchy_en.htm (2.12.2014).

[23] Bieńczyk-Missala, A. 'Międzynarodowa Ochrona Praw Człowieka. Wybór dokumentów', WUW, Warszawa 2009, pp. 377 – 402.

## 7. Summary

EU GCP and ICH GCP standards are not only principles or rules creating the procedures for clinical trials. They are binding legal rules having their origin in natural law, ethics, morality, justice and fairness[24]. At each level of European law there are rules providing for the principles of Good Clinical Practice. Besides the EU acts, there is a very important act in Europe - the Convention on Human Rights and Biomedicine (Oviedo, 4.IV.1997), related to principles of the Declaration of Helsinki. EU GCP aims to protect human beings involved in biomedical research[25]. The dimension of regulation EU GCP, process of its evolution, its origin and complexity and especially the highest values it protects are the reasons to define EU GCP as European health norm.

**Attachement 1**

| Basic Principles |
|---|
| 1. Biomedical research, involving human subjects, **shall conform to generally accepted scientific principles**, and should be **based on adequately performed laboratory** and animal experimentation, and on **thorough knowledge** of the scientific literature. |
| 2. The design and performance of each experimental procedure involving human subjects shall be clearly formulated in an experimental protocol which shall be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor, provided that this independent committee is in conformity with the laws and regulations in this country in which the research experiment is to be carried out. |
| 3. Biomedical research, involving human subjects, shall be **conducted only by scientifically qualified persons** and under the supervision of a clinically competent medical person. The **responsibility** for the human subjects shall always **rest** with a **medically qualified person** and **never with the subject of** the **research**, even though the subject has given his or her consent. |
| 4. Biomedical research involving human subjects **shall not legitimately be carried out**, **unless the importance of the objective proportion to the inherent risk to the subject.** |
| 5. Every biomedical research project involving human subjects shall be **preceded by careful as sessmentof predictable risks in comparison with foreseeable benefits** to the subject or to others. **Concern for the interests of the subjects shall always prevail over the interest of science and society.** |

[24] Dworkin, R. 'The Model of Rules', Faculty Scholarship Series, 1967, Paper 3609, p. 23 (www.umiacas.umd.edu/~horty/courses/reading/dworkin-1967-model-of-rules.pdf). See also 'Philosophy of law', Oxford University press, 2010, pp. 38 - 65, by Ronald Dworkin we should agree with him about the construction of GCP that standards as principles and policies we can treat in the same way we treat rules of law as elements of the law.

[25] Jasudowicz, T., Czepek, J., Kapelańska – Pręgowska, J. 'Międzynarodowe standardy bioetyczne', Wolters Kluwer, Warszawa 2014, p. 15.

| |
|---|
| 6. The right of the research subject to safeguard his or her **integrity** shall always be respected. Every effort shall be taken to respect the **privacy** of the subject and to minimize the impact of the study on the subject's physical and mental integrity, and on the **personality** of the subject. |
| 7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians shall cease any investigation, if the **hazards are found to outweigh the potential benefits.** |
| 8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. **Reports of experimentation**, **not in accordance with the principles** laid down in this Declaration, **shall not be accepted for publication.** |
| 9. In any research on human beings, each potential **subject** shall be **adequately informed** of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she shall be informed that he or she is at liberty to abstain from participation in the study, and that he or she is free to withdraw his or her consent to participation at any time. The physician shall then obtain the subject's freely-given informed consent, preferably in writing. |
| 10. When obtaining informed consent for the research project, the physician shall be particularly cautious if the subject is in a dependent relationship to him or her, or may consent under duress. In that case, **the informed consent shall be obtained by a physician** who is **not engaged in the investigation**, and who is **completely independent** of this official relationship. |
| 11. In case of **legal incompetence**, **informed consent shall be obtained from the legal guardian** in accordance with the law. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with the law. Whenever the minor is in fact able to give a consent, the minor's consent shall be obtained in addition to the consent of the minor's legal guardian. |
| 12. The research protocol shall always contain a statement of the ethical considerations involved, and shall indicate that the principles enunciated in the present Declaration are complied with. |

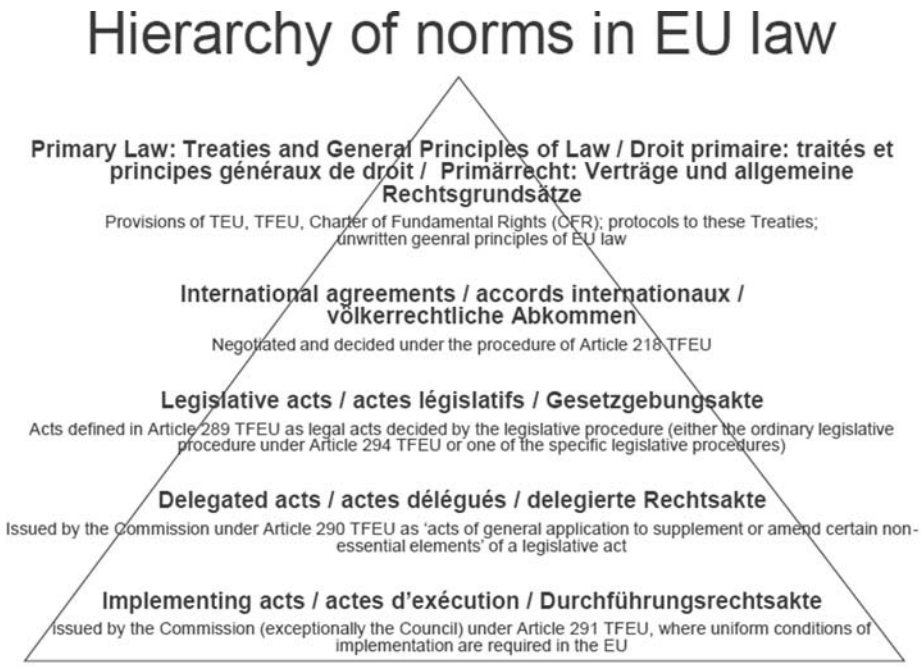
## Attachement 2

| The principles of ICH GCP |
|---|
| 1. **Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki**, and that are consistent with GCP and the applicable regulatory requirement(s). |
| 2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks. |
| 3. **Therights**, **safety**, **and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.** |

| |
|---|
| 4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial. |
| 5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol. |
| 6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion. |
| 7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist. |
| 8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s). |
| 9. Freely given informed consent should be obtained from every subject prior to clinical trial participation. |
| 10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification. |
| 11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s). |
| 12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol. |
| 13. Systems with procedures that assure the quality of every aspect of the trial should be implemented. |

**Attachement 3**

The hierarchy of legal norms in EU, after introduction of the Lisbon Treaty on 1 December 2009, is shown by professor Herwig Hofmann from University of Luxemburg, as a triangular construction:




Publication: 9 October 2012[26].

[26] www.cvceeu/kontent/publication/2010/11/9/1623b797-f93f-4255-9ad8-1ceea5e2b20/publishableen.pdf (27 December 2013).

**Natalia Łojko, attorney at law**
*Kieszkowska Rutkowska Kolasiński Law Firm*

# II. INFORMATION ON RX PRODUCTS TO PATIENTS – WHERE ARE WE HEADING?

## 1. Introduction

While the right to information has for a long time been treated as one of the essential patient's rights – the amount of information provided to patients on medicinal products which often constitute important, if not indispensable, component of medical services provided to patients – has been problematic. It was because one of the crucial principles of pharmaceutical law the EU (contrary e.g. to the US) is that prescription only ('Rx') products should not be advertised to the public. Even though at first sight this may not be problematic for provision of information – intuitively one differentiates advertising from information – in practice those spheres overlap. The most important reason for this is the fact that under EU law a definition of pharmaceutical advertising is extremely broad and encompasses also information where its aim is to increase of prescription, sale or consumption of medicinal products. Pharmaceutical law thus contains one of the broadest definitions of advertising that are laid down in statutes in Poland. This article describes the practical difficulties in differentiating advertising from information and a directive proposed by the Commission of the European Union to bridge the differences between various Member States and clarify problematic issues. While it is now clear that the work on the directive is closed[27] – amidst hot national debates – the draft is an interesting example of a solution to an uneasy intersection of information and advertising.

## 2. Advertising vs. information – the state of play in EU

One of the basic principles of medicinal products advertising under the EU law is a prohibition on advertising prescription-only products to the public. This principle, mentioned in Art. 88 par. 1 let. a) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ('**Directive 2001/83**')[28] needs to be understood in the light of

[27] Information on withdrawal of the proposal:
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2014:153:FULL&from=EN.

[28] The text of Directive 2001/83 available at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0083:20110721:EN:PDF (accessed 19th February 2014).

a very broad definition of 'advertising' included in Art. 86 par. 1 of Directive 2001/83 which explains that: *advertising of medicinal products' shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products*. As the European Court of Justice rightly underlined, *It is apparent from the outset from the wording of that provision, in particular from the expression 'any form', that* ***the concept of advertising of medicinal products adopted by the European Union legislature is very broad****. As is clear from recital 44 in the preamble to Directive 2001/83,* ***that concept may include the dissemination on the internet of information relating to medicinal products*** *(see, to that effect, Case C421/07 Damgaard [2009] ECR I2629, paragraph 28)* (Case C-316/09, *MSD Sharp&Dohme GmbH v. Merckle GmbH*, paragraph 29). [underline – author]

Further, Directive 2001/83 defines a list of activities which are and which are not considered advertising. The list proves how broadly the pharmaceutical advertising is understood under the EU law – the 'positive' list contains activities such as visits by sales representatives or sponsorship of scientific congresses[29], which in other areas of business would not necessarily be automatically classified as advertising. The 'negative' list is very limited and includes many statements which are 'obviously informative'[30].

The line between advertising and information is very thin – with the purpose of the message being decisive for its classification. This means that even dissemination of objective information may be considered advertising, if the message is designed to promote the prescription, supply, sale or consumption of medicinal products. Where, on the contrary, a material is purely informative, without promotional intent, it is not covered by the provisions of the directive relating to advertising of medicinal products. The very fact that a message originates from a manufacturer of a medicinal product does not *per se* mean that the message constitutes advertising. It will be the case only

[29] The list includes:
– advertising of medicinal products to the general public,
– advertising of medicinal products to persons qualified to prescribe or supply them,
– visits by medical sales representatives to persons qualified to prescribe medicinal products,
– supply of samples,
– provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,
– sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,
– sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

[30] The list includes:
– the labelling and the accompanying package leaflets, which are subject to the provisions of Title V,
– correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product,
– factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims,

if the purpose of dissemination of the message is to promote, via such dissemination, prescription, supply, sale or consumption of that medicinal product (Case C219/91 *TerVoort* [1992] ECR I5485, paragraph 26).

Some channels are more 'informative' than others. In this respect the Court underlined the importance of a 'pull' approach – i.e. provision of information through a channel where access to such information requires *active research steps by the internet user and a person who is not interested in the medicinal product concerned will not be unwillingly confronted with that information.* (Case C-316/09, *MSD Sharp &Dohme GmbH v. Merckle GmbH*, paragraph 47).

A broad understanding of what is advertising was underlined by the European Court of Justice in two most recent cases, whereby:

• it concluded that even the very publication of the summary of product's characteristics ('**SmPC**') on the pharmaceutical company website may be qualified as advertising. It will not be considered as advertising only if *that information is accessible on the website only to someone who seeks to obtain it and that dissemination consists solely in the faithful reproduction of the packaging of the medicinal product, in accordance with Article 62 of Directive 2001/83, and in the literal and complete reproduction of the package leaflet or the summary of the product's characteristics, which have been approved by the authorities with competence in relation to medicinal products. In contrast, the dissemination, on such a website, of information relating to a medicinal product which has been selected or rewritten by the manufacturer, which can be explained only by an advertising purpose, is prohibited.* (Case C-316/09, *MSD Sharp &Dohme GmbH v. Merckle GmbH*).

• an activity of disseminating information on a medicinal product including its therapeutic or prophylactic properties by a third party at patients' forum may be treated as advertising, even if the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller of the medicinal product (Case C-421/07 *Damgaard*).

A prohibition on advertising prescription-only products to the public has been justified as the protection of public health, to prevent the improper use or overuse of medicinal products (Case C-316/09, *MSD Sharp &Dohme GmbH v. Merckle GmbH*, paragraph 30). The aim is to ensure that any information provided to a patient does not lead directly to a decision to purchase a product and does not undermine the principle that the final decision related to taking the medicinal product is left to the discretion of his doctor (Case C-316/09, *MSD Sharp &Dohme GmbH v. Merckle GmbH*, paragraph 36). Even though, as the Court underlined, the doctor is required, from the point of view of professional conduct, not to prescribe the medicinal product, if it is not appropriate for the therapeutic treatment of his patient – this does not mean that the

very presence of a 'gatekeeper' would deprive a promotional message of its effect (Case C62/09 *Association of the British Pharmaceutical Industry* [2010] ECR I0000, paragraphs 39 and 40).

Undoubtedly, provision of information on medicinal products may have positive results – and this was explicitly recognized by the European Court of Justice. (Objectively accurate) information provided by a company may help patients who have lost the package leaflet for the medicinal product used, or to answer "public desire to be informed" or to "highlight the transparency of the undertaking" (Case C-316/09, *MSD Sharp&Dohme GmbH v. Merckle GmbH*, paragraph 35). Further, objective information which would stem from reliable source could "contribute to the prescription of appropriate treatment, in so far as there may be a more fruitful dialogue between the doctor and the informed patient" (Case C-316/09, *MSD Sharp &Dohme GmbH v. Merckle GmbH*, paragraph 38).

### 3. Advertising vs. information – the state of play in the Member States – diagnosis of the EU Commission

Thus, a line between advertising and information is very thin[31]. The EU legislator – undoubtedly aware of this – imposed on the EU Commission an obligation to evaluate the practice in this area, especially in relation to information provided on the Internet – and its risks and benefits for patients (Art. 88a of Directive 2001/83). The role of the Commission was to diagnose the status quo and present a report to the European Parliament and to the Council including, if appropriate, *proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question of the information source's liability*.

In 2007, having analyzed this issue in a cross country setting and having consulted a number of stakeholders, the Commission came to a conclusion that there is too much inconsistency across the EU in relation to what is considered to be information on medicinal products, as opposed to advertising - and, consequently, what may be provided to the public. Shortly before Christmas of 2007, the Commission published the "Report on current practices with regard to the provision of information to patients on medicinal products"[32].

**The Commission concluded that the Member States had been taking a very varied approach related to what is considered to be information (as opposed to advertising) and in what manner it can be provided to patients. Some Member**

[31] Krekora, M., Świerczyński, M., Traple, E. 'Prawo farmaceutyczne', Wolters Kluwer, Warszawa 2008, pp. 290-291; Ogiegło, L. (ed.), 'Prawo farmaceutyczne. Komentarz', CH BECK, Warszawa 2010, p. 519.

[32] The Report is available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0862:FIN:en:PDF (accessed 19th February 2014).

**States took a very restrictive view while others allowed quite a number of channels for providing non promotional information to patients. In some Member States, the public authorities were engaged in providing information to patients, while in others, certain forms of public-private partnerships were predominant. The type of information allowed – and its quality – also varied – from information on** efficacy to information on the costs and duration of treatment.

This, as the Commission concluded *results in unequal access of patients, and the public at large, to information on medicinal products*[33].

The Commission also acknowledged the fact that patients had become more proactive and empowered and that the Internet had been playing increasingly important role in the search for information. Even though the Member States might have had a key role in providing the information – this might not be sufficient, and *the pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available to patients and healthcare professionals throughout the EU.*

Thus, the Commission concluded that EU citizens had unequal access to information and that lack of EU quality standards for information to patients increased the risk of wrong, misleading or confusing information, creating health risks. The Commission underlined the importance of maintaining the principle that advertising to the public is prohibited for prescription-only medicines.

In conclusion, the Commission declared the intention to propose amendments to the rules on the provision of information to patients by the end of 2008. The aim was to reduce differences in access to the information and to ensure availability of good-quality, objective, reliable and non-promotional information on medicinal products.

### 4. Example of national approach to informing patients – the case of Poland

In the above context, Poland may serve as a good example of how the general prohibition of advertising prescription-only products to the public – provided for in Art. 88 of directive 2001/83 (implemented in Poland) is executed in practice.

Polish authorities seem to take strict approach as to what is considered to be the advertising[34] – the approach of the General Pharmaceutical Inspection (a body competent for monitoring of advertising compliance with the applicable law) to so-called disease awareness campaigns concerning HPV virus and pneumococcus may serve as example. Such campaigns were conducted by pharmaceutical companies to increase patients' awareness in this field, including importance of systematic testing and benefits of vaccination as means of prevention. The General Pharmaceutical Inspector, in a series

[33] Report on current practices with regard to the provision of information to patients on medicinal products, p**.** 9.

[34] Sławatyniec, Ł., Mazurek, K. 'Reklama produktów leczniczych', Wolters Kluwer, Warszawa 2011, p. 183.

of very controversial decisions issued in 2009, stated that pharmaceutical advertising (of prescription-only products) includes therapeutic campaigns / disease awareness campaign materials which included:

• a name of a medicinal product on campaign's website[35].

• information on campaign's sponsor and a name of a disease – the General Pharmaceutical Inspector argued that a consumer may simply put company's name and the name of the disease in a web browser – and will get to the name of an Rx product easily. This is the case even though pharmaceutical companies are actually obliged to disclose the financing of various healthcare initiatives – as this increases transparency and prevents publication of information, which resembles an independent press release, which is in fact sponsored by the company – an act which could be treated as unfair competition being against press law[36].

• a copyright note referring to the name of a pharmaceutical company. The argument was the same as in the point mentioned above – a consumer may easily find out the name of the product if he knows the disease area and a name of a pharmaceutical company[37].

• a list of healthcare facilities, in which the advice on the illness was available. The General Pharmaceutical Inspector explained that 'most probably' a patient who visits such a facility will be prescribed a product of campaign's sponsor[38].

Two further examples just prove how broadly advertising may be understood within the Polish law. Namely, the General Pharmaceutical Inspector defined advertising as:

• information on how the packaging of the original product looks like (and what are the special signs, which allow it to be differentiated from a counterfeit) – where the product is one of the often counterfeited medicines[39].

• a mention of the prescription-only product name on an envelope in which promotional materials (compliant with the pharmaceutical law) were sent to a healthcare professional. The General Pharmaceutical Inspector explained that a postman who delivered the letter might have noticed the name of a product and thus be subject to its advertising[40].

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[35] Decision of the General Pharmaceutical Inspector of 10th August 2009, no. GIF-P-R-450-83-3/JD/09; decision of the General Pharmaceutical Inspector of 19th May 2008, no. GIF-P-R-450-92-5/JD/09.

[36] Decision of the General Pharmaceutical Inspector of 5th June 2009, no. GIF-P-R-450-13-3/KP/09.

[37] Decision of the General Pharmaceutical Inspector of 5th June 2009, no. GIF-P-R-450-13-3/KP/09.

[38] Decision of the General Pharmaceutical Inspector of 5th June 2009, no. GIF-P-R-450-13-3/KP/09; decision of the General Pharmaceutical Inspector of 7th January 2009, no. GIF-P-R-450-73-3/JD/08/09.

[39] Decision of the General Pharmaceutical Inspector of 20th December 2007, no. GIF-P-R-450-99-2/RL/07.

[40] Decision of the General Pharmaceutical Inspector of 10th December 2004, no. GIF-P-R-481-51/RB/04.

Taking a very comprehensive approach to the question of advertising vs. information, the public authorities in Poland require advertising to be strictly in line with the SmPC. There is the extensive case law of the General Pharmaceutical Inspector, which requires that any information provided in advertising materials needs to be strictly in line (in a 'copy-paste' manner) with SmPC. This means that any generalization, transformation and softening of the scientific language included in the SmPC, in order to make it more 'user-friendly', is risky. This makes the informative potential of communication on medicinal products even smaller.

While undermining the right of a pharmaceutical company to conduct disease awareness campaigns and provide other forms of information, the public authorities do not offer any information instead. Only since the entry into force of the new reimbursement law in Poland (1st January 2012) the up to date SmPCs are published on the website of the President of the Registration Office – as the registered indications (as reflected in the SmPCs) are essential for determination of the scope of reimbursement under the new reimbursement law, which entered into force on that date. In addition, even in cases where publication of certain information is obligatory – the public authorities do not necessarily comply with such an obligation. Public assessment reports created by the registration authorities, whose publication is obligatory under Directive 2001/83 and the Polish pharmaceutical law, are not published. There is no public initiative to inform patients about the registered therapies (esp. in a user-friendly manner). Thus, there is quite a substantial gap between Poland and e.g. Scandinavian countries mentioned in Commission's report where public authorities are an important source of information.

## 5. Proposal of a new directive on providing information on prescription-only products to patients

Following the analysis of the state of play, regarding provision of information on prescription-only products to patients, the EU Commission proposed a draft Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code, relating to medicinal products for human use ('**Draft**').[41]

In the Draft, the Commission proposed to maintain a ban on advertising Rx products to the public. Information was to be allowed, but:

– only specific types of information;
– only through specific channels;
– compliant with quality standards;
– subject to specific review procedure.

[41] The text of the Draft is available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0663:FIN:en:PDF.

The Commission proposed differentiation between obligatory and voluntary information. Obligatory information (i.e. information which would be subject to obligatory publication), would encompass up-to-date SmPC, labelling and package leaflet, as well as public assessment report.

The Draft clearly excluded some pieces of information from the new framework (and new obligations) set out therein – i.e. public announcements by MAH re. pharmacovigilance concerns, information related to human health or diseases – if there is no reference, even indirect, to individual medicinal products, materials provided by MAH to healthcare professionals for their own use and information to investors/employees.

The Draft also specified the types of information which were to be allowed, i.e. information on environmental impact of a product, prices, pack changes, instructions for use, pharmaceutical and pre-clinical tests and clinical trials, summary of frequently submitted requests for information and answers and *other types of information approved by competent authorities that are relevant to support the proper use of the medicinal product*.

The Draft proposed that only specific 'reactive ('pull') channels' could be used – i.e. websites on medicinal products, printed materials about a medicinal product prepared by MAH, made available to the general public or members thereof, on request or through healthcare professionals and written answers to the specific requests for information about a medicinal product of a member of the general public. 'Push' channels – i.e. TV/radio/printed media – would be prohibited. Internet websites would be registered and their contents subject to pre-approval.

Importantly, the Draft clarified the role of independent third parties – subjecting the marketing authorization holders and third parties, acting on their behalf or following their instructions, to the requirements included in the Draft. It also provided for a – much needed – clarification concerning the status of informing investors and employees about business developments – if not promotional, it would be excluded from the scope of the Draft. If such information concerned individual products, it would be subject to the rules on provision of information.

Last but not least, the Draft made clear that the constitutional principles would apply to the provision of information on prescription-only products, such as: freedom of the press and freedom of expression in the media.

The Draft took into consideration that Member States would need to establish sanctions for violation of the rules provided for in the Draft, in the form of penalties, injunctions and 'name and shame' of the violators.

## 6. Assessment of the Draft and its political fate

The Draft offered to provide for a very much awaited clarification and harmonization of the rules concerning the provision of information on prescription-only products to the public. It addressed a number of doubtful situations such as the status of journalists, information to employees and shareholders.

Undoubtedly, an over-restrictive approach to what is informational and what promotional may lead (and does lead) to stiffening of scientific exchange, dissemination of information, and hampering empowerment of consumers. Even though a mere fact that a pharmaceutical company is a source of communication does not mean that such a communication is promotional; in practice, companies often prefer not to provide any information on scientific developments in view of the risk that such a communication will be qualified as advertising. This deprives scientific community, healthcare professionals and patients of valuable information which could allow further scientific development and offer treatment options.

Nowadays, with almost common access to the Internet, restrictive approach is no longer viable – it does not take into account that patients have access to websites located in countries, which not only have a more relaxed approach to information on prescription-only products to the public, but which explicitly allow to advertise prescription-only products (such as the USA). It also ignores the fact that patients are more and more proactive in their search for information – and that in absence of reliable, verified information, stemming from credible sources, they may be inclined to search in patients forums where the information may be misleading or based on emotions, not science.

Unfortunately, the Draft incited much debate and controversy. It has been vetoed by several countries, including Poland. The main argument was that the Draft would lead to an increase in the rate of prescription-only products prescribed. This argument did not account for the fact – underlined in the ruling of the European Court of Justice – that objective, verifiable information could actually contribute to better dialogue between the doctor and the patient and thus lead to better therapeutic choices. This means that the trend as regards information to patients on prescription only products is actually opposite to what is happening in other areas of medical law – where patient's right to information (and informed choice) is increasing in importance.

It is now clear that the Draft – amended by the Commission after a heated discussion in the Council and in the Parliament – will not be processed any longer and it will end in a bin with useful, but politically not viable, ideas[42]. The Member States, companies – and patients – will have to continue to rely on their own ways of interpreting what is information and how best to access it.

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[42] Information on withdrawal of the proposal:
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2014:153:FULL&from=EN.

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# III. MARKETING AUTHORISATION FOR HOMEOPATHIC AND ANTHROPOSOPHIC MEDICINAL PRODUCTS IN THE EUROPEAN UNION

## 1. Introductory remarks

The notion of a medicinal product is the key notion of the entire system of pharmaceutical law. The classification of a product to a group of medicinal products, and then to a specific type of these products, leads to serious consequences related to specific responsibilities and restrictions on the part of any entrepreneur placing a product on the market. Those responsibilities include a complicated, long-term and costly procedure of marketing authorisation, the performance of numerous tests, and the monitoring of product safety after marketing. Restrictions will result mostly from regulations concerning medicinal products advertising and the possibility of sales (restriction solely with regard to pharmacy sales).

According to Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[43], a medicinal product is any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

The Directive 2001/83/EC gives two definitions of medicinal products, one 'by virtue of their presentation' and one 'by virtue of their function'. A product is a medicinal product if it falls within either of those definitions[44]. It is also settled case-law that those two definitions are to be broadly construed[45].

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[43] O.J EC, L 311/67 from 28.11.2001; hereinafter referred to as: Directive 2001/83/EC.

[44] Compare e.g. the judgement of the CJEU of 21 March 1991 in case C-60/89 Monteil and Samanni, points 10 and 11.

[45] Compare e.g. the judgment of the CJEU of 16 April 1991 in case C-112/89 Upjohn, paragraph 16; Monteil and Samanni, paragraph 23

## 2. The specificity of homeopathic medicinal products

The EU legislation *expressis verbis* treats homeopathic medicinal products as a separate group. These are medicinal products manufactured from substances called homeopathic stocks in accordance with the homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the member states of the European Union. A homeopathic medicinal product may also contain a number of principles[46].

The notion of homeopathy comes from the Greek words *homois* (meaning 'similar') and *pathos* ('disease'), and therefore means a state of 'similarity to a disease'.

A theoretical basis for the homeopathic method of treatment, arising from the father of homeopathy, Samuel Hahnemann, is the 'law of similars', which states that the administration of a small dose of a specific medicine can cure symptoms similar to those that the medicine causes after it is administered in a larger dose: 'let like be cured by like' (*similia similibus curentur*). Currently, there is a trend, akin to the use of vegetable and herbal medicinal products, showing a return to the use of pharmaceuticals with the lowest possible content of chemical agents. It might be said that people using medicines are divided into avid backers of homeopathic methods and those who consider them 'shamanic practices', which in fact do not cure, but do not harm either[47].

Grating the status of a homeopathic product to a medicinal product, and the fulfilment by this pharmaceutical of the additional requirements of Article 14 of Directive 2001/83/EC, may lead to its inclusion in a simplified marketing authorisation procedure.

Such possibility, on the basis of the European law, was already introduced with Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to medicinal products and laying down additional provisions on homeopathic medicinal products[48].

In this place, it should be reminded that before the amendment introduced by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use[49], regulations on homeopathic medicinal products were different in the EU. According to the former provisions of law, member states had autonomy with regard to the introduction of regulations concerning a simplified marketing authorisation procedure to their national legal systems. Such possibility was stipulated *expressis verbis*

[46] See Art. 1(5) of Directive 2001/83/EC.

[47] On the problem of the relationship between homeopathy and doctors obligation to act on the basis of the current state of medical knowledge see more: Haberko, J. 'Aktualna wiedza medyczna a stosowanie homeopatii', Wokanda Medyczna, No. 1(2009), pp. 47-59.

[48] OJ EC L 297/8 from 13.10.1992.

[49] OJ EC L 126/34 from 30.4.2004; hereinafter referred to as: Directive 2004/27/EC.

in Article 13(2) of Directive 2001/83/EC in its previous wording. According to this provision, member states could decide to refrain from establishing a special, simplified registration procedure for homeopathic medicinal products and inform the Commission accordingly. However, in order to satisfy the principle of free movement of goods and mutual recognition of authorisations, a member state which did not introduce the simplified registration procedure for homeopathic products was obliged to allow in its territory the use of homeopathic medicinal products registered by other member states under a simplified marketing authorisation procedure.

Such possibility was excluded by Directive 2004/27/EC. Currently, EU member states are obliged to introduce into their national systems a simplified marketing authorisation procedure for homeopathic products, which fulfill the conditions listed therein.

At the same time, it should be remembered that the remaining scope of Directive 2004/27/EC confirms after Directive 2001/83/EC the necessity of registering and manufacturing homeopathic medicinal products in the same way as other medicinal products. The simplified procedure concerns only the conditions to be satisfied indicated in Article 14(1) of Directive 2001/83/EC. Due to the above, homeopathic medicinal products which are not subject to the simplified procedure must satisfy the same conditions as standard medicinal products.

Although Article 16(2) of Directive 2001/83/EC allows member states to introduce or retain in their territory *specific rules for preclinical tests and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practised in those member states*, this right to adjustment explicitly granted to member states under the EU legislation can be used only, as stated in Article 16(1) of Directive 2001/83/EC, within the general procedure of authorisation specified in Title III Chapter 1 of this Directive. Thus, member states do not have the possibility of establishing a specific procedure of marketing authorisation for homeopathic medicinal products that cannot be subject to the special, simplified procedure specified in Article 14 of Directive 2001/83/EC.

### 3. The simplified marketing authorisation procedure

Simplified procedure regarding marketing authorisation for homeopathic products concerns only these products which satisfy conditions specified in Article 14 of Directive 2001/83/EC.

*Ratio legis* of simplification is, in this case, a slight risk of danger for the health of patients using such products, as they are administered orally or externally, no specific indication for use appears on their labelling and leaflet, and there is a sufficient degree of dilution to guarantee the safety of their use.

A medicine, selected according to the law of similars, is prepared by a series of dilutions. The dilutions are made according to accurately specified techniques,

on a decimal or centesimal scale. In decimal scale, the starting point is the mother tincture from which one drop is collected and then mixed with nine drops of the liquid. One drop of the first solution is then mixed with nine drops of the liquid, and this second decimal solution is marked as D2. The centesimal scale requires the mixing of one drop of mother tincture with 99 drops of the liquid. One drop of the first centesimal solution is mixed with 99 drops of the liquid, giving the second centesimal solution, marked as C2 or CH2. Low dilutions range from D1 to CH5 (i.e. D10). High dilutions range from CH6 to CH30 or even CH100, etc.

The provisions of Article 14(1), tiret 4, of Directive 2001/83/EC state that homeopathic products can be subject to a simplified marketing authorisation procedure provided that they do not contain either more than one part per 10,000 of the mother tincture or more than 1/100th of the smallest dose of the active substance contained in a prescription medicinal product. The EU legislation assumes that such a dose incurs no risk for patients.

It should be mentioned that a medicinal product should have all the above-mentioned characteristics simultaneously.

For such products it is not necessary to conduct clinical trials on safety and efficacy but it is necessary to perform tests confirming their quality as well as biological and pharmaceutical composition (Article 15 of Directive 2001/83/EC).

According to motive 23 justifying the issuance of Directive 2001/83/EC, 'it is desirable in the first instance to provide users of homeopathic medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety'.

The labelling of a medicinal product informs patients whether the homeopathic medicinal product went through the full marketing authorisation procedure or not. It is worth noting that the provisions of Directive 2001/83/EC provide for stricter restrictions concerning the information with regard to therapeutic indications but prohibit actually including any such information[50]. According to the Polish law, the outer packaging should include information that this is a 'homeopathic medicinal product with no therapeutic indications'[51].

Considering the protection of public health, the European law establishes a rule that no medicinal product can remain on the market without a valid authorisation issued by an appropriate authority[52]. Depending on which authority issues the authorisation, one can distinguish between a national procedure: the authorisation is issued by an administrative authority of a member state (in Poland, since 1 May 2011 it is the President of the Office for Registration of Medicinal Products, Medical Devices and

[50] See Art. 14(1), tiret 2 *in fine*.

[51] See par. 11(12) of the Regulation of the Minister of Health of 20 February 2009 on the requirements with respect to the labelling of medicinal product packaging and leaflet contents (Journal of Laws No. 39, item 321).

[52] Article 6(1) of Directive 2001/83/EC.

Biocidal Products) or a central procedure: the regulator is the European Union which resolves disputes on the basis of an evaluation report of the European Medicines Agency. The basic EU regulation in this respect is the Directive 2001/83/EC, along with its most important revision – the Directive 2004/27/EC, as well as the Regulation (EC) 726/2004/EC of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[53].

The marketing authorisation of medicinal products is performed on the basis of an appropriate administrative procedure and an application that meets detailed criteria. Marketing authorisation for a medicinal product is issued on the basis of an evaluation of the product's safety, its therapeutic efficacy and quality. A marketing authorisation application should include the name and address of the responsible entity, the manufacturer or the importer who releases a batch of the medicinal product; manufacturing sites, including manufacturing sites where the batch is controlled or the site where import activity is conducted and where the batch is controlled; numbers of manufacturing authorisation for the medicinal product or for the import of the medicinal product; name and address of the manufacturer of the mother tincture to be used to manufacture the homeopathic medicinal product; product scientific name or name given in a pharmacopoeia, in accordance with the stock name in the European Pharmacopoeia or other pharmacopoeias officially used in the EU members states or, in absence thereof, a common name, including route of administration, pharmaceutical form and degree of dilution; product composition and excipients; storage and transport conditions; size and type of packaging and the content of the homeopathic medicinal product in the immediate packaging.

According to the cited requirements for homeopathic medicinal products subject to the simplified registration procedure, a product can be manufactured from any substance which does not even have to be listed in the European Pharmacopoeia or other pharmacopoeias officially used in the EU member states. This gives greater flexibility to responsible entities who would like to put such products on the market.

The application should include a description of the manufacturing method and control of primary substances together with the literature-based, including the scientific literature, confirmation of their homeopathic use; description of the manufacturing process, including the method of dilution and dynamisation; description of the control methods for each pharmaceutical form, including stability and microbiological purity tests; results, summaries and reports from quality, biological and pharmaceutical tests with an expert's report; original or certified copy of the manufacturing authorisation for the homeopathic medicinal product; copies of authorisations issued in other countries; obligation of the responsible entity to supply for analytical control a sample of the mother tincture to be used to manufacture the product and samples of the final product;

[53] OJ EC L 136/1 from 30.04.2004.

design of the labelling or leaflet; data concerning the immediate packaging, including quality requirements, and specimens of immediate or outer packages, the size of the packaging, including information on the content of the homeopathic medicinal product in the immediate packaging; expiry date of the homeopathic medicinal product; data and warnings on the storage and transport conditions as well as the method of use.

The importance of the SPC (Summary of Product Characteristics) and of the leaflet can be confirmed by the fact that even in the case of simplified marketing authorisation procedures, when e.g. the results of the clinical trials confirming the safety and efficacy of a medicine are not required, the legislation still decided to evaluate information that the medicinal product marketing entity intends to communicate to patients in the future. An example may be the marketing authorisation of homeopathic medicinal products subject to the simplified authorisation procedure (where a design of the labelling and leaflet is required - Article 21 of the Pharmaceutical Law of 6 September 2001[54]) or a traditional herbal medicinal product, referred to in Art. 20a of the PharmLaw.

The leaflet, the design of which needs to be mandatorily enclosed to the application for marketing authorisation, and the appropriate labelling of the medicinal product constitute a part of a system of informing the patient about the medicinal product. Its shaping is key to the safety of use of over-the-counter medicines.

The system includes various information tools[55] aimed at providing the patient with a maximum access to information about the medicinal product he purchases, and in particular about any possible risk related to product use.

Furthermore, it should be emphasised that the application for marketing authorisation may cover not only one product but an entire list of homeopathic agents coming from the same primary homeopathic substance(s). This demonstrates that entities that manufacture homeopathic products enjoy greater preferential treatment than entities manufacturing medicinal products (regardless of their origin), including homeopathic medicinal products which require indications for use.

## 4. The ordinary marketing authorization procedure

Directive 2004/27/EC provides for a possibility (Article 16) that in case of homeopathic medicinal products that do not fulfil the criteria of Article 14 of Directive 2001/83/EC, member states may implement or maintain in their territory specific regulations on preclinical tests and clinical trials in accordance with the rules and characteristics of the

[54] Consolidated text of 27 February 2008 Journal of Laws No. 45, item 271; hereinafter referred to as: PharmLaw.

[55] Apart from a leaflet and labelling, the patient acquires information on medicinal products from advertisements, doctors and pharmacists as well as public administration authorities; for more information see Miaskowska-Daszkiewicz, K. 'Information as an instrument of patient safety management in pharmaceutical law' [in] 8th International Conference on Human Rights: Right to Knowledge and Information in Heterogenic Society, eds. Sitek, B., Szczerbowski, J.J., Bauknecht, A.W., Kaczyńska A. Cambridge 2009, pp. 334-349.

homeopathy practised in the given member state. The above may cover homeopathic products intended for injection or those that do not fulfil the dilution criterion. However, Polish legislation did not adopt this option.

In connection with the above, in the case of other homeopathic products, for example those with a specific indication of use on their packaging or those administered by injection, the simplified procedure cannot be used. Instead, the full procedure needs to be conducted to control product's safety.

Clinical trials are primarily designed to check the safety and therapeutic efficacy of a medicinal product.

The notion of 'safety' should not be treated in absolute terms but rather relatively as the objective is to reach optimal safety of a medicinal product. Safety means the elimination of the adverse and harmful effects of a medicinal product.

The safety of medicinal products does not fully exclude risk related to their use. It is to exclude only such risk that can be avoided given the current state of medical knowledge. As far as the current state of medical knowledge is concerned, we should favour the opinion that it regards the knowledge and methods used on a regional, national or international scale, not in a specific health care facility[56].

Clinical trials are also, or first of all, the objective safety exponent of medicinal products in doctor's practice.

The examination of efficacy in clinical trials prior to the marketing authorisation procedure of a medicinal product refers to the therapeutic efficacy[57] indicated by the applicant. This efficacy should be justified by the applicant based on the current state of knowledge. Thus, the 'indicated therapeutic efficacy' is a material reference point for efficacy control[58].

Since it is the 'therapeutic efficacy indicated by the applicant, it is the applicant who specifies for which indications his product's 'therapeutic efficacy' is maintained. The applicant may indicate a range of use either for several different disease entities or for different stages of one disease. Pharmaceutical law states that marketing authorisation procedure will control each single indication and the authorisation will concern the indication(s) for which therapeutic efficacy was sufficiently proved in clinical trials. The efficacy of the tested medicinal product should be distinguished from the simple effect of the product. An effect is any reaction caused, in a measurable, noticeable or otherwise recognisable method, by the medicinal product used in the human body *in vivo* or *in vitro.* Thus, an effect will include any actions of administering the medicinal product without any reference to a specific therapeutic purpose. If, for example, in a clinical trial,

[56] See Poździoch, S. 'Prawo zdrowia publicznego', Wolters Kluwer, Kraków 2004, p. 130 and next pages.

[57] Art. 11(1), point 4.1. of Directive 2001/83/EC provides that the Summary of Product Characteristics includes therapeutic indication.

[58] See: Schwerdtfeger, G. 'Die Bindungswirkung der Arzneimittelzulassung', Baden-Baden 1983, p. 25.

following the administration of a medicinal product, the probants suffered a decrease of arterial pressure and the indicated therapeutic efficacy was supposed to relate to a pain-killing effect, one can talk only about the action of such product, not its efficacy. The efficacy will relate only to the specific indication assumed at the beginning of the clinical trial.

Due to the fact that we should not conflate the notions of 'effect' with the 'therapeutic efficacy' of a medicinal product, we cannot agree with the opinion[59] expressed in the relevant literature that, due to the lack of specific indications for use, the requirements of pharmacovigilance are not used towards homeopathic medicinal products registered according to the simplified procedure.

The regulations of the EU pharmaceutical law clearly indicate the categories of 'adverse reaction' of a medicinal product which is each response to the medicinal product, noxious and unintended, which occurs at doses normally used in men for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function[60], and a 'serious adverse reaction' of a medicinal product which includes an adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect[61]. Due to the necessity of monitoring safety in pharmacotherapy, Directive 2001/83/EC obliges member states to supervise the use of medicinal products by establishing a system of reporting adverse reactions[62].

## 5. The specificity of anthroposophic medicinal products

As regards the second category of products mentioned in the title of this paper, it should be said that although the EU pharmaceutical law uses the notion of an anthroposophic medicinal product, it does not define it. To encompass the necessity of regulating the marketing of this specific and popular category of medicines, the EU legislation, in motive 22 justifying the issuance of Directive 2001/83/EC, established a rule that anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated, as regards registration and marketing authorisation, in the same way as homeopathic medicinal products.

Anthroposophic medicine is based on the concept that a human being is made of four parts: the physical body, the ethereal body, the astral body and the self. Anthroposophic medicinal agents are supposed to restore the balance between these four parts

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[59] See Kondrat, M., Koremba, M., Masełbas, W., Zieliński W. 'Prawo farmaceutyczne. Komentarz', Wolters Kluwer, Warszawa 2009, p. 332.

[60] See Art. 1(11) of Directive 2001/83/EC.

[61] See Art. 1(12) of Directive 2001/83/EC.

[62] See Art. 102 of Directive 2001/83/EC.

of the human being and they may contain various vegetable, mineral, animal or metallic substances, prepared in various concentrations, depending on the method of application: externally, e.g. by rubbing onto the skin, orally, or by injection. Some medicinal products are similar to herbal medicines, other are prepared by homeopathic methods. However, a great part of anthroposophic medicinal agents is manufactured with the use of specific procedures compliant with the anthroposophic understanding of the human body. The anthroposophic medicines are manufactured by specially prepared manufacturers according to all the quality standards required in such manufacture. Anthroposophy has its own rules of medicinal research and preparation, often using additionally various thermal methods, such as preparation at 37 degrees, roasting, charring, incineration and so on, which aim at the stimulation of certain processes.

Opportunity to determine the legal status of anthroposophic medicinal product was proceeding before the Court of Justice of European Union in the case *Antroposana*.

The Court of Justice of the Netherlands referred to the Court of Justice of European Union to understand if the Directive 2001/83/EC applies to anthroposophic medicinal products with regard to registration and authorisation.

Fundamental question that arose in the realities of this case was: does Directive 2001/83/EC oblige member states to make anthroposophic medicinal products which are not at the same time homeopathic medicinal products subject to the requirements in respect of authorisation as set out in Chapter 1 of Title III of that Directive?

Although anthroposophic medicines are not defined *per se* in the Directive 2001/83/EC, the Advocate General Yves Bots concludes in this case that the EU directive is exhaustive and thatanthroposophic medicinal products shall be covered by the registration and authorisation procedures laid down by the Directive 2001/83. Arguing in favor of this view, the Advocate General concluded that an anthroposophic product is a 'medicinal product' within the meaning of the directive if it comes within the definition of a medicinal product 'by virtue of its presentation' or that of a medicinal product 'by virtue of its function'. This reference for a preliminary ruling concerns only anthroposophic products which are covered by one or other of those definitions. At the same time, the Advocate General pointed out that anthroposophic medicinal products do not fall under the category of homeopathic, nor traditional herbal medicines. He recommends that they are therefore to be considered under the same rules as 'standard' medicinal products**.**

The Court of Justice of European Unionin its judgment of 20 September 2007[63] shared the opinion of the Advocate General Bot and confirmed that anthroposophic medicinal products may be marketed only on condition that they have been authorised under one of the procedures referred to in Article 6 of Directive 2001/83/EC.

[63] Case C 84/06; OJ EC C 296/12 from 10.11.2007.

## 6. Summary

To sum up, as far as anthroposophic medicinal products fulfil the conditions of Article 14 of Directive 2001/83/EC, they may be subject to the simplified registration procedure for marketing authorisation. However, if there is even one unfulfilled condition, the pharmaceutical entrepreneur is obliged to gain a marketing authorisation as *per* full marketing procedure.

As homeopathic and anthroposophic medicinal products have been admitted to trading on the territory of European Union on the basis of the relevant authorization, regardless of the type of procedure, it is that they can be provided by a doctor withinpharmacotherapy by a doctor. However, this issue is in Poland debatable[64].

[64] More on this topic see Haberko, J., *op. cit.,* p. 47-51; Miaskowska-Daszkiewicz, K. 'Dopuszczanie do obrotu i ordynowanie przez lekarzy homeopatycznych i antropozoficznych produktów leczniczych stosowanych u ludzi' [in] Produkt leczniczy – aktualne problem prawne, eds. Mełgieś, K. Miaskowska-Daszkiewicz, K. Warszawa 2013, pp. 63-78.

# MEDICAL MALPRACTICE

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# I. AUTONOMY, CONSENT AND INFORMATIONAL NEGLIGENCE: ORIGINS AND PERSPECTIVES

"To violate a person´s autonomy is to treat that person merely as a means, that is, in accordance with others´ goals without regard to that person´s own goals. Such treatment is a fundamental moral violation because autonomous persons are ends in themselves capable of determining their destinies."

Beauchamp and Childress, *Principles of Biomedical Ethics,* 1994, 4th ed., p. 125.

## 1. Introduction

The modern relationship between physicians and patients from a legal point of view, is ruled by two center pillars, called Autonomy and Consent. And what binds these elements together is information. Not only the quality of information, but also the bureaucracy created to ensure patient´s rights and to protect doctors from accusations of malpractice.

Over the last fifteen years, the theories of informed consent were added with the notion of informational negligence, i. e., the damages suffered by a patient that were caused by an unsatisfactory or inadequate amount of information given during the process of treatment, or information withheld from the patient, or even information that were transmitted in scientific terms that could not be properly understood by a lay person.

What we seek to demonstrate here is that informed consent is not the final objective of disclosing proper information in a medical relationship. Consent is but a part of the process of exercising choice. Only by letting the patient choose, and therefore, truly enforcing autonomy, it will be possible to avoid negligence.

In modern medicine, legal requirements are just as important as scientific skills in order to fulfil the duty of care, and safe practice cannot be achieved without proper knowledge of these concepts.

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On this subject, Beauchamp[66] states:

"A widely acknowledged approach to informed consent is analysis of the concept in terms of its basic elements, the most generic of which are *information* and *consent.* The information component refers to the disclosure of information and the comprehension of what is disclosed. The consent component refers to a voluntary decision and an authorization to proceed. Legal, regulatory, philosophical, medical, and psychological literatures often propose the following five elements as the analytical components of these two generic units of informed consent: (1) competence, (2) disclosure, (3) understanding, (4) voluntariness, and (5) consent.

(...)

One gives an informed consent toan intervention if (and perhaps only if, but this claim is questionable) one is competent to act, receives a thorough disclosure, comprehends the disclosure, chooses voluntarily, and consents to the intervention.

(...)

First, competence is a threshold element, precondition, or presupposition of informed consent. It is not part of the process of informed consent. Second, disclosure is not a necessary condition of informed consent. If a patient or subject already possesses the relevant information, a disclosure is not needed to give an informed consent. Disclosure has had a prominent position in the literature of informed consent because informed consent has its roots in contexts of legal liability for nondisclosure, but the important matter for understanding informed consent is having the relevant information. Third, I said earlier that 'the consent component refers to a voluntary decision and an authorization to proceed.' The language of 'consent' covers both a *decision in favor* of a proposed course of action and an *authorization*. Authorization is a permition-giving act. It could be performed even if the consent were not informed. Accordingly, informed consent cannot be reduced entirely to permission giving."

However, when one speaks about the right to information in the healthcare context, there is an almost automatic association to the expression 'informed consent'. It is virtually unanimous nowadays in modern society the idea that every medical intervention or experiment must be previously understood and consented by the patient or subject of research, in order to prevent liability.

It wasn´t always like this. To a better understanding of the present situation, it is important to look at it with a historic perspective. The first centuries of medicine were defined by a dichotomy of presumed superiority between the guardians of the medical knowledge, and the patients. The art of medicine was seen as something divine, almost supernatural, and little or no questioning was allowed regarding the decisions and commands issued by those few men of science.

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[66] Beauchamp, T. L. 'Autonomy and Consent', [in] The Ethics of Consent – Theory and practice, eds. Miller, F., Wertheimer, A. Oxford University Press, 2010, pp. 56-57.

The concept that the patient – as a human being – was entitled to certain rights, began to grow after the French Revolution, and later, after the Industrial Revolution. The physicians were slowly stripped of their divine origin, being regarded as a normal citizen, an ordinary professional, subject thus to failure and questioning.

At the same time, medical services lost the personal touch, surrendering to the market and the image of the doctor became something distant and unknown to the patient, raising legal issues about criminal, civil, and ethical responsibility, establishing the grounds for the informed consent doctrine in the patient-doctor relationship.

## 2. Bioethics and the development of the principle of patient´s autonomy

Since the end of World War II, the bioethical concept of patient autonomy[67] has gained importance[68], shifting the centuries-old balance in the paternalistic relation between physicians and their patients[69].

Of course, case law stating the importance of consent can be found in the anglo-saxonic jurisprudence since the late years of the 18th Century[70], but it was only after

[67] "Autonomy is a form of personal liberty of action where the individual determines his or her own course of action in accordance with a plan chosen by himself or herself. The autonomous person is one who not only deliberates about and chooses such plans but who is capable of acting on the basis of such deliberations, just as a truly independent government has autonomous control of its territories and policies." Beauchamp, T., Childress, J. 'Principles of biomedical ethics', New York: Oxford University Press, 1979, pp. 56-57.

[68] "Respect for autonomy is the most frequently mentioned moral principle in the literature on informed consent, where it is conceived as a principle rooted in the liberal Western tradition of the importance of individual freedom of choice, both for political life and for personal development. ´Autonomy´ and ´respect for autonomy´ are terms loosely associated with several ideas, such as privacy, voluntariness, self-mastery, choosing freely, the freedom to choose, choosing one´s own moral position, and accepting responsibilities for one´s choices.". Beauchamp, T., Faden, R. 'A history and theory of informed consent', New York: Oxford University Press, 1986, p. 7.

[69] "Part of the explanation for the shift from beneficent paternalism toward autonomy lies in historical events of the twentieth century, primarily related to research, that called into question the trustworthiness of the medical profession. The atrocities revealed in the Nuremberg Trial of Nazi doctors, as well as highly publicized cases of human subjects abused in the United States, sparked suspicion of the general benevolence of physicians and researchers. In this context, informed consent was seen as a protection from abuse by untrustworthy professionals. Even if the medical and research establishment could not be trusted to conduct prospective review of the likely harms and benefits and to offer individuals only research and treatment opportunities that had acceptable risk-benefit ratios, individuals could safeguard their own interests if they were adequately informed and if their autonomous authorization was required before research or treatment could proceed. Individuals were thus called upon to exercise their autonomous decisional authority to safeguard their welfare". Berg, J. W. *et al.*, 'Informed Consent', 2nd ed, Oxford University Press, New York 2001, p. 20.

[70] Slater *v.* Baker and Stapleton, 2 Wils. K.B. 358 (1767). In this case, the plaintiff hired the defendants to remove the bandages from his fractured leg. Against the patient´s will and in spit of his protests, both physicians decided to refracture the plaintiff´s leg and place it in an experimental device to stretch and straighten it during rehealing. In the reasoning, the Court stated: "In answer to this, it appears from the evidence of the surgeons that it was improper to disunite the callous [bony material in healing] without

the Nuremberg trials[71][72], and moreover, the Tuskegee´s experiments[73], that informed consent became one of the pillars of modern medicine, and almost the Holy Grail of medical ethics.

The foundations of this doctrine can be found mostly in the North-American case law jurisprudence, though. In 1905, the leading case Mohr vs. Williams[74] raised the issue whether the patient gives a physician specific consent to operate, does the physician have general consent to perform other surgical operations undertaken to treat other problems? In this case, the patient arranged for the physician, an ear specialist, to perform surgery on her right ear After Williams began performing the operation he decided that Mohr's left ear rather than her right ear required surgery, although the condition was not life threatening. Williams operated successfully on the left ear without having received permission from Mohr.

Mohr sued Williams for battery and the court decided that when a doctor obtains a patient's specific consent for a particular operation he may not perform another operation on the patient without her consent. A patient's consent is implied when an emergency situation arises. However, this does not allow the doctor a free license to attempt to remedy all problems found that are not life threatening. The court held that

consent; this is the usage and law of surgeons: then it was ignorance and unskillfulness in that very particular, to do contrary to the rule of the profession, what no surgeon ought to have done; and indeed it is reasonable that a patient should be told what is about to be done to him, that he may courage and put himself in such a situation as to enable him to undergo the operation".

[71] For more detailed information, it is recommended reading Norbert Ehrenfreund´s 'The Nuremberg Legacy: How the Nazi War Crimes Trials changed the course of history' (2007, Palgrave Macmillan); Robert E. Conot´s 'Justice at Nuremberg' (1993, Basic Books); and Michael R. Marrus´ 'The Nuremberg War Crimes Trial, 1945-46: A documentary history'(1997, Bedford/St. Martin´s).

[72] The Nuremberg Code (http://www.cirp.org/library/ethics/nuremberg/) states in its article first that "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity."

[73] Again, for more information, it is recommended reading Susan M. Reverby´s 'Examining Tuskegee: The infamous Syphilis Study and its legacy' (2009, The University of North Carolina Press), with an analysis of the notorious study of untreated syphilis, which took place in and around Tuskegee, Alabama, from the 1930s through the 1970s. The study involved hundreds of African American men, most of whom were told by the doctors from the U.S. Public Health Service that they were being treated, not just watched, for their late-stage syphilis; and from the same author, 'Tuskegee´s truths: Rethinking the Tuskegee Syphilis study' (2000, The University of North Carolina Press).

[74] 1905, Mohr *v*. Williams, 104 N.W. 12

in this case, there was no evidence that the condition of the plaintiff's left ear presented a serious or life threatening situation.

Even though there was no showing that he had a wrongful intent or that he had been negligent, Williams was still liable for battery[75]. The court held that it was not relevant that the operation was successful.

The same understanding was reinforced in 1914 in the United States, during the leading case of *Schoendorff v. Society of New York Hospitals*[76], discussing a situation where the patient had undergone surgical intervention without his previous consent. The New York Court held accountable the hospital for violating the patient´s body integrity, in spite of the positive outcome. Justice Benjamin Cardozo stated in his ruling that "every human being of adult years and sound mind has a right to determine what shall be done with his own body", words that became paramount for the informed consent doctrine with the passing of the years.

The expression 'informed consent' appeared for the first time in 1957, in the leading case Salgo *vs*. Leland Stanford Junior University Board of Trustees[77], dealing with a malpractice case where the patient found himself paralyzed in his lower members after a surgical procedure, without being informed of such possibility as a risk. The case decided that proper consent required provision of information. In the ruling, the judges decided that the physician has the duty to disclose "any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment".

In the French doctrine, one of the first trials regarding patient´s rights happened in 1942, and not by chance deals with consent issues[78]. The concept of *consentement éclairé* is widely spread in France, present in several laws, like the Law from December 20th 1978 (regulating biomedical experiences), the Law 94.653 from July 29th 1994 (inserting article 16, section 3[79] in the French Civil Code), and the 1995´s French Medical Ethics Code, reinforcing the evidence and necessity of respecting the informed consent doctrine.

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[75] "The free citizen's first and great right – the right to himself …. this right necessarily forbids a physician to violate without permission the bodily integrity of his patient"

[76] Schoendorff v. Society of New York Hospital, 106 N.E. 93 (N.Y. 1914)

[77] Salgo *v*. Leland Stanford Jr. University Board of Trustees, 317 P.2d. 170 (Cal. App. 1957)

[78] Cf. Pereira, A. 'O consentimento informado na relação médico-paciente', Ed. Coimbra, Coimbra 2004, p. 61: *Cour Cassation,* 28-1-1942 *(arrêt* Teyssier): "... attendu que, comme tout chirurgien, le chirurgien d'um service hospitalier est tenu, sauf cas de force majeure, d'obtenir le consentement du malade avant de pratiquer une opération dont il apprécie, en pleine independence, sous la responsabilité, l'utilité, la nature et les risques; qu'en violant cette obligation, imposéé par le respect de la personne humaine, il commet une atteinte grave aux droits du malade, un manquement à sés devoir proprement médicaux et qui constitue une faute personelle se détachant de l'exercice de sés fonctions...".

[79] Code Civil, art. 16, n. 3: "Il ne peu être porté atteinte à l'integrité du corps humain qu'en cas de necessite médicale pour la personne. Le consentement de l'interessé doit être recuielli préalablement dans le cas ou son état rend nécessaire une intervention thérapeutique à laquelle il n'est pas à même de consentir".

In 1973, The American Hospitals Association were the first to implement the Patient's Bill of Rights which specified the right of any patient to receive complete and comprehensive medical information that he can evaluate and understand. The patient was given the right to accept or to refuse the recommended treatment after being advised of the consequences of his decision: "The patient has the right to obtain from the physician **complete current information** concerning his diagnosis, treatment and prognosis in terms the patient can reasonably expected to **understand.** The patient has the right to receive from his physician information necessary to give **informed consent** prior to start of any procedure and/or treatment[80]. The patient has the right to **refuse** treatment to the extent permitted by law, and to be informed of the medical consequences of his action."

### 3. Informed Consent, the duty to inform and informed choice

There are several legal issues regarding consent, and litigation is increasing in relation to consent issues. Too many aspects need to be taken into consideration for consent to be considered valid, such as when consent was obtained and whether the risks have been explained; moreover, whether they were understood by the patient (sometimes, cultural issues or language barriers can be a complication); whether the patient is a minor (if so, mature or not to decide by him/herself); whether an adult patient has legal capacity to decide (and also, if having legal capacity to decide, clinical capacity is absent); whether an oral consent constitutes enough evidence that information has been given and understood. But above all – and that´s precisely the object of this study – whether the patients have been given sufficient, adequate, complete information, so that they can actually decide, and not just consent to a physician´s suggestion.

Very often, tough, physicians and health care providers misunderstand the concept of the so-called *informed consent* [81].

Informed consent is the authorization given by the patient to undergo treatment, based on the knowledge of the nature of a medical procedure, and be submitted to risks, side effects, possible complications, benefits and alternatives to the proposed treatment. In other words, it is the acceptance of the services to be delivered by a healthcare professional, after understanding what is being consented to.

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[80] A physician should convey the risks of an operation when a reasonable person would be likely to attach significance to the risk in deciding whether or not to forgo the proposed therapy. The standard measuring performance of the duty to disclose is conduct which is reasonable under the circumstances. There are two exceptions to this general rule: (1) where the patient is unconscious and harm from a failure to treat is greater than any harm threatened by the proposed treatment; and (2) where disclosing the risk to the patient poses a threat to the patient´s well being.

[81] "It is always an open question whether an autonomous person with the capacity to give an informed consent actually has, in any specific instance, given an informed consent, in the sense of making an autonomous choice to authorize or refuse an intervention". Faden, R., Beauchamp, T. L. 'A History and theory of informed consent', Oxford University Press, 1986, p. 237.

It is necessary to understand that the process of consenting constitutes, at the same time, a patient´s right and a physician´s duty[82]. The patient must be informed in a clear and comprehensible way, according to his cognitive capabilities, about his diagnostic, risks, prognosis, and existing treatment alternatives, even those the doctor do not think fit for the specific case.

It is also important to point out that the mere act of reading and signing a paper, a consent form, is not enough to release the physician from his duties, from his obligation to inform accordingly (even if this written form is an important piece of evidence of due diligence).

The right to be informed has nothing, or very little, to do with the true exercise of patient´s autonomy. The act of consenting *to* some treatment, research, experiment or surgical procedure is just part of a bigger process, where the patient can exercise its autonomy. Someone can consent, based on the trust put over the doctor, based on indifference, fear, or even *because* it didn´t receive all necessary information to really *choose* among different possible options.

Informed consent is often mistaken by informed choice – this last one being essential to achieve the fulfilment of the right to be informed (and the physician´s duty to inform). The patient needs not only receive, but also understand the information that has been handed over, and not just simply receive it without processing it properly. Information without comprehension is legally void, because it could be proven that the patient consented (or signed a consent form), but did not exercise his right to free and informed choice. His autonomy would be jeopardized.

Article 5 of the Oviedo Convention (European Convention of Human Rights and Biomedicine, 1997), clearly provides that *An intervention in the health field may only be carried out after the person concerned has given free and informed consent. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequence and risks. The person concerned may freely withdraw at any time.*

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[82] Regarding this, see for example articles 22, 24, 26, 31 and 34 of the Brazilian Medical Ethics Code, issued by the Federal Council of Medicine as Resolution 1931/2009: "Art. 22 – [É vedado ao médico] Deixar de obter o consentimento do paciente ou de seu representante legal após esclarecê-lo sobre o procedimento a ser realizado, salvo em caso de risco iminente de morte"; "Art. 24 – [É vedado ao médico] Deixar de garantir ao paciente o exercício do direito de decidir livremente sobre sua pessoa ou seu bem-estar, bem como exercer sua autoridade para limitá-lo"; "Art. 26 - [É vedado ao médico] Deixar de respeitar a vontade de qualquer pessoa, considerada capaz fisica e mentalmente, em greve de fome, ou alimentá-la compulsoriamente, devendo cientificá-la das prováveis complicações do jejum prolongado e, na hipótese de risco iminente de morte, tratá-la"; "Art. 31 – [É vedado ao médico] Desrespeitar o direito do paciente ou de seu representante legal de decidir livremente sobre a execução de práticas diagnósticas ou terapêuticas, salvo em caso de risco iminente de morte"; "Art. 34 - [É vedado ao médico] Deixar de informar ao paciente o diagnóstico ou prognóstico, os riscos e os objetivos do tratamento, salvo quando a comunicação direta possa lhe provocar dano, devendo, nesse caso, fazer a comunicação a seu representante legal".

And what can be considered appropriate information? That is a difficult question, since the answer may differ, given the specific situation. But mostly, the communication between the physician and his patient must include the existing treatment options (not only the main options) with their purposes and details, their benefits and risks (commonly occurring risks and those unlikely to occur), possible side-effects, success rates, the reasons why an specific option is being recommended, the prognosis, and the risks of not having treatment.

That being said, the act of obtaining consent without allowing proper choice doesn´t represent an automatic release from professional duties regarding information, if this was withheld, distorted, tampered with, or incomplete. The physician would still be held liable for informational negligence.

Another North-American leading case followed in the same direction. *Canterbury vs. Spence*[83], from 1972. Its historical relevance lies on the demonstration of the imperative necessity of the patient´s understanding of the information transmitted by the doctor before a surgical intervention. In this case, the patient, who developed a paralysis after a laminectomy hasn´t been informed of a 1% risk possibility of occurring such side effect. The Court ruled that:

"A physician is under a duty to treat his patient skilfully but proficiency in diagnosis and therapy is not the full measure of his responsibility. The cases demonstrate that the physician is under an obligation to communicate specific information to the patient when the exigencies of reasonable care call for it. Due care may require a physician perceiving symptoms of bodily abnormality to alert the patient to the condition. It may call upon the physician confronting an ailment which does not respond to his ministrations to inform the patient thereof. It may command the physician to instruct the patient as to any limitations to be presently observed for his own welfare, and as to any precautionary therapy he should seek in the future. It may oblige the physician to advise the patient of the need for or desirability of any alternative treatment promising greater benefit than that being pursued. Just as plainly, due care normally demands that the physician warn the patient of any risks to his well-being which contemplated therapy may involve.

(...)

In our view, the patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is the information material to the decision. Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked. And to safeguard the patient's interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure.

[83] Canterbury v Spence, 464 F.2d 772 (DC Cir 1972).

(...)

The topics importantly demanding a communication of information are the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated. The factors contributing significance to the dangerousness of a medical technique are, of course, the incidence of injury and the degree of the harm threatened. A very small chance of death or serious disablement may well be significant; a potential disability which dramatically outweighs the potential benefit of the therapy or the detriments of the existing malady may summons discussion with the patient."

We have been stressing the importance of consent – and consent forms – over the past years, forgetting that there are more important situations to be dealt with, arising from the relationship in question. Let´s take as an example, article 5 of the European Convention on Human Rights and Biomedicine (the Oviedo Convention), as previously stated here. All attention is drawn to the first part of the text, which says that "an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it". However, the key to understand the true spirit of the law lies in the second part of the article, which states that "this person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks".

In the same direction, Sheila McLean[84] highlights the importance of information in the process of consenting and choosing:

"One way, it seems obvious, that we can facilitate the making of a valid choice, is by ensuring that the patient is provided with the wherewithal to make a decision in the first place. In other words, the patient needs information on which to base his or her choice. The 'informed', or more accurately informational, aspect of consent is the element that focuses on the patient´s right to receive relevant and sufficient information in order to enable him or her to make a decision. It is generally assumed, then, that – in the absence of a competent refusal to receive any information that might be offered – a valid consent (or refusal) depends on the sharing of information with the patient. The doctor is, therefore, under an obligation to share information with his or her patient".

Appropriate information seems to be the main element about patient´s autonomy rights. The information, to be 'appropriate', does NOT need to meet the doctor´s assessment of the situation, but the patient´s. All relevant data, alternatives (even those the physician thinks are not recommended to the case, based on its experience) and risks must be disclosed to the patient, in an understandable way, in order to provide sufficient elements for a decision – a choice – to be made. This – and not consenting – is the real exercise of autonomy. These exact same ideas are exposed in article 5[85] of the Inter American Convention of Human Rights (1969).

[84] McLean, Sheila A. M., 'Autonomy, Consent and the Law', Routledge-Cavendish, 2010, p. 42

[85] Article 5. Right to Humane Treatment - 1.Every person has the right to have his physical, mental, and moral integrity respected.

In the U.S., the *Patient Self-determination Act* (1991) regulates the idea of the right to information as a basic requirement, being the right to informed consent just a part of the process, not its final goal. A consent form signed by the patient is not a safeguard from lawsuits. Of course, it´s an important document, but cannot be seen as the only thing that matters in defensive medicine.

The examples of legal documents could go on and on, in Brazil[86], Portugal[87], Spain[88], France[89] and Israel[90], and all over the world, showing that there is a new way of dealing with old dilemmas, and that health care providers have to adapt their concepts to the new ideas. The world has evolved, and that requires adaptation.

A patient doesn´t need to consent to a proposed treatment. This may come as a shock to many doctors, as they are trained to 'fight' diseases, and save lives, no matter what. What they´re not taught in med schools is the fact that their main obligations – apart from acting with the best of their techniques and skills – is that they must provide information to the patient. The patient will decide, based on its personal life, values, morals and beliefs, which is the best option. Only then autonomy can be respected and enforced. These ideas are well explained in the words of Irene Switankowsky[91]:

"The ultimate purpose of informed consent is to ensure that the patient makes an autonomous, rational, reflective, well-understood decision about a medical procedure or treatment alternative that s(he) believes will be most beneficial. In short, the ultimate purpose of properly informed consent is to protect a patient´s autonomy under all medical circumstances".

It is a mistake to think that obtaining informed consent – as it happens today in most of the cases – is enough to exempt the physician from liability, excluding legal responsibilities in the event of occurring an undesired outcome during the treatment or procedure.

A treatment or procedure can be considered successful from a clinical point of view, but later seen as inappropriate when confronted with other possible outcomes that could be expected if a different therapeutic method had been informed to – and chosen by – the patient.

[86] In Brazil, Federal laws, such as Law 8.080/1990 (Consumer´s Defense Code) article 7, section V, reinforces to the patient the right to information about his/her health conditions; Law 10.741/2003 (Elderly´s Protection Act) ensures the right to choose the most favourable health treatment; Law 9.434/1997 (Organ and Tissues Transplantation) requires consent for every procedure. State Law salso regulates patient´s rights, such as Law 10.204/1999 (São Paulo); Law 14.254/2003 (Paraná); and Law 16.279/2006 (Minas Gerais).

[87] Deontological Code from the Portuguese Order of Physicians (Regulamento 14/2009), specially articles 44 to 51.

[88] Ley 41/2002.

[89] Law of March 4th, 2002. And also, for example, article 1111-2 of the Public Health Code.

[90] The Patient´s Rights Law, 1996.

[91] Switankowsky, I. S., 'A new paradigm for informed consent', University Press of America, 1998, p. 2

This lack of information doesn´t necessarily means negligence. It may represent the expression of the physicians beliefs, based in his own experience or in the medical literature, that the proposed solution was the most adequate to the situation faced at a given moment. The problem is that this behavior goes against ethical principles and legal commands that consider mandatory the disclosure of all information available. Withholding information about alternatives may be considered – in a lawsuit or in a disciplinary investigation – an undue interference in treatment, thus breaching confidence and contrary to the principles of good-faith and autonomy.

This notion is no different in several jurisdictions. In fact, it represents a tendency towards autonomy, as can be seen in the words of André Pereira[92], when stating that "recently, some authors have been proposing a more comprehensive concept. The expression *informed consent* has been criticized in the anglo-saxonic doctrine, since information is but an aspect of proper consent (´comprehensive or enlightened consent´). Thus, the use of the expression *informed choice* is being suggested. This concept could comprise, among other aspects, information about the consequences of refusal or withdrawing consent, therapeutic alternatives, choice of medicinal products (implicating changes in the regulatory frame of advertisement, choice of medical facilities, etc.). In the Portuguese law, it is well established the right to 'information on the existing health services' and the 'right to free choice of physician', and also the right to a 'second opinion'. All these aspects considered, they go beyond simple informed consent; they are advanced expressions of the right to an informed consent, in the modern version of *informed choice*: self-determination in health care implies not only patient´s consent or refusal to a proposed intervention, but in possessing all elements to analyze treatment possibilities in medical, chirurgical and pharmaceutical field"[93].

The right to consent, as an attribute of personal autonomy, is fundamental to ethical medicine. Its components are: information disclosure, voluntariness, and competency. Breach of informed consent may be actionable as battery or as malpractice.

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[92] Pereira, A., *op. cit.,* p. 74.

[93] Translated from the original "Mais recentemente, alguns autores vêm propondo um conceito mais abrangente. Assim, na doutrina anglo-saxônica critica-se a expressão informed consent, visto que a informação é apenas um aspecto do consentimento esclarecido ('comprehensive or enlightened consent'). Assim, vem sendo proposta a utilização da expressão informed choice. Este conceito teria a virtude de abranger, entre outros aspectos, a informação sobre as conseqüências da recusa ou revogação do consentimento, as alternativas terapêuticas, a escolha dos medicamentos (o que implica alterações à regulamentação da publicidade dos medicamentos, a escolha do estabelecimento de saúde, etc.). No direito português encontramos consagrado o direito à 'informação sobre os serviços de saúde existentes' e o 'direito à livre escolha do médico', e ainda o direito à *"*segunda opinião*"*. Tudo aspectos que vão para além do simples consentimento livre e esclarecido. São expressões avançadas do direito ao consentimento informado, na sua vertente mais moderna de *informed choice*: a autodeterminação nos cuidados de saúde implica, não só que o paciente consinta ou recuse uma (heteronomamente) determinada intervenção, mas que tenha todos elementos de análise sobre as possibilidades de tratamento possíveis, no domínio médico, cirúrgico e farmacêutico."

In other words, obtaining a so-called valid and regular informed consent may be considered void, if it is not a result of an informed choice, leaving the doctor vulnerable to the legal risks and to the unpredictability of the medical activity.

## 4. Informational Negligence

And what exactly are these legal risks? In recent years, some countries are establishing important legal precedents in their jurisprudence. Brazil and France are good examples on how doctrine influences the development of the law.

Regarding informational negligence, France has had a particular prolific year in 2010, with important decisions issued by the *Cour de Cassation* recognizing civil responsibility and negligence for the breach of duty to inform the patient properly. For an overview of the French jurisprudence, it is recommended reading the decisions from January 28th, June 3rd and October 14th.

In Brazil, the Superior Court of Justice (STJ) also decided in favor of the plaintiff, helding a blood bank liable for lack of proper communication of test results (REsp nº 1.071.969/PE).

In 2007, another case, involving plastic surgery (AgRg in Ag 818.144/SP) had a similar result, with the court ruling that "the physician who do not inform his patient about the risks of surgery is negligent, being liable for all damages resulting from the intervention".

In the opposite direction, a case judged in 2009 (REsp 1.051.674/RS) exempted the doctor from being considered responsible for an unexpected result, because he proved the fulfillment of the duty to inform.

Another very recent case, originated from the Justice Court of the State of Minas Gerais (Civil Appeal n. 1.0223.08.246703-4/001), and ruled in 2013, help in the task of defining the consequences of informational negligence. It refers to a litigation between a patient and his dentist. The dentist was forced to pay the patient a compensation for moral damages, due to a fracture caused in the patient´s jaw, during a tooth extraction procedure. Compensation was not granted as a direct result of the fracture, which was proved to be a potential risk of that particular treatment, but because the dentist failed to fulfil his duty to inform the patient about the risks inherent to that kind of procedure.

## 5. Closing remarks

As we can observe, the doctrine of informed consent is on the verge of evolution. With the rise of patient autonomy and informed consent as an important part of the daily medical practice, the relationship – and the balance of power – has changed between patients and physicians. In the majority of the western countries, more and more conflicts are brought to court, as a result of the lack of time, incomplete information,

and the failure of most physicians in understanding the legal trend that surrounds the medical profession.

There´s a modern tendency in considering patient´s consent a safeguard from bad outcomes, but the concept of shared decision-making lost its meaning among hospital bureaucracy and paperwork.

Contrary to popular opinion, one of the main problems in providing excellence in health care is not lack of money but lack of information. Patients are not properly advised about risks, consequences, possible results and alternatives to a proposed treatment. Therefore, even if they consent, they are not exercising choice. They do not share responsibility for their treatments in the way they were meant to.

Understanding this (r)evolution is the key for prevention against malpractice and informational negligence.

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# II. PROCEDURAL OBLIGATIONS UNDER ARTICLE 2 AND 8 OF THE EUROPEAN CONVENTION ON HUMAN RIGHTS IN MEDICAL NEGLIGENCE INVESTIGATION AND ADJUDICATION

## 1. Introduction

Medical malpractice liability is a relatively new but rapidly growing area of law. Medical errors (negligent conduct by medical professionals) may entail both civil and criminal liability, as well as disciplinary responsibility. Additionally, in recent years, many countries have introduced extrajudicial procedures, in order to provide patients with an alternative to, for the most part, lengthy judicial proceedings. Medical malpractice (in a broad sense) is associated with liability of certain people and institutions (usually doctors and hospitals) operating in the healthcare field. This paper will nevertheless explore the issue of responsibility from a different perspective.

The article will focus on the international obligations and responsibility of States Parties to the European Convention on Human Rights (hereinafter referred to as: the Convention or ECHR)[94], with respect to domestic adjudication of medical negligence. Research methodology concentrates on the analysis of the European Court of Human Rights (hereinafter referred to as: the Court or ECtHR) jurisprudence, relevant academic literature and selected legal sources.

The paper commences with some preliminary considerations regarding the typologies of state obligations with respect to human rights, with particular emphasis on the concept of positive (substantial and procedural) obligations. Consequently, this concept is applied to the specific context of healthcare, which is followed by detailed analysis of Strasbourg's case law. The article concludes with a discussion on a possibility of harmonizing laws and practices governing medical malpractice in Europe through international standards (i.a. ECtHR jurisprudence).

## 2. Multidimensional state obligations

There are different types of state obligations with respect to realising human rights. A prevailing typology – the so-called tripartite typology – distinguishes between an

[94] Convention for the Protection of Human Rights and Fundamental Freedoms, opened for signature in Rome on 4 November 1950; entered into force on 3 September 1953. Text available at www.conventions.coe.int.

obligation to respect, protect and fulfil human rights and fundamental freedoms[95].

Obligation to respect entails that the state should refrain from interfering with the enjoyment of human rights. This obligation is clearly based on 'negative' understanding of responsibility and does not require any specific measures and actions to be taken by the state in order to secure or realise human rights.

Obligation to protect requires that the state protects holders of rights from the interference caused not only by state agents and organs but also by third parties (that are not state agents), and to punish the perpetrators. This obligation also covers protection from dangers caused by natural disasters, such as floods. Thus, the states are required to beactive and adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of human rights.

Obligation to fulfil or implement is related to specific, positive measures to give full realisation and effect to the right. Within the obligation to fulfil some sub-obligations have been distinguished, that is: to facilitate, provide and promote[96].

State obligations regarding the right to health care include all three types of obligations described above[97].

Traditionally, state obligations related to the so-called first generation rights (civil and political rights) were considered to be limited to ensuring that state organs and agents did not violate (infringe) individual rights. Essentially, first generation rights were considered to impose negative obligations/obligation to respect. As state obligation was, in that case, an obligation of result the rights were justiciable, but attributability of responsibility to the state was limited. On the contrary, second generation rights (economic, social and cultural rights) were regarded to impose an obligation to protect and fulfil, and thus, as obligations of means, they were seen as non-justiciable.

Today, the theoretical division of human rights into generations or families gradually loses its justification and practical use. This process is driven by two major tendencies –blurring the divisions (typologies) of duties[98] and empowering international human rights bodies with new procedural instruments[99]. J. E. Koch claims that justifiability

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[95] This typology has been developed by Asbjørn Eide in: 'Realization of Social and Economic Rights and the Minimum Threshold Approach*',* Human Rights Law Journal, Vol 1-2(1989), p. 35-51. Van Hoof offers slightly different typology. He adds the fourth obligation to promote (and refers to the obligation to ensure, instead to fulfill) – see: Van Hoof, G.J.H. 'Legal Nature of Economic, Social and Cultural Rights: A Rebuttal of Some Traditional Views', in: P. Alston, K. Tomasevski (eds.), 'The Right to Food', Utrecht: Martinus Nijhoff Publishers 1984, pp. 106-108.

[96] CESCR, General Comment No. 14 (2000), The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights), para 33.

[97] Ibidem, para 33. See also San Giorgi, M. 'The Human Right to Equal Access to Health Care*'*, Cambridge-Antwerp-Portland: Intersentia, 2012, p. 45-51.

[98] For an illustration of this tendency related to the right to health care and its elements see: San Giorgi, M., *op. cit.,* pp. 97-110.

[99] See Optional Protocol to the International Covenant on Economic, Social and Cultural Rights

issue of economic, social and cultural rights will remain far from clear if insistency in the tripartite typology continues[100]. I support this opinion with an observation that the 'blurring' process has to be continued in order to achieve true justiciability. Another question – of rather political nature – is whether governments see it feasible and desirable to support this tendency.

A similar tendency may be observed in Strasbourg's jurisprudence – i.a. widening the scope of state responsibility related to the rights enshrined in the Convention through developing positive obligations[101]. The adjudication on the right to health care (and on economic, social and cultural rights in general) via civil and political rights is described as the 'integrated approach'[102] or the 'umbrella concept'[103]. It results from recognition of the principle of human rights indivisibility [104].

The tripartite typology has been developed within the universal system of human rights. For the system of the European Convention on Human Rights another typology has gained a dominant position – i.a. division into positive and negative obligations[105].

The fundamental negative obligation (which corresponds with an obligation to respect) that requires of state's organs and agents not to commit violations themselves is supported by positive obligations. A concept of positive obligations is based on the idea that the state might be responsible for actions performed by non-state agents, as well as for not taking appropriate measures to ensure effective enjoyment of rights. In other words, the positive obligations require certain actions of the state.

The positive obligations are subject to 'secondary' division into substantial (material) and procedural obligations. The substantial obligations are basic measures necessary for full enjoyment of the rights guaranteed, e.g. laying down proper rules, regulating patient's safety, necessary equipment in hospitals. The procedural obligations are related to organisation of domestic procedures to ensure better protection of persons. It requires

of 10 December 2008 which recognizes the competence of the Committee to receive and consider communications. The Protocol came into force on 5 May 2013 – that is three months after the tenth instrument of ratification or accession has been deposited with the Secretary-General of the United Nations.

[100] Koch, J.E. 'Dichotomies, Trichotomies or Waves of Duties?', Human Rights Law Review, Vol. 5 (2005), No. 1, p. 101.

[101] See ia.Mowbray, A.R. 'The development of positive obligations under the European Convention on Human Rights by the European Court of Human Rights', Oxford-Portland Oregon 2004; Akandji-Kombe, J-F. 'Positive obligations under the European Convention on Human Rights', Human rights handbooks, No. 7, Council of Europe Publishing 2007.

[102] San Giorgi, M., *op. cit.,* p. 110.

[103] Jasudowicz, T. 'Zasady ogólne prawa międzynarodowego praw człowieka', [in:] Prawa człowieka i ich ochrona, ed. Gronowska, B., Jasudowicz, T., Balcerzak, M., Lubiszewski, M., Mizerski, R., Toruń 2010, p. 211.

[104] Ibidem, pp. 210-212.

[105] Mik, C. 'Teoria obowiązków pozytywnych państw-stron traktatów w dziedzinie praw człowieka. Na przykładzie Europejskiej Konwencji Praw Człowieka', [in:] Księga jubileuszowa Profesora Tadeusza Jasudowicza, Toruń 2004, pp. 260-271.

the existence (not only in theory but also in practice) of sufficient remedies for violation of rights.

Finally, it has to be noted that it is difficult to make rigid division between different types of obligations. Moreover, they do not necessarily correspond with eachother, e.g., every obligation of means is a positive one, but not *vice versa*[106]. It is not my intention to offer an in-depth analysis of different types of obligations and their interrelations, but to determine the scope of positive (substantial and procedural) obligations in the specific context of healthcare and medical negligence.

### 3. Death in hospital. Procedural obligations under Article 2 ECHR

Initially, an obligation to investigate unnatural deaths was connected with the possible use of lethal force by state agents[107]. Subsequently, the obligation was extended to cases where "the state agents potentially bear responsibility for loss of life[108,109]". The Court recognized that the procedural obligation implied by Article 2 cannot be confined to circumstances in which an individual has lost his life as a result of an act of violence. Thus, "the obligation at issue extends to the need for an **effective independent judicial system** for establishingthe cause of death of an individual under the care and responsibility of health professionals and any liability on the part of the latter"[110].

Applicability of Article 2 of the Convention to cases of death in hospitals was confirmed by a landmark judgment of the Grand Chamber of the Court in the case *Calvelli and Ciglio v. Italy* of 17 January 2002[111]. The judgment is definitely one of the 'hard cases' among health-related cases, for the following reasons. First of all, the Court clearly pointed out both substantial and procedural obligations incumbent upon the state. As for the substantial obligation, the Court observed that Italy was required to make regulations compelling hospitals to adopt appropriate measures aimed at the protection of their patients' lives. It was also required to provide an effective independent judicial system in order to determine the cause of patients' deaths in the care of the medical staff and make the responsible ones accountable. Second of all, the Court determined that

[106] Balcerzak, M. 'Odpowiedzialność państwa-strony Europejskiej konwencji o ochronie praw człowieka i podstawowych wolności. Studium prawnomiędzynarodowe' Toruń 2013, p. 96.

[107] Chevalier-Watts, J. 'Effective Investigations under Article 2 of the European Convention on Human Rights: Securing Right to Life or an Onerous Burden on a State?', European Journal of International Law, Vol. 21 (2010), No 3, p. 703 et seq. The article outlines the problem in a wide variety of contexts, deaths in hospitals being only one of them. It focuses on anti-terrorist operations and armed conflicts.

[108] Erikson v. Italy, decision of 26.10.1999, application no. 37900/97. The case concerned death of applicant's mother following medical examinations.

[109] All judgments and decisions of the European Court of Human Rights referred to in the article are available via HUDOC database.

[110] Erikson v. Italy, op. cit. and Powell v. United Kingdom, decision of 4.05.2000, application no. 45305/99.

[111] Application no. 32967/96.

those obligations applied not only to public, but also to private hospitals, which solved the problem of attributing responsibility for the interference that took place in private institutions to the state.

It is now a matter of well-established case law that acts and the authorities in the field of health care services may, in certain circumstances, bear responsibility for omissions under the positive limb of Article 2. "However, where a Contracting State has made **adequate provision for securing high professional standards among health professionals and the protection of the lives of patients**, matters such as **error of judgment** on the part of a health professional or **negligent co-ordination** among health professionals in the treatment of a particular patient are **not** sufficient of themselves to find a Contracting State responsible for a violation of Article 2"[112]. To put it simply, not all (nor even the majority) instances of death caused by medical negligence will be attributable to the state. If the state satisfies substantive positive obligations, such as the conditions highlighted above, it may be absolved from responsibility.

Strasbourg's jurisprudence reflects upon a rational and logical interpretation of the scope of positive obligations. It is impossible to make the Stateaccountable for all cases of malpractice and medical errors since they may happen even in the safest and most organized institutions and health care systems – *impossibilium nulla obligatio est.* Thus, the state authorities are required to adopt appropriate measures (legislative, regulatory and administrative) setting up professional standards and safety rules. Nevertheless, errors and incidents may still happen. In that case, a procedural obligation comes into play.

It shall be emphasised that when a dispute is brought before the ECtHR, the issue is not the liability of a doctor as such. The Court determines whether the respondent state in question has fulfilled its duty to secure the rights enshrined in the Convention; in that case, the right to have the cause and circumstances of death properly investigated within a reasonable time. The question is – how exactly this duty is carried out?

### 3.1. Definition of an 'effective independent judicial system'

The ECtHR requires that states have the 'effective independent judicial system' in order to establish the cause of death of an individual under the care and responsibility of health professionals and any liability of the latter. Investigation must lead to the identification and punishment of the person responsible. However, it has to be emphasised that it is **not 'an obligation of result, but of means'.** It is obvious that sometimes even the most diligent and thorough investigation will not lead to the ultimate result. In that case, the key question is: what measures and what standards of diligence are required? Strasbourg's standards require domestic authorities to take **measures that are reasonably open** to them.

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[112] Powell v. the United Kingdom, op. cit.; Nitecki v. Poland, decision of 21.03.2002, application no. 65653/01; Byrzykowski v. Poland, judgment of 27.06.2006, application no. 11562/05, para 104.

However, we shall ask, if there is any 'model' system, or if there are at least minimum standards concerning medical negligence investigation and proceedings? With regard to the judicial proceedings, it is natural to seek guidance in standards set out in Articles 6 and 13 of the Convention.

The primary requirement of Article 6 is that the case should be considered (heard) by an independent and impartial tribunal established by law. A 'fair' trial requirement contains several elements, such as an 'adversarial' principle, equality of arms, personal presence and effective participation. An example of violation of the equality of arms principle was found in the case *Sara Lind Eggertsdottir v. Iceland*[113] where a conflict of interests between medical experts and the defendant in civil case occurred when the medical institution was suspected of malpractice. Another problem, often of a systemic nature, concerns the length of proceedings. Article 6 requires a 'reasonable' time of proceedings which is assessed by an extensive test involving three main criteria established in the jurisprudence:

1) nature and complexity of the case;
2) conduct of the applicant;
3) conduct of the authorities[114].

Delays that are attributable to the authorities most often result from repeated return of cases to investigators on the same grounds, recurring attempts to summon the same witnesses to trials, and a long time taken by judges to give their decisions after hearing the parties[115]. It is impossible and undesirable to set up general or fixed time limits because each case has to be considered *ad casum,* taking into account many different factors. Nevertheless, the number of instances involved is taken into account when assessing 'reasonableness'. More rigorous scrutiny is applied when the proceedings take longer than 3 years (in first instance), 5 years (two instances), or 6 years (three instances)[116].

All the above-mentioned general procedural standards apply to medical negligence disputes; nevertheless, their nature require both particular diligence and promptness. Complexity of medical litigation is a very common argument presented by the domestic authorities to justify delays. The fact that the medical questions may be somewhat complex cannot be taken for granted and used as an excuse for unacceptable delays[117].

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[113] Judgment of 05.07.2007, application no. 31930/04.

[114] Mole, N., Harby, C. 'The right to a fair trial. A guide to the implementation of Article 6 of the European Convention on Human Rights', Human rights handbooks No. 3, Council of Europe Publishing 2006, pp. 24-29.

[115] Vitkoauskas, D., Dikov G., 'Protecting the right to a fair trial under the ECHR', Human rights handbooks, Council of Europe Publishing 2012, pp. 72-75.

[116] Ibidem, p. 74.

[117] For example, in case Byrzykowski v. Poland (op. cit.), the overall length of proceedings reached almost 7 years.

As vital interests (health and life) of individuals are at stake, apart from an obligation to observe the procedural rules set out in Articles 6 and 13, the States must also fulfil a specific duty of diligence, thoroughness and efficacy. An analysis of the Court's case law allows to single out a few key elements and specific conditions that will be addressed in the following parts of the paper.

### 3.2. Available remedies

The first issue relates to a question: **what type of remedies should be available** for a person seeking compensation? The ECtHR has stated on numerous occasions that the effective judicial system may, and under certain circumstances must, have recourse to the criminal law. However, if the infringement of the right to life or to personal integrity is not intentional (and this is usually the case in the health care field), the positive obligation imposed by Article 2 to set up the effective judicial system does not necessarily require a criminal law remedy in every case. In the specific sphere of medical negligence the obligation may also be met e.g. if the legal system affords victims a remedy in civil courts, either alone or in conjunction with a remedy in criminal courts, enabling the establishment of doctors'liability and seeking the appropriate civil redress, such as an order for damages or publication of the decision[118]. Disciplinary measures may also be envisaged[119].

The remedy should exist **not only in theory, but it also must operate effectively in practice**, within a period of time allowing to examine the case without unnecessary delays[120]. In order to fulfil a positive obligation under Article 2 the state has a duty to ensure, by all means at its disposal, that the legislative and administrative framework, set up to protect patients' rights, is properly implemented and any breaches of these rights are put right and punished. For example, a dissonance between theory and practice was found in the case *Mehmet Şentürk and Bekir Şentürk v. Turkey*[121]. The Court observed that, on the one hand, the Turkish legal system affords injured parties criminal proceedings and, on the other, a possibility of bringing an action before the competent civil court, with a possibility of disciplinary proceedings, if civil liability is established. In fact, criminal remedies existed in the case only in theory, because the persons responsible for endangering life were neither charged

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[118] In case Konczelska v. Poland (decision of 20.09.2011, application no. 27294/08), the applicant complained that the investigation and judicial proceedings concerning criminal responsibility in connection with the medical care she received when giving birth to her daughter lasted too long and were ineffective. The Court did not review the merits of this complaint since the applicant has lost a 'victim status' due to a compensation of PLN 408,847 that has been awarded to her by the civil courts. The application was therefore found to be inadmissible *ratione personae*.

[119] Byrzykowski v. Poland, op. cit., para 105.

[120] Calvelli and Ciglio v. Italy, op. cit., para 53; Ibidem, para 117.

[121] Judgment of 09.04.2013, application no. 13423/09.

with a criminal offence, nor prosecuted (investigations were discontinued as being time-barred)[122].

Another requirement is that persons responsible for investigations and those carrying out inquiries must be independent of persons involved in the events. This condition may be particularly problematic with respect to disciplinary proceedings.

### 3.3. Promptness and diligence

It is extremely important in the cases of possible medical negligence that the investigation is **prompt and thorough**[123]. The cases brought before the ECtHR reveal numerous shortcomings and factors that are likely to cause undue delay of the proceedings and/or impede its thoroughness. The conditions underlying promptness, reasonable expedition and diligence are interrelated. Usually, lack of diligence and inactivity of domestic bodies result in undue delays; nevertheless, it would be enough to find a violation of a procedural aspect of Article 2 if only one of the conditions was not satisfied.

Undue delays are a common problem of medical negligence litigation. Lengthy proceedings strongly indicate that they are defective to the point of constituting a violation of the state's positive obligations under the Convention, unless the state provides highly convincing and plausible reasons to justify such course of proceedings. Of course, it may happen that the proceedings are prompt but do not satisfy the requirement of diligence and thoroughness.

A violation of procedural limb of Article 2 was found in the case *Süleyman Ege v. Turkey*[124] where the criminal proceedings lasted for more than seven years. This delay was neither caused by particular complexity of the case, nor by the conduct of the applicant. The administrative proceedings took twelve years. In the case *Eugenia Lazăr v. Romania*[125] a requirement of promptness and reasonable expedition was not satisfied either because the proceedings lasted for approximately four years and five months at two levels of jurisdiction, and the investigation by the prosecution service took nearly four years. Similarly, in the judgment *Kudra v. Croatia* the overall length of the proceedings, which took thirteen years[126], together with several long periods of unexplained inactivity on the part of the domestic authorities, constituted a violation of Article 2 ECHR.

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[122] Ibidem, para 103, 105.

[123] Šilih v. Slovenia, judgment of 9.04.2009, application no.71463/01, para 195.

[124] Judgment of 25.07.2013, application no. 45721/09.

[125] Judgment of 16.02.2010, application no. 32146/05.

[126] Judgment of 18.12.2012, application no. 13904/07. The proceedings in respect of the death of the applicants' relative commenced in May 1994, but then no relevant steps in the proceedings were taken before January 1997 when the trial court commissioned a medical report. The report was submitted only in March 1999, without any findings having been adopted. The proceedings ended in April 2011, more than thirteen years after the Convention had entered into force in respect of Croatia.

In the case *Byrzykowski v. Poland*[127] the criminal investigations were **discontinued** four times and subsequently resumed on the ground that the evidence gathered so far in the case was incomplete and did not allow to establish relevant facts. In the Court's opinion, remittal of cases for re-examination is usually ordered as a result of errors committed by lower authorities; repeating such orders within one set of proceedings displays serious deficiencies of the judicial system[128]. Case *Byrzykowski v. Poland* illustrates another problem that may arise in cases of alleged medical malpractice when the criminal, civil and disciplinary proceedings are conducted concurrently (simultaneously). In the subject case the authorities repeatedly referred to the other sets of pending proceedings as a justification for **staying them or for the refusals to resume them.** The disciplinary proceedings were stayed pending the outcome of the criminal investigations and the civil proceedings were stayed pending the outcome of the disciplinary proceedings. ECtHR noticed that the evidence obtained in one set of proceedings could be relevant for the decisions in other proceedings, and that the outcome of such proceedings could have an impact on further conduct of the proceedings which were stayed. It considered that such decisions could have been dictated by reasonable considerations related to the fair and efficient administration of justice[129]. Nevertheless, bearing in mind the overall period (almost 7 years) which had elapsed since the death of the applicant's wife and also the fact that the procedures instituted with the view of establishing the circumstances of her death seemed rather to hinder the overall progress in the proceedings, the Court stated that it could not be said that the procedures that were applied in order to elucidate the allegations of medical malpractice resulted in the effective examination into the cause of death in the case[130].

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[127] Judgment of 27.6.2006, application no. 11562/05. Facts: In July 1999 the applicant's 27-year-old wife was about to give birth to their child and was admitted to a hospital. As there was no progress in the delivery and the child showed signs of heart distress a decision was made the next day to perform a caesarean section. The wife was given an epidural as a result of which she went into a coma. All resuscitation efforts failed. She was subsequently transported to the intensive therapy unit where she died 19 days later. Their son was born by a caesarean section, suffering from serious health problems, mostly of a neurological character. He requires permanent medical attention. In December 1999 a criminal investigation was started into the suspected offence of manslaughter. In 2006 when the ECHR judgment was giventhe criminal proceedings were still pending.

[128] One of the general measures aiming at execution of the judgment that was introduced in order to simplify and accelerate criminal proceedings was an amendment of Article 465 § 2 Code of Criminal Proceedings (in force from 12.07.2007). In the light of this provision, an appeal against the decision to refuse an investigation or to discontinue it shall be lodged directly to the court not via the prosecutor. Moreover, prosecutors' decisions on non-initiation of the investigation or on its discontinuation, in cases in which a victim may become an auxiliary prosecutor, are subject to close scrutiny of their superiors, in line with guidelines issued by the Prosecutor's General Office on 30 November 2012. The aim of the guidelines is also to prevent irregularities similar to those found in the judgment Byrzykowski v. Poland.

[129] Ibidem, para 116.

[130] Ibidem.

In other cases, the Court dealt with a very common procedural problem of the medical negligence cases, i.a. the necessity of ordering **expert opinions** and their impact on the overall length of the proceedings. The necessity of ordering forensic medical expert examinations is obvious since judges usually do not have sufficient medical knowledge. Therefore, medical expert opinions are extremely important in the medical malpractice cases. Due to their significance, it is crucial to ensure not only lawful and impartial assignment and performance of this procedure, but also fair and objective assessment of expert opinions. It is equally important to empower the court with the appropriate means to discipline the experts in order to get their opinions within a reasonable time.

In judgment *Dvořáček and Dvořáčková v. Slovakia*[131] the Court acknowledged that the determination of the points at issue required special knowledge in the field of medicine. It was considered natural that the domestic court decided to have recourse to experts with a view to obtaining their opinion[132]. However, the Court noted that the provided documents contained no information indicating that the determination of the point at issue required so many (i.a. five) expert opinions. Furthermore, no explanation was given as to the period of more than two years that the District Court needed to decide that the fourth and the fifth opinion is required[133]. The proceedings before the District Court lasted for more than 3 years and 8 months without the merits of the case being determined. This led the ECtHR to the conclusion that there has been a violation of Article 2 of the Convention.

The Court reached a different conclusion in the case *Z. v. Poland*[134] where the only delay in the investigation occurred when three medical academies refused to prepare medical opinions due to lack of time and resources. In consequence, the proceedings were stayed for almost two years. However, during that time the prosecutor's office obtained six medical opinions and heard evidence of several experts. The Court accepted that the medical questions involved in the case were very complex and required a thorough analysis. Consequently, the period of two years and four months, during which the case had been stayed, did not seem substantial in the Court's opinion.

While the issue of ordering expert opinions is usually connected with the length of proceedings, it may also reveal lack of effectiveness. In the case *Eugenia Lazăr v. Romania*[135] the Court noted two significant shortcomings in the conduct of the investigation in the subject case. Firstly, the lack of cooperation between the forensic medical experts and investigating bodies; and secondly, the lack of reasons given in the experts' opinions. Since this case reveals a problem that has not been considered by the Court so far, it will be presented below in detail.

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[131] Judgment of 28.7.2009, application no. 30754/04.

[132] Ibidem, para 69.

[133] Ibidem.

[134] Judgment of 13.11.2012, application no. 46132/08.

[135] Judgment of 16.2.2010, application no.32146/05.

The main problem was that the prosecuting authorities encountered resistance of the forensic medical institutes which had refused to answer their questions citing the Government ordinance. The ordinance, in their opinion, prevented them from carrying out fresh expert examinations if the supreme national authority on forensic medicine had given its opinion and/or no new evidence had emerged. The subject case revealed that the problem of non-cooperation between the forensic medical experts and investigating bodies in Romania was a general one. The Court made it clear that "The very existence in domestic law of provisions authorising the forensic medical institutes responsible for issuing opinions to ignore requests by the judicial authorities and thus to refuse to cooperate with them whenever the needs of the investigation so dictated was scarcely compatible with the State's primary duty to secure the right to life by putting in place an appropriate legal and administrative framework to establish the cause of death of an individual under the responsibility of health professionals"[136].

Similarly, the lack of reasons in the expert opinions resulted from defective domestic legislation on forensic medical reports. According to Romanian law, the formulation of an opinion by the supreme national authority prevented lower institutes from producing fresh reports or supplementing previous ones. In the subject case the forensic medical laboratory that issued the first report clearly noted that there were shortcomings in the hospital's emergency medical assistance protocol, which had resulted in a delay in performing the surgery. That conclusion was confirmed, at least partially, following the review by the second forensic medical institute. However, the Higher Forensic Medical Board, whose function was to issue opinions solely on the basis of the reports of lower-level institutes without making on-the-spot visits, simply rejected the conclusion without any explanation. That led the ECtHR to the conclusion that "the domestic rules on forensic reports should include sufficient safeguards to preserve their credibility and efficacy, in particular by requiring experts to state reasons for their opinions and to cooperate with the judicial authorities whenever the needs of the investigation so dictated"[137].

Another problem considered by the ECtHR was the alleged improper conduct of investigations or proceedings due to **frequent changes of prosecutors or judges.** In the case *Z. v. Poland*[138] the applicant claimed thatresults of the investigation could have been questioned due to the fact that six different prosecutors were consecutively in charge of the case. In this respect, the Court accepted the Government's argument that changes were inevitable as there were some issues of jurisdiction. On the contrary, in the case *Šilih v. Slovenia*[139] the proceedings did not meet the standard of the 'effective judicial system' because six judges were responsible for the case in a single set of first

[136] Ibidem, para 80.

[137] Ibidem, para 85.

[138] Judgment of 13.11.2012, application no. 46132/08.

[139] Judgment of 9.04.2009, application no. 71463/01.

instance civil court proceedings which were still pending 13 years after they had been commenced[140].

### 4. Serious health impairment. Procedural obligations under Article 8 ECHR

According to Article 8 ECHR everyone has the right to respect for one's private and family life. The notion of private life is broad and includes i.a. a person's physical and psychological integrity[141]. The essential object of Article 8 is to protect the individual against arbitrary interference by public authorities. However, there may be additional positive obligations inherent in this provision extending to, inter alia, the effectiveness of any investigating procedures relating to one's family life or private life[142]. Jurisprudence concerning procedural limb of Article 8 is nevertheless very limited.

Only on a few occasions the Court had to face the issues of procedural obligations concerning medical negligence investigation and adjudication with regard to the cases in which the patients suffered serious health impairment allegedly as a result of negligent conduct on the part of the medical professionals.

In the case *Codarcea v. Romania*[143] the applicant, whose right to compensation was recognized by the Romanian court, had **no legal remedy available to render that right effective**. The Romanian court did not give a final ruling on the applicant's compensation claim until more than nine years after lodging the criminal complaint and civil-party action. However, by that time the doctor's criminal responsibility was time-barred. Furthermore, she did not receive the sum awarded to her for non-pecuniary damage because a few days after being ordered to pay compensation to the applicant the doctor divested himself of his property and became insolvent, thereby releasing himself from his obligations towards the applicant. The consequences of the doctor's insolvency were also aggravated by the fact that no medical negligence scheme existed in Romanian law at the time. While the domestic law has changed since then, making it compulsory for doctors to take out professional civil-liability insurance, the changes did not apply retrospectively to the applicant's situation. Moreover, refusing to consider the hospital civilly liable the domestic courts deprived the applicant of the effective legal protection of her physical integrity, despite the fact that there was some authority in the case law of the country's highest courts and in the legal doctrine to support acknowledging liability of hospitals for the actions of doctors they employed[144].

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[140] Ibidem, para 210.

[141] Niemietz v. Germany, judgment of 16.12.1992, para 29.

[142] M.C. v. Bulgaria, judgment of 04.12.2003, application no. 39272/98, para 152 and 153.

[143] Judgment of 02.06.2009, application no. 31675/04.

[144] See Information Note on the Court's case-law No. 120.

In the case *Spyra and Kranczkowski v. Poland*[145] the application concerned both substantial and procedural aspects of Article 8 ECHR. Applicants alleged that their son's disability had been caused by the lack of appropriate medical treatment when the mother had given birth in the hospital. They also complained about the lack of effectiveness of the procedures undertaken by the Polish authorities to establish the origin of the child's disability.

The civil proceedings initiated by the applicants lasted for 4 years, the length of the proceedings, however, was assessed as 'reasonable' because it concerned three levels of jurisdiction. In the domestic courts' opinion there was no causal link between the doctor's actions and the child's disability. Experts clearly explained the origin of the child's disability in 4 opinions and they all were consistent. The ECtHR acknowledged that the domestic courts' decisions were based on expert opinions, medical documentation and witness statements. The ECtHR noticed that the applicant was present during the proceedings and her effective participation was ensured. She had a legal representative, she was questioned in the courts, she had opportunity to appeal, ask questions to experts and raise objections. Accordingto the documents provided to the Court, she made use of all these rights. Thus, there were no indications that the proceedings were not sufficiently diligent.

Criminal investigation in the case was initiated by the applicants in 2006 (i.a. 7 years after the birth of the child). The investigation lasted for 3 years and could not be continued due to the prescription of crime. The ECtHR assessed that during those 3 years the authorities undertook actions actively. A decision to remit (discontinue) the proceedings was given after 15 months from its initiation. The decision was quashed because of shortcomings in the medical opinion. Another opinion (that was given to the authorities after 9 months) could not be admitted for the same reasons. The Court noted that actions undertaken by the investigators were not completely satisfying, taking into account limited time that was left to the prescription of crime. Nevertheless, the Court underlined that the aim of the case at issue was to ascertain whether the judicial system as a whole worked adequately in this particular case. In a specific context of medical negligence positive obligations implied by Article 8 are fulfilled when individuals are able to use civil, administrative or disciplinary measures[146]. In the case at issue the applicants used civil remedies (3 instances) and disciplinary measures. The Court's general conclusion was that although there could be some reservations as for the criminal investigation, Polish judicial system as a whole ensured that the applicants had a possibility of adequate investigation if their claims were justified[147].

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[145] Judgment of 25.9.2012, application no 19764/07.

[146] Ibidem, para 98.

[147] Ibidem, para 99.

The last judgment – *Csoma v. Romania*[148] is particularly interesting because it concerned a specific type of negligence, that is, informational negligence. The applicant experienced severe bleeding and other complications as a result of medical procedures inducing an abortion (the foetus was diagnosed with hydrocephalus and the doctor advised abortion to which she agreed). In the case, both types of positive obligations were at issue.

Ms Csoma complainedthat she no longer was able to have children due to medical errors and the lack of appropriate information concerning the risks that the medical procedure entailed. She also argued that the investigation of the case was superficial and that the forensic authorities lacked impartiality in issuing medical expert reports.

The Court observed that the medical reports had established that despite the obvious mistakes made in the handling of the case, there was no medical negligence on behalf of the doctor. However, in the Court's opinion the prosecutor did not weigh the conflicting factual issues presented in the case and as a result did not clarify the events[149]. Moreover, the Court assessed if a civil claim (which she had not filed) by the applicant against the doctor or the hospital would be an effective remedy. Taking many factors into account the Court concluded that it would be disproportionate to require her to bring another action before the civil courts[150].

## 5. Conclusions

Development of positive obligations (especially of the substantive ones) has considerably broadened the range of Strasbourg's scrutiny concerning health care issues. It is essential to bear in mind that the fact whether death or health impairment was a consequence of medical misconduct is irrelevant to state responsibility under the Convention. Violation of Article 2 or 8 (in its procedural aspect) could be found even if a doctor's actions were diligent and consistent with professional standards and ethics. The issue remains whether the domestic proceedings to establish facts and liability met all standards required by the Convention (as interpreted by the Court).

An overview of Strasbourg's jurisprudence concerning medical negligence complaints reveals major shortcomings shared by many domestic systems. Remedies for victims often exist only 'on paper' and are ineffective in practice due to undue delays and lack of required diligence on the part of domestic bodies. While it may be true that medical cases are often complex, this assumption cannot generally justify the inability of domestic authorities to review a case within a reasonable time, especially when somebody's life or health is at stake - justice delayed is justice denied. As the ECtHR

[148] Judgment of 15.01.2013, application no. 8759/05.

[149] Ibidem, para 55 and 56. The prosecutor based his decision only on the forensic reports issued at his request and did not take into account other reports prepared by respectful bodies available to him.

[150] Ibidem, para 61-68.

emphasises: "Even where there may be obstacles or difficulties which prevent progress in an investigation in a particular situation, a **prompt response by the authorities is vital to the maintenance of public confidence in their adherence to the rule of law** and to the prevention of any appearance of collusion in or tolerance of unlawful acts"[151].

Apart from the measures that should be undertaken to improve the conduct of criminal investigations and civil proceedings, the Committee of Ministers of the Council of Europe has recommended that barriers and obstacles to obtaining redress could be mitigated by offering mediation, conciliation and administrative procedures as alternatives to a traditional procedure before the court[152]. There are unquestionable benefits of setting up special tribunals with the mission of resolving disputes and compensating patients for damage, as well as setting up the administrative system offering compensation for avoidable injuries, regardless of negligence, error or omission[153].

Comparative research proves that there are significant differences between national legislations and a variety of existing practices in the Council of Europe member states in resolving medical liability complaints[154]. Therefore, it is justified to reflect upon a question if Strasbourg's jurisprudence could serve as a tool for harmonisation. An analysis of the case law proves that the ECtHR has set out a blueprint for effective domestic investigations. But it only applies to purely procedural aspects. It is not for the Court to substantiate the findings of the domestic authorities as to i.a. causal connection between the injury (or the alleged inappropriate medical treatment) and death of the applicants' relative or health impairment suffered by the applicant, but to verify whether the domestic authorities discharged their procedural obligation under Article 2 or 8 of the Convention when confronted with the allegation of unintentional deprivation of life or interference in physical and mental integrity.

The final thought on the subject concerns the issue of learning from mistakes. It is essential to recognise that although an error is inherent in all fields of human activity, it is possible to learn from mistakes and prevent their reoccurrence. Knowledge of facts and possible errors committed in the course of medical care should be established promptly in order to be disseminated among medical staff of the institution concerned so as to prevent the repetition of similar errors and thereby contribute to the safety of users of all health services[155].This systemic and general effect of an individual remedy should not be underestimated.

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[151] Šilih v. Slovenia, op. cit., para 196; Mehmet Şentürk and Bekir Şentürk v. Turkey, op. cit., para 101.

[152] Committee of Ministers Recommendations: Rec(2006) on management of patient safety and prevention of adverse events in health care and Rec (2002) on mediation in civil matters.

[153] Ibidem.

[154] Koch, B.A. 'Medical Liability in Europe: A Comparative Analysis'[in:] Medical Liability in Europe: A Comparison of Selected Jurisdictions, ed. Koch, B. A.,Walter de Gruyter, 2011, p. 611 et seq; Kilby, E. 'Conclusions from European Conference "The ever growing challenge of medical liability: national and European responses"', Strasbourg 2-3.06.2008.

[155] Byrzykowski v. Poland, op. cit., para 117.

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# III. MEDICAL ERROR AND EXPERT OPINION IN CRIMINAL PROCEEDINGS IN THE CONTEXT OF POLISH LAW – SELECTED ISSUES

The problems associated with medical errors and criminal or civil liability of physicians has become an issue raised more and more frequently on the medical, sociological but also legal grounds. Among the representatives of the above fields of science, as well as the general public, this issue causes intense discussion, which manifests itself in publicizing this phenomenon by media and rapidly emerging literature on the subject[156]. The opinions prepared by court-appointed medical experts on actions related to medical errors are frequently commented by the doctrine, the case law and the public at large.

The subject of medical error and expert opinion related to it is vast. A detailed analysis of the issues presented in this paper would result in a very long piece of work. Therefore, due to the requirements and editorial limitations, the writer – facing the challenge of discussing the subject of giving expert opinions on medical errors – decided to review only the most important issues.

Following this assumption, the author has not analysed the errors in opinions made by the adjudicating group of experts, whose job is to give an opinion about a physician that is reliable and consistent with the truth. She has not researched all issues related to evidence in criminal proceedings related to medical error in detail, because the literature in this area is extensive[157].

## 1. Preliminary issues

Moving on to the key considerations of this study, it is relevant to indicate that in criminal actions related to medical error, there are different sources of evidence. These

[156] See 'Leksykon prawa medycznego. 100 podstawowych pojęć' ed. Górski, A., Warszawa 2012; Zajdel, J. 'Prawo w medycynie dla lekarzy specjalności zabiegowych', Łódź 2008, p. 211-212; Augustyn, R. 'Zarys metodyki obrony lekarza w postępowaniu karnym w sprawach o błąd medyczny, Poznań 2010. p. 17-18

[157] *Cf.* Waltoś, S. 'Proces karny. Zarys systemu', Lexis Nexis, Warszawa 2009; Grzegorczyk, T.,Tylman, J. 'Polskie postępowanie karne', Lexis Nexis, Warszawa 2011; Cieślak, M. 'Zagadnienia dowodowe w procesie karnym', Wydawnictwo Prawnicze, Warszawa 1955; Horoszewski, P. 'Nazwa i pojęcie „dowodu" w teorii i praktyce prawa sądowego', Państwo i Prawo, Vol. 10 (1956), Grzegorczyk, T. 'Dowody w procesie karnym', Wydawnictwo Prawnicze, Warszawa 1998; Sehn, J. 'Dowód z biegłych w postępowaniu sądowym', Nowe Prawo, No. 3(1956).

include in particular: documentary evidence, evidence from witness, evidence from visual inspection, hearing of the parties, as well as evidence of other types, such as blood test. Evidence, which is very important in criminal proceedings in actions related to medical error is the evidence given by an expert. This type of evidence will be discussed in this study.

At this point, it should be noted that in spite of so many sources of evidence, difficulties in proving cases, involving medical error, recur.

To issue a reliable medical opinion broad medical knowledge is needed and on the other hand - the ability to properly understand the intentions of justice as well as the ability to issue an opinion focusing on the appropriate scope so that it is delivered to the audience in an undistorted form. Competent communication between a lawyer and a medical expert is possible after agreeing on a common language, what should consists in mastering some legal terms and reducing specific terms used in medical science to the minimum.[158] Lack of legal knowledge on the side of doctors and insufficient knowledge of medical terms on the side of lawyers is often the source of misunderstanding between the lawyer and the expert. J. Kunz rightly points out that following the above reasoning would be a great facilitation. He points out that the essence of disagreement is a difference in the 'mental workshop' of the doctor and the lawyer, because the medical expert must take into account that various biological phenomena smoothly switch from to one another, without sharp boundaries. That is why not always the doctor can satisfy the lawyer, who usually demands that the 'borders' of the studied phenomenon have been established so that he could issue an unambiguous opinion.[159]

It is worth emphasizing that there are also significant differences in social roles between the medical expert and the judge (lawyer).[160] That is why the communication between them may be often distorted.

Before I move to the main issue, I would like to discuss the issue of medical error (doctor's error).

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[158] Berent, J. 'Rola biegłych z zakresu medycyny sądowej w opiniowaniu dla potrzeb sądów i instytucji ubezpieczeniowych', Archiwum Medycyny Sądowej i Kryminologii,No. 4 (2005), p. 249.

[159] Kunz, J. 'Niektóre przyczyny rozbieżności stanowisk prawników i biegłych lekarzy w opiniowaniu sądowo – lekarskim. Część I: Problematyka związku przyczynowego', Archiwum Medycyny Sądowej i Kryminologii, No. 1(1992), p.39.

[160] Jaegermann, K. 'Kategoryczne opinie sądowo-lekarskie', Archiwum Medycyny Sądowej i Kryminologii, No. 2(1978), p. 109.

## 2. Medical errors classification

The literature[161] introduces various classifications of medical malpractice, but in this study the following breakdown will be outlined:

**1.** diagnostic error
**2.** therapeutic error
**3.** technical error
**4.** organizational error.

Diagnostic error is an error that has a significant impact on further stages of treatment. Committing this type of error can have irreversible negative effects on a patient's life.[162] The reason for such error may be an unprofessional analysis of the test results or taking the wrong patient's medical history. Wrong diagnosis is also a result of violation of caution when conducting diagnostic actions[163], as well as failure to take reasonable steps in order to make a correct diagnosis such as an improperly conducted patient interview or physical examination[164].

Article 42 of Act on the Profession of Physician and Dentist[165] states that *The doctor predicates on the state of health of a person after personal examination of the subject save as required by separate regulations*. According to that provision a physician is competent to make diagnosis only after direct examination of a person. However, there is an exception to this rule set forth in Article 9 of the Medical Code of Ethics[166]:

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[161] Zoll, A. 'Odpowiedzialność karna lekarza za niepowodzenie w leczeniu', Wydawnictwo Prawnicze, Warszawa 1988, pp. 51–77; Rejman, G. 'Odpowiedzialność karna lekarza', Wydawnictwo Uniwersytetu Warszawskiego, Warszawa 1991, pp.178–188; Nesterowicz, M. 'Prawo medyczne',7th edition, Dom Organizatora, Toruń 2005, pp. 155–161; Marek, Z. 'Błąd medyczny, odpowiedzialność etyczno – deontologiczna i prawna lekarza', 2nd edition, Wydawnictwo Medyczne, Kraków 2007, pp. 33–37; Szczepaniak, L. 'Błąd medyczny – przyczyny, skutki i odpowiedzialność', Bioetyczne Zeszyty Pediatrii, No. 4(2007), pp. 97–109; Dziekońska – Staśkiewicz, I. 'Tak zwany błąd w sztuce lekarskiej (definicje, zakres pojęcia, propozycje)', Studia Kryminologiczne, Kryminalistyczne i Penitencjarne, Vol. 1(1974), pp. 233–238; Dyttus, E. 'Błąd w sztuce lekarskiej a prawo pacjenta do należytej opieki lekarskiej' [In] '*Lege artis*: problemy prawa medycznrgo. Praca zbiorowa', eds. Haberko, J., Kocyłowski, R.D., Pawelczyk D., Uniwersytet im. Adama Mickiewicza, Wydział Prawa i Administracji, Poznań 2008, pp. 144–147.

[162] Nesterowicz, M. *op. cit.*, p. 77.

[163] Kędziora, R. 'Odpowiedzialność karna lekarza w związku z wykonywaniem czynności medycznych', Wolters Kluwer business, Warszawa 2009, pp. 213 – 218.

[164] Rutkowski, S. 'Wybrane zagadnienia z zakresu odpowiedzialności karnej lekarza', Prokuratura i Prawo, No. 9-12(1999), p. 73.

[165] The Act on the Profession of Physician and Dentist of 5th December 1996 (Journal of Laws 2010.107.679).

[166] Medical Code of Ethics of 2nd January 2004 (consolidated text with amendments adopted on 20th September 2003 by the Extraordinary 7th National Congress of Physicians).

*a doctor can undertake treatment only after examining the patient. Situations where medical advice can only be given from a distance constitute an exception*. Such specific situation may be a threat to life and health of a patient with whom the direct contact is not possible, for example due to a snowstorm or natural disasters. It should be noted, however, that in these cases the doctor has to examine the patient when the obstacles disappear[167].

Causes of diagnostic error may also result from the confidence of a doctor, who does not want or does not know how to admit to a wrong diagnosis[168]. In such event the court will have to determine whether the cause of the failure to diagnose correctly was justified by the symptoms or it was caused by the doctor's fault[169].

Another type of error is a therapeutic error. It can be either spontaneous – occurring despite a proper diagnosis, or it may be the continuation of the diagnostic error. It involves the use of methods inconsistent with the current medical knowledge and practice, and the application of an inappropriate method of treatment in the course of therapy[170].

The essence of this error is perfectly illustrated by the sentence issued on July 19 1999[171] in which the District Court in Bydgoszcz acknowledged the liability of a medical institution for a surgeon, who performed unnecessary amputation of both breasts, basing solely on a palpable examination, without consulting an oncologist and without verifying the results of histopathological examinations. The wrong diagnosis of the patient, who actually suffered from mild mammary dysplasia, suitable for pharmacological treatment, led to a permanent mutilation of the young woman. It is also assumed that a misdiagnosis can cause a therapeutic error in the form of improper conduct of a labour (i.e. natural labour instead of necessary *in casu* Caesarean section). Primarily, these negative actions of doctors result in various forms of perinatal injury (e.g. severe cerebral palsy). The Supreme Court in its judgment of December 24,1954[172] expressed the opinion that a therapeutic error may consist in carrying out a procedure despite the existing medical contraindications. The Supreme Court admitted the physician's liability for a failure to thoroughly examine the patient before the surgery, what resulted in failure to detect the patient's exudative diathesis, which is a contraindication to thyroid surgery.

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[167] Sawicki, J. 'Błąd sztuki przy zabiegu leczniczym w prawie karnym', Państwowe Wydawnictwo Naukowe, Warszawa 1965, p. 114.

[168] Fiutak, A. *op. cit,*. p. 78.

[169] Nesterowicz, M., *op. cit.,* p. 209; Fiutak, A., *op. cit.,* p. 77.

[170] Bączyk-Rozwadowska, K. 'Błąd lekarski w świetle doktryny i orzecznictwa sądowego', Prawo i Medycyna, No. 3(2008), p. 39, available at: www.prawoimedycyna.pl.

[171] Judgement of the Regional Court in Bydgoszcz of 19th of July 1999 (IC 1150/98), (as cited in) Bączyk-Rozwadowska, K., *op. cit.,* p. 38.

[172] Decision of the Supreme Court of 24th December 1954 (IC 1673/53) (as cited in) Bączyk-Rozwadowska, K., *op. cit.,* p. 39.

In conclusion, it should be emphasized that therapeutic activities do not come down solely to the performance, and therapy is a continuation of a diagnosis established together with therapeutic activities[173].

A technical error can be described as an ordinary negligence or improper implementation of medical decisions that have already been made. Therefore, strictly speaking, it is no longer a medical error. This type of error may, among others, include confusion of the patients' identity or a limb qualified for surgery or leaving a foreign body in the operation area[174]. It usually occurs during complex operations, where sophisticated technical equipment is used[175].

The literature on the subject also distinguishes an organizational error that results from improper organization of doctors and medical staff work and wrong functioning of a health facility. The causes of this error include: inappropriate flow of information within a health care unit, as well as insufficient financing of a therapeutic centre, because lack of funds negatively affects work organization of both doctors and medical personnel.

The organizational error is much more common in large hospitals or clinics than in small outpatient clinics[176].

At this point it is worth noting that the issue of criminal liability of a doctor is problematic and, therefore, mentioned in the theory of law as well as medical practice.

Treatment provided by doctors should be divided into therapeutic and non-therapeutic. The latter include: biological experiment, euthanasia, artificial insemination, castration and eugenic sterilization, abortion due to economic or social reasons, collection of blood and other medical treatments for forensic purposes or drug analyzes for evidentiary purposes. This study will discuss a group of therapeutic treatment methods, which include: diagnosis, treatment and prophylaxis[177].

Therapeutic activities should be carried out following the principles developed on the basis of knowledge and medical art (*lege artis*). *Lege artis* operating condition includes all actions taken by a doctor in relation to a patient, either in prophylaxis, diagnosis or rehabilitation, as well as in causative and symptomatic treatment[178].

This state of affairs has its foundation in Article 4 of the Act on the Profession of Physician and Dentist[179], according to which a physician has a duty to practice his profession *according to the current medical knowledge, methods and means of*

[173] Rejman, G., *op. cit.,* p. 184.

[174] *Cf.* Rutkowski, S., *op. cit.,* p. 76; Fiutak, A., *op. cit.,* p. 82; Zoll, A., *op. cit.,* pp. 71–73.

[175] Fiutak, A., *op. cit.,* p. 82.

[176] Tołłoczko, T. 'Błąd lekarski. Spojrzenie kliniasty', Prawo i Medycyna, No. 5(2000), p. 53; Rutkowski, S., *op. cit.,* p. 77; Fiutak, A., *op. cit.,* p. 83; Marek, A. 'Prawo karne', C.H. Beck, Warszawa 2009, pp. 91–100.

[177] Sawicki, J., *op. cit.,* p. 11.

[178] Daniluk, P. 'Błąd w sztuce lekarskiej – wybrane problem, No. 4(2004), p. 45.

[179] The Act on the Profession of Physicians and Dental Practitioners of 5th December 1996 (Journal of Laws 08.136.857).

*prophylaxis, diagnosis and treatment available to him, in compliance with the rules of professional ethics, and with due diligence*.

Failure to adopt the principles of knowledge and medical art results in the doctor's unlawful behaviour, which manifests itself in the form of 'medical malpractice'.[180]

Legal and medical interpretation of this concept is not uniform. It is proven by the fact that the authors of medical-legal studies use terms such as 'medical malpractice', 'medical error', 'medical art error' or 'problem of medical knowledge' interchangeably. It seems that the term 'medical malpractice' is broader than the others, because it also applies to professionals who are not doctors, which, in particular, can include nurses or obstetricians[181].

### 3. Medical error definitions in literature and jurisprudence

The doctrine provides various definitions of the above mentioned terms, which are characterized by divergent views[182]. The difficulty of providing one common definition arises from the fact that these concepts are present both in the literature of criminal law, case law and judicial practice, medical literature and in everyday language. It should also be noted that the concept of medical malpractice (medical error) is not defined in the Polish legislation and only the doctrine and the case law provide for its interpretation[183].

It should be noted that there are ongoing, fierce debates on the doctrine concerning the definition of an 'error' in view of the doctor's criminal liability for failure in treatment.

A. Liszewska defines medical malpractice as "a violation (knowingly taking medical action) of the principles of professional conduct that bind the doctor in the particular case and are developed on the basis of professional knowledge and practice related to legal interests concerning human life and health, which under the law constitute the basis for acknowledging the failure to provide the required standard of care."[184]

L. Wachholz, however, contends that an error in medical art is "unintentional body injury or deprivation of life of a patient [...] as a result of unawareness of the rules of art or negligence and that error can only be regarded as culpable if it was apparent and could have been avoided by the application of ordinary and not extraordinary knowledge or skills"[185].

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[180] Daniluk, P., *op. cit*, p. 45.

[181] Fiutak, A., *op. cit*, p.73; See Dyttus, E., *op. cit.*, p. 145.

[182] Świątek, B. 'Błędy lekarskie w praktyce medyka sądowego', Prawo i Medycyna, No. 5(2000), p. 39.

[183] Kędziora, R., *op. cit*, p. 192.

[184] Liszewska, A. 'Odpowiedzialność karna lekarza za błąd w sztuce lekarskiej', Zakamycze, Kraków 1998, p. 28 (as cited in) Fiutak, A., *op. cit.,* p. 73.

[185] Marek, Z., *op. cit.,* p.34.

According to B. Popielski medical malpractice is a term that continues to appear in legal language due to its presence in the judicial practice and the case law of the Supreme Court, although it is not defined in the code[186].

T. Tołłoczko defined malpractice from the viewpoint of the everyday medical experience of a patient and his family as "a mismatch between the reality and expectations […] everything that does not match the representation and expectation may be understood by a patient and his family as an error, and expectations always exceed the reality and capabilities"[187].

In order to make the concept of error more specific, the Supreme Court in one of its judgments stated that: "An error in medical art is an action (or omission to act) by a doctor in relation to diagnosis and treatment, contrary to medical science to the extent available to a doctor. Neglecting by a doctor a duty to provide patient with care and hygiene safety is not an error in the art of medicine"[188].

One can advance a thesis that the change of the above mentioned terms is unjustified, as in the majority of the doctrine, the case law and everyday language the terms of medical malpractice or medical error are used interchangeably.

Therefore, one can agree with the view of R. Kędziora, who states that the term 'malpractice' and 'medical error' may be used interchangeably, though it should be noted that 'malpractice' is a wider term since, apart from doctors, it may be committed by other medical staff while 'medical error' is limited only to a doctor.

The above definitions of medical error have been developed by theorists.

### 4. 'Medical error' perception among judges and prosecutors environment

I will now present the results of a survey conducted by M. Legienia and M. Kubka in the circle of judges and prosecutors working in the first instance and the appellate court. The survey concerned the issue of medical error, but the author, for the purposes of this article, drew attention to the part related to the definition of 'medical error'.

The answers have been gathered from 78 surveys, including 24 (30.8%) judges and 54 (69.2%) prosecutors 67 of which (85.9%) represented the first instance and 11 (14.1%) the second instance. Average seniority of respondents is 11 years of professional practice. Respondents had to choose from three different definitions of medical error:

1. as much as 35 (44.9%) of the respondents chose the option 'actions in conflict with the basic medical knowledge'

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[186] Popielski, B. 'Odpowiedzialność lekarza. Pogranicza etyki i prawa' [In] Wybrane zagadnienia z etyki i deontologii lekarskiej, ed. Kielanowski, T., Państwowy Zakład Wydawnictw Lekarskich, Warszawa 1980, p. 113.

[187] Tołłoczko, T., *op. cit.,* p. 49.

[188] Decision of the Supreme Court of 1st of April 1955 (IV CR 39/54), OSN 1957, Item 7.

2. only nine (11.5%) respondents stated that it is „action in conflict with the basic medical knowledge and the principles of medical ethics"

3. as much as 31 (39.7%) respondents shared the view that it is „an action in conflict with the basic medical knowledge, principles of medical ethics and commonly accepted rules of clinical practice in various medical facilities"

4. only 7 (9.0%) respondents provided their own definition e.g. medical malpractice is a culpable action.

Only 19 (24.3%) respondents considered terms 'doctor's error' and 'medical error' as identical and 50 (64.1%) respondents believed that these are distinct concepts. In addition, they gave a number of definitions on their own such as 'the doctor's malpractice is the doctor's error, and the medical error is an error of a team of doctors', or 'medical malpractice is a violation of the rules of caution'.

The authors of the study indicate that the survey results reflect diverse level of legal practitioners' knowledge on medical error. In some cases, there is also the apparent similarity between the definition of doctor's or medical malpractice and definitions functioning in the literature[189].

Generally, the causes of medical errors include: wrong interpretation of symptoms, undertaking therapeutic actions by individuals without appropriate competences, unjustified delay in carrying out surgery, under-utilization of available diagnostic methods, application of wrong pharmacological treatment and wrong organization of hospitals[190].

## 5. The evidence from an expert in the criminal proceedings

At this point, it seems appropriate to analyze the evidence from an expert in the criminal proceedings, which is the key issue of this study.

The court-appointed medical expert plays an important role in the hearing of evidence as a subsidiary body of the judiciary. In the literature, attention is paid to the expert, his character or behaviour, and - more importantly - his role in court. J. Olbrycht presented valuable comments related to the expert. He wrote: „Opinion is not and cannot be a war of textbooks. The expert draws on his/her own knowledge and experience and his line of thought is based on typicality, but does not forget about the possible exceptions". „If an expert has doubts, he/she must have courage to say «I do not know»". „Expert's confidence when expressing opinion is sometimes inversely proportional to his knowledge".[191]

[189] Legień, M., Kobek, M. 'Problematyka błędu lekarskiego w ocenie sędziów i prokuratorów', Prawo i Medycyna, No. 8(2000), pp. 67- 69.

[190] See more Świątek, B., *op. cit.,* pp. 43-45; Fiutak, A., *op. cit.*, pp. 74–75.

[191] Marek Z., '"Nie można wykluczyć, że…" – Rozważania o opiniowaniu', Archiwum Medycyny Sądowej i Kryminologii, No. 2(1992), p. 98.

In order to determine whether the actions of a doctor can be considered medical malpractice (violation of rules *lege artis*) one has to use the expertise (specialized knowledge). Such knowledge is in possession of experts, whose job is to issue a medical opinion. According to Article 193 § 1 of the Code of Criminal Procedure (k.p.k.)[192] „If the assertion of circumstances crucial for resolving the case requires specialist knowledge, one shall consult an expert or a panel of experts". A similar viewpoint is expressed by the case law: the Supreme Court in its judgment of June 2, 2003[193] indicated that „… The task of an expert is to provide the court, on the basis of professional know-how and work experience, with information and facts necessary to ascertain and evaluate the circumstances of the case. The expert's statements that exceed the scope ordered by the court and his statutory tasks shall not be considered as evidence…" However, the Court of Appeal in Katowice in its judgment of January 6,1992[194] stated that „…the difference between an evidence from an expert and other type of evidence is that its purpose is not to determine the facts relevant to the case, but to provide explanations to the court in matters requiring specialist knowledge. Therefore, an expert does not have to substitute the court in clarifying the real meaning of all factual relations …"

### 6. Term 'matters requiring specialist knowledge' criminal procedure on medical error

It should also be noted that the Polish legislator does not define the expression 'matters requiring specialist knowledge', however, without a doubt, it can be classified as a 'piece of knowledge' beyond the range of information of an average person. This may include fields of science in which opinions are given in court, such as forensic medicine, psychiatry and psychology, as well as criminology in a broad sense (e.g. fingerprint examination, osmology or mechanoscopy). The 'specialist knowledge' should also include the skills that allow the expert to practice even without the specialized training, on condition that such skills were acquired through practice i.e. by mastering a skill.[195] The 'specialist knowledge' referred to in Article 193 of the Code of Criminal Procedure (k.p.k.) is not the knowledge of the science of law, which is a domain of the judge. The specialist knowledge is known only to specialists in the particular field (in this case to doctors) who acquired it through education and long-term practice[196].

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[192] Act of 6th June 1997, Code of Criminal Procedure (Journal of Laws, No. 89, item. 555 as amended).

[193] Judgement of the Supreme Court of 2nd June 2003(IV CKN1763/00, LEX No. 78280).

[194] Judgement of the Court of Appeal in Katowice of 6th January 1992 (I ACr 225/92OSA, 1993/1/2).

[195] Widła, T. 'Ocena dowodu z opinii biegłego', Uniwersytet Śląski, Katowice 1992, pp. 12 – 13.

[196] Turek, J. 'Dopuszczenie dowodu z opinii biegłego' [In] Rola biegłego we współczesnym procesie, ed. Turek, J., Wydawnictwo Zrzeszenia Prawników Polskich, Warszawa 2002, pp. 11 – 12.

According to the judgement of the Supreme Court of July4,1933[197], the 'specialist knowledge' within the present meaning of Article 193 § 1 of the Code of Criminal Procedure *is not the facts known to an adult human with appropriate life experience, education and knowledge*.

According to the applicable regulations of the Code of Criminal Procedure, apart from an expert, every person known to have adequate knowledge of the subject has an obligation to act as an expert (Article 195 of the Code of Criminal Procedure). Comparing Article 193 and Article 195 of the Code of Criminal Procedure one must agree with J. Kunz who claims that the latter is imprecise for the purpose of the criminal proceedings related to medical error, because in the lawyers' understanding every doctor may be considered to be such a person. He also indicates that the list of skilled experts in the field of forensic science is not extensive and for that reason physicians with various specialties are appointed as experts.

### 7. Categories of medical experts appointed by the court

J. Kunz distinguishes three categories of medical experts appointed by the court. These are:

1. forensic medicine specialists at university departments of forensic medicine or medical facilities located at voivodeship hospital complexes
2. experts from the lists of regional courts which means that if a physician is registered in the court he/she automatically becomes an expert in the proceedings involving the medical expert's opinion.
3. experts appointed *ad hoc,* separately for each case, upon a decision of the prosecution or court[198].

It should be noted that errors in opinions are most frequently committed by the untrained experts, appointed ad hoc, but also by clinicians, because they do not know the strict rules for issuing opinions, applicable in the criminal proceedings, in which there is no place for supposition, analysis and reasoning. The clinicians are eminent specialists in the specific subject they deal with, but do not know the rules for issuing opinions in court. These doctors do not fully understand that forensic medicine is a separate medical specialty requiring not only vast knowledge, but also experience and knowledge of legal principles[199].

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[197] Decision of the Supreme Court of 7th April 1933, K.136/33.

[198] Kunz, J. 'Błąd w opiniach sądowo – lekarskich w sprawach przestępstw przeciwko życiu i zdrowiu', Prawo i Medycyna, No. 3(2004), p. 59.

[199] Marek, Z., Kłys, M. 'Opiniowanie sądowo- lekarskie i toksykologiczne', Zakamycze, Kraków 2001, pp. 144–145.

However, it is not a mistake to say that errors made by clinicians are not culpable. The basis for this assertion is that clinicians and medical experts have different ways of thinking. In practice, it is assumed that the main task of a medical expert is to adhere to the rules applicable to forensic medicine[200].

To resolve doubts related to the position of clinicians in the criminal proceedings in the cases of medical malpractice, it should be noted that according to the original principles, the Head of Forensic Medicine Chair should supervise the issuing of a medical opinion in the court. It may authorize the panel of clinicians to participate in the proceedings and their specialty fields may be used in the specific case. It is generally thought that opinions on medical errors committed by doctors should be issued by specialists having an academic title. Doctors without the title can act in the proceedings as 'reporters'[201].

Good practice of selecting the panel of experts should be based on avoiding the choice of specialists working in same medical unit that the accused doctor works (worked).[202] Z. Marek indicates in his work that "It is not an isolated phenomenon, that in almost every case the accused doctor finds an 'expert' who will defend him. Such defence, combined with dramatic straining of facts, deserves to be treated as an error in opinion giving. We even know cases where allegations of deliberate fraud of an expert were justified."[203] J. Olbrycht rightly points out that " in such cases the expert doctor must, on the one hand, often act against his colleague - a doctor and on the other hand, be careful not to expose himself to public allegation of being too loyal to his colleague[204].

Discussing the relation between the expert and the physician it is worth noting that they share a common feature, which is the ability to obtain information, which is important in the given case. The rules of interpretation only slightly differentiate their positions, as the physician, who takes into consideration the needs of treatment, has more tolerant approach to treatment methods, while medical expert takes more restrictive position in this regard. The third element, which completely differentiate the way of their is the rule of inference[205].

In conclusion, it would be reasonable, if a panel of experts, preparing a medical opinion for the court, consisted of both clinicians, who have vast knowledge in the particular field of medicine, and expert doctors. The clinicians with the skilful use of

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[200] Gromadzki, C. 'Rola biegłego w „procesach lekarskich"' [In] Rola biegłego we współczesnym procesie, ed. Turek, J., Wydawnictwo Zrzeszenia Prawników Polskich, Warszawa 2002, pp. 45–46.

[201] Marek, Z. 'Wybrane problemy opiniowania sądowo – lekarskiego. Podręcznik dla prawników i lekarzy', Zakamycze, Kraków 2004, p. 137.

[202] *Ibidem*, p.138.

[203] Marek, Z. 'Błąd…', *op. cit.*, p. 85.

[204] Olbrycht, J.S. 'Wybrane przypadki z praktyki sądowo – lekarskiej', PZWL, Warszawa 1964, p. 276.

[205] Jaegerman, K. 'Opiniowanie sądowo- lekarskie (Eseje o teorii)', Wydawnictwo Prawnicze, Warszawa 1991, pp. 28–29.

their knowledge would ensure that the prepared opinion is correct as far as the merits are concerned, while the forensic doctors' task would be to ensure that the opinion has been prepared in compliance with the applicable regulations and formal requirements. Therefore, it is legitimate and beneficial for the criminal proceedings in the cases of medical malpractice to create the panel of experts.

### 8. Expert opinion criminal procedureon medical error

Another issue, closely related to the institution of court-appointed medical expert, is the opinion he prepares.

Before I take a closer look at the problem under discussion here, it should be noted that in accordance with the applicable provisions of the Code of Criminal Procedure, the prosecutor or the court may issue a decision to admit the evidence from an expert, which should specify, among others, name, surname and specialty of the expert, subject matter and scope of opinion and, if necessary, specific questions and the time of delivering the opinion (Article 194 of the Code of Criminal Procedure). This decision forms the basis of an expert opinion as it outlines the circumstances to be proved in the related opinion[206].

The provisions of the Code of Criminal Procedure provide for the guidelines that should be followed by an expert preparing the opinion. These, apart from persons or institutions who/which participated in preparing (were preparing) the opinion, should include the time line of the studies carried out and the date of issuing the opinion, a report on the activities, observations and conclusions derived, as well as signatures of all the experts who participated in the preparation of the opinion (Article 200§2 of the Code of Criminal Procedure). The above provisions constitute only the general framework for such wide subject matter as an expert opinion.

In the literature, a medical expert opinion is defined in different ways.

J. Kunz writes that "... the medical expert opinion is nothing but a search of compliance or lack thereof between the results of biological and medical observations and hypotheses arising from the inspection and investigation. In short, the medical expert opinion is the set of expert's conclusions resulting from properly planned and carried out research, proper recording of observations, knowledge of the case file that constitutes a basis for devising hypotheses"[207]

K. Jaegerman believes that "... a perfect medical expert opinion is a document that based on the resource of information and its interpretation allows to explain a piece of reality important from the legal point of view. (…) Full implementation of all the three elements that constitute a model medical expert opinion is assumed. These are:

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[206] Drzewiecki, A. 'Błędy pozwanych jednostek ochrony zdrowia w sprawach o zakażenia szpitalne', LIBRA PL, Rzeszów 2012, p. 42.

[207] Kunz, J., *op. cit.*, p. 40.

a) cognitive research that constitute the basis for creating a resource of information, b) an interpretative analysis in view of the knowledge of typicality, as well as knowledge about the efficiency of the applied methods, and finally c) reaching a conclusion with caution to the requirements of applicable law and in accordance with the principles of law".[208] Giving expert opinions aims to serve the justice. At this point, the expert is required to know how to apply the law[209].

Expert opinions in the medical malpractice cases take a special place among the opinions issued for the purposes of legal proceedings as their subject matter is to evaluate whether the physician's actions were consistent with the principle of *lege artist*[210].

Based on the knowledge and experience of experts the final result must also be logical and there should be applied the principles of cause and effect thinking. It should be emphasized that the opinion made by an expert (experts) pursues the lawyer's objective reflected in the questions listed by the ordering authority[211].

T. Cyprian and P. Asłanowicz indicate that the main task of an expert in the criminal cases is to determine whether a physician, against whom a statement of offense was filed, committed malpractice. In order to perform the task, the medical expert must answer the following questions:

„1. Whether a detriment to health or death have a causal link with the treatment applied by a doctor?

2. Are or could these negative consequences be the result of other causes?

3. How certain it is that a different treatment would not lead to similar consequences?

4. If the treatment conditions were better than those in which the doctor had worked, could the harmful consequences be avoided even if the same wrong methods of treatment have been applied".[212]

A slightly different set of questions, being a model for assessing the proper medical procedure, is derived from Z. Marek. According to it, a doctor should:

1.evaluate *ex ante* how the doctor comprehended the situation and how he assessed the circumstances and the possibility of providing help

2. establish whether the doctor in the particular situation did 'everything he could and should do' for a patient – i.e. did he use all available or possible measures to provide aid

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[208] Jaegerman, K. 'Opiniowanie…', *op. cit.*, pp. 23–24.

[209] Kunz, J., *op. cit.*, p. 38.

[210] Baran, E. 'O wydaniu opinii w sprawach o błąd lekarski w postępowaniu karno–sądowym', Archiwum Medycyny Sądowej i Kryminologii, No. 3-4(1998), p. 221.

[211] Kunz, J., *op. cit.*, p. 40.

[212] Cyprian, T., Asłanowicz, P. 'Karna i cywilna odpowiedzialność lekarza', Księga Wydawnicza Dr L. J. Jaroszewski, Kraków 1949, p. 67.

3. establish whether he used the required level of knowledge, or knowledge corresponding to the knowledge contained in the then current instructions for doctors (specialists)

4. establish if the doctor observed the required standard of care when providing first aid. Were further decisions concerning the patient correct?

5. establish whether he could diagnose correctly (save, heal) had he done 'everything what he could and should do in the situation', and if not, why.

6. establish what errors he made, what was the nature of the potential error and what were the negative effects of this error to the health or life of the patient"[213].

The above are the exemplary catalogues of issues and questions that may be the subject of a medical expert opinion. The catalogues differ from each other in the scope of the subject matter and the volume. This shows that no one should generalize the criminal proceedings in the cases of medical malpractice, because all proceedings are different, one of a kind. Forensic experts in each case can obtain a different 'set of questions' from judges. Answering these questions, based on the provided evidence, results in issuing an expert opinion – which is the essence of their work.

An expert giving his opinion in the particular case of medical malpractice is not always able to prepare the opinion in accordance with the principles of objectivity and fairness. It is usually caused by incomplete and unclear evidence material which contains only explanations of the defendant, or medical records made by him. Patients who claim that the doctor committed malpractice should be personally examined by a medical expert, and the results of these examinations should complement the medical records of the case. Individuals preparing the medical opinion should not only carefully check the patient's state of health, but also analyze the pre-and post-event treatment[214].

One of the reasons why expert opinions are sometimes inconsistent with the truth, is insufficient amount and quality of the evidence material. Sometimes, experts have incomplete medical records, incorrectly prepared autopsy protocol in which, for example, an error made by an operator was not stated. Often, the case files made available to the experts contain the witness statements that are mutually exclusive. Despite the contradictions related to the object and subject of the opinions prepared by medical experts, they should be subject to comprehensive, critical evaluation of the trial court, who should use all procedural remedies to eliminate the existing defects[215].

The authority ordering a medical opinion is obliged to ensure that the entire history of illness is included in the documentation. These includes all stages of treatment, laboratory tests, X-rays, records of autopsy and surgical procedures, as well as the doctor's records documenting prescribed medications and recommendation for additional tests.

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[213] Marek, Z. 'Wybrane…', *op. cit.*, p. 137. *See*: Marek, Z. 'Błąd…', *op. cit.,* pp. 114 – 115.

[214] Marek, Z. 'Wybrane…', *op. cit.*, p.138.

[215] Gromadzki, C., *op. cit.*, p. 46–47.

If the patient was treated in several medical institutions or was referred to other hospitals or other departments, medical records of procedures carried out in the indicated units should also be attached to the case file[216].

Lack of a complete medical record may hinder the preparation of a proper medical opinion that is in accordance with requirements, reduce the efficiency and extend the time of achieving the goal.

The purpose ordering a medical opinion by the court is to determine whether the doctor violated the canons of current knowledge and medical practice in his actions, and thus, whether he committed medical malpractice. In order to obtain a comprehensive opinion, clear and understandable for both parties to the proceedings and the court, the expert must prepare it according to the established principles, which should include the principle of impartiality and the principle to stay within the court's question. Preparing a medical opinion one should also be aware that the parties to the proceedings, as well as the court, do not have scientific knowledge of medical issues.

Z. Marek indicates that, in practice, clinicians defend the accused doctor. Therefore, the objectivity of the trial should be supervised by a forensic medicine expert provided that he has at least general clinical knowledge, authority among co-experts and the ability to notice and determine unequivocally whether the defendant did make an error or not[217].

## 9. Conclusions

In conclusion, it should be noted that today medical and legal science complement each other in the quest for eliminating or minimizing the occurrence of medical errors. Its specific nature affects many fundamental matters. Diligent application of knowledge, gained during medical or legal studies, should minimize the rate of errors made by doctors, medical personnel, as well as lawyers in the field of preventive medicine, legal prevention, diagnosis, treatment or rehabilitation.

It should also be noted that the major problem, associated with criminal liability of a doctor for medical error, is also the hearing of evidence, which in the cases against doctors is extremely difficult, because the persons with 'specialist knowledge' usually have 'scant' evidence available on the basis of which they are required to deliver an opinion.

The issue of medical malpractice and issuing the related opinions was and will certainly be the subject of many debates in legal and medical circles. The basic principles of medical knowledge and art should be applied at each stage of treatment[218]. It is worth emphasizing that the knowledge of doctors, regarding medical error, should not be

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[216] Baran, E., *op. cit.*, p. 223.

[217] Marek, Z. 'Wybrane…', *op. cit.*, p. 150.

[218] Daniluk, P., *op. cit,.* p. 57.

limited to medical issues only. Such behaviour of medics causes a lot of controversy in legal circles, and frequently, among doctors[219].

Finally, it is worth noting that a doctor should also bear disciplinary and moral responsibility in addition to criminal or civil liability for medical malpractice. The primary obligation of a doctor carrying out medical procedures is to act according to the Act on the Profession of Physician and Dentist, the other related acts, as well as the Medical Code of Ethics.

[219] Efir, M. 'Błąd lekarski – aspekty prawne', Dermatologia Praktyczna, No. 2(2009), Vol.I, p. 88.

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# IV. CRIMINAL LIABILITY OF A PHYSICIAN IN THE POLISH LAW. SELECTED ISSUES[222]

## 1. Physician's liability for failing to render assistance

The limits of physician's liability for failing to render healthcare assistance have been paid great attention to in the doctrine of criminal law. Obviously this issue has also been taken up in the jurisprudence. In brief, the core of the matter lies in answering the question to what extent legal norms read from provisions other than Article 162 of the Penal Code[223] (hereinafter abbreviated as PC), which provides the ground for liability for failing to render (omission of) medical assistance, modifies the scope of physician's criminal liability for failing to render medical assistance (omission)[224]. It includes both the issue pertaining to modification (broadening) of liability within the legal qualification of failing to render assistance (art. 162 PC), as well as the problem of attributing the effect of unlawful nonfeasance (omission) to a physician, which causes that his/her conduct becomes an offence with the attributed effect against life or health (with criminal consequences).

Thus, the paper shall consider two significant problems. First of all, a potential influence of AMP on the scope of the criminal liability of a physician. Then, a possibility of interpreting Article 30 AMP as a norm creating a guarantor's duty within the meaning of Article 2 PC. In addition, at the end of the thesis the issue of the protection of patient's autonomy by the criminal law will be considered.

The first issue requires considering, whether Article 30 of the Act on the Medical Profession[225] (hereinafter abbreviated as AMP) functions in a way as a 'compound' of criminal liability of a physician in the sense that it also penalizes omission in situations,

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[222] The following chapter is partly derived from the study by Górski, A. 'Prawnokarne problemy określania relacji lekarz – pacjent z uwzględnieniem orzecznictwa Sądu Najwyższego (kwestie ogólne)', Studia i Analizy Sądu Najwyższego, Vol. VI (2012), pp. 309–331.

[223] The Penal Code (Act of 6 June 1997).

[224] See also Kwiecińska, K. 'Lekarski obowiązek udzielenia pomocy, a prawo pacjenta do samostanowienia na tle uregulowań kodeksu karnego z 1997 r.', available at: http://www.prawoimedycyna.pl/?str=artykul&id=182, (23 December 2013).

[225] The Act on the Medical Profession (Act from 5 December 1996).

when a person other than a physician would not bear any criminal liability. Article 30 of AMP, which provides the basis for a professional duty to render medical assistance, expresses a wider obligation than the one provided in Article 162 PC[226], namely, to render assistance in eachcase, where a delay would result in death or grievous bodily harm. The legal duty to act, understood in this way, would also bring about penalising the professional medical actions (omissions) which require sacrificing analogous legal interest (life or health of a physician).

Continuing the first issue (modifying features of the offence of failure to render assistance), one ought to answer the question what is the relationship between the above-mentioned provisions of AMP and Article 162 PC? Dependence of *lex specialis* is debatable to the extent that Article 30 AMP does not regulate special (including qualified or privileged) criminal liability. It is not a subject to any further discussion that the legislators, providing the basis for criminal liability, should specifically refer to other legal provisions being a source of sanctioned obligation, which they have not done in this case.

The thesis that the duty to render medical services under Article 30 AMP does not influence obligations of criminal law, is also supported by principles of criminal law, including the *ultima ratio* principle (regulating legal relations only when necessary and leaving other situations to be regulated by other areas of law[227]), and by definite character of offence features (elements). The last statement means that an addressee of a legal norm must clearly know the scope, within which his/her conduct is liable to criminal sanctions.

Precising the scope of criminal liability of a physician for failure to render (omission of) medical service (assistance) has never been done by any general reference to the content of the Act on the Medical Profession.

It also seems that such a solution, if chosen by the legislator, would contradict the proportionality principle as a constitutional principle for law making.

This last statement becomes even more convincing when we note the fact that Article 30 AMP would extend the scope of criminal liability for failure to render medical assistance by solving the conflict of interests, which the criminal-law legislators leave to the general rules, codified in Article 26 PC.

Furthermore, the valuation of life and health of a physician and a patient itself may not be easily compared with the valuation of health and autonomy of will of a patient alone. The latter valuation (of life, health of a patient and his/her freedom) is being done within different legal interests.

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[226] Kwiecińska, K., *op. cit.*

[227] On this subject see Zoll, A., Wróbel, W. 'Polskie prawo karne część ogólna', Kraków 2010, pp. 25-26.

There are no prevailing arguments, which would decide on the matter of interests superiority mentioned above, which are absolutely equivalent by definition, from the constitutional point of view. It must, therefore, be stated that failure to perform medical assistance, in the case when equivalent interest of medical personnel (a physician and a nurse), who has a duty to do it, is threatened, decides exclusively about their liability in the professional sphere, not affecting the scope of criminal liability[228].

It is worth noting that regarding Article 30 AMP as a norm adding precision to the scope of punishable (omission) failure to render assistance by a physician may also provide supporting arguments for a thesis that Article 30 AMP creates a guarantor duty (duty to act) within the meaning of Article 2 PC[229], sayingthat **'**Penal liability for an offence with criminal consequences committed by omission shall be incurred only by a person who had borne a legal, special duty to prevent such a consequence'. This line of interpretation is pronounced by court's jurisprudence[230].

If guarantor's duty (specific legal duty to prevent consequences) results from the Act on the Medical Professions, is it possible to interpret the time-situation limit of the duty from the context of the whole act?

It does not seem possible to find such limit from the general statement of Article 1 of AMP, stating that 'The act defines the principles and terms of practicing the physician profession'.

Above all, making 'profession practicing' (broader notion, scope) and 'work performance' (narrower notion, scope) equal is debatable. In consequence, the legal duty to act would extend beyond work performance and cover ' everyday situations'.

For these reasons, the specific legal duty to prevent consequences, provided for in art. 2 PC, is rooted in and restricted only to labour law obligations of a physician. Strictly speaking, it shall not be extended to everyday situations[231].

As far as AMP is concerned, the issue of criminal law valuation of non-performance (omission) by a physician is not fully explained in Article 30. It would be equally essential to establish the relation between other legal norms and the obligation to provide medical services. Above all, it pertains to the conscience clause, defined in Article 39 of AMP. The provision runs as follows: 'A physician may refrain from providing medical

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[228] See Górski, A. 'Leksykon prawa medycznego', Warszawa 2012, p. 114.

[229] See Kubicki, L. 'Obowiązek udzielenia pomocy lekarskiej', Prawo i Medycyna, No. 13(2003), p. 16; Boratyńska, M., Konieczniak, P. 'Prawa pacjenta', Warszawa 2001, pp. 461-462; in a different manner: Zielińska, E. 'Odpowiedzialność zawodowa lekarza i jej stosunek do odpowiedzialności karnej', Liber, Warszawa 2001, pp. 354-355; Buchała, K. 'Niektóre prawno-karne problemy nieudzielenia pomocy przez lekarza w aspekcie postępu w medycynie', Przegląd Lekarski, No. 3(1972), p. 379; Filar, M 'Odpowiedzialność karna lekarza za zaniechanie udzielenia świadczenia zdrowotnego (nieudzielenie pomocy)', Prawo i Medycyna, No. 3(1993), p. 36.

[230] See reasons for Judgment of Supreme Court of September 27, 2010, V KK 34/2010 (Krakowskie Zeszyty Sądowe 2011/1, Vol. 13).

[231] Such a view was also expressed by Kulesza, J. in 'Źródła obowiązku gwaranta a odpowiedzialność karna lekarza za zaniechanie pomocy', Prawo i Medycyna, No. 1(2008), pp. 14-25.

services incompatible with his conscience, subject to the provision of Article 30, but he is under obligation to indicate realistic possibilities for getting these services from another physician or in other healthcare unit and recording this fact in the medical documentation. A physician pursuing his profession under contract of employment, or within a service has an additional duty to inform his superior beforehand'[232]. This right does not constitute lawful justification for special rights, which could have an effect on the criminal liability of a physician for an offence under Article 162 of PC. It is because an amendment to physician's duty to provide medical services, regulated in Article 30 of AMP, excludes a possibility of physician's refraining from providing medical services for reasons related to his/her conscience[233].

Professional duties of medical staff are also in clear relationship with the offence of failure to render assistance by a physician. The law should precisely specify these duties, but at the same time, it has a very difficult role in ensuring freedom of choice for medical staff. The latter involves making the choice ethically acceptable to a physician, but on the other hand, ensuring professionalism of the treatment process. The majority of these situations are decided against a background of necessity considered as a legal institution. It will always be considered in the case of choosing to render assistance necessary to save life or health. The 'valuation', particularly in the situation of limited means, may be done on the basis of conflict of interests, which is, in fact, variety of necessity.

By failing to render assistance, we understand medical staff not undertaking professional actions aimed at saving life or health. Although Article 162 § 2 of PC says about medical assistance, there are no doubts that it consists in therapeutic activity. In practice, the therapeutic goal of a given action is a matter of controversy. At this point, we should mention the way, in which defining a therapeutic action has far-reaching legal effects. In the criminal-law doctrine, there is a prevailing view that therapeutic actions are physician's primarily lawful action, and not a lawful excuse[234]. If we assume that the action is therapeutic, then the basic criterion of its legality will consist in professional correctness (acting *lege artis*), while an issue of lack of consent will be considered in relation to illegality i.e. in the context of unlawful exposure to risk or infringing the freedom of a human being to make an autonomous decision. Deeming an action to be therapeutic will automatically and primarily be associated with legal justification of (increased) risk, if the action was undertaken *lege artis*. The situation occurs when a medical professional undertakes an action aimed at restoring health and stopping disease, posing the least possible health risk to the person subject to treatment. Since actions aiming at protecting and saving legal interests other than life and health are

[232] For the subject of this legal institution, see Kubicki, L. 'Sumienie lekarza jako kategoria prawna', Prawo i Medycyna, No. 4(1999), pp. 3-15; Zielińska, E. 'Klauzula sumienia', Prawo i Medycyna, No. 13 (2003), available at: www.prawoimedycyna.pl.

[233] See more in Górski, A. 'Leksykon prawa medycznego', Warszawa 2012, pp. 78-79, compare also with Zielińska, E. 'Klauzula…', *op. cit*.

[234] E.g. Zoll, A. *op. cit.,* pp. 6–16; Filar, M., *op. cit.,* p. 94.

regulated by the criminal law to a smaller degree, the increased risk involved in these non-therapeutic actions is not that easily justified in legal terms. Recently, the Caesarean section has been a controversial health benefit (within the broadest meaning of this term), subject to legal analysis in relation to doctrine, without the implied meaning of being therapeutic. Elimination of excessive pain in medical procedures should be simply regarded as a therapeutic objective[235]. However, in the case when welfare (life and health) of a child is involved, the Caesarean section without therapeutic meaning should only be accepted as an alternative to natural birth, when there is no slightest additional risk to life involved – of both mother and child. Despite the views presented in the doctrine, such action of a physician can hardly be regarded as particularly therapeutic. The contentious issue is not whether these interests (life and health of the mother and the child to be born) are in any legal conflict, but if protection of interest of the child to be born is judged on the basis of legal protection of human being or conceived life.

## 2. Protection of patient's autonomy by the criminal law

One may say that the situations where physician's conduct is evaluated in terms of criminal law are somehow in a contraposition to the other situation, where we have to consider the relationship between omission of treatment and assessment of patient's will[236]. Obviously, the legal line*s* between an action of a physician, aimed at protecting life and health, and a prohibited medical intervention without patient's consent must be precisely delineated, not only because of the lex certa principle. Here, the preciseness is motivated by proper practice of a public trust profession. The 'basic' provisions, which constitute legal norms liable for imposing sanctions, are not formulated in a way that will enable unambiguous understanding of the sanctioned sphere of conduct. Thus, it is not clear what kind of physician's conduct (or other medical worker) is a breach of patient's rights, regulated by the civil code and also what the conduct (act) is within the scope of the criminal law.

This vagueness is caused by several factors. Above all, there is a controversy pertaining to the question whether a misdemeanour consisting in performing medical intervention

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[235] For this subject see Zielińska, E. 'Zabieg cesarskiego cięcia a autonomia kobiety i wolność lekarza do decydowania o sposobie postępowania medycznego' [In] *Gaudium in litteris est*. Księga Jubileuszowa ofiarowana Pani Profesor G. Rejman z okazji osiemdziesiątych urodzin, eds. Gardocki, L., Królikowski, M., Walczak-Żochowska A., Warszawa 2005, p. 341 and following. For some legal issues of Caesarean section see also Judgment of Supreme Court of October 26, 2006, I KZP 18/06, OSN 2006, Nr 11, poz. 97.

[236] For this subject Zoll, A. 'Zaniechanie leczenia - aspekty prawne', Prawo i Medycyna, No. 5(2000), available at: www.prawoimedycyna.pl.; Zoll, A. 'Stan wyższej konieczności jako okoliczność wyłączająca przestępność czynu w praktyce lekarskiej', Prawo i Medycyna, No. 2(2005), p. 6 and following; Daszkiewicz, K. 'Uchylenie odpowiedzialności lekarza za wykonanie zabiegu leczniczego bez zgody pacjenta', Palestra, No. 11-12(2002). Compare also Judgment of Supreme Court of November 28, 2007, V KK 81/2007 (Krakowskie Zeszyty Sądowe, No. 3(2008), position 6).

without consent is a universal (committed by anyone) or an individual offence. Although the legislator uses the expression 'whoever', we can interpret the subject of this offence as 'the only person who is entitled to perform a medical intervention'[237], despite the literal meaning. Such an interpretation requires a more general overview of offence's features (elements). The basic issues include a question of the scope of legal interests protection. The misdemeanour consisting in performing a medical intervention without consent obviously strikes at freedom of patient's choice.

Under Article 3 § 1 item 4 of the Act of 6th November 2008 on patient's rights and the Spokesperson for Patient's Rights[238], a patient is a person who applies for medical services or who benefits from medical services rendered by a person practicing a medical profession[239]. The Act on patient's rights defines the patient as a beneficiary of medical services. In the most general meaning, it seems that it can also be a person who is a beneficiary of such services provided by a person who is *tempore criminis,* unauthorised to perform this kind of medical activity. It would be irrational to interpret this issue as depriving the beneficiary of using patient's rights. It pertains, above all, to situations where a medical procedure is undertaken by a person deprived of the right to practicing as a professional physician, or by a person who (already) cannot practice the profession for statutory temporal reasons, or who is not yet entitled to practice the profession[240].

In line with the accepted principles of understanding offence elements, it is difficult to do it in a way that would reduce the scope of its regulatory power.

When the issue of the scope of meaning of the misdemeanour consisting in therapy without consent is deliberated in relation to the concept of 'patient', one has to state that using this expression by legislators does not clearly define the range of penalisation. The criminal law, protecting human freedom by introducing this provision, may also do it in the situations where – in an admissible act of paternalism – the law establishes other types of consents, different from the exclusive consent of a patient. In this connection, the 'consent' referred to in the provision is equivalent to the concept of consent used in the Act on the Medical Professions within the context of providing medical services.

Besides the subject matter of the reference, there is the issue of consent to an experiment[241], as the disposition of Article 192 of PC also says about a therapeutic intervention performed without patient's consent, which again may be considered controversial.

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[237] Such a view was expressed e.g. by Marek, A. in 'Kodeks karny. Komentarz', Warszawa 2006, p. 370.

[238] The Act on patient's rights and the Ombudsman for the Patient's Rights (Act of 6 November 2008).

[239] For the subject of patient see more in Górski, A. 'Leksykon prawa medycznego', Warszawa 2012, pp. 142-145.

[240] Compare Górski, A., *op. cit.,* p. 260.

[241] See e.g. Kubiak, R. 'Zgoda uczestnika eksperymentu', Prawo i Medycyna, No. 8 (2000), p. 44 and following; Kubicki, L. 'Medyczny eksperyment badawczy (warunki dopuszczalności w prawie polskim)', Państwo i Prawo, Vol. 7(1998), p. 54 and following.

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# V. COMMISSIONS ADJUDICATING ON MEDICAL EVENTS

## 1. Introduction

Several recent years have brought new legal regulations regarding patients' rights, which were firstly considered only in relation to human rights. Numerous domestic, European and international acts of law made patients' rights the center of interest for governments, organizations, foundations and associations.

The activity of the World Health Organization, development of health systems and easy access to health care services have had a great impact on the development of patient's rights[243]. In 1994, the World Health Organization introduced the Declaration on Promotion of Patients' Rights in Europe (hereinafter referred to as: the **Declaration**). The Declaration constitutes a common European framework for action and should be interpreted as an enhanced entitlement for citizens and patients to improve partnership in the process of care with health care providers and health service managers. According to this Declaration national situations vary in respect of legal frameworks, health care systems, economic conditions, and social, cultural and ethical values, but there are some common approaches, which can be appropriately adapted to the circumstances in each country, related to the following components:

• legislation or regulations, specifying the rights, entitlements and responsibilities of patients, health professionals and health care institutions;

• medical codes and other professional codes, patients' charters and similar instruments, drawn up in the light of common agreements between representatives of citizens, patients, health professionals and policy-makers, and periodically revised in response to changing circumstances;

• networking between and among patients and health care providers, recognizing the distinction between citizen and user participation;

• government support for the establishment and effective management of non-governmental organizations (NGOs) in the field of patients' rights;

• national colloquia and conferences to bring the parties together in order to create and promote the sense of common understanding;

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[243] Nestorowicz, M. 'Prawo medyczne', 9th edition, Toruń 2010, pp. 16-20.

• involvement of the media in informing the public, stimulating constructive debate and maintaining awareness of the rights and responsibilities of patients and users and their representative organs;

• improved training in communication and advocacy skills for health professionals as well as for patients and other users, for further development of a proper understanding of a perspective and role of all parties;

• promotion of researching to evaluate and document the effectiveness of provisions - legal and other, and various initiatives undertaken in different contexts of different countries[244].

The Declaration serves as guidelines that shall be applied in particular countries. The reference can be found in the Polish Charter of Patient's Rights, which was presented and publicized in 1998 by the Minister of Health. Simultaneously, Health Maintenance Organizations (HMO) established the institution of the contemporary Ombudsman for Patient's Rights, which was still present after formation of National Health Fund (**NFZ**). Another step towards protecting and executing patient's rights was establishment of the Office for Patient's Rights in 2002 – under the regulation of the Minister of Health of December 28, 2001, – as a single budget entity and the spokesperson for patient's rights at psychiatric hospitals. All the initiatives mentioned above had limited scope of action, which led to the need of establishing a new institution that would operate in Poland to protect patients' rights, and would be independent from the Minister of Health, NFZ and medical governments.

The need was also indicated in the recommendations, presented at the conference 'Biały Szczyt' on March 19, 2008 – "there is a need of establishing an institution, which would deal with the protection of patient's rights. It would monitor patients' situation in the health care system, represent the public institutions and address public institutions in systemic cases, regarding solutions improving protection and enforcement of patient's rights. It may happen, when the separate, independent institution of the Ombudsman for Patient's Rights is established or when Ombudsman's Insurance activity increases"[245].

It was decided to regard the Ombudsman for Patient's Rights as the central body of governmental administration, competent in cases regarding protection of patients' rights. On November 6, 2008, the Sejm of the Republic of Poland introduced the act on the patient's rights and the Ombudsman for Patient's Rights[246] (hereinafter referred to as **Apr**), which became effective on June 5, 2009. On October 2, 2009, the Prime

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[244] http://www.who.int/genomics/public/eu_declaration1994.pdf.

[245] The website of the Ministry of Health-www.mz.gov.pl
http://www2.mz.gov.pl/wwwmz/index?mr=q101&ms=&ml=pl&mi=&mx=0&mt=&my=0&ma=010277.

[246] Act dated November 6, 2008 on patient's rights and the Ombudsman for Patient Rights (Journal of Laws**,**No. 52, Item 17).

Minister, Donald Tusk, appointed Krystyna Barbara Kozłowska to the position of the Ombudsman for Patient's Rights.

The Apr regulated patient's rights in a comprehensive manner, but we also have to bear in mind other legal regulations in this regard, for example: the act on the professions of physician and dentist[247], the act on health care services financed with public funds[248], the act on medical activity[249], the act on mental health[250].

Patient's position in a society is closely related to the value that health is for every human being. Health determines the relationship between a patient and a physician, who should be an authority on medical issues and his actions should serve to improve health. The physician-patient relationship is not an artificial construct, but its existence determines real facts, such as a fact of illness, profession and healing[251].

Asking about *telos* of treatment it indicates the interest of the whole person: physical, emotional and spiritual[252]. One should keep in mind that a physician usually see people as they really are (as a disease makes it hard to pretend to be someone else, or wear a mask). Since the times of Hippocratic medicine, paternalism grew into primary and the only rule in communication between a patient and a physician. It seems that in such gentle matter as human life and health it cannot be one 'right' position. Patients themselves came to that conclusion, started to ask questions about their health, treatment, and expected results. Moreover, development of medicine, and thus, expansion of health services range has influenced this activity. However, it has also contributed to inequality in access to health care services, dividing people into more and less privileged[253]. It turns out that in case of those who require treatment the most (belonging to disadvantaged group) it isusually less likely that they receive high quality service, often not so much because of inability to pay, but due to other discriminatory factors, such as place of residence, social status or education[254]. In consequence, it is more and more important to improve ability to use the power, encourage free choice in health care, create chances of free use of opportunities associated with it and aim at building mechanisms for the right quality of care[255]. Therefore, the development of patient's rights was a natural

[247] Act dated December 5, 1996 on the professions of doctor and dentist ( Journal of Laws of 2011, No. 277, Item).

[248] Act dated August 27, 2004, on health care services financed with public funds (Journal of Laws, No 164, Item 1027).

[249] Act dated April 15, 2011 on medical activity (Journal of Laws of 2013, Item 217).

[250] Act dated August 19, 1994 on mental health (Journal of Laws, No 231, Item 1375).

[251] Biesaga, T. 'Elementy etyki lekarskiej', Kraków 2006, p. 57.

[252] Pellegrino, E.D. 'The Internal Morality of Clinical Medicine: A Paradigm for the Ethics of the Helping and Healing Professions', Journal of Medicine and Philosophy, No. 26(6) (2001), pp.559-579,

[253] Karkowska, D. 'Prawa pacjenta', Warszawa 2009, pp. 19-26.

[254] Maciejko, P. 'Pojęcie i koncepcje równości w zdrowiu', Antidotum, No. 12(1992), p. 27.

[255] Karkowska, D., *op. cit.,* pp. 24-26.

consequence of changing reality – the medical paternalism was no longer a mainstream and patients gained awareness of their rights and stopped to be only passive participants of treatment process.

## 2. The members of voivodeship commissions adjudicating on medical events

The growing numbers of legal cases have been noticed, due to the development of regulations, which are related to patient's rights in Poland. Moreover, time of waiting for court's decision has been prolonged. Taking the above into account, the Polish legislator decided to reduce the load of common courts of law and introduced the model of extra-judicial way of enforcing claims. It was based on French and Scandinavian experiences. Provincial commissions adjudicating on medical events have been operating in Polish legal order since January 2012. This type of action has facultative and alternative character. The entitled entity has got the possibility of submitting a proposal to commission on adjudicating on medical events or to refer the claim to court. The principles and mode of enforcing claims, resulting from medical events, has been regulated in chapter 13 Apr.

According to Article 67a of Act 3 Apr, the panel of voivodeship commission consists of 16 members (including 8 members with at least a university degree and M.SC or equal in the field of medical sciences, who have been performing profession of a physician for at least 5 years or have PhD in medical sciences; as well as 8 members with at least university degree and M.A in the field of legal sciences and who have been employed on the positions related to law creation or execution or have PhD in legal sciences – who have knowledge of patient's rights and fully enjoy their public rights). It seems that the above mentioned provision gives too much freedom in choosing commission members – for instance, it should be emphasized that a person does not have to graduate from a university in order to perform the medical profession - and if the information from the media is considered to be credible, it occurs that 5 commissions have only three of them, which means that some of the panels will adjudicate without a physician involved[256]. It is also possible that in cases regarding ophthalmic issue, the commission including a cardiologist or a gynaecologist etc. will adjudicate. It should be note that the voivodeship commissions adjudicate in the panel consisting of 4 persons, who are appointed by the president of a voivodeship commission in the order of receipt of applications regarding decision on a medical event from an alphabetical list of voivodeship commission members, where only2 members of the panel meet the legal education requirements. Term of office of the voivodeship commission shall be six years. In the event of commission's member dismissal, tenure of a member appointed in his place terminates on the same day as tenure of the whole commission.

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[256] Śliwka, M. 'Wybrane czynniki determinujące działalność wojewódzkich komisji do spraw orzekania o zdarzeniach medycznych', Prawo i Medycyna, No. 3-4(2012), p. 9.

The president of a commission supervises its work. The president of a voivodeship commission sets a date of the first session of the adjudicating panel. A voivodeship commission acts on the basis of self-adopted statutes during sessions that are recorded. Members of the voivodeship commission are obliged to keep in secret all the information regarding a patient, obtained during the commission proceedings, also after discontinuation of working as a commission member. Members of the adjudicating panel are entitled to remuneration in the amount not exceeding 430 PLN for their participation in a session; reimbursement of travel expenses and salary for a day-off on the day of commission's session, without the right to remuneration. Activity of a voivodeship commission is financed with public funds, allocated to the particular voivodeship governor. In view of the fact that the amount of remuneration, referred to in Article1, section 1, is established by the proper governor, the remuneration of commission members may vary, depending on the voivodeship.

Members of the adjudicating panel, their spouses, lineal descendants and ascendants must not be owners, employees or persons cooperating with a medical subject conducting a hospital, or with an insurer. In addition, members of the adjudicating panel must not be members of bodies or employees of an entity performing medical activity in accordance with the provisions on medical activity, if the entity established a medical entity, which is not an entrepreneur conducting a hospital, and does not possess shares representing more than 10% of the initial capital in commercial companies, which are medical entities conducting hospitals, mentioned in Article 67i, section 2 point 1 and an insurer, mentioned in 67i, section 2 point 2. Moreover, a member of the adjudicating panel is excluded in the cases where:

1. he is an entity, which submits the application or is in a relation with the entity, which causes that the result of the proceedings before a voivodeship commission influences his rights and obligations;
2. his private relation with an entity submitting the application makes his impartial assessment doubtful;
3. a spouse, relative or lineal affinity, collateral relative to fourth degree or collateral affinity to second degree is the entity that submits the application;
4. the entity that submits the application is related to him by adoption, custody or guardianship;
5. he was or he is a proxy or a statutory representative of an entity that submits the application.

The reasons for dismissing adjudicating panel's member are valid also after discontinuation of marriage, adoption, custody or guardianship.

### 3. 'Medical events'

New Polish regulations, regarding extra-judicial claim for redress or compensation are applied only in the case of so called 'medical events'. The concept does not occur in other legal regulations and it is understood in the Act as infecting a patient with a pathogenic biological factor, body injure, deterioration of health or patient's death as a result of a diagnosis contrary to the current medical knowledge of diagnosis (if it caused inappropriate treatment application or delayed general treatment, which caused disease development) treatment, including performing an operation and application of a treatment product or medical device being the result of health care benefits in the hospital in the light of provisions on medical treatment activity. Thus, not all patients or their families can enjoy this mechanism. What's more, a definition of a 'medical event, used by the legislator, is not clear. There are other limitations to the terms, because the application to a voivodeship commission for decision regarding a medical event can be submitted only within 1 year from the date of learning by the interested party about the infection, body injure or deterioration of health condition or patient's death. Apart from the above, the period cannot be longer than 3 years from the day of getting the infection, body injure, health deterioration or patient's death. In the case of submitting the application by patient's heirs, the above period does not start until the inheritance proceedings are finished. The date provided for submitting the application may occur to be too short - some medical damages can be found after many years and it is easy to imagine the situation, where a patient got the information on a harmful medical event and cannot submit the application, as the date has already expired.

In order to give a decision, a voivodeship commission is entitled to call for clarifications by particular entities, in particular, the entity, who submitted the application for the decision regarding medical event, a manager of a medical entity conducting a hospital, whose activity is connected with the application and persons, who practiced medical profession in the entity conducting a hospital. In the scope of the proceedings, the commission may also request the records, kept by the medical entity conducting a hospital, including medical records. The commission may also conduct the explanatory proceedings in the medical entity conducting a hospital and inspect hospital rooms and equipment.

According to Article 67 b, section 2, item 1 Apr, the proceedings before a voivodeship commission for adjudicating on medical events shall be suspended if other proceedings are in progress, which are connected with the same event in the scope of professional responsibility of a person performing the medical profession or criminal procedure in the case regarding criminal offence. In the event of its closure, the commission adjudicating on medical events shall take proceeding *ex officio*. It does not seem that in such cases, there is a need of suspending of the proceedings before the commission, as the already mentioned procedures serve different purposes[257].

[257] Śliwka, M., *op. cit,* p. 20.

In voivodeship commissions for adjudicating on medical events the *quasi* construction of the expert opinion has been introduced. According to Article 67i, section 7 Apr, if a statement on circumstances, which are crucial for delivering the opinion requires extra information, a voivodeship commission can consult a physician of a particular specialization from the list of potential members of the Medical Board operating at the Ombudsman for Patient's Rights or a voivodeship consultant in the certain field of medicine, pharmacy or other area important for health protection. However, there are no consequences of failing to give such opinion or failing to cooperate with the commission. At this point, it is worth mentioning the civil and penal provisions, which contain tools that may serve to discipline experts. According to Article 286 of the Polish Code of Civil Procedure, for unjustified non-appearance, unjustified refusal to take an oath or make an opinion or for unjustified delay in opinion delivery, the court may impose a fine on an expert. In Supreme Court's assessment, an expert should not be involved in an action, which, for any reason, he cannot perform within the specified period, resulting from a type of the task and objective need, and he should ask the court for extension of a given period, if he considers it to be too short to prepare an opinion[258]. Moreover, apart from the above mentioned fine, the court may - in the case of fulfilment of prerequisites from Article 100 of the Code of Civil Procedure - adjudge reimbursement of costs from the expert. On the other hand, in case of criminal procedure an expert, who failed to appear at the place, where he was summoned by the entity conducting the proceedings with no justification, or left the place of operation before its end without entity's permission, failed to provide a testimony or fulfil his obligation, can be imposed a fine in the amount of 10.000 PLN. Moreover, there is a possibility of detaining and bringing the expert using force. Provision of Article 285, par. 1 of the Polish Code of Criminal Procedure is applied in case of unjustified avoidance of fulfilling expert's obligations. A possible consequence of persistent avoiding to fulfil expert's obligations is imposing sanctions – arresting for the time not longer than 30 days. This measure shall be imposed regardless of pecuniary fine, which means that the expert may be arrested after being imposed the fine or simultaneously.

If the opinion is delivered in the scope of the proceedings before a voivodeship commission for adjudicating on medical events, there are no time frames for its preparation. In accordance with Apr, the voivodeship commission shall deliver the decision on medical event or its lack together with a justification not later than within 4 months from the day of submitting the application. The legislator following the right aim, which is shortening of the proceedings, seem not to take into consideration the nature of hearing the evidence in medical cases. In my opinion, the above mentioned insufficiencies may cause far-reaching consequences and even lead to blocking voivodeship commission's work. Moreover, when we realize the amount of remuneration that an expert receive

[258] Supreme Court 21.08.1967, I PZ 1/67, LexPolonica nr 322891, Supreme Court 23.01.2002, II CKN 691/99, LEX 54339, Supreme Court 21.06.2012, III CSK 279/11, LEX 1228591, Court of Appeal 11.07.2013, I ACz 1135/13, LEX 1342335.

for opinion delivery[259] and no sanction for lack of obligation fulfilment, it is not hard to imagine a situation where such opinions will not be prepared or their meritorious value will be doubtful. Threats can be also seen in the field of lack of political neutrality of opinions' authors, as the position of a national or voivodeship consultant is strictly connected with the Minister of Health and the governor, who appoints both national and voivodeship consultants.

The objective of the proceedings before a voivodeship commission is to ascertain, if the event, whose consequence consisted in financial or nominal damage, was a medical event or not. A voivodeship commission does not refer to the guilt, which in extra-judicial system of damages compensation is an 'irrelevant circumstance'[260].

### 4. The maximum amount of compensation

A voivodeship commission, after deliberation, delivers an opinion on a medical event or its lack, together with its justification. The opinion is passed with the absolute majority of three quarters of votes, cast in the presence of all members of the adjudicating panel. As it was already mentioned, a voivodeship commission delivers decision on a medical event or its lack, together with its justification not later than within 4 months from the day of submitting the application.

Within 14 days from the moment of delivering the justified decision, to an entity, who submitted the application, a manager of a medical entity conducting a hospital and an insurer are entitled to submit a justified application for re-examination of the case. It should be remembered that granting compensation or satisfaction shall not be included in the scope of commission's responsibilities. The insurer, whose intermediary is a voivodeship commission, presents the proposal on compensation and satisfaction to the entity submitted the application within 30 days from the day of getting the opinion on a medical event, delivered by the voivodeship commission as a result of the re-examination application. The offer cannot be higher than the maximum amount of compensation and satisfaction, which means the maximum amount (compensation and satisfaction) concerning one medical event in relation to one patient, in case of:

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[259] Remuneration of the specialist for opinion delivery has been specified in Regulation of the Minister of Health of December 23, 2011 on the flat rate costs of the proceedings before a voivodeship commission for adjudicating on medical events. (Journal of Laws 2011, No. 294, Item 1749) and it is PLN 300, however, it can be raised by PLN 150 when the opinion is delivered by a person with a professor title, PLN 100 – when the opinion is delivered by a person with PhD and habilitation, PLN 60 – when the opinion is delivered by a person with PhD title.

[260] Świderska, M. 'Zgoda uprawnionego a postępowanie przed wojewódzkimi komisjami odszkodowawczymi' [In] Kompensacja szkód wynikłych ze zdarzeń medycznych, ed. Kowalewski, E., Toruń 2011, pp. 221-223.

1. infection, body injury or deterioration of health condition of a patient – PLN 100.000
2. patient's death – PLN 300.000.

In the event when an insurer does not give an offer within the specified period, he is obliged to pay the amount of money specified in the application. A voivodeship commission issues a certificate, which is treated as an executive title and which confirms submitting the application for the medical event examination, the amount of compensation or satisfaction and the fact of not presenting the offer by the insurer.

It should be remembered that the entity submitting the application has a possibility of accepting or rejecting insurer's offer within 7 days from the day of its reception. After receiving the offer, the entity submitting the application makes a declaration on waiving the financial compensation and satisfaction for the damages, which may be considered by the voivodeship commission as medical events, in relation to damages that can be seen before the date of submitting the application. In the case of rejection, one may refer the claims to the court. However, the question arises, what happens when a complainant does not make a declaration regarding insurer's offer? Legislator does not mention such cases.

For the example in the analysis prepared by the Ombudsman for Patient Rights for the period of January 1, 2012 – February 2, 2013, it can be seen that Lower Silesia Voivodeship was the region, where the biggest amount of money was proposed and accepted – PLN 150.000[261] and the lowest amount (PLN 500) was rejected.

As it can be seen from the information sent by representatives of voivodeship commissions for adjudicating on medical events, hospitals and insurance companies propose rates, which are even 10 times lower than the ones claimed by the sufferers – it may be expected that the cases will end in court[262]. In my opinion, from the point of view of the further proceedings in court, the situation is much more convenient for the complainant, who has received an opinion determining occurrence of a medical event and does not accept insurer's proposal, because it can serve as evidence in the case.

## 5. Summary

The suggested mode of compensation claims recognition was supposed to be an alternative to the general rules specified in the Polish Civil Code, which means that it depends on sufferer's decision, whether claims enforcement will end in court or before one of commissions[263]. The legislator, in the justification of his decision on creating

[261] Extrajudicial compensation for medical harm- report from01.01.2012 to 28.02.2013 http://www.eib.com.pl/uploads/news/sprawozdanie_komisje_wojewodzkie_02.2013.pdf.

[262] http://www.rynekzdrowia.pl/Prawo/Komisje-orzekaja-o-zdarzeniach-medycznych-pacjenci-nie-przyjmuja-odszkodowan,132306,2.html.

[263] Karkowska, D. 'Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz', Article 67a,

extra-judicial model of claims enforcing, presents data, which show that "if in 2001-2009 no new claims for compensations appear, taking into account the rate of remains, the examination of such case would last approx. 4 years (assuming that the case would be examined by the first and the second instance, without referring the case to reconsidering and that the complaint cassation has not been made). However, in view of the fact that cases regarding medical errorsare highly complex in nature, they are examined longer - even to 10 years"[264]. Past experience and statistics state that the goal has not been fully achieved. The final summary of 2012 will be possible only after December 31, 2015, because on that day all claims will terminate (except for the inheritance proceedings).

For the example according to the report prepared by the Ombudsman for Patient's Rights for the period between 1 January 2012 and 28 February 2013, the commissions rejected 143 applications, which is approximately 24% of all applications that were returned to the applicants. In contrast, 148 proceedings ended (about 25% of all applications), in case of 40 of which it was established that a medical event occurred. Still, the commissions have to work on 312 remaining applications (52% of all applications), and 48 proposals relates to reconsideration. Together, the commissions received 603 applications, most of which were submitted in Mazowieckie Voivodeship- 95, and the least in Lubuskie Voivodeship- 12. The commissions also received 48 applications for reconsideration, which gives together 651 applications within the above mentioned period[265].

Taking into account the total number of application, which are still pending, we can see that the new mode of claims enforcing by patients is not as 'fast' as it was expected at the time the provisions on the voivodeship commissions were introduced[266].

In the presumptions the bill of October 2013 regarding amendments to patient's rights and the Ombudsman for Patient's Rights as well as other bills (which are available on the Minister of Health website)[267], it has been noted that short time of the proceedings still requires the examination to be conducted by the commission with due diligence. However, in practice, which is confirmed by the information given by the Ombudsman for Patient's Rights, the deadline determined by the bill is not meet. As we can conclude from the above presumptions, the most common causes of this situation are: prolonging time of waiting for experts' opinions delivery, difficulties in establishing session's date (caused by personal reasons of each member of the adjudicating panel), the need of taking into account the dates connected with summons, notifications and sessions

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on-line (2012).

[264] Government justification for the change of patient's right act (28.04.2011).

[265] Extrajudicial compensation for medical harm - report from01.01.2012 to 28.02.2013 http://www.eib.com.pl/uploads/news/sprawozdanie_komisje_wojewodzkie_02.2013.pdf.

[266] *Ibidem*.

[267] The website of the Ministry of Health www.mz.gov.pl.

supply, and the estimation of these extensive records[268]. In order to make the procedures more dynamic, the legislator suggests shortening - from 30 to 14 days - the period, within which a manager of a medical entity presents his opinion about the application for establishing a medical event (failure to present the opinion within the specified period will be seen as the acceptance of the application in the scope of the indicated circumstances and the proposed amount of compensation and satisfaction). The legislator also presumes failure to provide the opinion in writing by the insurer at this point (from the insurance practice related to claims settlement with the insurance, for the benefit of patients by virtue of medical events, it can be seen that the insurer does not participate in commission's sessions and the presence of insurer's representatives bring neither new circumstances nor arguments, except for the ones which are raised in the medical opinion). The legislator also suggests, with the reference to extremely complex cases, to prolong the period for opinion delivery by a commission 'maximum to 6 months' – such a solution, according to project's author, will enable detailed insight in the cases requiring hearing of many witnesses, examination of more evidence, experts' opinions etc. The number of commissions would be divided, depending on the size of a voivodeship, number and types of medical entities conducting hospitals within the territory of the particular voivodeship. In order to reduce the time of the proceedings, prolonging due to witnesses non-appearance, the legislator suggests a possibility of omitting witness' testimony by a commission in case of his unjustified non-appearance, so that the party which files such evidence do esits best to make the witness appear in the court. In the light of the proposed amendments, a set of questions arises - who will be the one to assess? Was the non-appearance justified or not? How will the commission proceed in the situation, when a party did its best, but the witness failed to appear on the specified date? Is date extension to 6 months enough? How did commissions deal with such complex issues so far?

The new procedure was established in order to deal with problems related to judicial procedure for claiming compensation for malpractice: length of the proceedings, formality and costs, but, unfortunately, the new procedure does not take into account the already existing and well-established notion of medical malpractice, it does not contribute to clarity and it is non-fault liability procedure[269].

Above, there have been presented only some of the proposed amendments regarding voivodeship commissions for adjudicating on medical events. However, the current state of legal regulations in this scope and the new proposals of the legislator are very doubtful. Huge interest in this procedure may stem from a relatively small fee[270], lack of

[268] *Ibidem.*

[269] Łojko, N. 'Based on French and Scandinavian experiences, Poland introduced extrajudicial route for claiming compensation for medical malpractice in front of administrative bodies – commissions for adjudication on so called medical events*'*, Book of Abstracts, Fourth European Conference on Health Law, EAHL, 88.

[270] Fee of PLN200 should be paid on the account of the particular voivodeship office and shall be in-

formalised judicial procedure, however, regulations in force regarding extra-judicial way of compensation for medical damages are not fully precise and clear.

cluded in the costs of the proceedings before the voivodeship commission.

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# VI. MODELS OF PROFESSIONAL LIABILITY OF HEALTH CARE WORKERS IN POLAND – DE LEGE LATA AND DE LEGE FERENDA PROPOSITIONS

## 1. Introduction

Professional liability is connected with the violation of the rules of particular profession. It is different from criminal, civil and employee responsibility. In contrast to civil liability, there is no requirement for harming a patient, or – as in case of criminal liability – committing a crime[272]. Professional liability is also not dependent on a legal form of a profession itself, e.g. the employment relationship, as it is in case of employee responsibility. The basis for professional liability is violation of the rules of the particular profession and acting in conflict with professional ethics. Hence, the essence of the discussed liability is to ensure the quality of services and take care of the image of the profession as a whole, not only its repressive-educational functioning. The difference between professional liability and civil, criminal and employee responsibility also refers to other two questions – occupational court consisting exclusively of representatives of the particular profession with a possibility of ruling a penalty of ban on practicing the profession. The above mentioned right is especially important as it is reserved for occupational courts only. No common court is entitled to adjudicate on a penalty of ban on practicing a profession.

Professional liability is related to membership of a professional group that is important from the point of view of the society[273]. Professions, whose proper practice is particularly meaningful for the entire society, shall be connected not only with social respect, or even prestige, but also with special consequences, which are borne by the society by virtue of the improper practice of the profession. There is no doubt that the above mentioned professions include health care professions.

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[272] The doctrine expresses the view that disciplinary liability is similar to criminal-judicial liability, however, the scope of professional liability is wider than in criminal liability. Professional liability is also borne when there is no criminal liability yet. The above is explained by membership of the particular professional group, which is related to complying with common obligations and special obligations connected with the particular profession or membership of particular organization. Zielińska, E. 'Odpowiedzialność…', *op. cit.,* pp. 93-94.

[273] Fiutak, A. 'Odpowiedzialność zawodowa' [In] Leksykon prawa medycznego. 100 podstawowych pojęć, ed. Górski, A., C.H. BECK, Warszawa 2012, p. 127.

The aim of these deliberations is an analysis of regulations relating to professional liability of health-care workers in Poland. However, it shall be emphasized that the presented deduction is not going to be focused on a detailed analysis of professional liability of every one profession that applies to health care, as the existing reference books mention it very often. The presented deliberations will concentrate on distinctness of regulations of the chosen professional liability aspects for particular professions, and development of assumptions in order to regulate these professions, which with their present legal status are not professionally responsible. The analysis will include the following fields of professional liability: essence, parties, stages of proceedings, trial's openness, courts, penalties and registers of the punished.

For the purpose of this paper, the analyzed professions will be divided into three groups: physicians, dentists, nurses and obstetricians (group A), physiotherapists and laboratory diagnosticians (group B) and professions applicable in the health care system, which do not belong to any of these categories: paramedics, occupational health and safety specialists, physiotherapists, dieticians and human nutrition specialists, audiophonologists and speech therapists, optometrists, epidemiologists, coordinators of clinical studies, cosmetologists, pharmacists, psychotherapists, addiction psychotherapists, addiction therapists, toxicologists, psycho-oncologists, psychotraumatologists, radio-pharmacists, medical engineers and electro-radiologists (group C). This division is related to the type – or its lack – of a legal act regulating the analyzed matter – in case of physicians, dentists, nurses and obstetricians it will be the act[274], laboratory diagnosticians and pharmacists – the decree[275]. The professions included in the third group (for the purpose of this paper – group C), despite legislative attempts, do not bear any professional liability[276]. Moreover, the above mentioned division is

[274] Professional liability of physicians and dentists has been regulated in chapter 5 of the act on medical chambers (LJ 2009 No. 219, item 170 with amendments), whereas, liability of nurses and obstetricians – chapter 6 of the act on association of nurses and obstetricians (LJ 2011, No. 174, item 1038 with amendments).

[275] The acts include only basic rules of professional liability; detailed norms are included in executive regulations: the decree of the Minister of Health from 24.09.2004 on detailed rules and procedures of disciplinary proceedings for laboratory diagnosticians (LJ 2004 No. 225, item 2295) issued on the basis of statutory entitlement under art. 70 of the act from 27.07.2001 on laboratory diagnostics (official codification: LJ 2014, item 1384) and the decree of the Minister of health from 31.03.2003 on proceedings in cases of professional liability of pharmacists, issued on the basis of statutory entitlement under art 62, par. 2 of the act from 19.04.1991 on proceedings in cases of professional liability of pharmacists.

[276] The example of action undertaken in order to regulate medical professions are two bills: parliamentary (the bill on the chosen medical professions – 4th cadence of Polish Parliament, paper no. 846) and governmental (the bill on the chosen medical professions and rules of acquiring a specialist title in other fields, applicable in health care). The first bill determined terms and conditions of performing 23 professions called medical professions (dental assistant, dietician, physiotherapist, dental hygienist, school hygienist, addiction therapy instructor, speech therapist, masseur, medical caregiver, child caregiver, optometrist, optician, audiologist, paramedic, medical analyst, dentist, electro-cardiologist, pharmacist, orthopaedist, occupational therapist). The bill also assumed that persons practicing the above mentioned medical professions are subject to professional liability for actions conflicting with the rules of

in accordance with the position expressed in the doctrine, as the regulations referring to professional liability may be divided into two categories – acts of the old and the new generation. The first group includes standards for laboratory diagnosticians and pharmacists (which does not have any legal solutions, yet), whereas, the second group includes physicians, dentists, nurses and obstetricians[277]. In conclusion, the analysis of the effective standards, especially, distinctness illustrating changes of the legislator's position, will allow to develop a model (scheme) of regulation of professional liability, being a proposition of regulation of professional liability for the professions applicable in the health care system, which do not have these regulations.

I shall also start with an explanation of the use of such terms as 'health care workers' and 'professions applicable in the health care system' instead of 'medical professions', both in the title and the paper. In the present legal state there is no legal definition of a medical profession. It is true that in the act from 15.04.2011 on medical activity[278] the legislator provided a definition of *a person practicing the medical profession*[279], however, the definition was provided only for the purpose of that act and besides the cases of statutory reference it is not applicable to other acts. In consequence, there are no unambiguous rules classifying professions as the medical professions. The reference literature refers the above term both to professions directly used by the legislator (physician, dentist, nurse, obstetrician, pharmacist) and laboratory diagnosticians[280]. Lack of the legislator's consequence in using the term 'medical professions' is also visible in another document

professional ethics and violation of regulations on medical profession practice (art. 51 of the bill). The second bill included regulations on practicing 19 professions, called medical professions, (similarly to the parliamentary bill, except for the following professions: addiction therapy instructor, medical caregiver, orthoptist, paramedic). The bill also assumed that persons practicing medical profession are subject to professional liability for violation of rules of practicing medical profession, consisting in: 1. Malpractice of medical profession resulting from lack of knowledge necessary for practicing that profession or lack of due diligence; 2. Abusing professional entitlements; 3. Disrespect for intimacy and personal dignity of a patient; 4. Failing to inform a patient or his legal representative or informing him inappropriately about the patient's rights or undertaken professional actions. 5. Failing to maintain professional confidentiality (art. 45 of the bill). The works on the bill were not completed.

[277] See Wrześniewska – Wal, I. *et. al.* miting Zielińska, E. [In] Wrześniewska – Wal, I., Augustynowicz, A., Tatara, T. 'Porównanie regulacji prawnych dotyczących odpowiedzialności dyscyplinarnej diagnosty laboratoryjnego w odniesieniu do przepisów prawnych odnoszących się do wybranych zawodów medycznych' (Comparison of legal regulations concerning disciplinary responsibility of a laboratory diagnostician with reference to legal acts relating to chosen medical professions), Journal of Laboratory Diagnostics, No. 51(2)/ 2014, pp. 169 – 172.

[278] LJ. 2013 item 217

[279] According to art. 2, par. 1 item 2, a person practicing medical profession is a person entitled to provision of health care services under separate regulations and a person able to prove acquisition of professional qualifications for health care services provision within the specified range or in the particular medical field. See more on the definition of a person practicing the medical profession in: Potulski, J. 'Osoba wykonująca zawód medyczny' [In] Leksykon prawa medycznego. 100 podstawowych pojęć, ed. Górski, A., C.H. BECK, Warszawa 2012, pp. 136-141; Dercz, M., Rek, T. 'Ustawa o działalności leczniczej. Komentarz', WoltersKluwer, Warszawa 2012, pp. 27-27, 100-109

[280] Karkowska, D. 'Zawody medyczne', Wolters Kluwer, Warszawa 2012, pp. 107-108

that is often referred to by the doctrine – Classification of professions and specializations for the purposes of the labour market[281]. The above mentioned act does not include any list of medical professions, but only a group of health specialists (No. 22) in which he included: physicians, nurses, obstetricians, emergency medical service specialists, veterinarians, dentists, laboratory diagnosticians, pharmacists[282] and other health care service specialists, including: occupational health and safety specialists[283], health protection specialists, physiotherapists[284], dieticians and food specialists[285], audio-phonologists and speech therapists[286], optometrists and health protection specialists, who are not classified anywhere else[287] (epidemiologist, coordinator of clinical studies, cosmetologist, a person qualified in pharmacy, psychotherapist, addiction psychotherapist, addiction therapist, toxicologist, psycho-oncologist, radio-pharmacist, medical engineer, electro-cardiologist, other health care services specialists, who are not classified anywhere else). In conclusion, according to the applicable regulations and the standpoint expressed in the doctrine, the term 'medical professions' refers only to a physician, dentist, nurse, obstetrician, pharmacist and laboratory diagnostician. The term 'health care system professions' is much wider than the term 'medical professions'[288]. It includes both medical

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[281] Due to the fact that on 01.01.2015 there has been iintroduced a new Classification, which is an appendix to the decree of the Minister of Labour and Social Politics from 07.08.2014, replacing the previous classification from 2010, these solutions will concentrate on the new regulations, and the applicable regulations will be referred to only for the purposes of showing changes in the legislator's standpoint on the subject matter.

[282] There has been a change in the classification. Previously, pharmacists were a subgroup of other health care services specialists (No. 2281), since 01.01.2015 they are treated as a large group within the group of health care services specialists (228).

[283] A health promoter has been replaced with a health promotion and education specialist. The new classification also includes environmental health specialist and other specialists in the occupational health and safety and environmental protection, who were not included in the classification from 2010.

[284] The new classification includes a new subgroup – physiotherapists (no. 229202).

[285] The legislator expanded the catalogue by other dieticians and food specialists (no. 229390).

[286] Three subgroups were added: neuro-speech therapists (no. 229403) surdo-audiology therapists (no. 229404), and other audio-phonologists and speech therapists (nr 229490).

[287] The classification includes four new professions: psycho-oncologists (no. 229909), psycho-traumatologists (no. 229910), medical engineer (no. 229912), electro-cardiologist (no. 229913).

[288] An interesting analysis of the medical professions was conducted by W. Preiss, who – following the criterion of the field of work and names – assumed that the professions acting within the scope of widely understood health care service include: physicians and dentists; veterinarians; clinical diagnosticians, microbiologists; pharmacists, nurses, obstetricians, paramedics, medical assistants; clinical psychologists; speech therapists, nursing staff: hygienists, dieticians, physiotherapists, masseurs, orthoptist; veterinarian staff: veterinary technicians, veterinarian sanitary controllers; pharmaceutical staff: pharmacy technicians; technical occupations: biomechanics, dental technicians, orthopaedic technicians, opticians, orthopaedic mechanics, audio-prosthetists, and auxiliary occupations: orderlies, hospital medics, veterinarian medics, dental assistants, pharmaceutical assistants, balneological surgeons etc. See: Preiss, W. 'Zawody w sferze ochrony zdrowia' [In] Prawo medyczne, ed. Kulbicki, L., Urban&Partner, Wrocław 2003, p. 116.

professions and the professions that are applicable in the health care system, but are not presently regarded as medical professions[289] - despite postulates.

## 2. Comparison of professional liability of physicians, dentists and nurses (group A), and laboratory diagnosticians and pharmacists (group B)

This part of the publication will concentrate on a comparative analysis of legal regulations of professional liability of physicians, dentists, nurses and obstetricians (group A), as well as pharmacists and laboratory diagnosticians (group. B). The consideration will include the following fields: nature of liability, parties of proceedings, stages, penalties and register of the penalized.

At the beginning, we shall notice the differences in the legal bases of the discussed groups. The professional liability of group A is regulated by the act, whereas, group B – the decree. The solution produced by the legislator causes considerable reservations. The Constitution of the Republic of Poland states in art. 92 that *Regulations shall be issued on the basis of specific authorization contained in, and for the purpose of implementation of, statutes by the organs specified in the Constitution. The authorization shall specify the organ appropriate to issue a regulation and the scope of matters to be regulated as well as guidelines concerning the provisions of such act* [290]. Moreover, the Constitutional Tribunal emphasized that the statutory entitlement cannot be of a blank nature, giving the executive authorities the freedom to shape its essential meaning. The entitlement shall determine the instructions regarding the act's contents, so that the legislator's intention referring to solutions provided for in the executive act were clear[291].

It is worth analyzing the statutory entitlements, authorizing the Minister of Health to issuing decrees on professional liability of the professions from group B. In art. 70 of the act on laboratory diagnostics the legislator authorized the Minister of Health

[289] What is worth attention is the fact that the list of medical professions include only the professions, which are subject to professional liability. Thus, in the opinion of the author, we may draw the wrong conclusion that the list of medical professions means the list of public trust professions.

[290] The Constitution of the Republic of Poland does not include the definition or the subject of the act. Whereas, in the Legal Sciences it is assumed that the act in its material meaning is the legal act including abstractive and general norms (the issuing procedure is not important), and in a formal meaning – the act issued in a special mode, but not necessarily including abstractive and general norms. Among the features of the act the doctrine lists: the highest legal power after the Constitution; being enacted by the parliament; special procedure of enacting and general nature. Banaszak, B. 'Konstytucja Rzeczypospolitej Polskiej. Komentarz', 2nd edition, Warszawa 2012; access: System of Legal Information: Legalis.

[291] Ruling of the Constitutional Tribunal from 28.10.2014, sign. K 8/14. The doctrine emphasizes the lack of consequence of the Constitutional Tribunal in the interpretation of the act's exclusivity. On the one hand, the Tribunal has no possibility of issuing non-statutory acts, regulating the matter exclusive for the acts, and on the other hand, it allows such a possibility, and at the same time gradates the scope of necessary statutory regulations, based on the essence of regulated matter (dominating view). See more: Skwara, B. 'Rozporządzenie jako akt wykonawczy do ustawy w polskim prawie konstytucyjnym', Wolters Kluwer, Warszawa 2010, p. 81.

(in agreement with the Minister of Justice, after consulting the National Council for Laboratory Diagnosticians) to issuing the decree including: *detailed terms and procedures of disciplinary proceedings in relation to laboratory diagnosticians, with special emphasis on composition, procedure of issuing and features of disciplinary courts, mode of investigation, disciplinary proceedings at first instance and on appeal, as well as rules for implementation of decisions and bearing proceedings costs*. The above entitlement is equivalent to the competence norm resulting from art. 62, par. 2 of the act on the Chambers of Pharmacists: *In agreement with the Minister of Justice and after consulting the General Council of Pharmacists the Minister of Health defined the decree on the proceedings in cases of professional liability of pharmacists, taking into consideration features and composition of pharmaceutical courts and mode of investigation, proceedings at 1st and 2nd instance, proceedings costs and way of implementation of pharmaceutical courts decisions.*

One shall agree with the standpoint expressed in the doctrine that not only do not the statutory delegations include any instructions on a way of regulation, but they also leave legislative freedom. The above results in regulation by the act that is less important that the act on the matter from the sphere of civil rights and freedoms[292].

It is also worth paying attention to the standpoint of the Constitutional Tribunal that the construction of entitlement allowing to issue a decree in order not to implement the act but to allow independent regulation of comprehensive issue, on which there are no direct norms of instructions in the act, is constitutionally unacceptable[293]. Confrontation of the above mentioned standpoint with the solution accepted by the legislator cannot be clearly assessed, for one shall not accuse statutory regulation of not including any aspects of professional liability, as e.g. a list of penalties, proceedings after issuing a decision, register of the punished are statutorily regulated. However, extensiveness, or one shall even say comprehensiveness, of the regulated matter in the decree unable us to give it the primacy of the executive regulation.

Reassuming, it shall be stated that the solution, accepted by the legislator, for regulating professional liability of laboratory diagnosticians and pharmacists in the non-statutory act is in conflict with a constitutional hierarchy of the legal acts, and it is unacceptable in the Polish law system. One shall only assume that the legislator's intention was to accelerate legislative works by concealing debatable questions, however, even a good intention cannot justify violation of the rules being the basis of the legal system. Despite the fierce criticism from the doctrine, the legislator has not undertaken any actions to change the above mentioned solution, yet.

Deliberations on the analysis of regulation of professional liability shall also include the nomenclature used by the legislator. Regulating the discussed matter, he used

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[292] Huzarska, D., Piątkiewicz, J. A., Nowacki, P., Huzarska, J., Szpak, A. 'Różnice dotyczące odpowiedzialności zawodowej w ochronie zdrowia – regulacje prawne' (Differences in Professional liability in health care – legal regulations), Zdrowie Publiczne, No. 120(3)/2010, p. 288.

[293] See decision of the Constitutional Tribunal from 02.09.1997, K 25/97 from 13.11.1999, K 12/99 from 20.05.2003, K 56/02.

different terms – liability of a physician, dentist, nurse, obstetrician and pharmacist was described as professional, whereas, laboratory diagnostician – disciplinary. However, the variety of terms has no influence on the contents of the regulation[294]. Moreover, the doctrine indicates that the terms professional and disciplinary liability may be used interchangeably[295].

Analyzing the substantive scope of professional liability we shall draw a conclusion that it is broader that legal liability. Both representatives of professions from group A and B are subject to professional liability for violation of professional ethics rules and regulations of practicing the professions defined by the legislator as professional misconduct. At this point it is worth emphasizing that professional liability – unlike criminal, civil and occupational liability – includes actions that are in conflict with professional deontology. The previously mentioned regulation will have a special meaning for the relationship between representatives of the same profession, which – besides the question of professional confidentiality – is usually not regulated by any legal act. An example of the discussed actions is the free provision of health care benefits to other physicians, treated by the Code of Medical Ethics as a good custom (art. 67) or – in case of doubts – informing the controlled physician about the control by the controlling physician (art. 55)[296]. Whereas, the previously mentioned regulations are not included in the codes of professional ethics of the other professions under discussion[297].

The parties in the proceedings on professional liability are: the sufferer (a natural or legal person, or organizational entity with no legal identity, whose legal rights have been directly violated or threatened by professional misconduct), the accused (a representative of one of the discussed professions against which the spokesman for professional liability pressed charges in the process of investigation or issued a motion for punishment) and the spokesman for professional liability conducting the investigation and being a prosecutor before the occupational court. Despite literal and constructive differences between the norms, the entitlements of the parties in all the analyzed professions are analogous. Both the sufferer and the accused may appoint not more than 2 proxies from

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[294] Huzarska, D. *et al., op. cit.*, p. 287.

[295] See: Fiutak, A. 'Odpowiedzialność zawodowa' [In] Leksykon…, *op. cit.,* p. 127.

[296] The regulation causes my reservations, as the control of health care benefits provision shall ensure their high quality, therefore, warning about the control may significantly affect the process. Physicians shall always take care of provision of health care services, irrespective of circumstances of the control or its lack.

[297] What is interesting – however, beyond these deliberations – the codes of professional ethics of the discussed professions refer to regulating the rules of behaviour of their representatives differently. The code of professional ethics of nurses and obstetricians in the RP limits the regulations, defining relationship between nurses and norms including relationships between representatives of the discussed profession, to the requirement for mutual respect, helping nurses with shorter professional experience and banning dishonest competition. The Code of Pharmaceutical Ethics concentrate exclusively on maintaining good customs and good pharmaceutical practice, whereas, the Code of Laboratory Diagnostics Ethics imposes the need for informing another diagnostician about observing faults in his behaviour.

among representatives of their professions, lawyers or legal advisors. It is interesting that the legislator did not provide for participation of legal representatives in judgment, however, he allowed all the parties to have a professional proxy. Based on the above we shall conclude that the legislator based the question of parties of the proceeding and their rights in the professional liability proceedings on one scheme.

The differences between representatives of both analyzed groups are most visible in the procedure of professional liability. One may acknowledge that the legislator based the proceedings stages on general assumptions, such as the requirement for investigation, proceedings before occupational court and opportunity to appeal against the decision of the occupational court, however, there is a significant difference in particular stages in both groups. The differences are insignificant within the analyzed groups, i.e. between laboratory diagnosticians and pharmacists, and physicians and nurses. The above confirms the previously presented view, expressed in the doctrine, that professional liability may be divided into the old generation and the new generation.

This part of deliberations will concentrate exclusively on the goals established by the legislator and the essence of particular stages of proceedings, exclusively in the context of differences between the two analyzed groups, as a detailed presentation of all aspects of professional liability is not the subject of this paper.

The legislator divided the proceedings on professional liability of physicians and nurses into four stages: verification activities, investigation, proceedings before court (respectively medical court or nurses and obstetricians court) and enforcement proceedings. The medical act *expressis verbis* defines aims only for the two first, however, an analysis of regulations allows us to state that particular stages of the professional liability proceedings of physicians and nurses have similar regulations[298]. The verification activities are concentrated on establishing, if the circumstances are the basis for investigation. The evidence of an expert opinion is not examined, nor are activities requiring execution of a protocol, except for hearing of the accusing party as a witness. The legislator cannot define the precise moment of completion of the verification activities, he can only determine that the spokesman for professional liability, after receiving the information about the possibility of committing professional misconduct, issues a decision to initiate or to refuse to initiate an investigation, aimed at examining, if the analyzed deed is a professional misconduct, which ends with a motion for punishment or discontinuance of the proceedings. It shall be assumed that the basis for initiating the investigation is a complaint or notification from the sufferer, however, if after reading the documentation from the event and/or hearing the sufferer as a witness, it appears that an offence took place, the spokesman initiates an investigation, whereas, if he suspects commitment of an offence – he applies for punishment.

[298] More on proceedings on the stages of professional liability of physicians and nurses: Rozwadowska, E. 'Położna w systemie prawnym. Prawo dla położnych', PZWL, Warszawa 2012, pp. 99-106; Sarnacka, E. 'Lekarz dentysta w systemie prawnym. Prawo dla lekarzy dentystów', PZWL, Warszawa 2014, p. 184.

The legislator regulated stages of proceedings on professional liability of laboratory diagnosticians and pharmacists differently. Most of all, there is no clear distinction of initial activities and enforcement proceedings. After receiving the credible information about an offence from the scope of professional liability, the spokesman for professional liability has a duty to initiate an investigation. The decree does not precise the term 'credible', however, one may assume that the basis for initiating the investigation shall be a justified suspicion. One may only assume that it is the spokesman that is an entity authorized for deciding, if the information is credible or not.

Confronting the above mentioned regulations one may state that there is no consequence in the legislator's regulation of the stages of proceedings for professional liability. Not only particular stages for each group are different, but also different is the basis for initiation of the proceedings – for group A it is 'a possibility of offence', and for group B – 'the credible information'. It results in the circumstances, where for one profession an investigation would be initiated and for the other, it would not, with the same factual state for both of them.

The legislator did not decide to determine duration of the proceedings, regulating only the time of investigation, differently for both groups. An investigation for physicians and nurses shall be completed within 6 months from the moment of its initiation by the spokesman for professional liability. In justified cases, the Supreme Spokesman may extend it for another period, however, no longer than another 6 months. Files of the proceedings lasting 12 months shall be transferred to the occupational court, which may extend the proceedings by another, unspecified period. An investigation for laboratory diagnosticians and pharmacists is regulated differently – relatively: 3 months, 3 months and 6 months.

No specified period for the proceedings before the occupational court shall be recognized as a significant breech by the legislator, as the lack of such regulation may cause significant delays in the proceedings, harming both reputation of physicians/nurses, and patients. Specifying the duration of the proceedings before the occupational court does not have to be categorical, however, the legislator's assumption that it shall be completed within 12 months – with a possibility of extending it by another 12 months in justified cases – could significantly affect the effectiveness of professional liability and its role in ensuring high quality of health care services. Lack of precision in determination of durability of the proceedings is well exemplified by experiences of voivodeship commissions for adjudication on medical events, which should give their decision within 4 months from the moment of receiving a motion[299]. However, a failure to meet the deadline neither imposes any duties on the commission, nor causes consequences, which means that it is a regulation that do not cause any consequences. Reassuming, the lack of norm determining duration of the proceedings and its imprecision significantly limits execution of the regulated procedure's goal.

[299] Art. 67j par. 2 of the act on the patient's rights and the Spokesperson for the Patient's Rights (LJ 2012, item 159 with amendments).

Another question causing reservations is the lack of legal representatives in adjudication panels. A solution accepted in the commissions for adjudication on medical events seems to be much better at this point, as the medical aspect is assessed by medical representatives, and meeting procedural requirements is a duty of the legal environment. Moreover, adjudication panels in the occupational courts could avoid charges pressed against commissions, i.e. failure to ensure that a representative of the particular profession is a member of the panel[300].

The aspect of penalties which may be imposed by the occupational courts is especially important in the discussed question, as the legislator decides to give the courts the power to impose a penalty of deprivation of the right to practice, which the common courts do not have. The importance of the above mentioned entitlement results from the rules of the regulated professions, applicable in the health care system. Representatives of each of the discussed professions may practice their profession only after acquiring the right to do it[301].

The legislator provided for a broader list of penalties for physicians and nurses. All analyzed occupational courts are entitled to adjudicate penalty, warning, reprimand, suspense or deprivation of the right to practice the profession. The penalty of suspension of the right to practice may be adjudicated in case of all professions for different periods – the medical court, the court of nurses and obstetricians and the disciplinary court of laboratory diagnosticians may adjudicate it for a period of a year to five years, whereas, the pharmacological court – 3 months to 3 years. Penalties reserved only for group A are: pecuniary penalty, ban on managerial functions in medical facilities (broader for physicians – in health care organizational facilities) for 1 to 5 years, limitation on the scope of practice for 6 months to 2 years. Moreover, only the court of nurses and obstetricians may adjudicate on a ban to practice in the association organs for 1 to 5 years.

Analyzing the list of penalties one shall remember that it is also a part of execution of the main task of professional liability, which – most of all – shall be a guarantee of high quality of services. The essence of the spokesman's for professional liability and the occupational courts function mostly consists in making sure of high quality of health care services. Analyzing the extended list of penalties for physicians and nurses one shall see indolence of the legislator in actualizing previous regulations. In my opinion,

[300] Voivodeship commissions for adjudication on medical events adjudicate in groups of four consisting of two legal representatives and two medical representatives. Their members are chosen randomly, in alphabetical order, which may cause that the panel does not include a specialist from the discussed field of medicine, See more: Sarnacka, E., Jacek, A., Porada S. 'Odpowiedzialność szpitala z tytułu zdarzeń medycznych' [In] Etyczne problemy zarządzania w ochronie zdrowia, eds. Hartman, J., Zalewski, Z., Wolters Kluwer, Warszawa 2013, p. 176.

[301] The right to practice a profession is issued on the basis of a diploma of graduating from a proper school. See: art 2b of the act on pharmaceutical chambers, art. 28 and 31 of the act on the professions of nurses and obstetricians, art 5 of the act on the professions of physicians and dentists, art. 9 par. 1 of the act on laboratory diagnostics.

it would be a mistake, if one assumed that the discrepancy results from the lack of relevance of introducing penalties limiting the practice of professions or performing managerial functions, all the more that the codes of professional ethics of the discussed professions include special regulations addressed to people having the previously mentioned functions.

It is worth paying special attention to the penalty of ban on performing a function of one's choice in the organs of professional associations, which may be adjudicated only by the court of nurses and obstetricians. The above certainly results from the fact that the act on the association of nurses and obstetricians was enacted as the last from among the analyzed acts.

In conclusion, one shall state that the legislator provided for significant discrepancies between the regulation of professional liability in both discussed groups, and sometimes even within professions from one group. What is the most visible is the fact of extending the meaning of professional liability and competence of the spokesman for professional liability among professions that were regulated later (physicians, nurses) and not introducing newer solutions in professions regulated earlier (laboratory diagnostician, pharmacist). Moreover, the legislator does not use the experience of voivodeship commissions for adjudicating on medical events. One may even state that besides the moment of a basic regulation, the field of professional liability stays beyond the interest of the legislator.

### 3. Proposition of regulating professional liabilities applicable in the health care system

It would be illusive to assume that the solution to a problem of lack of regulation of professional liability in many professions applicable in the health care system, could be one legal act. Previous experiences clearly show that putting a regulation covering many professions in one act causes delay and fruitless end of works, resulting in no regulation at all[302] instead of helping to regulate other professions. On the other hand, accepting many – often completely different – solutions for each profession would also not be a good idea. Developing many models, and novelizing them later seems to be illogical, as none of the professions could use experiences of others and the novelization of e.g. 20 acts would be time-consuming from the point of view of the legislator. Thus the above mentioned situation may result in no regulation for several professions.

A solution to the above may be the development of one model (scheme) of professional liability, which could be applied to all the discussed professions, however, it would not be one legal act, but an element (chapter) of the act regulating the practice of the particular profession. The suggested regulation is also an answer to a lack of detailed

[302] The above is confirmed by legislative experiences gained while working on the bills on chosen medical professions, described above.

regulations of practicing the medical professions. However, it is impossible not to see a fault of the suggested direction of legislative activities, which is time-consumption of the legislative process. Yet, accepting a uniform model of profession liability of personnel applicable in the health care system, and its subsequent regulation by the acts addressed to particular professions or their groups, is a comprehensive solution. In this paper I present a standpoint that even a time-consuming legislative process, which would however include the entire aspect of practicing particular profession, is a better solution than one legal act including only a part of required regulation, which is professional liability, addressed to all the discussed professions. However, looking at the previous legislative activities one may state that the legislator will not decide to regulate all professions applicable in the system of health care. All attempts end at the stage of project or social consultations. Thus, one shall conclude that the comprehensive regulation I suggested, would not be appreciated by the legislator and another solution shall be sought for. Therefore, it is worth considering creating a separate institution, concentrating on professional liability of medical representatives, similar to voivodeship commissions for adjudicating on medical events – appointing a commission for professional liability in professions applicable in the health care system, which would work with a voivode. The commission would consist of lawyers and representatives of all the discussed professions. The commission would be appointed similarly as commissions for adjudicating on medical events, however, the president's duty would be to appoint the members from among representatives of particular profession. Commissions working with a voivode would be more accessible for patients than institutions working within the framework of professional associations, as social trust in institutions working within one profession is weaker than in external institutions. What is more, a presence of legal representatives would help in increasing social trust in the discussed institution. A patient submitting a complaint would not have an impression that accusing a physician he was heard as a witness by e.g. a physician, and a decision on the subject matter would be also given by an adjudicating panel consisting of physicians only.

An advantage of the suggested solution is also the fact that all medical professions can be subject to professional liability *stricte*, not only those having professional associations[303].

A question that requires a detailed analysis is defining an essence and scope of professional liability, assuming that the discussed professions do not have any legal regulations, regarding practicing the professions. The only rational solution would be basing the liability on failure to provide health care services with due diligence and violation of the patient's rights. At this point it is required to be careful so that the commissions were not an institution that copied tasks of the commissions for adjudicating on medical events or civil courts. Professional liability – contrary to civil liability – is not

[303] Professional liability *stricte* is the liability of representatives of particular professions before occupational courts, whereas, *largo* – before common courts and tribunals.

and shall not be compensatory, thus, the presented commissions shall not adjudicate on compensation.

The key aspect related to a question of parties and stages of proceedings is a function of the spokesman for professional liability, whose task would be to conduct verification proceedings and investigations. In my opinion, an institution analyzing complaints and initially investigating the circumstances of their submission is a good solution of the legislator. The spokesman contributes not only to the efficiency of the process by deciding on submitting an application for punishment or its rejection in the absence of grounds for suspicion of committing a crime. Assuming that the discussed commission would be an equivalent of the institution of the spokesman for professional liability and the occupational court in the regulated medical professions, particular stages of the proceedings shall be similarly regulated. However, it would be a good solution to introduce the maximum duration of the proceedings before the occupational court which would be 6 months with a possibility of doubling it by the president of the commission by another 6 months in complicated cases.

The regulated medical professions subject to professional liability before the occupational courts were provided by the legislator with a possibility of applying to courts of second instance. However, that possibility was not provided for in case of commissions for adjudicating on medical events, which causes considerable reservations of the doctrine, especially, in the aspect of constitutionality of the accepted solution. Regulating professional liability of medical personnel the legislator shall opt for a comprehensive and pro-constitutional solution, which means that consideration shall be given to the creation of the board of appeal. At this point it is possible to use a model accepted in relation to bioethical commissions, examining purposefulness and relevance of medical experiments. The commissions are created at medical universities and medical chambers, whereas, the Bioethical Commission of Appeal appointed at the Ministry of Health adjudicates on appeals of local commissions. The General Commission for Professional Liability would be appointed from among representatives of legal and medical environments by the Minister of Health, and it would be an organ of II instance.

The specialists, analyzed in this part of the treatise, practice their profession based on a diploma of graduation from a university or one of the forms of post-graduate studies, as their professions do not require a document giving 'the right to practice the profession'. The above is of crucial importance for defining the scope of penalties, especially, an equivalent of penalty of deprivation of the right to practice the profession. One shall think about the aspect of penalty of limiting or depriving of the right to practice the profession. Previously, the legislator did not decide to introduce a requirement to have the previously mentioned document, thus, implementation of such penalties would be groundless.

Authorizing a commission to impose a penalty that is more serious than warning, reprimand or pecuniary penalty is a sign of rationality. The lack of equivalent of the penalty of limiting or depriving of the right to practice the profession would contribute to weakening the role of the presented institution. In the subject matter it is problematic to regulate an influence of penalty on professional activity of the punished person. After being imposed with one of the described penalties, representatives of group A and B are required to immediately return the document stating their 'right to practice the profession'. The period of penalty is counted only from the moment of the return. As an employer is informed about the penalty, the punished employee must not continue his work at the same position, or start working in another medical facility, for he is required to provide a new employer with the document. The discussed professions are not required to have such a document, whereas, the possible requirement to return the document confirming graduation from the studies is not an equal penalty, as it confirms not only qualifications required for the profession, but also the fact of having higher education. A solution to that question could be the introduction by the legislator of an institution of register of the punished employers of the health care system, kept by a voivode, operating similarly to the register of punished persons, kept by professional associations of the above mentioned professions.

Regulation of professional liability of all professions applicable in the system of health care is not simple, as the analyzed group was not included by the legislator in the group of regulated professions. There are clear differences in practicing the professions by the groups catalogued here as group A and B.

## 4. Summary

One shall draw several conclusions from the above presented questions related to professional liability of medical professions. First of all, in Poland there is no single model of professional liability investigation. The dichotomous division into professions statutorily regulated, non-statutorily regulated and without professional liability *stricte* used by the legislator is not justified and causes serious reservations. The question that is especially controversial is the combination of professional liability not with the character of the work (health care), but with the fact of existing or not existing of the professional association. The lack of statutory regulation of the professional liability institution for laboratory diagnosticians and pharmacists shall be especially criticized. The question that is fiercely criticized by the doctrine and regarded even as an unconstitutional solution has still not become subject to the legislative procedure.

The previous lack of uniformity of the discussed proceedings shall be explained only by indolence of the legislator. Each of the described occupational courts is a separate entity, unable to learn from experiences of other institutions having the same goal – ensuring high quality health care services. Moreover, the legislator did not decide to

novelize norms regulating similar aspect for different professions of that field, when he was implementing newer solutions (e.g. a penalty of ban on working in institutions of professional associations).

However, analyzing the legal status of health care professions defined here as group C, one shall unambiguously state that the assumption that the legislator will regulate all professions separately with particular emphasis on questions of professional liability is a mistake, as the development of medicine causes development of new professions, such as e.g. electro-cardiologist. Nevertheless, it is worth thinking about creating an institution that would conduct the discussed proceedings for all professions, using experiences of institutions already existing in the legal system, such as voivodeship commissions for adjudication on medical events and bioethical commissions.

Thus, taking into consideration all observations presented in the paper, one shall determine that a condition for fulfilling the role of an institution for professional liability – ensuring high quality of services and professionalism – is a comprehensive regulation covering all professions applicable in the system of health care. Thus, the presented standpoints are only an introduction and foundation of the detailed legal regulation. It means that the legislator shall initiate the discussion on the subject of implementation of a systemic model of professional liability of all professions applicable in the health care system that would eventually lead to development of a uniform solution.

## Organization of professional liability

**Table 1. The basis of professional liability**

| Nurses/ Obstetricians | Physicians/ Dentists | Laboratory diagnosticians | Pharmacists |
|---|---|---|---|
| Members of self-government are subject to professional liability for violation of professional ethics rules or regulations referring to practice of the profession | Members of Chambers are subject to professional liability for violation of medical ethics rules and regulations referring to practice of the medical profession | for culpable, improper performance of laboratory diagnostics actions, and for actions conflicting with the rules of professional ethics or regulations referring to performance of actions of laboratory diagnostics | Members of pharmaceutical self-government are subject to professional liability before pharmaceutical courts for acting against the rules of professional ethics and deontology, and legal regulations referring to practice of the pharmacist profession |
| The act from 1 July 2011 on self-government of nurses and obstetricians | The act from 2 December 2009 on chambers of physicians and dentists | The act from 27 July 2001 on laboratory diagnostics | The act from 19 April 1991 on pharmaceutical chambers |

## Table 2. Courts of 1st instance

| Nurses/ Obstetricians | Physicians/ Dentists | Laboratory diagnosticians | Pharmacists |
|---|---|---|---|
| District court of nurses and obstetricians | District Medical Court | Disciplinary court (art. 49) | District pharmaceutical court |
| - considers cases of professional liability, brought by district spokesman;<br>- chooses deputies of the president of the district court, from among the members of that court;<br>- submits a report on the state of ongoing cases to the district council;<br>- submits annual and term reports to the district congress | - considers cases of medical professional liability<br>- considers protests against validity of elections of delegates for the district congress of physicians, and protests against validity of applications for dismissal<br>- it submits an annual and term report on activity | - considers disciplinary cases of laboratory diagnosticians, brought by disciplinary spokesperson<br>- exercises disciplinary jurisdiction | - adjudicates in all cases as 1st instance, reserving the rights of the Supreme Pharmaceutical Court<br>- in cases of professional liability of members of the district pharmaceutical council and district audit committee, there adjudicates the district pharmaceutical court, appointed by the Supreme Pharmaceutical Court |

## Table 3. Courts of 2nd instance

| Nurses/ Obstetricians | Physicians/ Dentists | Laboratory diagnosticians | Pharmacists |
|---|---|---|---|
| Supreme Court of Nurses and Obstetricians | Supreme Medical Court | Higher Disciplinary Court | Supreme Pharmaceutical Court |
| 1. Considers cases of professional liability<br>2. Considers appeals against decisions of district courts<br>3. Considers complaints e.g.:<br>a) about a decision of the Supreme Spokesperson on starting or refusal to start proceedings, referring to professional liability<br>b) about a decision on suspending the right to practice the profession by the accused obstetrician<br>4. Chooses deputies of the President of the Supreme Court from among its members<br>5. Submits term reports on cases of professional liability to the Supreme Council<br>6. Adjudicates on resuming proceedings, referring to professional liability<br>7. Provides trainings for members of district courts. | 1. Considers cases of medical professional liability<br>2) Considers complaints in cases determined by the act<br>3) Considers protests against validity of elections to and in organs of medical chambers, subject to art. 30, par. 2, item 2, and protests against validity of voting in case of request for an appeal;<br>4) submits an annual report on activity to the Supreme Medical Council<br>5) submits term reports on activity to the Polish Medical Congress | - enacts internal regulations of the disciplinary court and Higher Disciplinary Court<br>- considers appeals against decisions of the Disciplinary Court | 1) Considers appeals against decisions of district pharmaceutical courts<br>2) adjudicates as 1st instance on cases of professional liability of members of: Supreme Pharmaceutical Council, Supreme Audit Committee, Supreme Pharmaceutical Court, Supreme Spokesperson for Professional Liability and his/her deputies, and members of district pharmaceutical courts, and district spokesman for professional liability and their deputies;<br>3) considers appeals against judgements pronounced on the bases, determined in point 2 |

## Table 4. Professional liability spokesman

<table>
<tr><td>Nurses/ Obstetricians</td><td>Physicians/ Dentists</td><td>Laboratory diagnosticians</td><td>Pharmacists</td></tr>
<tr><td colspan="2">District spokesman for professional liability</td><td>Disciplinary Spokesman</td><td>District spokesman for professional liability</td></tr>
<tr><td>- conducts explanatory proceedings in cases of professional liability<br>- has a function of an accuser before courts for nurses and obstetricians<br>- submits annual and term reports to the district congress<br>- organizes trainings on professional liability for members of self-government</td><td>- conducts inspections and explanatory proceedings in cases of professional liability of physicians and dentists, being members of the chamber<br>- performs a function of an accuser before medical courts<br>- submits annual and term reports on activity to the district medical congress</td><td rowspan="2">Disciplinary Spokesperson prepares disciplinary proceedings and performs actions of an accuser before the Disciplinary Court and the Higher Disciplinary Court</td><td>District spokesperson for professional liability conducts proceedings in cases of professional liability</td></tr>
<tr><td colspan="2">Supreme Spokesman for Professional Liability</td><td>Supreme Spokesman for Professional Liability</td></tr>
<tr><td>1. Conducts proceedings in cases of professional liability<br>2. Supervises the activity of district spokesman<br>3. Has a function of an accuser before the court for nurses and obstetricians<br>4. Considers complaints e.g.:<br>a) about decisions on refusal to start explanatory proceedings (the right to lodge – a sufferer)<br>b) about decision on discontinuance of explanatory proceedings (the right to lodge – party to proceedings)<br>5. Considers complaints against prolongation of district spokesman' proceedings<br>6. Submits report on activity to the Polish Congress<br>7. Trains district spokesman and their deputies on professional liability<br>8. Performs preventive actions within professional offences and actions conflicting with the rules of professional ethics.</td><td>1. Conducts explanatory proceedings in cases of medical professional liability;<br>2. Supervises the activity of district spokesman for professional liability<br>3. Has a function of an accuser before medical courts;<br>4. Considers complaints in cases determined by the act<br>5. Resolves disputes over rightness between district spokesman for professional liability<br>6. submits an annual report on activity to the Supreme Medical Council<br>7. Submits term report on activity to the Polish Medical Congress</td><td></td><td>Supreme Spokesman for Professional Liability conducts proceedings in cases of professional liability of pharmacists and supervises the activity of district spokesman for professional liability</td></tr>
</table>

## Table 5. Disciplinary punishments

| Nurses/ Obstetricians | Physicians/ Dentists | Laboratory diagnosticians | Pharmacists |
|---|---|---|---|
| - admonition<br>- reprimand<br>Fine given for the social purpose (1,000-10,000 PLN)<br>- ban on performing managerial functions<br>- ban on performing functions received by election in organs of self-government<br>- suspension of the right to practice the profession<br>- limitation of the scope of actions in the practiced profession<br>- deprivation of the right to practice the profession | - admonition<br>- reprimand<br>- fine<br>- ban on performing managerial functions in organizational units of healthcare for 1 to 5 years<br>- limitation of the scope of actions in practicing the medical profession for 6 months to 2 years<br>- suspension of the right to practice the profession for 1 to 5 years<br>- deprivation of the right to practice the profession | - admonition<br>- reprimand<br>- suspension of the right to practice the profession for the period of 12 months to 5 years | - admonition<br>- reprimand<br>- suspension of the right to practice the pharmaceutical profession for 3 months to 3 years<br>- deprivation of the right to practice the profession of pharmacist |

# VARIA

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# I. THE RIGHT TO HEALTH, THE RIGHT TO A HEALTHY ENVIRONMENT

## 1. Introduction

In the catalogue of human needs, the right to health and the right to a healthy environment, that is closely connected to it, are the most significant needs. A healthy environment is a precondition of human's health. At the same time, health is a precondition for the full enjoyment of life. The same correlation can be observed in the field of human rights. Both the right to life and the right to dignity, which form the basis for human rights theory, are functionally related to human health and environmental conditions, in which those rights are to be exercised. Moreover, the right to the environment of proper quality is internationally recognized as one of the human rights. It is also recognized as the matter of justice to provide everyone, despite differences in race, development, sex etc., with access to the environment adequate for life and development.

At the same time, national states and their duties related to providing protection in the field of human rights, are facing challenges which stem from environmental issues. Economic development, development of infrastructure and even scientific discoveries, have environmental implications that create dangers for human health and life[304]. Modern social life takes place in a so called 'risk society', in which creation of wealth goes hand-in-hand with social creation of environmental risk to health and sometimes even straightforward risk to life[305]. This is especially true in developing countries and among poor and vulnerable groups that are exposed to the greatest environmental hazards associated with poverty, industrialization and rapid urbanization[306].

In the above mentioned scenario, we have to combine protection of human rights with protection of other basic rights, such as the right to life, food, or health, as well as economic rights, or rights related to development, fulfilment of which may pose an environmental risk to a human being. According to the Vienna Declaration of 1993, it has to be understood that the human rights are universal, indivisible, interdependent

[304] Louka, E. 'International Environmental Law. Fairness, Effectiveness and World Order', Cambridge 2006, p. 54.

[305] Beck, U. 'La società del rischio. Verso una seconda modernita'. Rome 2007, p. 25.

[306] McMichael, A. 'The urban environment and health in a world of increasing urbanization: issues for developing countries',Bulletin of the World Health Organization, No. 78 (2000), pp. 1117 – 28.

and interrelated[307]. Therefore, logical links between the right to life, health and adequate quality of the environment are also provided for in positive law. As a consequence, the vision of elimination of any economic or developmental pressure on the environment would also be problematic from the perspective of human rights protection. This is because by many human rights standards, environmental protection and economic development are considered to be contemporary and not necessarily opposing disciplines[308].

An attempt to find a solution to this paradox consists in the development of an international system of governance[309], which would deal with difficult choices from the perspective that would provide for the holistic protection of all human rights. One of the important elements of the system would be a tailored system of international laws and institutions. From the perspective of environmental protection, the system has to be based on the concept of the human right to the adequate environment and environmental justice, with the former being responsible for issuing a minimum standard of protection, and the latter for implementation of a non-discriminatory principle in this sphere.

## 2. Origins of the right to health

Throughout centuries, the question of health and its protection was not in the realm of the state. Health was a private matter and it was regulated by private law and contacts, such as agreements between a patient and a doctor. Not later than in the 19th century some governments started to recognize their limitations in relation to the right to health concerning certain categories of citizens. Those were social regulations as they were concentrating on the most vulnerable members of society. An example of such regulation is the British Health and Morals of Apprentices Act of 1802, also known as the Factory Act 1802. The aim of this regulation was to oblige mills and factories to provide proper ventilation, and the required minimum standard of cleanliness. It also regulated the treatment of apprentices, generally children, by limiting their working hours and requiring the provision of suitable clothing. It was also the effect of fear that no improvement of living conditions of labourers might have led to diseases, which could have resulted in a revolution. Similarly, the social grounds and, especially, the fear of cholera epidemics which was spreading across Europe, led to the implementation of the Public Health Act of 1848. This legal act was aimed at the regulation of communal

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307 Piechowiak, M. 'Filozofia praw człowieka. Prawa człowieka w świetle ich międzynarodowej ochrony', Lublin 1999, p. 122.

308 Maggio, G., Lynch, O. 'Human Rights, Environment and Economic Development: Existing and Emerging Standards in International Law and Global Society', Paper prepared for the Earth Council, Costa Rica, p. 1; Louka, E., *op. cit.,* p. 54.

309 See Popiuk-Rysińska, I. 'Instytucjonalizacja współpracy międzynarodowej na rzecz ochrony zdrowia' [In] Ochrona zdrowia w stosunkach międzynarodowych, eds. Lizak, W., Solarz A., Warszawa 2013, p. 9.

services, especially, water supplies, sewerage system, food quality, paving of the streets, disposal of garbage and others[310].

However, it was, not until the mid-20th century when the Universal Declaration of Human Rights, article 25, identified the universal right to a standard of living, adequate for health and well-being. This is the way of fulfilling the basic goal of this legal act that is determined in its preamble, and consists in social progress and better living standards in greater freedom. Article 12 of the International Covenant on Economic, Social and Cultural Rights[311] recognizes everyone's right to enjoy the highest attainable standard of physical and mental health. A similar right to health is also identified by the Committee on Economic, Social and Cultural Rights, which adds that the right to health is conducive to living a life in dignity and that it is a fundamental human right, indispensable for exercising other human rights. Thus, it confirms the thesis on the integrity of human rights, stressing the importance of the right to health as one of the bases for functioning of a human being. The constitution of the World Health Organization (WHO) also defines the right to health as a human right by saying that to enjoy the highest attainable standard of health is one of the fundamental rights of every human being, without any distinction.

The Cold War paradoxically catalysed discussion about the right to health and the guaranteed access to health care. Western countries had to develop an alternative to the general access to free healthcare, which was one of the most attractive aspects of communist regimes[312] and it was one of the areas of interest of socialist governments. The idea of implementing international acts, which would develop the general idea of the right to health, enclosed in the Universal Declaration of Human Rights, appeared in the western world. It had to adopt the goal of the state's actions in the sphere of social services provision to the market economy conditions, and the development of human rights in this sphere seemed to be a good argument for the state to get engaged in this sphere.

What is interesting the 20th century also brought a change in the definition of health. Health stopped to be considered a state without illness, a state of full ability and fitness. The constitution of the World Health Organization defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. By this, WHO sets a quite high standard stressing the importance of social factors and opening it to factors, which are outside the scope of narrowly defined medicine. On the other hand, WHO's definition sets the standards very subjectively and, thus, allows the acceptance of some illnesses, as long as the symptoms do not influence well-being.

[310] Fee, E., Brown, T. 'The Public Health Act of 1848', Bulletin of the World Health Organization, November No. 83(11)/2005, p. 866.

[311] Adopted and opened for signature, ratification and accession by UN General Assembly resolution 2200A (XXI) of 16 December 1966.

[312] Kinney, E. 'Realizing the international human right to health.: the challenge of for-profit health care',West Virginia Law Review, Vol. 113 (2010), p. 49.

It may be said that the WHO's definition concentrates more on the satisfaction with life than on the state of health. It may be a sign of modern ages with societies getting older and people living longer but suffering from social exclusion, disabilities and other symptoms, which were totally unknown to the medicine in the times of Hippocrates. Furthermore, security, including health security, becomes an increasingly important element in the international legal agenda. Half of the Millennium Development Goals are dedicated to health, including a reduction of child mortality, the improvement of maternal health, fighting against HIV/AIDS, malaria and other diseases, and ensuring sustainable access to safe drinking water and basic sanitation.

### 3. Contemporary national instruments for protection of the right to health

Generally, the doctrine analyses a relationship between human rights and health in one of the four dimensions. Firstly, this relationship can be described as **H→HR**, which means that it predominantly analyses the impact of health policies, programs and practices on human rights[313]. This perspective often shows the parities between public health goals and human rights protection goals. It is often argued that the ability to combine health protection goals with human rights protection goals may cause that the health programs are more effective and more complex. Secondly, the most commonly recognized relationship is the reverse relationship – **HR→H,** which is based on the presumption that a violation, or lack of fulfilment of some or all human rights leads to negative effects in the sphere of physical, mental and social well-being. Here, we may find a perspective which implies that protection of health is a consequence of human rights implementation. Thirdly, there is a concept which, to some extent, merges the above mentioned relationships, which can be described as **H←→HR** relationship[314]. This perspective conveys the idea of an inextricable connection. According to it, there is a synergy between health and human rights. Protection of health is directly connected with protection of human rights, such as the right to food, the right to housing, the right to health care and economic rights, whereas, the full protection of human rights gives strong support for efforts to protect them. Finally, we may also create a relationship which may be described as **H = HR** in which we can claim that the right to health is actually a human right and, due to that, it benefits from the principles which govern the protection of human right, and most important is that they are universal, indivisible, interdependent and interrelated.

Modern concepts of health derive from two related, although quite different, disciplines; medicine and public health. The former focuses on health of an individual, the latter is predominantly connected with ensuring the conditions, in which people

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[313] Mann, J., Gruskin, S., Grodin, M., Annas G. (eds.) 'Health and human rights', New York, London 1999, p. 5.

[314] *Ibidem*.

can be healthy[315]. The goal of public health is different from the medicine's goal and it emphasizes prevention of disease, disability and premature death[316]. The international human rights law scholars focus mainly on public health and the obligations of the government they stem from[317]. Medical ethics or bioethics focus on the individual right to health and on the perspective of health as a kind of social good, which is quite problematic in attempts to define it. This problem stems from the fact that the individual health, in the opinion of many, is not an appropriate focal variable for assessing human rights, whereas utilities, community values, liberties and opportunities are such focal point. Health is not the right object but health care – an action which promotes health, is capable of becoming an object of such analysis[318]. The right to health implies the right to be healthy, which is an impossible standard, whereas the right to health care implies the right to certain services, which fits perfectly into the human rights protection system[319]. Such a perspective guarantees that the aim of the analysis would consist in the access to care and not in the differences in health, which are subjective by definition and include factors like genome predestinations and others[320]. The presumption which has to be made before the human right to health can be established is that health is not only a purely biological or genetic state, but that there are also social determinants which may be fundamental causes of a disease[321].

Today, many constitutional orders of countries in the world identify the right to health or the right to a healthy environment (public health), and some go even further giving constitutional guarantee for the access to healthcare. It is, of course, not only a constitutional matter to give such guarantee, it can be also applied to other legal acts, but introducing them into the constitutional regimes prioritizes them as the basis for the construction of the state legal system. The fact that constitutions are usually less likely to be changed than the other legal acts also stabilizes such guarantees. The research conducted in 2011 on constitutions of 191 countries showed that less than 40% of the countries decided to introduce some form of a guarantee for protection of health into their national constitutions[322]. The right to public health was guaranteed

[315] Institute of Medicine, 'Future of Public Health', Washington 1988.

[316] Mann, J. *et al., op. cit.,* p.8.

[317] Mann J., 'Health and Human Rights', British Medical Journal, No. 924 (1996), p. 312; Ruger, J. 'Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements', Yale Journal of Law & Humanities, Vol. 18 (2006), p. 274.

[318] Daniels, N., 'Just Health Care', Cambridge 1985, p. 6.

[319] Hessler, K., Buchanan, A. 'Specifying in the Content of the Human Right to Health Care'[In] Medicine and Social Justice: Essays on the Distribution of Health Care, Oxford 2002, p. 84.

[320] Brock, D. 'Broadening the Bioethics Agenda', Kennedy Inst. Ethics Journal, Vol. 21 (2000) p. 10.

[321] Yamin, A. 'The Right to Health Under International Law and Its Relevance to the United States', American Journal of Public Health, Vol. 7 (1995), p. 1156.

[322] Heymann, J., Cassola, A., Raub, A., Mishra, L. 'Constitutional rights to health, public health and medical care: The status of health protections in 191 countries', Global Public Health: An International Journal for Research, Policy and Practice, No. 8(6)/2013, pp. 639-653.

by constitutions of 25% of the countries, whereas 45% of the remaining 143 countries, which did not ensure the right to public health, gave some guarantees for a healthy environment. The right to medical care services was granted by constitutions of 38% of the countries but only 9% of them granted the general access to free health care[323]. It is worth noting that there is a strong tendency towards introducing different types of the right to health into modern constitutions – e.g. only one of the 33 constitutions adopted between 2000-2011 did not have any guarantees of health in its wording[324]. This illustrates the change in the functioning of modern countries in the direction of guarantees of security including, in this case, health and environmental security.

The right to health is sometimes divided into other 'sub-rights' which show the special areas of focus and vulnerable groups. In the collectivity of the right to health we can identify the reproductive rights, the rights connected with mental health, the women's right to health, the right to access to essential medicines and others. They are also interdependent and co-supportive. The modern right to health is also closely connected with labour rights and access to health care[325]. The provision of proper quality of environmental issues, such as clean air, clean water or safe food, can also be added to the agenda.

### 4. Legal sources of the human right to health

In 1966, two international covenants were prepared under the auspices of the United Nations. The International Covenant on Civil and Political Rights[326] and the International Covenant on Economic, Social and Cultural Rights[327] share the human right perspective on the right to health. Moreover, as the Universal Declaration of Human Rights also identified the right to health, it can be stated that all three documents, which form the International Bill of Human Rights, identify the existence of the human right to health. Out of these three, the International Covenant on Economic, Social and Cultural Rights formulates the existence of this right in the strongest form[328]. Apart from the above mentioned legal acts, the right to health can be also identified in the International Convention on the Elimination of All Forms of Racial Discrimination of 1965[329],

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323 *Ibidem* p. 647.

324 *Ibidem* p. 650

325 Łukaszuk, L., Tomaszewski A. 'Ochrona zdrowia a współczesne ryzyka zagrożeń ze strony środowiska naturalnego' [In] Ochrona zdrowia w stosunkach międzynarodowych. Wybrane zagadnienia., eds. Lizak, W., Solarz A., Warszawa 2013, p. 61.

326 Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966.

327 Adopted and opened for signature, ratification and accession by UN General Assembly resolution 2200A (XXI) of 16 December 1966.

328 Kinney, E., *op. cit.,* p. 52.

329 Adopted and opened for signature and ratification by General Assembly resolution 2106 (XX) of

the Convention on the Elimination of All Forms of Discrimination against Women of 1979[330] and the Convention on the Rights of a Child of 1989[331]. New aspects of protection of human dignity and other human rights, including the right to health, are regulated by the UN Universal Declaration on the Human Genome and Human Rights. It is also worth mentioning that during the 2000 Millennium Development Summit, various aspects of the right to health dominated the agenda with Millennium goals 4 (Reduction of Child Mortality), 5 (Improvement of maternal health) and 6 (Combat AIDS, malaria and other diseases) out of the 8 directed precisely at the protection of the right to health.

The right to health is not just a matter of UN organizations and institutions or specialized international organisations. It has to be mentioned that protection of health is also on the agenda of international economic law, including WTO law. Exceptions, which are enclosed in art. XX of GATT agreement, art. XIV GATS agreement[332] and also the SPS agreement[333], aim at the protection of human, animal and plant life and health. An interesting point is that the World Trade Organization presents a view that is similar to the main thesis of this article – i.e. the interdependence of the right to health and the right to a healthy environment. Health and environmental health can also be identified in the agenda of the World Bank and the International Monetary Fund or OECD[334]. A similar trend can also be observed in regional agreements on economic integration. The European Union law, which encompasses health problems, including a healthy environment and NAFTA, are definitely examples of such attitude[335].

Protection of the right to health is also identified by regional international legal instruments of which Europe can be a very good example. One of the first regional legal acts on the protection of human rights was the Council of Europe Convention for the Protection of Human Rights and Fundamental Freedoms of 1950. Although it is predominantly considered to be a source of civil and political rights, its content, thanks to the interpretation of the European Court of Human Rights, also acquired a dimension of various negative human rights in the field of health[336]. Article 2,

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21 December 1965.

330 Adopted and opened for signature by General Assembly resolution 34/180 of 18 December, 1979

331 Adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989

332 Nyka, M. 'Handel Światowy w Zintegrowanym Porządku Prawnym', Poznań 2010, pp. 98-113.

333 See generally Gruszczyński, Ł. 'Regulating Health and Environmental Risks under the WTO Law. A Critical Analysis the SPS Agreement', Oxford University Press, Oxford 2010.

334 Łukaszuk, L., Tomaszewski, A. 'Ochrona zdrowia a współczesne ryzyka zagrożeń ze strony środowiska naturalnego' [In] Ochrona zdrowia…, *op. cit.,* p. 63.

335 Kinney, E., *op. cit.,*pp. 44-66.

336 McHale, J. 'Fundamental rights and health care' [In] Health Systems Governance in Europe The Role of European Union Law and Policy, eds.Mossialos, E., Permanand, G., Baeten, R., Hervey T., Cambridge University Press 2010, p. 286.

the right to life, obviously leaves room for interpretation in a way that would consider not only the right to health, especially in the area of the status of foetus and abortion[337], but also euthanasia[338] and resource allocation in health care systems[339]. The right to liberty and security mentioned in art. 5 of the Convention, found use in protection of mental health[340]. Article 8, – the right to privacy, and article 12, the right to marry and create a family, has occasionally been used for claims concerning reproductive rights[341]. What should also be taken into account, the European Court of Human Rights has interpreted the Convention as being not only the source of obligations between governments, their representatives and members of society, but also as the source of such obligations among the members of society. It means that governments are also obliged to shape the social relations in the society in a way that would protect the rights, which stem from the Convention [342].

The European Social Charter is considered to be the document concentrated on socio-economic rights and, thus, it is more likely to address the issues connected with the right to health, without the need of using creative interpretations of the European Court of Human Rights. Article 11 of the European Social Charter creates the positive human right to protection of health. This positive right states that the member states should undertake actions in order to ensure the effective enforcement of the right to protection of health. As far as possible, according to art.11 of the Charter, the measures should aim, *inter alia,* at removing, causes of ill health; provide advisory and educational facilities for the promotion of health and encouragement to individual responsibility in matters of health; prevent, as far as possible, epidemic, endemic and other diseases. According to the European Committee of Social Rights, states need to act in six areas in order to guarantee the right to health[343]. These are, first, a health care system, including public health arrangements, providing for generally available 'medical and paramedical practitioners and adequate equipment consistent with meeting its main health problems ensuring a proper medical care for the whole population'. Second, it requires the provision of special measures safeguarding health and health care access for vulnerable groups. Third, public health protection measures, preventing air and water

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337 Paton v. UK (1981) 3 EHRR 408, H. v. Norway (1992) 73 DR 155, Open Door and Dublin Well Woman v. Ireland (1992) 15 EHRR 244.

338 Pretty v. UK (2002) 35 EHRR 1.

339 Osman v. UK (1998) 29 EHRR 245, Scialaqua v. Italy (1998) 26 EHRR 164.

340 Winterwerp v. The Netherlands (1992) 15 EHRR 437.

341 Evans v. UK (2007) 43 EHRR 21, Dickson v. UK (2006), 46 EHRR 419.

342 Moser, B. 'Die Europäische Menschenrechtskonvention und das Bürgerliche Recht – Zum Problem der Drittwirkung von Grundrechten', Wien 1972, p. 17 and 18; Hahne, M. 'Das Drittwirkungsproblem in der Europäischen Konvention zum Schutz der Menschenrechte und Grundfreiheiten', Heidelberg 1973, p. 12 and 13; Hofmański, P. 'Konwencja Europejska a prawo karne', Toruń 1995, p. 125.

343 Council of Europe, Case Law on the European Social Charter (Strasbourg: Council of Europe, 1982), Conclusions I, p. 59.

pollution, noise abatement, food control and environmental hygiene, must be provided. Fourth, there is a requirement to provide health education. Fifth, in order to prevent epidemics, measures providing vaccination, disinfection and control of epidemics are required. Sixth, collective bodies bear all or at least a part of the costs of health care services[344].

To some extent, the European Union law also regulates different factors influencing the right to health. This is partly the consequence of introducing the freedom of movement of persons and the freedom to provide services to the internal market of EU. What is also important is that the European Court of Justice, in the field of human rights protection, ascertains that the European Convention for the Protection of Human Rights and Fundamental Freedoms forms part of EU law and has an influence on formation of the fundamental rights of the European Union[345]. This attitude, stemming from the Lisbon Treaty obligation of EU, is confirmed to access the European Convention on the Protection of Human Rights. This means that EU engages its effective and obligatory judicial system of ensuring compliance in the protection of human rights, including the aspects of the right to health, developed by the Council of Europe.

The European Charter of Fundamental Rights also provides some regulations supporting the right to health. Article 2 refers to the right to life with all the consequences related to the status of foetus and euthanasia. Article 3 refers to the integrity of a person and guarantees the right to informed consent, prohibition of eugenic practices, prohibition against making the human body and its parts a source of financial gain and prohibition of reproductive cloning. It may be stated that the scope of art. 3 echoes the right to dignity as mentioned in art. 1 of the Charter. Article 7 touches upon the problem of protection of private life, which can be understood as protection of physical and psychological integrity in the area of medical treatment. Article 9 on the right to marry and create a family influences the right to reproductive health. What is important, yet quite uncommon in the system of protection of different aspects of the right to health, is article 26, which calls for integration of physically and psychically disabled persons into life of community. The most direct link with the right to health is article 35 of the Charter, which indicates the universal right of access to preventive health care and the right to benefit from medical treatment. The strength of this entitlement is reduced by the addition that these entitlements are subject to conditions established by national laws and practices. It is however worth mentioning that art. 2, in conjunction with art. 35, can be used in the situation, when the access to health care has been limited on the basis of a lack of resources[346].

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[344] McHale, J., *op. cit.,* p. 286.

[345] Opinion 2/94 on Accession by the Community to the ECHR (1996) ECR-I-1759, case C-274/99 Conolly v. Commission [2001]ECR-I-1611.

[346] McHale, J., *op. cit.,* p. 299.

## 5. Normative content of the right to health

Normative content of the right to health raises a difficult question that has to be answered by each regime, which aims at protection of the right to health. The most popular attitude assumes that the content is defined judicially in a case by case manner. It means that vague interpretations of different paragraphs of international legal acts are to be specified by international courts. This method is certainly the most responsive to different needs and circumstances, but there is always a question of law stability and a negative attitude to creative interpretation of law by courts. This is especially true in the countries that remain in the continental legal tradition. For this reason, the attempts to define the content of the right to health in an abstract way deserve a special attention.

The Committee on Economic Social and Cultural Rights, – the UN institution responsible for the implementation process of the International Covenant on Economic, Social and Cultural Rights, issues the implementation directives and comments to the Covenant. In 2000, the Committee published the General Comment 14 to the International Covenant on Economic, Social and Cultural Rights[347]. In this document, the Committee outlines the content of the right to the highest attainable standard of physical and mental health, which is guaranteed by art. 12 of the Covenant. The goal of this document is to describe the normative content of the human right to health, which is extremely ambitious. It is unique in this assumption as other sources of the right to health lack such an in-depth analysis of the content of this right. Its relative success is somewhat reduced by the fact that the Covenant in art. 2 sets quite vague time-frames for the implementation of the obligations which stem from this document. The language of progressive implementation with the use of all available resources also suggests different standards for different countries[348].

Article 12.1 of the Covenant sets a new benchmark of the highest attainable standard of physical and mental health. It is worth mentioning that neither the Covenant nor the Committee use the definition of health of the WHO Constitution in its interpretation, but they try to implement their own standard, which certainly goes beyond the right to health care, but they reasonably also do not try to implement the right to be healthy as an international legal standard. The Committee states that the right to health contains both freedoms and entitlements. The freedoms include the rights to control one's health and body, including sexual and reproductive freedom, as well as freedom from interference, such as non-consensual medical treatment and experimentation. The entitlements concern the right to a system of health protection which gives equal access to health care services. The right to health, as defined in article 12.1, is an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health, such as the access to safe and potable water and adequate sanitation, supply of safe

[347] Doc. E/C.12/2000/4 (2000).

[348] Yamin, A., *op. cit.*,p. 1157.

food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information, including sexual and reproductive health. Another important aspect is the participation of the population in health-related decision-making at local, national and international levels[349].

The endless list in art. 12.2 of the International Covenant on Economic, Social and Cultural Rights is interpreted by the Committee on Economic Social and Cultural Rights as a list of guidelines for actions that the states have to undertake in order to comply with obligation of protecting the right to health in the sense implied in the Covenant. It may be said that art. 12.2 lists areas of special focus or risks, which have to be resolved on the road to the full implementation of the right to health. The areas are: providing for the reduction of the stillbirth rate and infant mortality rate, as well as the healthy development of a child, which can be identified as the right to maternal, child and reproductive health; improvement of all aspects of environmental and industrial hygiene, which can be understood as creating the right to a healthy natural and workplace environment; prevention, treatment and control of epidemic, endemic, occupational and other diseases, which can be identified as the right to prevention, control and treatment of diseases; creation of conditions which would ensure all medical services and medical attention in the event of sickness, which can be understood as the right to health facilities, services and goods[350].

The implementation of the right to health in the field of health care is subject to the implementation of a few essential elements of the system protecting this right. Among these elements, the **availability** of facilities, drugs, and services is primary. The second element is the **accessibility** of facilities, goods and services connected with health protection. The availability has a non-discriminatory, physical and economic dimension. The third element is the **accessibility**, which means tolerance of health facilities, goods and services providers towards cultural differences, as well as ethical aspects of using the facilities and providing goods and services. The fourth element is the **quality** of the facilities, goods and services from the scientific and medical perspective.

### 6. Interrelations between the human right to health and environmental protection

The question that we should ask at the beginning of this paragraph is if there are any good arguments for using the human rights model for the protection of the environment. The answer is, yes. The first argument is a deep interrelation between human rights and the environmental protection, which has already been mentioned. The second argument is that the human rights law may serve as a vehicle for securing higher standards of

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[349] Committee on Economic, Social and Cultural Rights. 'The right to highest attainable standard of health'. General Comments Doc. E/C.12/2000/4 (2000).

[350] *Ibidem*.

the protection of the environment[351]. A very important argument is that the use of human rights in order to protect the environment helps to promote the rule of law, as governments become directly accountable for their failure to control environmental nuisances. Finally, the extension of economic and social rights embraces the elements of public interest in the environmental protection in a way that the identification of the human right to a decent environment seems to be a logical consequence of this development[352].

Human rights doctrine and practice identifies a set of human rights which guarantee a certain standard of the environment. The general idea is that this environment should have a quality that would enable to take advantage of the other human rights. In different sources of law, this standard is formulated differently. We may identify the right to a healthy environment[353]; the right to living in an environment of a quality that permits a life of dignity and well-being[354]; the right to live in an environment adequate to health and well-being[355]; the right to a generally satisfactory environment favourable to development[356]; the right to an environment adequate to health and well-being[357], and other standards that can be found in various international legal sources. The exact content of these rights is uncertain and the problems with specifying this content is being considered as one of the problems that have to be faced when trying to use them. There is, however, a kind of agreement in the doctrine that the content of these rights can be generally described as the right to a healthy environment, as these rights are closely connected with the right to health.

The interrelations between the right to health **(RtH)** and the environmental protection instruments **(E)** can be analyzed from two perspectives. First, it is **RtH→E** which means that the right to health implies the need to protect the environment. Such an attitude is presented by the most classic legal acts on human rights. Examples of such an approach can be found in article 12 of the International Covenant on Economic, Social and Cultural Rights which states that:

*1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*

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[351] Kenig-Witkowska, E. 'Międzynarodowe Prawo Środowiska. Wybrane zagadnienia systemowe', Warszawa 2011, p. 44.

[352] Boyle, A. 'Human Rights and the Environment: Where next?', European Journal of International Law,Vol. 23 No. 3 (2012), p. 614.

[353] Art. 11 of the Protocol of San Salvadore to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights.

[354] art. 1 Stockholm Declaration 1978.

[355] Resolution 45/94 of the UN General Assembly A/RES/45/94.

[356] *African* [Banjul] *Charter on Human and Peoples' Rights*, adopted June 27, 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982).

[357] Brundtland Group Report 1987, article 1.

*2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:*

*(a) (…)*

*(b) The improvement of all aspects of environmental and industrial hygiene.*

The Covenant shows us directly that the difference between the environmental protection and the human right to health is related to the difference between the means and the ultimate end. Similar mechanisms can also be observed in other legal acts on human rights protection, such as the Convention on the Rights of a Child which states in article 24 that:

*1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.*

*2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:*

*(a) (…)*

*(b) (…)*

*(c) To combat disease and malnutrition, including within the framework of primary health care, though, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution.*

Again, the fight against diseases and malnutrition, which also includes the access to clean drinking water and elimination of dangers and risks, which stem from the environmental pollution, are the only means that shall be used in order to guarantee the right of a child to enjoy the highest attainable standard of physical and mental health.

The other perspective is **RtH←E**. It does not mean that the environment dominates the human rights' argumentation; the discourse on human rights and the environment is dominated by the anthropocentric perspective and it would be hard to present the otherone, as long as human rights are involved, – but it shows that environmental protection results in the improvement of human rights protection standard, especially the right to health[358]. Some authors correctly state that the future of the entire humanity depends upon maintaining a habitable planet; therefore, effective measures for protecting the environment are crucial for protection of any human right[359]. The example of such

[358] Kenig-Witkowska, M., *op. cit.,* p. 44; Ciechanowicz-McLean, J., 'Międzynarodowe Prawo Ochrony Środowiska', Warszawa 1999, pp. 189-194; Ciechanowicz-McLean, J., Nyka, M. 'Human rights and the environment', Przegląd Prawa Ochrony Środowiska, No. 3(2012), p. 83.

[359] Merills, J. 'Environmental rights' [In] The Oxford Handbook of International Environmental Law,

a perspective can be observed in the wording of the definition of pollution from the Convention on Long-Range Transboundary Air Pollution 1979.

*Art. 1 Air Pollution means the introduction by man, directly or indirectly, of substances or energy into the air resulting in deleterious effects of such a nature as to endanger human health, harm living resources and ecosystems and material property and impair or interfere with amenities and other legitimate uses of the environment.*

It shows a direct link, or close similarity, between environmental harm and the harm done to human health. So, the legislators who prepare legal norms, which are designed to protect the environment, are perfectly aware of the positive effects of these regulations on human health. Similar examples can be also found in paragraph 3 of the Stockholm Declaration 1972.

*Par. 3*

*(…)We see around us growing evidence of man-made harm in many regions of the earth: dangerous levels of pollution in water, air, earth and living beings; major and undesirable disturbances to the ecological balance of the biosphere; destruction and depletion of irreplaceable resources; and gross deficiencies, harmful to the physical, mental and social health of man, in the man-made environment, particularly in the living and working environment.*

Also in this legal act the immediate health effect of man-made environmental harm is stressed and the relation between environmental protection and the protection of human rights seems to be obvious.

## 7. The development of the right to a healthy environment

The right to a healthy environment is a right which has been developing since the early 70's of the XX century. In 1968, the General Assembly of UN recognized the relationship between the quality of the human environment and enjoyment of the basic rights[360]. It prepared the ground for the Stockholm Conference on Human Environment, 1972[361]. The Declaration of the Conference recognised the right to a proper environment as one of human rights[362]. It is often mentioned that the idea of the human right to a healthy environment is a consequence of the environmental problems, which influence human rights, as well as the problems connected with the functioning of environmental law[363]. Through the decades, new initiatives were showing new perspectives, and to date, three types of approaches to the right to a healthy environment have been developed

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eds, Bodansky, D., Brunnee, J., Hey, E., Oxford 2007, p. 664.

[360] Drzewicki, K. 'Koncepcja prawa do środowiska jako prawa człowieka', Państwo i Prawo, No. 10 (1985), p. 5.

[361] Symonides, J. 'Ochrona środowiska ze stanowiska prawa międzynarodowego' [In] Prawo a ochrona środowiska, ed. Łustacz, L., Wrocław-Warszawa 1975, p. 188.

[362] Ciechanowicz-McLean, J., Nyka, M., *op. cit.,* p. 84.

[363] Drzewicki, K., *op. cit.,* p. 52.

and still function both in the doctrine and in the practice of international legal order[364].

The first approach, which can be found in the text of the Stockholm Declaration of 1972, treats the environment as a precondition to the enjoyment of human rights. This approach can be very well seen in principle 1 of the Declaration which states that, *Man has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being…* The environment is the substance in which human rights may be enjoyed. Without proper environmental conditions it may be impossible to enjoy the benefits of human rights. Therefore, a Man … *bears a solemn responsibility to protect and improve the environment for present and future generations*[365]. Twenty years later, in Resolution 45/94, the UN General Assembly recalled this approach by stating that, *all individuals are entitled to live in an environment adequate for their health and well being*[366].This resolution called for efforts to ensure a better and healthier environment, that would support the enforcement of the right to health[367].

Such attitude can also be seen in the provisions of some international courts. The case of the European Court of Human Rights, *Guerra and Others v. Italy* (1998) may be one of the examples[368]. The case concerned the failure of public authorities to inform local citizens about risks connected with the fertilizer industry functioning. The citizens of Manfredonia, neighbouring with a factory, were not provided with sufficient information about the risks related to the functioning of this company. Through this failure, the citizens' right to respect their private and family life was breached. In its ruling, the Court stated *that severe environmental pollution may affect the individuals' well being and prevent them from enjoying their homes by affecting their private and family life adversely*. The state of the environment was recognized by the court as a factor that could adversely affect the human right to protection of one's private and family life.

The second approach treats protection of the environment as a consequence of protection of human rights. This approach can especially be seen in all participatory or democratic rights that can be found in the human rights protection system.

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[364] Those three ways are also reflected by the judicial decisions as well as the doctrine in its publications. See eg. Weston, B., Bollier, B. 'Regenerating the Human Right to a Clean and Healthy Environment in Commons Renaissance' available at: http://commonslawproject.org/sites/default/files/Regenerating%20Essay,%20Part%20I.pdf. Similar approach can also be found in Shelton, D. 'Human Rights, Health & Environmental Protection: Linkages in Law & Practice. A Background Paper for the World Health Organization', WHO 2002, pp. 3-5; see also Boyle, A. *op. cit.,* p. 617.

[365] The Stockholm Declaration on Human Environment – Declaration of the United Nations Conference on the Human Environment, Stockholm, 16 June 1972.

[366] UN Genral Assembly Resolution – Need to ensure a healthy environment for the well-being of individuals 14. December 1990. A/RES/45/94.

[367] Ciechanowicz-McLean, J., Nyka, M., *op. cit.,* p. 85.

[368] Guerra and others v. Italy 1998-I, no. 64.

The 1992 Conference in Rio de Janeiro[369] stressed that protection of the environment should not be treated only as a duty of the state, but it also confirmed that protection of the environment should be carried out mostly for citizens and that they should have a possibility to participate in it and control the process of providing them with an environment of proper quality. Therefore, principle 1 of the Rio Declaration on Environment and Development confirms that human beings are entitled to a healthy and productive life in harmony with nature, but principle 10 adds a new quality of rights, – namely, participatory rights in the field of provision of a healthy environment. It says that: "Environmental issues are best handled with participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided*"*. During the Conference in Rio de Janeiro, much focus was put on procedural aspects of environmental protection[370].

It may be observed that this approach recognizes human rights as participatory, or the right to fair trial in the specifics of environmental regulations and uses them as procedural rights in providing the access to a healthy environment. On the basis of Principle 10 of the Rio Declaration, the Aarhus Convention of 1998 has been adopted, which develops and specifies the wording of soft Declaration law in a binding text of an international agreement. The Aarhus Convention is based on three interrelated fundamentals. First, the right to environmental information, second, the right to participate in environmental decision-making and last, as a safety vault to provide for access to justice in environmental matters, – especially when there are problems with enforcing the first two fundamentals[371].

Article 1 of the Aarhus Convention 1998 states: *In order to contribute to the protection of the right of every person of present and future generations to live in an environment adequate to his or her health and well-being, each Party shall guarantee the rights of access to information, public participation in decision-making, and access to justice in environmental matters in accordance with the provisions of this Convention.* As we can see, the philosophy of the Aarhus Convention states that access to information, public participation and access to justice in environmental matters, protection of the right to living in an environment adequate to health and well being of present and future generations should be provided.

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[369] United Nations Conference on Environment and Development Rio de Janeiro 3 June to 14 June 1992.

[370] Ciechanowicz-McLean, J., Nyka, M., *op. cit.,* p. 85.

[371] Kenig-Witkowska, M., *op. cit.,* p. 44.

The third perspective sees the right to a healthy environment as an independent, substantive human right. In this perspective, the right to a healthy environment stems directly from human dignity which is a source of all human rights. In this approach, the right to a healthy environment is not a precondition for human rights protection or a consequence of the functioning of the human rights protection system. It is recognized as such in constitutional regulations of over 60 countries in the world[372].

However, at the international level the right to a healthy environment (or other similar environmental human rights) experiences some hardship in its universal recognition. One of the reasons is the fact that the human right to an adequate environment is recognised by many authors, who support the division of human rights into different categories, as a representative of the third generation of human rights[373]. Still, some representatives of the doctrine refuse to give full legal power to this category of rights, emphasizing problems with their effective execution[374]. Another problem is the legal consequence of providing people with effective remedies and the obvious need to make those rights more precise and operative[375]. For this reason, the OECD countries, the countries with a developed judicial system of protection of human rights are reluctant to confirm material human rights in the sphere of the environment[376]. Also another problem appears. The attempt to define the right to a decent or healthy environment in a quantitative manner may be understood as an attempt to turn an essentially political question of environmental standards into a legal one[377]. However, definitional problems can be solved quite easily. It is enough to allow the courts to redefine the scope and characteristics of the right to a healthy environment in a case by case manner[378]. This attitude has been confirmed by the European Court of Human Rights in the case Fadeyeva v. Russia, where the Court in its ruling confirmed the role of the national authorities and courts to initially limitat some aspects of the right to a healthy environment[379].

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372 *Ibidem.* Other sources show that this number can be even higher. eg. Sands and Peel speak about approximately 100 countries in which the constitutions recognize a right to a clean environment. Sands, P., Peel, J. 'Principles of International Environmental Law*',* 3rd edition, Cambridge 2012, p. 776.

373 Mik, C. 'Zbiorowe prawa człowieka. Analiza krytycznych koncepcji'Toruń 1992, p. 68; The right to health is identified as one of the most developed human rights from third generation (solidarity) human rights. Drzewicki, K., *op. cit.,* p. 53.

374 Jasudowicz,T. 'Administracja wobec praw człowieka', Toruń 1996, p. 41; Alston, P. 'Conjuring Up New Human Rights: A Proposal for Quality Control', American Journal of International Law, Vol. 78 (1984), p. 607.

375 Minimum standard of precision would make it necessary to set the objective scope of the regulation and to define basic institutions, – like the notion of the environment itself. Kenig-Witkowska, M., *op. cit.*, p. 41.

376 Birnie, P., Boyle, A. 'International Law and the Environment', 2nd edition, Oxford 2002, p. 263.

377 Boyle, A., Anderson M. 'Human Rights Approaches to Environmental Protection' [In] Human Rights Approaches to Environmental Protection, eds. Boyle, A., Anderson M., Oxford 1996, p.2 ; Sands, P., Peel J., *op. cit.,* p. 778.

378 Kiss, A., Shelton, D. 'International Environmental Law', New York 2004, pp. 24-26.

379 Amechi Enhancing, E. 'Environmental Protection and Socio-Economic Development in Africa:

Two good examples of such attitude to the right to an environment of a certain quality exist in international legal order. Article 24 of the African Charter on Human and Peoples' Rights of 1981 states that: *all peoples shall have the right to a generally satisfactory environment favourable to their development*. The second example can be the Protocol of San Salvador of 17 November 1988, which affirms that *everyone shall have the right to live in a healthy environment and to have access to basic public services.* The above mentioned examples show completely different approaches towards human rights and, specifically, human rights in the field of environmental protection. While the Protocol of San Salvador treats the rights as an individual right, the African Charter adopts a collective perspective[380]. The second approach is more commonly accepted by the doctrine[381].

These regulations can be used as a point of reference to the initiatives in Europe which lack the courage of the above mentioned documents. This omission is, however, supplemented by legal actions of the European courts which show a proactive attitude in the sphere of recognizing the right to a healthy environment. Although most of the contemporary provisions protect that right through creative interpretation of provisions connected with protection of family life, a very interesting statement was given by the Judge Costa in the case of Hatton and Others v. the United Kingdom. Although the judges presented a traditional attitude and used the rules of the European Charter of Human Rights on the protection of home and family life in this clearly environmental case (noise pollution), the Judge Costa prepared a separate opinion. He stated that "(…) having regard to the Court's case-law on the right to a healthy environment (…), applicants had to pay too high a price for an economic well-being, of which the real benefit, moreover, is not apparent from the facts of the case.(…) Since the beginning of the 1970s, the world has become increasingly aware of the importance of environmental issues and of their influence on people's lives*"*. It may be understood that the Judge Costa was opting for the recognition of the human right to a healthy environment as an independent human right.

An interesting perspective on recognition of the right to a healthy environment is also given by one of the newest regional legal acts on protection of human rights, the EU Charter of Fundamental Rights. Article 37 states that: *a high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development.* At the beginning, it should be stated that the wording of art. 37 fails to take a stance on the right to a healthy (or decent) environment[382]. Articles 51 and 52

A Fresh Look at the Right to a General Satisfactory Environment under the African Charter on Human and People's Rights Law', Environment and Development Journal,Vol. 5/1 (2009), pp. 64-65.

[380] Merills, J., *op. cit.,* p. 667.

[381] Shutkin, W. 'International Human Rights Law and the Earth: The Protection of Indigenous Peoples and the Environment*'*, The Virginia Journal of International Law, No. 31 (1990) p. 479; Merills J., *op. cit.,* p. 667.

[382] Boyle, A., *op. cit.*, p. 616.

of the Charter state that some of the provisions of this document do not create rights which may be executed by the courts, but simply create the principles which may be implemented by the legislative and executive acts taken by the UE and Member States' institutions and bodies. Furthermore, the European Union Charter of Fundamental Rights fails even to confirm the procedural aspects of the right to the environment, which is included in the Aarhus Convention[383], and also ignores some of the already existing rulings of the Strasburg court and ECJ in this field.

## 8. Mutual support of environmental law and human rights to health and a healthy environment

The analysis of legal acts and statements of the doctrine shows that the right to a healthy environment is positioned between two dynamicly developing regimes, namely, human rights law and environmental law[384]. It guarantees the development of this concept. In the fields where adequate standards cannot be achieved by the development of environmental law, they can be supported by human rights protection. On the other hand, the factors which may negatively influence these standards, due to its close connection with anthropocentric human rights regime, may be overcome with solutions provided by environmental law[385].

Agenda 21, an act which has been adopted during the Conference in Rio de Janeiro in 1992, together with 2002 Earth Summit in Johannesburg, stresses the need to promote human health, among others, by encouraging preventive efforts and reduction of risks associated with environmental pollution. Human health has been recognised as one of the five priorities of sustainable development. Agenda 21 and development of international environmental law has created the platform where health organizations, such as WHO, can promote health[386].

Many multilateral environmental agreements have health implications. This is especially true as international environmental law is anthropocentric in its nature[387]. The link between environmental protection and protection of human health is most obvious in: the Montreal Protocol on Protection of the Ozone Layer (1987), the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989), the Convention on Biological Diversity (1992), with its Cartagena Protocol on Bio-safety, the Kyoto Protocol of the United Nations Framework Convention on Climate Change, the Rotterdam Convention on Prior Informed Consent Procedure

383 Gracia, M., Morgera, E. 'Commentary on Article 37 of the EU Charter of Fundamental Rights Environmental Protection (2013). Europa Working Paper No. 2013/2.

384 Kenig-Witkowska, M., *op. cit.*, p. 47.

385 Ciechanowicz-McLean, J., Nyka, M., *op. cit.,* pp. 87-88.

386 von Schirnding, Y., Onzivu, W., Adede, A. 'International environmental law and global public health', Bulletin of the World Health Organization, No. 80 (12) 2002, p. 970.

387 Ciechanowicz-McLean, J., Nyka, M., *op. cit.,* p. 87.

for Hazardous Chemical and Pesticides in International Trade (1998), the Aarhus Convention on Access to Information, Public Participation in Decision making and Access to Justice in Environmental Matters (1998) and the Stockholm Convention on Persistent Organic Pollutants (2001).

The Stockholm Convention on Persistent Organic Pollutants is a good and fairly new example of an international environmental protection legal act which has an enormous impact on promotion of the right to health together with protection of the environment. Organic pollutants influence the environment and human health[388] as they accumulate in adipose tissue of organisms and can disturb their normal biological functioning[389]. However, it is worse that human beings, as organisms at the end of the nutrition chain, have higher levels of organic pollutants in their food and it has been shown that even the societies that do not practically create pollution, such as Inuit societies, also suffer from the effects of accumulation of those substances in migratory species, which are eaten by members of those societies[390]. The Convention creates the legal regime for elimination, or restriction of using 12 contaminants due to their toxicity, persistence and mobility in the environment. Among them, pesticides, industrial chemicals and persistent organic by-products can be identified.

## 9. Execution of the right to health and the right to a healthy environment

As it has already been mentioned in this text, the most important legal acts, promoting the right to a healthy environment, are not legally binding. Of course, one may take the natural law's point of view and say that "the law does not live of executives, legislators and judges alone"[391] and that the law can also exist beyond the formal corridors of power[392], but the lack of binding power surely is a limitation for the functioning of legal obligations. There is no such problem with protection of the right to health. In this sphere we have a well- functioning systems both at the UN and regional level. That is why there can be observed a process of 'greening' of human rights which can be

[388] It is worth mentioning that most of the definitions of the environment include the human being as an element of the environment itself, so the harm to the human health may be considered as a breach of environmental safety. Of course, this relation is not so important as long as human life and health usually is a subject of the legal instruments which are more effective and more direct than the environmental treaties.

[389] Damstra, T., Page, S., Herrman, J., Medith, t., 'Persistant organic pollutants: potential health effects?', Journal of Epidemiology and Community Health, No. 56 (2002), p. 824.

[390] See eg. Laird, B., Goncharov, A., Chan, H. 'Body burden of metals and persistent organic pollutants among Inuit in the Canadian Arctic', Environment International, Vol. 59 (2013), pp. 33-40.

[391] Weston, B. 'The Role of Law in Promoting Peace and Violence: A Matter of Definition, Social Valuses, and Individual Responsibility' [In] Toward World Order and Human Dignity. Essays in honour of Myres S. McDougal, eds.Reisman, W., Weston B., Free Press 1976, pp. 114-117.

[392] Weston, B., Bollier, B. 'Regenerating the Human Right to a Clean and Healthy Environment in Commons Renaissance' available at: http://commonslawproject.org/sites/default/files/Regenerating%20Essay,%20Part%20I.pdf, p. 12.

described as discretional interpretation of the traditional human rights treaties in a way that would be supportive for the human environment[393]. This process can be observed on all levels of human rights governance, and evidence of convergence in environmental case law can be given, as well as proofs of cross-fertilization of ideas connected with protection of human rights in the field of the environment in different human rights systems[394].

The United Nations system for the protection of right to health is executed by multiple bodies. They can be divided into three categories. First are the bodies and mechanisms which are created on the basis of the United Nations Charter. An example of an action in this field can be the fact that the United Nations Human Rights Council adopted resolution 2005/60 (2005) on human right and the environment as a part of sustainable development[395]. This document stresses the links between the environment, human rights and sustainable development. The second category would be the bodies which are set by the UN's seven major human rights treaties. As an example of an action in this field, we may refer to the report for the Office of the High Commissioner on Human Rights that sets a point, "While universal human rights treaties do not refer to a specific right to a safe and healthy environment, the United Nations human rights treaty bodies all recognize the intrinsic link between the environment and the realization of a range of human rights such as the right to life, to health to food to water and to housing"[396]. Similarly, the 2011 Analytical Study on the Relationship between Human Rights and the Environment states that, "human rights obligations and commitments have the potential to inform and strengthen international, regional and national policymaking in the area of environmental protection and promoting policy coherence, legitimacy and sustainable outcomes"[397]. The third category would be the UN specific treaties in the fields other than direct protection of human rights. Here the Aarhus Convention can be given as an example[398].

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393 Boyle, A., *op. cit.,* p. 614.

394 *Ibidem*.

395 Human Rights Resolution 2005/60: Human Rights and the Environment as Part of Sustainable Development E/CN.4/2005/96.

396 Report of the OHCHR on the relationship between climate change and human rights. UN Doc.A/HRC/10/61 of 15.01.2009, par. 18. Similarly, The United Nations Human Rights Council adopted Resolution on Human Rights and Climate Change A/HRC/10/61 which shows the links of the climate change issue with the range of traditional human rights like the right to life, the right to adequate food, the right to the highest attainable standard of health, the right to adequate housing, the right to self-determination, the right to water and others.

397 UN Office of the High Commissioner for Human Rights Report of 16 December 2011 'Analytical Study on the Relationship Between Human Rights and the Environment' UN Doc. A/HRC/19/34.

398 Kofi Annan a former Secretary General of the United Nations in a forward to the Implementation Guide to the Aarhus Convention states: "Although regional in scope, the significance of the Aarhus Convention is global. It is the most ambitious venture in the area of 'environmental democracy' so far undertaken under the auspices of the United Nations. (…) Convention will be open to accession by non-ECE countries, giving it the potential to serve as a global framework for strengthening citizens'

Among the bodies which stem from the United Nations Treaty itself, the most important from the perspective of human rights protection is the Human Rights Council with the greatest competences in the field of human rights protection. Its competences in environmental protection become greater after UN started to regard climate change matters as common concern of humanity[399]. Apart from the Human Rights Council Complaint Procedure, individual proceedings can also be commenced before specialised bodies administrating execution of individual human rights. A Special Rapporteur on the right to enjoy the highest attainable standard of physical and mental health can be regarded as a body that administrates execution of the right to health. Specialised bodies were also created to support rights related to the right to health like a Special Rapporteur on the right to food, – for execution of the right to food, or an Independent Expert on human rights and international solidarity for protection of the right to development. Among the specialized UN Charter bodies, there also exists a Special Rapporteur on the adverse effects of the illicit movement and dumping of toxic and dangerous products and wastes on the enjoyment of human rights that has a huge impact on execution of the right to a healthy and clean environment.

The bodies whose existence derives from provisions of specific legal treaties of the United Nations also play a very important role in supporting and executing the operation of the right to health and the right to a healthy environment. Among those bodies, seven are crucial for execution of the right to health. The Committee on Economic Social and Cultural Rights is a body which considers five-year reports submitted by the UN member states on their compliance with the International Covenant on Economic, Social and Cultural Rights[400]. Its competences also include dealing with matters related to compliance with the right to health, which stems from art.12. Individual complaints can be considered by the Committee on the Elimination of Racial Discrimination, which can work on complaints concerning violation of art.5 of the International Convention on the Elimination of All Forms of Racial Discrimination[401]. The Committee on the Elimination of Discrimination against Women have similar competences; in that case the complaints are based on the art.12 and 14 of the Convention on the Elimination of All Forms of Discrimination against Women[402]. In the context of children's health,

environmental rights*"* Stec, S., Casey-Lefkowitz, S. 'The Aarhus convention. Implementation Guide'. New York, Geneva 2000, p. V.

[399] UN GA resolution 10/4 (2009) on Human Rights and Climate Change. Boyle, A., *op. cit.,* p. 618. In this context it is worth mentioning that climate change problems can have an effect on the rise in numbers of so called environmental refugees – people who had to leave their homes and possessions due to environmental problems. It can therefore be observed that environmental devastation affects multiple human rights and not only the right to health; Sands, P., Peel J., *op. cit.,* p. 776.

[400] Adopted and opened for signature, ratification and accession by UN General Assembly resolution 2200A (XXI) of 16 December 1966.

[401] Adopted and opened for signature and ratification by General Assembly resolution 2106 (XX) of 21 December 1965.

[402] Adopted and opened for signature and ratification by General Assembly resolution 34/180 of 18

it is worth mentioning the Committee on the Rights of the Child, which controls enforcement of the right to health that stems from art. 24 of the Convention on the Rights of the Child[403].

There are also treaty-based bodies that function within the UN system which support the right to life that is certainly supportive to the operation and protection of the right to health. Among these, it is worth mentioning the Human Rights Committee which has a competence for hearing the individual complaints based on art. 6 of the International Covenant on Civil and Political Rights[404]. The protection of the right to life in the specific context of the rights of the child is controlled by the Committee on the Rights of the Child. There is, however, some conflict of interest between functioning of the United Nations human rights bodies and the initiatives to use human rights to protect the environment. Apart from the fact that UN is an organization in which states play a crucial role and development of environmental human rights extends their responsibility in other fields (a lot of countries have omission and implementation problems in those fields), also other conflicts arise. We should be aware of the cooperation between the UN human rights institutions and the private sector, namely, enterprises for corporate responsibility for human rights abuses[405]". If we take into consideration the scope of the potential responsibility of corporations in the field of environmental degradation, it should be obvious to us that such propositions would ruin the current achievements of cooperation between UN and the corporations.

There are also compliance mechanisms in regional systems of human rights protection. The Council of Europe and its European Convention on Human Rights may be held up as an example. The fact that the Council of Europe has rejected the proposals of introducing environmental rights into the agenda the European Court of Human Rights decisions at least twice[406] shows the need of judicial activism in this field[407]. The rights

December 1979.

403 Adopted opened for signature and ratification by General Assembly resolution 44/25 of 20 November 1989.

404 Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966.

405 Boyle, A., *op. cit.,* p. 619.

406 On the 16 June 16, 2010 the Committee of Ministers once again refused to add environmental protocol or simply the right to healthy environment in to the European Charter of Human Rights. Boyle, A. 'Human Rights and the Environment:. Where next?', European Journal of International Law, Vol. 23 No. 3 (2012), p. 615. On earlier attempts – from the early 70ties - to add environmental protocols to the European system of human rights protection see. Drzewicki, K. 'Koncepcja prawa do środowiska jako prawa człowieka', Państwo i Prawo, No. 10 (1985), pp. 58-59.

407 In the years 1980-2012 the European Court of Human Rights heard around 90 cases on the protection of the environment despite the fact that there are no exact legal measures in the European Convention which would protect the environment. Council of Europe, 'Manual on human rights and the environment', Strasburg 2012. It can be shown that in many cases the European Court of Human Rights used the non binding standards set in the principles of the Stockholm Declaration of the 1972 as

concerning the environment are thus protected as a consequence of protection of other values and rights which are protected on the basis of the convention. Some authors call it the 'ricochet' protection[408]. The Court hears individual cases basing its case law on environmental protection and solves them on the basis of the protection of the right to life (art. 2), protection of the right to the protection of private and family life (art.8). The freedom of expression (art. 10) and the right to assemble and associate (art. 11) was also found useful in environmental protection. The protection of the right of possession in art. 1 of protocol 1 to the convention also created the basis for pro-ecological interpretation of the Convention. In this field procedural rights are also important, which can be used in environmental protection, like the right to fair trial (art. 6) and the right to effective remedy (art. 13). Similarly, the European Social Charter, whose art.11 protects the right to health, has a collective complaints procedure under which certain categories of collective persons can lodge complaints to the European Committee of Social Rights.

The Aarhus Convention also has a mechanism to enforce compliance. Article 15 of the Convention establishes a 'non-confrontational, non-judicial and consultative procedure' which is carried out by the non-compliance committee. Some of the essential guarantees of independence of the committee's members were included in the convention, as well as a possibility of individual or collective complaints. Independence, transparency, and NGO involvement in the Convention's novel compliance mechanism represent an ambitious effort to bring democracy and participation to the very heart of compliance itself [409]. It should also be noted that the main elements of the convention – access to information, public participation in environmental decision-making and access to justice, are all deeply rooted in the European legal culture and, due to that, are recognized as human rights and protected by the European Charter of Human Rights, independently from the Aarhus Convention mechanisms[410].

As most of human rights treaties had been drafted and adopted before international environmental protection became the subject of international concern[411], the direct protection of the right to the environment as an independent human right is problematic, although some positive examples can also be given in this matter. In the field of compliance mechanisms, the international regime for the protection of human rights

a binding standards for the protection of human environmental rights by the Convention. Michańska, H. 'Europejska Konwencja Praw Człowieka jako instrument ochrony praw jednostki w związku z zanieczyszczeniem środowiska', Europejski Przegląd Sądowy, No. 1 (2014), pp. 60-65.

408 *Ibidem,* pp. 60-65.

409 Kravchenko, S. 'The Aarhus Convention and Innovations in Compliance with MEAs', Colorado International Journal of Environmental Law and Policy, No. 18 (2007), p. 49.

410 A good example of the above mentioned reasoning may be found in the Strasbourgh Court's Taskin v. Turkey case (42 EHRR (2006) 50. Although the Turkey is not party to the Aarhus Convention the European Court of Human Rights, the text of the European Charter of Human Rights reads in a way more consistent with the obligations stemming from the Aarhus Convention than the Charter itself.

411 Shelton, D., *op. cit.,* p.6

has an obvious advantage over the international environmental law regime. In the latter, although there exist some examples of successful complaints before international courts, there is no specialized judicial forum that would deal with the problems of environmental protection in a professional and specialized way. Most of the legal acts of international environmental law are neither binding nor have any control mechanisms. A possibility of using the general international law instruments is closed for the claims of individuals. This makes the regime of human rights protection, with its specialized institutions and openness to an individual that is so attractive in protection of the environment.

## 10. Right-holder of the right to health and the right to a healthy environment

Analyzing the obligations that are introduced into international human rights regime in relation to the right to health and the right to a healthy environment brings, the answer should be given as to who is entitled to these rights. Human rights are universal[412] and thus it may be said that everyone is entitled to them. This universalism is reflected, for example, in article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and requires governments to recognize *the right of everyone to the highest attainable standard of physical and mental health*. Similarly, article 25 of the Universal Declaration of Human Rights sets this standard universally by saying that, *everyone has the right to a standard of living adequate for the health and well-being of himself and of his family (…).* Certainly, this way of defining the group of entitled entities causes that the scope of this standard is the widest possible. So it may be stated that its application is subject to intergenerational solidarity i.e. it should be applied to all members of the human race without any discrimination.

Another crucial problem connected with the entitlement to the rights, which stem from the human right to a healthy environment, is the question if this right should be individually or collectively recognised. Interdependence of human rights can affect individual entitlement in the situation when the environment affects individual human rights. On the other hand, human rights of the third category are called solidarity rights and are based on the collective entitlement of a certain category of entities or group of entities[413]. This brings us to another question, if this universalism of human rights is applied only 'here and now', or does it also have an intergenerational dimension.

Certainly, the argument in favour of identifying future generations as subjects entitled to protection that stems from the protection of human rights may seem odd. On the other hand, future generations, such as those entitled to the protection, are

412 Henkin, L., 'The Universality of the Concept of Human Rights. Annals of the American Academy of Political and Social Science', Human Rights around the World, Vol. 506 (1989), pp. 10-16; Donnelly, J. 'Universal Human Rights. In theory and practice', 2nd edition, Ithaca London 2003, (see generally); Zajadło, J. 'Uniwersalizm praw człowieka w konstytucji – bezpieczne i niebezpieczne relatywizacje', Przegląd Sejmowy, No. XV 4 (81) 2007, pp. 93-111.

413 Drzewicki, K., *op. cit.,* p. 61.

mentioned in many international legal acts, including the United Nations Charter[414]. The preamble of the Charter of the United Nations sets, as one of its aims, a goal to save succeeding generations from the scourge of war. The Vienna Declaration of 1993 presents the intergenerational context of human rights protection in article 11, which states that *The right to development should be fulfilled so as to meet equitably the developmental and environmental needs of present and future generations*[415]. Thus it shall be stated that the fundamental documents of the international legal order identify the existence of the interest of future generations in legal measures created today. The Vienna Declaration shows that this interest or rights that reflect this interest, can also be found amongst human rights. The universalism of human rights can be understood as a statement that human rights existed, exist and will exist in the future[416], and similarly, we may imagine breaching human rights of future generations by an action undertaken today. It is simply the other perspective of the universalism of human rights[417].

Some of the most important agreements in the field of environmental protection recognize the future generations as the beneficiaries of the regulations[418]. In the United Nations Convention on Climate Change, art. 3 states that, *The Parties should protect the climate system for the benefit of present and future generations of humankind, on the basis of equity and in accordance with their common but differentiated responsibilities and respective capabilities*[419]. Climate, as one of the preconditions of human existence on the Earth, is surely protected for both current and future generations. Furthermore, an adverse effect on the climate through our current activities will be fully visible no sooner than in a few decades, so it may be stated that the climate is protected predominantly for the future generations. Similarly, a preamble of the aforementioned Aarhus Convention identifies the right to an adequate environment of both current and future generations and introduces the instruments for protection of this right; *Recognizing also that every person has the right to live in an environment adequate to his or her health and well-being, and the duty, both individually and in association with others, to protect*

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414 Menkes, J. 'Kształtowanie prawa międzynarodowego zasobów wodnych', Warszawa 2000, p. 206; Piechowiak, M. 'Aksjologiczne podstawy Karty Praw Podstawowych Unii Europejskiej', Studia Prawnicze, No. 1(155) 2003, p. 25.

415 Vienna Declaration and Programme of Action adopted by the World Conference on Human Rights in Vienna on 25 June 1993.

416 Piechowiak, M. 'Powszechność Praw Człowieka. Zagadnienia filozoficznoprawne' [In] O prawach człowieka. W podwójną rocznicę Paktów. Księga Pamiątkowa w hołdzie Profesor Annie Michalskiej T. Jasudowicz, ed. Mik, C., Toruń 1996, pp. 51-52.

417 For complex analysis of the concept of the rights of future generations together with deep insight into the axiological and legal grounds see Brown Weiss, E. 'Fairness to Future Generations.International Law, Common Patrimony, and Intergenerational Equity, Tokyo 1989, (generally)

418 Ward, H. 'Beyound the Short Term: Legal and Institutional Space for Future Generations in Global Governance', Yearbook of International Environemntal Law, Vol. 22, No. 1 (2011), pp. 3-36.

419 Caney, S. 'Climate Change, Human Rights and Moral Thresholds' [In] Climate Ethics, eds. Gardiner, S., Caney, S., Jamieson, D., Shuea, H., Oxford 2010, pp. 163-177.

*and improve the environment for the benefit of present and future generations*[420]. Article 1 gives a similar scope of the right; *In order to contribute to the protection of the right of every person of present and future generations to live in an environment adequate to his or her health and well-being.*

The rights of future generations in the field of health protection and protection of environmental rights are also recognized by some internal legal orders. One example can be the Constitution of Germany which states in article 20a; *"*Mindful also of its responsibility toward future generations, the state shall protect the natural foundations of life and animals by legislation and, in accordance with law and justice, by executive and judicial action, all within the framework of the constitutional order.*"*[421] Similarly, environmental rights of future generations are identified by the Constitution of the Republic of Poland in article 74; *Public authorities shall pursue policies ensuring the ecological security of current and future generations*[422]. With certainty, the impact of current generations on the conditions of living of future generations is potentially so big that such a relation should be identified. The protection of future generations is an underlying principle behind the Estonian Constitution as well; *"*Unwavering in their faith and with an unswerving will to safeguard and develop a state; (...) which shall serve to protect international and external peace and provide security for the social progress and general benefit of present and future generations (...)"[423]. The South African Constitution also expressly states and affirms the rights of future generations; *Everyone has the right (...) to have the environment protected, for the benefit of present and future generations (...)*[424]. The right to a healthy environment is also recognized by the constitution of Argentina, which states that; *All inhabitants are entitled to the right to a healthy and balanced environment fit for human development in order that productive activities shall meet present needs without endangering those of future generations (...)*[425]. Further examples of similar guarantees can be given. It is a kind of standard to invoke the rights of both current and future generations to a healthy environment.

There are, of course, some difficulties about the practical means of protection of the right to health and the right to a healthy environment for future generations. One of them is surely the problem with representation. There are initiatives for the introduction

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[420] The UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters adopted on 25th June 1998.

[421] Gruber, M. 'What is it like to be unborn?. Our common fate with future generations' [In] Efficiency, Sustainability and Justice to Future Generations, ed. Mathis, K., Springer 2011, p. 124.

[422] Journal of Law 1997, No. 78, item. 483

[423] Fitzmaurice, M. 'Contemporary Issues in International Environmental Law'. Edward Elgar Publishing 2009, pp. 148-149.

[424] Republic of South Africa Constitution of 19 December 1996, art. 24.

[425] World Future Council 'National Policies & International Instruments to Protect the Rights of Future Generations A Legal Research Paper' available at: http://www.worldfuturecouncil.org/fileadmin/user_upload/PDF/RepresentationFuture_Generations.pdf (25.01.2014)

of an ombudsman to protect the rights of future generations, a special parliamentary commission giving the court the obligation to take the future generations' perspective when giving rulings etc.[426]. An interesting attempt was made in the Philippines. The 1993 Philippine Supreme Court Case, *Minors Oposa v. Secretary of the Department of Environment and Natural Resources ('DENR'),* is a domestic court decision on intergenerational equity in both 'intra-' and 'inter-' dimensions. The case addressed intergenerational equity in the context of state management of public forest land. In a novel situation under Philippine law, the Philippine Supreme Court permitted a class action, although it has yet to issue a decision, taken by the Philippine children acting as representatives of themselves and future generations. The petitioners wanted to stop government-licensed timber cutting in the remaining national forests. The plaintiffs alleged that the logging violated their right to a healthy environment under the Philippine Constitution and would entail irreparable harm to them and future generations of the nation. The Court considered the issue of intergenerational responsibility and decided that the petitioners had *locus standi*, i.e., were qualified to file suit on behalf of present and future generations in the Philippines.

The problems with protection of the right to health and the right to a healthy environment, in the context of future generations, are certainly possible to overcome. The right mentioned in so many national and international legal acts cannot be treated as a purely rhetorical[427] figure. But even without proper representation, recognition of the rights of future generations can also be treated as a standard for the use of precautionary principle, a standard which takes into consideration the effects that can become visible in the near future. A test which takes into consideration the consequences for currently living people and for future generations seems to be a high but reasonable standard for protection.

## 11. Conclusions

Human rights are interrelated and supporting each other. This relationship can be clearly seen in the context of the links between the right to health and the right to a healthy environment. Both of these rights are anthropocentric and the relationship with human well-being brings the right to the environment into the area of interest of human rights. The right to health and the right to a healthy environment are

[426] Quite popular is the view that the government is a body who should act in favor of the right of future generations and thus protect them. This however does not leave the governments with carte blanche in the field of the protection of the interest of future generations. A good example can be the case Apirana Mahuika et al v. New Zealand (2000) ICCPR Communication No. 547/1992, in which the UN HRC upheld the state's right to conserve and manage natural resources in the interests of future generations provided this did not amount to a denial of the applicant's rights.

[427] Cook, K., Taylor, R. 'The Rights of Future Generations in International Law' [In] Do We Owe Them a Future? Opportunities of a representation for future generations in Europe, eds. Javor, B., Racz, J., Budapest 2006, p.146.

often regulated by the same legal acts, but the doctrine very rarely analyzes them together.

The right to health emerged in the 19th century and, initially, it functioned in the area that today we identify as public health. This remains the core of the right to health even today, as the state policy in these fields is easy to justify. It is different with health care systems, as they are biased by economic and political arguments. Today, many countries have decided to introduce some guarantees of the right to health into their constitutional legal order. This is a consequence of recognition of the right to health by the basic international legal acts which constitute the Bill of Human Rights.

The recognition of the right to health and its protection seems to be more effective than the right to an environment of adequate quality or the right to a healthy environment. This is probably caused by the fact that for many people the right to health is more closely related to protection of the right to life than the right to the environment. It should also be underlined that recognition of the right to health was a process that started in the early 1950's, whereas the right to a healthy environment started to be developed in the 1970's. However, it should, be mentioned that a big impact of the right to a healthy environment on the right to health creates the situation in which different aspects of healthy environment are identified as aspects of the right to health.

The right to health and the right to a healthy environment are also identified by regional human rights documents. It is interesting that the right to health is more often recognized and more precisely drawn in European systems than in any others, whereas the right to a healthy environment is recognized in a more specific way only in its procedural aspects. It may result from a relatively socialistic attitude of those countries towards protection of health. The right to the environment seems to be more important in the regimes of human rights protection in Africa or South America. It also has to be underlined that protection of the right to health and the right to a healthy environment entails intragenerational and intergenerational equity. The universalism of these rights obliges us to ensure the possibility of taking advantage of these entitlements, not only universally in the current timeframe, but also in relation to the needs of future generations. This is predominantly the consequence of the fact that to some extent, humanity developed technological potential to shape health and environmental conditions in which future generations will function.

All the above mentioned arguments shows us that there certainly exists an international system of governance designed to protect human rights. It is multi-centric in its nature as is the system of institutions which create legal norms designed to protect human rights. The system provides for protection of the right to health – this right is almost universally recognized. More problematic is recognition of the right to healthy environment, as it is directly recognized only by some international regimes of human rights protection. However, even in the regimes which do not recognize the human right to a healthy environment it can be protected by judicial activism, as it is commonly recognized that

the environment influences human health. However, it does not mean that there is no need for future development of human rights in those areas, as they touch upon the very current problems of the contemporary world.

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# II. THE NEW COSMETIC REGULATION – EVOLUTION OR REVOLUTION?

## 1. The aim

The aim of this work was to overview the current legislation regarding cosmetic products in the European Union. This overview is done in comparison to the Cosmetic Directive 76/768 just to assess whether the changes in this two regulations are so distinct that we can call it the revolution. Do the main definitions and principles remain unchanged? What is the current role of responsible person and safety assessor and finally is Regulation 1223/2009 an effective tool from the safety for human health point of view?

## 2. Introduction and historical background

The New Regulation in cosmetics has been in force since 11th July 2013. It is Regulation (EC) No 1223/2009 of The European Parliament and of The Council of 30 November 2009 on cosmetic products[428]. In recent years, it has been the third regulation regarding cosmetics in Poland. Before 2002 registration of cosmetics placed on the market via Państwowy Zakład Higieny (The National Institute of Hygiene) was obligatory. The main document, which was required by PZH was the result of Draize Test - irritation test made on a rabbit eye. There were other necessary parts of the documentation included formulation, analytical specification and label. An applicant also had to prepare samples of the product which allowed to make physical, chemical and microbiological analyses. The official certificate of the National Institute of Hygiene took part of the responsibility for the product from a producer.

Since 2002 Ustawa o kosmetykach (**Cosmetics Act**)[429] has been in force. The act was direct implementation of 'Cosmetics Directive 76/768'[430]. Poland accepted and implemented all principles from 'Cosmetics Directive' such as: cosmetics should be safe for human health, a producer is responsible for a product, every product should have 'documentation' prepared and kept, information on cosmetics properties must not

[428] Official Journal of the European Union L342/59.

[429] Journal of Laws 2001 Nr 42 poz 473 (Journal of Laws of the Republic of Poland 2001, No 42 item 473.

[430] Official Journal of the European Union L262, 27.9.2976 p169

lie. Other principles regarding a cosmetic product are: it should not have any curative properties and all claims should be confirmed. The same opinion about priciples of old regulation can be found in many publications e.g Dr Giesberts and Dr Streit [431]

The first information regarding a ban on animal testing occurred, and finally, in March 2009, the animal testing ban for cosmetic ingredients came into force. The ban on animal testing for a ready product had already been in force since September 2004. The notification of cosmetics in Poland was obligatory and Krajowy System Informowania o Kosmetykach (KSIoK) (the National System of Cosmetics Information) was established. Although the system was just a database of cosmetic products, verification of the data took place very often and discussion with the authorities was possible. The procedure of the notification was very simple (only one A4 sheet with the basic information such as name of a cosmetic and a producer was required. It usually was free of charge (if confirmation of such notification was necessary for a producer, the cost was about 25 Euro). The System was also responsible for collecting all pieces of information on undesirable effects caused by cosmetics. However, for several years only a few pieces of such information were collected.

## 3. Current regulations

### a) Definitions

Corresponding to the 'old directive', we can observe rather evolutive changes in the principles and definitions. The most important definition remains unchanged and the cosmetic product is *any substance or mixture intended to be placed in contact with the external part of the human body (epidemis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.*

All producers should be aware that all products used as insect repellents are not cosmetics and the institution responsible for the registration of such products is Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (**The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products),** which has a special department, responsible for the biocides and repellents. Also, all veterinary cosmetics do not fall into the above mentioned definition. Sun protection preparations, which in the United States of America are identified as medical products, in the EU are cosmetics and should meet the requirements of the New Regulation 1224/2009. There are many nuances about what is the cosmetic product and what is not. A good example of such a nuance is the situation with toothpaste.

[431] Giesberts, L., Streit, T. 'New Cosmetics Regulation already in effect – 9 things for manufacturers and importers to know' available at: https://www.dlapiper.com/en/us/insights/publications/2013/09/new-eu-cosmetics-regulation-already-in-effect---__/.

If it has any medical indication (e.g. anti plaque), it is a medical product. However, 'ordinary' toothpaste is defined as a cosmetic product. The best way to verify whether the product we have is a cosmetic or not is to try to categorize it. The defined categories are as follows:

- creams, emulsions, lotions, gels and oils for the skin
- face masks
- tinted bases (liquids, pastes, powders)
- make-up powders, after-bath powders, hygienic powders
- toilet soaps, deodorant soaps
- perfumes, toilet waters and eau de cologne
- bath and shower preparations (salts, foams, oils, gels)
- depilatories
- deodorants and antiperspirants
- hair colorants
- products for waving, straightening and fixing hair, hair-setting products
- hair-cleansing products (lotions, powders, shampoos)
- hair-conditioning products (lotions, creams, oils),
- hairdressing products (lotions, lacquers, brilliantine)
- shaving products (creams, foams, lotions)
- make-up and products removing make-up
- products intended for application to the lips
- products for care of the teeth and the mouth
- products for nail care and make-up
- products for external intimate hygiene
- sunbathing products
- products for tanning without sun
- skin-whitening products
- anti-wrinkle products.

**b) Responsible person**

The definitions which are very important to the cosmetic producers are the definition of the producer/manufacturer and the definition of the responsible person. *The manufacturer means any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured and markets that cosmetic product under his name or trademark*. This definition solves the problem of subcontracting production of cosmetics. The responsibility for a product rests on an organization or a person, using its trademark for marking the product. The New Regulation allows to assign a responsible person for a cosmetic product to a producer within the European Community and obliges a foreign producer to assign such a responsible person which

should have address within the EU. In both cases, an agreement between a responsible person and a producer/manufacturer should be prepared in writing.

As a matter of fact, obligations of the 'responsible person' introduce personal responsibility for a cosmetic product. Although, the liability of 'responsible person' is defined as fulfilling requirements of several articles (3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24), it can be clearly stated that the responsible person is liable for:

Art 3 Safety
Art 8 GMP Compliance
Art 10 Safety Assessment
Art 11 Product information File
Art 12 Sampling and analysis
Art 13 Notification
Art 14 Restriction for substances listed in Annexes
Art 15 Substances classified as CMR
Art 16 Nanomaterials
Art 17 Traces of prohibited substances
Art 18 Animal Testing
Art 19 Labelling
Art 20 Product claims
Art 21 Access to the information to the public
Art 23 Information on serious undesirable effects
Art 24 Information on substances

The responsible person should not be mistaken with a safety assessor. The responsible person is required to be established within the European Community and it can be a person or an institution. A safety assessor should be a person with a higher degree in medical sciences, pharmacy, toxicology or similar. The role of the safety assessor is very important because he is the person who takes decisions whether a product is safe for human health or not. This is a very important decision which can close the way to the market for a product which gives some doubts regarding safety for human health or open that way in spite of the fact that the product bears some risk for human health. According to the new regulation safety assessor prepares for every cosmetic product Safety Report according to the Appendix I.

**c) Documentation**

As for documentation in the new regulation, it is clearly defined how the Safety Report should look like and what is the integral part of the documentation. This is also an evolutive change, because the safety of the cosmetic product should be assessed

on the basis of theoretical analysis of the toxicological data of every ingredient. In the new regulation, however, some new definitions, such as MoS (Margin of Safety)[432] have occurred. Many other pieces of information, which have not been obligatory, should now be presented in the Safety Report. One of the examples of such item of information is the one regarding packaging of a cosmetic product. It is expected to provide information not only on a material of which the packaging is made, but also on impurities in the packaging and possible interaction with the cosmetic inside.

The Microbiological Challenge Test Result is indispensable for products with high microbiological risk. The assessment whether the product is of low microbiological risk or not should be made according to the standard ISO 29621:2011[433]. There is also norm ISO11930:2012 containing a description of the procedure regarding the Challenge Test[434]. The alternative method of confirmation that the preservative system in cosmetic product is efficient could be the European Pharmacopeia method. However, in the situation where many of the preservative systems such as parabens or isothiazolones have very bad publicity, the preservation of a cosmetic product has become a really important issue. Qualification whether product belongs to the group with low microbiological risk is based on the water activity value. Some products e.g. containing more than 16% of alcohol or hot poured one (more than 80 C) belong to the group with low microbiological risk.

**d) Notification**

What is revolutionary in the new regulation is notification of cosmetic products. There was established and prepared the Cosmetic Products Notification Portal (CPNP), which is common for all European Countries. The system of notification is simple and orientated on the safety of cosmetics for human health - it means that primarily it is a tool which should be helpful in case of undesirable effects or even poisoning caused by cosmetics products. The system enables quick and reliable identification of a product (by means of the picture of the product and the label) and quick access to the important toxicological information (e.g. alcohol content). This portal is prepared for poison centers, rather than for controlling authorities because it is said that authorities have access only to the part of the data such as the name of the cosmetic product and the responsible person address. The data placed on the notification portal is not verified by the administrator (General Directorate of SANCO). Only the responsible person can make changes in the records and it should be explained, whether the changes are

[432] The SCCS Notes of Guidance for the testing of Cosmetic substances and their safety evaluation 8th revision 11.12.2012.

[433] PN-EN ISO 11930 maj 2012 Kosmetyki – Mikrobiologia – Przewodnik do oceny ryzyka I identyfikacji produktów niskiego ryzyka mikrobiologicznego.

[434] PN-EN ISO11930 maj 2012 Kosmetyki – Mikrobiologia – Test skuteczności i ocena zakonserwowania produktów kosmetycznych.

caused by mistake or because of actualization. All the official languages of the European Community members could be used for putting the data on the Portal. The data will be kept there for at least 20 years. For the convenience of the customers the special manual of CPNP was prepared[435]. The Portal itself has also a direct connection with 'Cosing' databases and many of the functions are prepared proactively. It means that users can choose from the options of the portal. It is also possible to use the portal in 'trial mode'.

The Portal is free, however, all cosmetic producers should have in mind that notifying cosmetic products means having to prepare documentation. The documentation = cost because of necessary microbiological analyses (Challenge Test), Patch Test, physicochemical analysis, stability and compatibility test, as well as Repeated Open Application Test, if necessary. The cost, multiplied by the number of cosmetic products, for which the documentation should be prepared, can give quite a significant amount of money, which should be invested to fulfill the new requirements.

**e) Labeling**

There is also a new thing in the labeling of cosmetic products – a sandglass symbol. This is something that could be used instead of 'best before' or phrases with the same meaning in other languages. Next to the sandglass symbol there should be information about validity of the product (month and year or day, month and year). Unfortunately the new regulation still allows to use PAO (Period After Opening) symbol (an open jar with the number of months), which is poorly recognized and often misunderstood by the users. This symbol means that a cosmetic product, which should have at least 30-month validity period, can be used only for the indicated number of months since opening. It also means that, in practice, we may have a cosmetic product which is 'eternally' valid, because it is not allowed to give any other date (e.g. production date) just not to confuse the user. The PAO symbol is used only for cosmetics products, whereas the sandglass symbol is also commonly used for pharmaceuticals and food. There are also some exceptions among the cosmetics products, such as perfumes and perfumery products, where it is allowed not to put the best before date on them.

Regarding the GMP system, there is ISO Norm 22716, which every cosmetic producer should follow. There is no external certification system, so in that case self-certificates are in use. Norm 22716 is not as demanding as the Pharmaceutical GMP, however, some of the standards directly derive from the pharmaceutical practices.

As far as substances allowed to be used in cosmetics are concerned, there is no such thing as 'a positive list' of such substances. There is only a list of prohibited substances and substances allowed to be used with limitations, as well as a list of preservatives, pigments and dyes, UV filters. An unofficial list of ingredients allowed to be used in

[435] Cosmetics Products Notification Portal Users Manual'2013.

cosmetics is presented as 'cosing' (cosmetic ingredients) database accessible via official pages of the European Community (ec.europa.eu/consumers/cosmetics/cosing).

**f) Nanometrials, CMR substances**

A new approach to the nanomaterials used in cosmetics has been presented. Generally nanomaterials are under special notification conditions (they must be notified six months prior to the intended placing on the market) and some specific data regarding such substances should be presented. This opinion is in opposite to that presented in Ph D Perry Romanowsky article [436] where is said that it is only 'nano' word presented on the label where nanomaterials occur.

The situation with nanomaterials is quite similar to what has occurred in the food industry with regard to GMO food. Having no proof that this kind of food is 100% safe and in the presence of no evidence that it could be harmful, many countries decided to forbid the use of Genetically Modified Organisms on their territories. In case of nanomaterials we can also say that there is not enough evidence to say, whether it could have influence on our health or not, so their use is controlled by special conditions and regulations. A similar situation can occur in the nearest future, as far as the group of substances, defined as endocrine disruptors is concerned. Besides the official 1223/2009 Regulation, there are also SCCS – Scientific Committee on Consumer Safety (Former SCCP – Scientific Committee on Consumer Products) opinions. The opinions are very important to the safety assessors, because they give the most current toxicological data regarding groups of chemicals and chemical substances. From the practical point of view, such opinions have almost the same importance as Annexes to the 1223/2009 Regulation.

CMR Substances (Cancerogenic, Mutagenic and Reprotoxic substances) from categories 1 and 2 are not allowed to be used in cosmetics, however, with some exceptions. Some traces of substances, unpermitted in cosmetic products, can occur, however, it should be noted in the Safety Report and proved that such occurrence is unavoidable from the technological point of view.

**g) Alternatives to animal testing**

Referring to the ban on animal testing, there are things that should be taken into consideration. Due to the situation where it is not allowed to test ready cosmetic product or ingredients on animals and due to the shortage of alternative methods[437], testing on

[436] Romanowski, P. 'New EU Cosmetics Regulations – A Quick Guide for Busy Formulators. Chemists Corner'available at: http://chemistscorner.com/new-eu-cosmetics-regulations-a-quick-guide-for-busy-formulators/

[437] Ward, S. 'Upcoming changes to cosmetic regulations in the EU in 2013', available at: http://alttox.org/upcoming-changes-to-cosmetic-regulations-in-the-eu-in-2013/

human volunteers becomes more and more popular. However, standards of such testing are very often the same as during clinical studies of medical products and pharmaceuticals (Helsinki's declaration[438]). Therefore, it should be precisely stated, what standards and procedures could be implemented here – see opinion of Martina Klaric from National Centre for the Replacement Refinement and Reduction of animal in Research [439]. It is also a challenge to the authorities to offer alternatives for biological testing, especially in the field of irritations and allergies, caused by cosmetic products.

## 4. Conclusion

Over the last few decades, a very complicated regulatory system, regarding cosmetic products in the European Union has been prepared. Main differences with other regulatory systems e.g. US or Australia regards sun protective products and other specially dedicated cosmetics like depilatory products. Dr Annelie Streussmann has presented an interesting theory that European new regulation will have a strong influence on other reulations [440]. In fact the differences are still clearly visible. In Europe all sun protective products belongs to cosmetics products in the US this group is treated like OTC drugs. Over last decades the regulatory system regarding cosmetics bring us to the situation where we have a very precise definition of cosmetic product, efficient notification portal, strictly defined documentation. We have also list of substances prohibited in cosmetic products, list of substances with restrictions, list of dyes and pigments, UV filters and preservatives. There is also an animal testing ban, obligatory preservative system efficiency test and labeling requirement. Although the changes in the last regulation are evolution rather than revolution, we can say that cosmetics placed into the European market are safe for human health and there was little data regarding undesirable effects caused by cosmetic products. This is the final proof, whether the law regarding cosmetics is effective or not. In my opinion, it is effective.

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[438] 18th WMA General Assembly June 1964 with current changes.

[439] Klaric, M.'The science of cosmetic testing without the use of animals', National Centre for the Replacement Refinement & Reduction of animal in Research available at: https://www.nc3rs.org.uk/news/science-cosmetic-testing-without-use-animals.

[440] Streussmann, A. 'How European cosmetics legislation influences regulatory frameworks world – wide', Houdehols and Personal Care, Vol. 9(5) September/October 2014, pp. 14-17.

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# III. CIVIL ASPECTS OF ARTIFICIAL FERTILIZATION

## 1. Introduction – remarks on the nature of issues

Progress of medical technology, characterized by considerable impetus, poses new challenges to humanity, which were unknown several years ago. These are social and legal challenges, but most of all ethical challenges. The state of affairs, in which human procreation becomes a training ground for unreflective progress, is unacceptable. Procreation and the resulting succession of generations is, in fact, the essence of humanity. Heritage of mankind is both physical and spiritual, and in general, it is called civilization. It is the result of creative continuation of phenomena that co-create human consciousness. It should also be remembered that it is equally important to use advanced science to the fullest extent. Thus, interference in such important spheres cannot be deprived of due attention and scientific reflection[441].

In recent years we have witnessed tremendous progress of medical intervention in the sphere of human procreation. Meanwhile, it is still important to remember, that this is probably the secret of human life creation that, to some extent, contributed to the fact that everyone see themselves as equal beings. Dynamic progress in science and medical technologies - biotechnology revolution, makes the mystery of human development prenatal stage disappear. In this connection, it will redefine the way we assess and see ourselves[442].

Already more than twenty-five years ago *J. Testart* anexcellent French biologist and pioneer of IVF in France, found that humanity was going step on the path to new challenges, achievements and fears, associated with artificial embryogenesis. As a result of the above, a new scientific duty would arise, i.e. determination of ontological status of human embryo[443]. *Testart* described, in realistic manner, the imaginary and caricatured results that could be caused by uncontrolled and inconsiderate progress of treatment and surgery techniques. He stated that the unlimited use of extracorporeal

[441] Compare: Safjan, M. 'Prawo wobec ingerencji w naturę ludzkiej prokreacji', Warszawa 1990; This same: 'Prawo i medycyna. Ochrona praw jednostki a dylematy współczesnej medycyny', Warszawa 1998; also: Bosek, L. 'Gwarancje godności ludzkiej i ich wpływ na polskie prawo cywilne', Warszawa 2012; Tokarczyk, R. 'Prawa narodzin, życia i śmierci. Podstawy biojurysprudencji', Warszawa 2012.

[442] Compare: Nawrot, O. 'Ludzka biogeneza w standardach bioetycznych Rady Europy', access: System of Legal Information: Lex 2011.

[443] See: Testart, J. 'De l'éprouvette au bébé spectacle', Edition Complexe, Coll. Le Genre Humain, 1984and also: 'L'oeuf transparent', Editon Flammarion „Champs", 1986 and also: Le Magasin des Enfants Collectif, sous la direction de J. Testart, Edition François Bourin, 1990.

fertilization methods would lead to aberrations. For the creation of human beings comply with the 'order', and with 'laboratorial guaranteed' features.

Jürgen Habermas came, among others, to very pessimistic conclusions about the development of modern medicine[444]. The author identifies power of creating the biological identity of a man with possible changes in the perception of people depending on their embryogenesis. That may result in changes in foundations of the current state of affairs concerning human rights and freedoms that all people are entitled to. Laboratory-created, improved human beings can be seen as different from those conceived in a natural way. The catalogue of differences, which will certainly expand in the nearest future, will determine bases for different treatment of individual units. One cannot exclude cancellation of civilization achievements by future generations such as e.g. democracy, equality before the law or human autonomy. This perspective should be evaluated as exclusively negative.

Of course, it is difficult to accept that natural procreative processes lose their preference in favor of artificial human biogenesis. This is obviously exaggeration. However, it correctly indicates that in the era of medical progress we have to deal with modernization of solutions, which certainly exceeds legal reflections.

Meanwhile, implementing new ideas by legal tool seems to be a right way to make progress. Law can create good conditions for scientific development as well as barriers, which are deemed to be impassable by humans.Focusing on the issues of extracorporeal fertilization consequences, we should take into account the basic postulate. Namely, this area of medical intervention in human life cannot be deprived of legislative interference.

Currently, rights of European countries regarding in vitro fertilization are characterized by numerous differences. For example, implantation of a human embryo collected from another woman is acceptable and specifically addressed in the Kingdom of Belgium. While there is a clear prohibition on similar procedures in the Republic of France[445]. Polish legislative passiveness in this case may result in great irreversible abuse.

The purpose of this paper is to analyze *de lege lata* conditions, which are connected with the discussed matter. It is also an attempt to indicate some limited lines related to legal aspects of in vitro fertilization[446]. The presented thesis and doctrinal statements provide an overview on scientific reflection created by selected authors. It is obvious that, the formula of such study does not allow for comprehensive representation of all scientific achievements that accompany this issue in the Polish civil law doctrine. In addition, it is appropriate to give a legal definition of in vitro fertilization contract,

[444] Habermas, J. 'Die Zukunft der menschlichen Natur. Auf dem Weg zu einer liberalen Eugenik?', Frankfurt am Main 2005, *passim*.

[445] Zatorska, J.'Komentarz do ustawy z dnia 6 listopada 2008 r. o zmianie ustawy – Kodeks rodzinny i opiekuńczy oraz niektórych innych ustaw', access: System of Legal Information: Lex 2011.

[446] As to the ethical nature of medically assisted procreation compare: Tokarczyk, R., *op. cit.*, p. 182 et seq.

and indicate the basic features of such contractual relationship. In particular, focusing on civil law aspects of in vitro fertilization.

## 2. Selected civil law aspects of the contract for in vitro fertilization

As it has been already mentioned, in the current Polish legal system there is no statute that would comprehensively regulate the medically assisted procreation issues. Therefore, all legal issues arising from such proceedings should be solved on the basis of the currently binding law. Proceedings with in vitro method can be carried out entirely from private funds, or may be wholly or partly refunded[447]. However, detailed analysis of bases for such procedure is not the subject of this study, and it is enough to say that implementation of such proceedings is preceded by conclusion of a contract. In the absence of detailed regulation of this issue, the agreement of in vitro fertilization - bearing in mind the very specific subject - should use general regulations of the civil law, which is hereinafter called the law on contracts.

Regarding the unique nature of considerations resulting from such agreement, acceptability of such contractual obligations should be scrutinized. In the interim, on the basis principle of freedom of contract in the Polish civil law, which was expressed explicitly in Article 353 (1) of the Civil Code, entitling the parties to determine the content of legal bonds to a contractual relationship according to its discretion[448]. This provision was added to the Civil Code in a fundamental amendment of July 1990[449]. Before introduction of this amendment, the above mentioned rule had been inferred from the principle on legal entities autonomy of the civil law ensuring freedom of shaping their legal relation.

The freedom of contract principle gives entities an opportunity to establish different types of contractual relations, other than normatively defined by the Civil Code or other laws.[450] They can also be created on the basis of nominate contracts. What is more, the parties are entitled to make some modifications or additions, which creates a legal tool that is more suitable for them[451]. The entities may shape the content of contractual obligations within the limits defined by article 353 (1) of the Civil Code at their own discretion.[452] This article shows three sources of these restrictions: *law*, *rules of social*

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[447] Program Infertility Treatment by in vitro fertilization for the years 2013 - 2016, implemented on the basis of Art. 48 of the Act of 27 August 2004 on healthcare services financed from public funds.

[448] Act of 23 April 1964 of the Civil Code (Journal of Laws of 18 May 1964No. 16, item 93 with subsequent amendments).

[449] article added by article 1, point 48 of the Act of 28 July 1990 amending the Civil Code with effect from 1 October 1990.

[450] Olejniczak, A. 'Comment to art. 353 (1) of the Civil Code' [In] Kodeks cywilny. Komentarz. Tom III. Zobowiązania - część ogólna, ed. Kidyba, A. access: System of Legal Information: Lex 2010.

[451] *Ibidem*.

[452] *Ibidem*.

*coexistence* and finally *features (nature)* of legal relation[453]. This provision also requires to test not only the content but also the objective (aim) of the undertaking. The assessment is based on the question whether parties' transaction have a suitable legal content, which is indicated by limits imposed by the principle of freedom of contract. For the aim of the commitment, it should be understood as the preferable legal state between the parties[454]. To make it clear, it is worth mentioning that the sanction for nullity of legal action, expressed in art. 58 of the Civil Code, is also a limitation of legal actions acceptability. Considering the above mentioned matters, the appropriate question is whether the subject of a contract for in vitro fertilization is set within the scope of the freedom of contract and nullity of legal action. This issue requires a solution, because freedom of contract face certain limitations that arise from the above mentioned factors. Lack of clear regulation of the issue makes legal sciences attempt to answer that question.

There are divergent doctrinal statements on this question. The arguments in favor indicate that a contract for in vitro fertilization is within the scope of freedom of contract[455]. However, there are also statements in favor of unacceptability of such contractual obligations[456]. Assuming correctness of the first statement, we should consider applicability of provisions of other agreements typical to the in vitro fertilization contract.

At the beginning, it is appropriate to briefly analyze a contract for specific task, which is defined in provisions of particular obligation law section. The contract for specific task[457] is an agreement on result. In case of the contract for specific task it is essential for the contractor to make every effort to fulfil a specific, individually determined result. Meanwhile, as it is noted: "IVF treatment is not a kind of health care benefits delivery, because the medical procedure leading to fertilization outside the body is not associated with the provision of any object, and its essence is to conduct special actions, which allow to bypass medical disorder of reproductive functions of human body"[458]. Similarly: "The results of an in vitro service is not subject to the contractual obligation, in particular, the

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453 *Ibidem*.

454 *Ibidem*.

455 Compare: Boratyńska, M. 'Umowa w sprawie zapłodnienia pozaustrojowego', Prawo i Medycyna, No. 30(2008), available at: www.prawoimedycyna.pl.„IVF contract [in vitro fertilization] is a kind of a civil contract of treatment to which, the provisions of the commission contract are applicable (Article 750 of the Civil Code) [...]" (author's own translation).

456 Haberko, J., Olszewski, K. 'Jeszcze o moralnych i prawnych aspektach dopuszczalności zabiegów in vitro – polemika', Prawo i Medycyna, No. 31(2008), available at: www.prawoimedycyna.pl:„ Referring to the agreement and in vitro fertilization, we believe [...] that there are arguments for the invalidity of such agreement on the grounds of Art. 58 of the Civil Code. What is more, insemination performed using cells derived from persons other than spouses is inadmissible on the basis of the principles of social coexistence" (author's own translation).

457 Civil Code, articles: 627-646.

458 Maciejko, W. 'Commentary on the judgment of the Regional Administrative Court of 30 August 2006, VII SA / Wa 997/06' ( author's own translation).

creditor cannot raise the objection that the effect did not occur, as long as the debtor tried to achieve it with due diligence. […] In addition to the provisions of a commission contract defined in the Civil Code, in the scope of treatment based on IVF contract, the provisions of the act on the profession of physician and dentist, the act on protection of personal rights and patient's rights and the act on health care also apply"[459]. Taking into account these reflections, it should be anticipated that application of the contract for specific task in this area is unacceptable. The rules applicable to the contract for IVF will therefore be the principles of a commission contract (especially contract for services - article 750 of the Civil Code) and, to a lesser extent, the provisions of other acts.

Article 750 of the Civil Code applies to the contracts that are generally characterized by two factors. First is about contracts for providing services, while the second, contracts that are not regulated by any other existing provisions.[460] It defines boundaries to this type of agreements and indicates that it is a very wide category of contracts. In the market economy, which is characterized by significant dynamics of business relations, such agreements are of major importance in legal transactions.[461] Generally, it happens because a legal regulation does not keep up with rapidly changing needs of the economy. Therefore, the parties are forced to create an appropriate legal relation with the use of existing legal instruments. The above mentioned attribution is a result of the civil law flexibility.

The rule defined in article 750 of the Civil Code applies to agreements, which are known in literature as innominate contracts[462]. Their objective is to provide a variety of services. The content of the shaped contractual relationship may be a one-time, periodic or continuous service[463]. In case of in vitro fertilization, the contractor performs complex medical operations and actions, aiming at achieving a state of fertilization. In essence, these actions are aimed at omitting natural negative conditions, which do not allow a patient to have children without interference of assisted reproduction techniques. As it was mentioned above, contractual liability for improper performance or non-performance of obligation will not include responsibility for non-occurrence of result[464]. As the statements of doctrine make it clear, this view should be considered as well-established[465]. Therefore, it should be accepted that a negative premise of the

459 Boratyńska, M., *op. cit.*(author's own translation).

460 Kopaczyńska-Pieczniak, K. 'Comment to art. 750 of the Civil Code' [In], Kodeks cywilny. Komentarz. Tom III. Zobowiązania - część szczególna, ed. Kidyba, A. access: System of Legal Information: Lex 2010.

461 *Ibidem*.

462 As for the standard contract and innominate contract compare: Gawlik, B. 'Pojęcie umowy nienazwanej', Studia Cywilistyczne, Vol, XVIII (1971), also: Gawlik, B. 'Umowy mieszane - konstrukcja i ocena prawna', Palestra, No. 5(1974).

463 As to the nature of performance compare: Tracz, G. 'Sposoby jednostronnej rezygnacji z zobowiązań umownych', Warszawa 2008, p. 51 – 64.

464 Boratyńska, M., *op. cit.*

465 Kopaczyńska-Pieczniak, K., *op. cit.,* and literature there invoked.

contract provisions is the fact that according to covenanters' intentions, the contract would be an agreement on result.[466]

Admittedly, the range of contract for services provision is broad. Notwithstanding, an analysis of the Civil Code allows us to draw aconclusion that the concept of services means the factual steps.[467] There is no doubt that performing legal actions on behalf of other persons is in fact governed by other typical agreements. In particular, a commission contract.[468]

To clarify it, consideration of services included in an agreement on medically assisted procreation may, in essence, be payable. Simultaneously, there are no legal impediments to accepting its being gratuitous. Nonetheless, such contract would be consensual. The parties of in vitro fertilization contract may be any entities recognized by civil law.[469] It is imposed by essence of these obligations that the covenants may be individuals. They can also be legal persons and organizational units which are not legal persons, where the law recognizes the legal capacity - in practice they are entities providing medical services.[470] The agreement on in vitro fertilization can be, therefore, a commercial contract. It happens, when at least one party is an entrepreneur.[471] This may be especially a health care facility that has an obligation to comply with the contract, which is within the scope of their business or profession. In such circumstances, according to article 355 § 2 of the Civil Code, in the assessment of obligation performance, elevated *due diligence* criteria are applicable. It is qualified as standard care that includes professional nature of the business. A characteristic feature of in vitro fertilization agreement is undoubtedly an obligation to provide the service personally. Due to the actual and crucial conditions a patient is induced to conclude a contract, with no other entity providing medical services. Typically, these agreements are based on trust between the parties.[472] Accordingly, it requires personal performance by the service provider. Provision of the service is entrusted by a client to a specialized individual, in trust for skills, qualifications, knowledge and other qualities that the person represents.

Summing up, in case of in vitro fertilization agreement, the general principles of contract law, in particular, provisions of a contract for service provision, defined in article 750 of the Civil Code are applicable. What is important is that analogous application of other civil law provisions and principles should be preceded by a thorough analysis of applicability of the previously mentioned regulations to provision of a specific benefit, resulting from IVF contract.

[466] *Ibidem*.

[467] *Ibidem*.

[468] Civil Code, articles: 734 – 751.

[469] Kopaczyńska-Pieczniak, K., *op. cit.*

[470] Compare also: Pietrzykowski, K. 'Kodeks Cywilny. Komentarz', Warszawa 2011, comments on art. 1, item 13, p. 41.

[471] Kopaczyńska-Pieczniak, K., *op. cit.*

[472] *Ibidem*.

### 3. Other legal aspects of in vitro fertilization

At this point it is appropriate to mention other issues that are related to the discussed matter. The provision that is associated with the discussed issue is Article 61 (9) of the Family and Guardianship Code.[473] This regulation is a response to possibilities of modern medicine. It turns out that modernization of medical technology has important legal implications. Roman law maxim *"mater semper certa est..."*[474] expresses certainty over the identity of the mother, which now requires confirmation in the form of the provision of the Act that explains the issue of motherhood. Possibilities of fertilization and conception without sexual intercourse have caused that currently even maternity is questionable. It concerns surrogate motherhood, also known as surrogacy. It consists in the fact that the pregnancy is carried by a woman other than the donor of gametes. In relation to the above, it seems to be a serious problem, which needs to be resolved. Namely, it has to be determined, which woman is the mother of the child. The woman who is a donor of gametes or the female in the actual pregnancy. There is no clear answer to the question, which was a serious gap in the Family and Guardianship Code. The legislature has already solved this problem. Article 61 (9) was introduced to the Family and Guardianship Code as the amendment of November 6, 2008, and its contents literally indicate that the mother is the woman who gave birth to the child. It expresses the idea that legally, a female who gave birth to a child has the right to be the mother. According to this provision, the mere fact of having a baby is the only necessary and sufficient condition for motherhood, and it is the basis for preparation of a birth certificate and it determines its content.[475] The axiological assumption that underlies this thesis is the specific nature of motherhood. A state of pregnancy and childbirth has a crucial influence on formation of an emotional bond with the child. It is worth mentioning that this solution is consistent with the European Convention on the legal status of an illegitimate child of 1975. The Convention indicates that the origin of an illegitimate child is determined only on the basis of birth.[476]

Another important question is the legal connection between in vitro fertilization and the issue of access to patient's data and also the issue of consent to medical treatment. The duty of confidentiality is imposed on a physician by Article 40 of the act on the profession of physician and dentist.[477] Generally, the scope of the obligation of medical confidentiality is broad, but it refers to an individual patient. However, in case of

[473] Family and Guardianship Code, Act of 25 February 1964, Journal of Laws of 1964.No. 9, item 59 with subsequent amendments).

[474] Digesta Iustiniani 2.4.5.

[475] Zatorska, J. 'Komentarz do ustawy z dnia 6 listopada 2008 r. o zmianie ustawy – Kodeks rodzinny i opiekuńczy oraz niektórych innych ustaw', access: System of Legal Information: Lex 2011.

[476] Art. 2 of the Convention of Strasbourg, 15.10.1975, Journal. Laws of 1999 No. 79, item. 888.

[477] Act of December 5, 1996 on the professions of doctor and dentist, Journal of Laws No. 277, item. 1634.

medically assisted procreation, the obligation of medical confidentiality refers to a patient and the persons involved. In case of in vitro fertilization, the consent to the disclosure of information to third parties should be given by all parties. On the other hand, it seems that patient's consent to disclosing information to another person involved is not required. Especially when it comes to report about outcomes of IVF treatment to patient's husband. It seems reasonable to believe that there is no basis for concluding that in case of contact with a person, who remains in the actual relationship with family members of patient, a physician may decide about giving the information on patient's health status to those persons, without the need of the consent of the treated patient. In addition, the law does not require to preserve any special form of the consent which excludes an obligation of medical professional secrecy. However, the consent must be clear.[478]Although it must be remembered that patient's statement of will, which means the consent to disclosure of medical information and empowers a physician to give the information to other entities, would be a variety of declarations, which due to the accompanying circumstances, could actuate reasonable belief that such authorization was granted. This may be a statement of intent implied or expressed in a manner, that reveals the will of the patient clearly enough.

The consent issue is closely connected with, e.g., the impact on a certain procedural claim. It is rightly noted that, in vitro fertilization should be treated as a high-risk treatment within the meaning of the act on profession of doctor and dentist.[479] It is particularly supported by the fact that preparatory steps are performed using surgical technique.[480] Thus, explicit consent to treatment should be given in writing by each patient. The consent of both parties is a prerequisite condition for starting of the procedure legally. Withholding such consent should result in immediate cessation of activities.[481] The issue of consent and authorization applies to both patients involved. However, interventions in the body of each patient is of a different kind and degree of severity.[482] Thus, respecting patient's autonomy it requires individual consent to the procedures.[483]The Supreme Court had noted it and after some time there was created a new provision on this basis. Namely, the legal phenomenon of consent[484] for surgery results in the subsequent loss of specific claim before the court. It is defined in resolution

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[478] Zielińska, E. (ed.), Barcikowska-Szydło, E., Kapko, M., Majcher, K., Preiss, W., Sakowski, K. 'Ustawa o zawodach lekarza i lekarza dentysty. Komentarz', comment on art. 40 and following, access: System of Legal Information: Lex 2011.

[479] Boratyńska, M., *op. cit.*

[480] *Ibidem.*

[481] *Ibidem.*

[482] *Ibidem.*

[483] *Ibidem.*

[484] In this area, the consent should be understood as widely as possible. Including not only the acceptance of conducting medical treatment, but also the confirmation of all the legal and familial implications of using the medically assisted procreation techniques.

7 of the Supreme Court of October 27, 1983[485],, concerning denial of paternity by a husband of mother of a child conceived by artificial insemination with semen from another man. The Supreme Court stated that the action undertaken by the husband, who agreed to such medical procedure, may be considered contrary to the principles of social coexistence.[486] The Supreme Court gave priority to protection of family relationships at the expense of the principle of objective truth. This jurisprudence was approved by science.[487]It is worth noting that the consent may take any form which allows to confirm the intention of giving it beyond any doubt.. In the current legal state of affairs, correctness of such theory, shown by the Supreme Court, is no longer discussed. Article 68 of the Family and Guardianship Code, in the version articulated by the above-mentioned amendment, excludes the admissibility of such an action.[488]

### 4. Summary, *lex ferenda* perspective?

While there is no detailed regulation concerning matters of contractual obligations related to in vitro fertilization in the Polish law, the practice of performing such procedures is long. As rightly noted: „ Currently, Poland has no legislation [...] on the [issue of in vitro fertilization], although in vitro fertilization treatments are carried out in the country successfully for many years. However, this situation does not imply medical arbitrariness of a physician and a medical facility in the scope of assisted procreation procedures".[489] It seems obvious that the previously mentioned entities are forced to comply with general principles and other provisions, which are applicable on the basis of justified reasoning by analogy. Essentially, application of the general principles of the civil law and analogous application of the provisions of nominated contracts has a certain defect. Legal tools created with the use of such method do not reflects specifics of this sensitive medical and legal issue. Already existing law related to contract principles is not an optimal instrumentation for such important questions. The law, which is not a precise tool to regulate complicated legal relationships, may lead to claims, damages and several other negative legal implications. For instance, difficulties or even lack of possibility to enforce contractual liability arise from failure to fulfill contractual

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485 Compare: III CZP 35/83, OSNC 1984, No. 6, pos. 86.

486 Compare also: Safjan, M. 'Klauzule generalne w prawie cywilnym (przyczynek do dyskusji)', Państwo iPrawo, No. 11(1990).

487 A. Szpunar, wrote that family status laws should not be an exception to assess the operation of legitimate from the perspective of the principles of social coexistence (author's own translation), see Szpunar, A. 'Stosowanie art. 5 k.c. w sprawach o prawa stanu', Państwo i Prawo, No. 6(1981).

488 Haberko, J., Sokołowski, T. comments on article 68 The Family and Guardianship Code [In] Kodeks rodzinny i opiekuńczy. Komentarz, eds. Sylwestrzak, A., Zielonacki, A., access: System of Legal Information: Lex2013.

489 Ostojska, J. 'O problemie podmiotowości prawnej embrionu in vitro', available at: http://www.prawoimedycyna.pl/index.php?str=artykul&id=1038, (6.06.2014).

obligations. Jurisdictional difficulties may also be an outcome of such state of affairs. Such legal and factual condition is undesirable in a democratic state of law and it should be reformed as soon as it is possible.

At the time of printing this paper, legislative work on the **Infertility Treatment Law** are ongoing.[490] The project aims to, *inter alia*, the implementation of European Union law. Pursuant to art. 1 of the bill, the Act defines: 1) the principle of protection of the embryo and reproductive cells in relation to their application in biology and medicine in connection with infertility treatment; 2) methods of infertility treatment, including the use of medically assisted procedures procreation; 3) tasks of public authorities in the protection and promotion of reproductive health; 4) the conditions for the donation, procurement, processing, testing, storage and distribution of reproductive cells and embryos intended for use in the procedure medically assisted procreation; 5) the operating principles of medically assisted procreation centers and banks reproductive cells and embryos;

The Act provides different types of donation. Donation has been divided into **three types**. **Partner donation**, **donation other than the partner** and the **donation of embryos**. 'Donation' bill defines as "the transfer of **reproductive cells** or **embryos** in order to apply in humans"[491]. Proposed bill provides definition of **partner donation**[492] – as the transfer by the donor of reproductive cells - the man in order to use them in the procedure of medically assisted procreation in recipient - women remaining from the donor are married or in cohabitation consistent statement confirmed the donor and recipient - women; the donation partner reproductive cells are used recipient - women; and also: **the donation of the embryo** - embryo transfer in order to apply it in the procedure of medically assisted procreation in the recipient - a woman who is not a female donor cells reproductive and not married or in cohabitation with the donor male germ cells, from which the germ has been created.

The draft do not define (even negatively) human embryo which is a serious shortcoming of the proposed Act. The legislator probably refused to settle the problem of the ontological status of the human embryo, which indirectly address also the issue of the beginning of human life.

The bill includes in its title the **'infertility treatment'**[493]. While IVF proceedings are not treatment – there are not health care benefit delivery. It should be noted that 'treatment' is a term of legal language that has its doctrinal definition[494]. Treatment is

[490] Form No. 3245 of 13 March 2015, available at: http://orka.sejm.gov.pl/Druki7ka.nsf/0/1A86D4AD4E83BE46C1257E0C0040423A/%24File/3245.pdf (6.07.2015).

[491] Art. 2 point 7 of the draft.

[492] *In genere*partner donation is one in which there is no foreign genetic material. Can be carried out regardless of formal ties (or lack of thereof) that bind partners.

[493] See: Art. 5 point 1, sect. 5 of the draft.

[494] Compare: A. Górski terms: 'Czynność lecznicza' and 'Czynność nielecznicza' [In] Leksykon prawa medycznego 100 podstawowych pojęć, ed. Górski, A., Warszawa 2012, pp. 13 – 18.

aimed at improving human health, while the IVF methods results (only) in a fertility condition without removing the causes of prior infertility.[495]

The law seems to be excessively complicated. Its use in practice might be difficult. Doubts arise, for example, with the competence to withdraw consent (art. 22), and in addition, with – in its essence – 'selection' of embryos described in art. 23.[496] Aforementioned Act may give rise to a number of legislative and ethical doubts. Complete impact of **Infertility Treatment Law** will be able to evaluate after its introduction.

[495] As to the ethical nature of IVF compare: Tokarczyk, R., *op. cit*., p. 190 *et seq*.

[496] Compare: 'Preimplantation genetic diagnosis procedure' described in art. 26 of the draft.

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# IV. BIO-PIRACY AS A MODERN ETHIC PROBLEM

## 1. Introduction

The aim of this article is to find an approach to the problem of bio-piracy with a particular consideration over the influence of the pharmaceutical industry in this kind of activity. This issue has just been highlighted within the fringes of the European culture. Nevertheless, there is still lack of effective regulations which are just about to be put together. The ethnic problem of bio-piracy which has to be worked out by considering concrete regulations either at national or international level is not of the least importance, because either way, the current situation is simply unacceptable.

It is very important for this massive problem to be taken to the level of open public discussion so that societies will be aware of bio-piracy and the threat that it carries alongside with it. The effect of this problem should not be viewed only on the basis of our contemporary times. We need to take a broader view that will let us understand the kind of implications and negative attitudes bio-piracy could have in the future. Bio-piracy is not a problem that only affects poorer countries that are often victims of exploitation by big pharmaceutical companies or conglomerates. It equally affects every ethnic group that possess a definite local knowledge. Above all, it is also important to include the problem of cultural identity which in a particular way could be a reason for the ignorance of bio-piracy. There is nothing wrong in deriving from the knowledge of the local folk, but on the contrary, one should not scoop from it at the cost of the original administrator.

The issue highlighted in this article is not meant to go a long way in addressing the problem of bio-piracy. The aim of the author is not to delve into the complex aspect of the issue, but to bring to light and raise attention over certain phenomena which demand a deeper reflection in order to put into effect definite legal measures. There are not many essays or writings that have directly addressed the issue of bio-piracy yet.

## 2. The idea and nature of bio-piracy

The increase in human population has its own natural tendency that has got to do with the process of globalization, which led to the division between developed countries and so called third world countries. International corporations that are in possession of huge capital to carry out potential global businesses strictly operate on the basis of these

divisions. Such activities often take place at the cost of developing countries that do not possess the legal resources to protect their own rights. These kind of activities often bypass the intellectual ownership right of the knowledge of the local folk which is often claimed by big pharmaceutical companies. This is what is generally referred to as bio-piracy. Although this problem is well known for very many years[497], there is still lack of effective legal regulations, particularly in the scope of countries which should have been defended in the face of such activities.

Talking about bio-piracy, it is important to first of all clarify a few concepts. The way out is to briefly explain what we really understand by the meaning of the knowledge of the local folk[498]. This notion became widely used in the 70s of the twentieth century[499]. It could be seen as local knowledge as a result of the practicality based on experience which has an empirical, recurrent and asymmetrical arrangement that has its own basis on a broad cultural matrix[500]. There is a clear picture surrounding this definition that is based on definite cultural knowledge. It is directly connected to a specific culture (in other words it reflects to a particular nationality from a geographical point of view). This in a natural way make use of accessible natural resources in the process of healing. In this regard, the key word in the meaning of a local folk's knowledge is biodiversity.

Biodiversity could be described as the changes in the living organisms that are present in the land, water and other aspects of the eco-system as well as the complicated ecology which is part of the entire eco-system[501]. It embraces the internal changes of a type between types and within the frames of the eco-system. It is important to indicate that this biodiversity with regards to the knowledge of the local folk has become an area of interest for the pharmaceutical industry which maintains the boundary of practical exclusion to ethno-botanic. This knowledge refers to plants and their possessions. The search for this knowledge by big pharmaceutical companies is universal. This further leads to bio-prospect which is not practically based on the search for definite species of plants, but the search for substances found in the plants which have pharmaceutical uses. This kind of activity is often carried out with the use of the knowledge of the local folk, because it makes it significantly easier to accomplish definite results as well as minimizing cost which are of key contemporary importance. If such knowledge is used on commercial basis and at the same time the local folk from which it originated is not rewarded, this is what could be describe as bio-piracy.

[497] The first cases of bio-piracy have been in the days of the so-called. conquest, that is, the Spanish expeditions of armed areas of the Americas, Africa and India in the fifteenth century.

[498] Synonyms are: local knowledge or traditional knowledge.

[499] Warren, D. M.'Comments to P. Sillitoe's The Development of Indigenous Knowledge: A New Applied Anthropology', Current Anthropology, No. 39(2)/1998, p. 244.

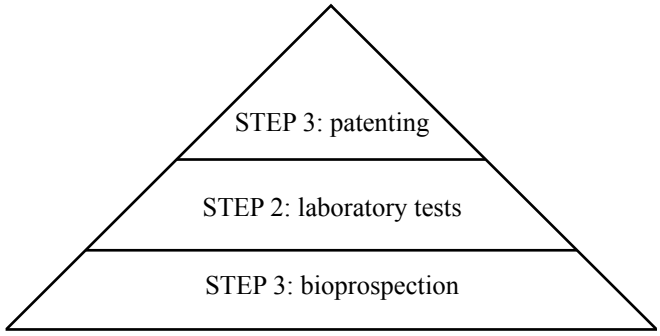
[500] Ellen, R. 'Comments to P. Sillitoe's The Development of Indigenous Knowledge: A New Applied Anthropology', Current Anthropology, No. 39(2)/1998, p. 238.

[501] Zaid, A., Hughes, H. G., Porceddu, E., Nicholas, F. 'Glossary of biotechnology for food and agriculture. A revised and augmented edition of the Glossary of biotechnology and genetic engineering', Food and Agriculture Organization of the United Nations, Rome 2001, p. 30.

Dealing with bio-piracy, we also have to remember that the definite knowledge of the local must have been given that process of conceptualization and acknowledged as something worthy and as such should be given some form of legal protection (at least in a theoretical way)[502]. So what is bio-piracy then? It is a notion which could be described as the practice of patenting genotypes and result to the privatization of collected genetic resources. This definition also has to do with the lack of the agreement of this practice from the side of the local folk from which the knowledge and resources originated[503]. In this sense bio-piracy which through the use of definite legal resources, allows big pharmaceutical companies to exploit resources which do not actually belong to them.

In practice, activities of bio-piracy lead to the use of the knowledge of the local folk, who identifies with the healing properties of certain plants, which could as well be used in commercial activities with the aim of making profit. After a certain plant and its healing qualities have already been identified, pharmaceutical companies move in and patent the rights and earn all the money from the commercial proceeds. On the other hand, the local folk who actually discovered the medicinal properties of the plant receives nothing for it. This action is only a simplification of the procedure, which is expected to show a general charge of bio-piracy. Bio-piracy action can be included in three main steps (look diagram 1).

**Diagram 1. The main stages of bio-piracy**




*Source: own study based on: Biopiracy Collective, Understanding, resisting and acting against bio-piracy Understanding, Resisting and Acting Against Biopiracy: a guide on how to act in the face of illegal appropriation of life and traditional knowledge, 2012, p. 3 and nexts.*

[502] Świerk, K.'Bioprospekcja, biopiractwo i wiedza tubylcza. Przykłady z Ameryki Łacińskiej', [In] Antropologia Stosowana, ed. Ząbek M., Instytut Etnologii i Antropologii Kulturowej UW & Międzynarodowe Centrum Dialogu Międzykulturowego i Międzyreligijnego UKSW & WDR, Warszawa 20013, p. 326.

[503] Zaid, A. *et al., op. cit.*, p. 29.

Of course on the other side of the coin, pharmaceutical companies deny the act of bio-piracy completely. Their argument is based on the fact that, their patent rights do not embrace plants but only particular chemical substances which particular plants possess and can as well readily give. Equally, in relation to plants, specific laboratory tests are carried out which allow the isolation of certain substances and determine their properties. Those are the actual substances that are subjected to patent rights. They maintain that these substances and their properties are not usually known by the local folk and as such the containment of such substances by way of patent rights should not be taken as an act of bio-piracy.

However, it is difficult to succumb to such an argument that is based on fiction just for the companies to defend their own interest. Their argument is also based on the point that the knowledge of the local folk is not conceptualized because the local folk does not know how a certain substance is called and does not know its chemical properties. The folk is only aware that the use of a certain plant results to certain effect, for instance healing. That knowledge is not a derivative of laboratory test but a derivative of long years of traditional and empirical experience. The only problem in this case is the lack of formalization of the knowledge, that is used by pharmaceutical companies. In this case the activity of bio-piracy has to do with problem of the law of nature as well as the law of ethics.

This further raises the question as to whether or not the substances obtained as a result of bio-piracy fulfill the condition or status of patent rights. There is often an indication that such patent rights have no element of innovation[504], because they rely on the knowledge of the local folk which is universally known to a certain region or nation. The only element of innovation in this sense could be seen as the copying of the conceptualized knowledge of the folk but the activity in itself has no element of innovation.

When it comes to the sphere of ethics, it is worth quoting the idea of V. Shiva "the patenting of the local folk's knowledge in the use of plant is equivalent to the hijacking of the intellectual and biological resources which the poor folk relies on for his existence. The robbing of his right and possibility of independent use of the resources or capital of nature – the one and only to which he has access - resulting that poor people from the third world will be subjected to extinction in a similar way to plants on which their lives depend. The people of the third world are equally endangered species"[505]. This shows that bio-piracy does not only has in itself the element of material losses for the local folk, but could also be a potential threat for his existence.

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[504] Compare: Prawo własności przemysłowej of 30 June 2000, Journal of Law from 2013, item. 1410.

[505] Shiva, V. 'Regulacje rolne WTO: zagrożenie dla chłopów Trzeciego Świata, Raport Międzynarodowego Forum ds. Globalizacji, Czy globalizacja pomaga biednym?', Stowarzyszenie OBYWATEL, Łódź 2003, p. 64.

### 3. Examples of bio-piracy

In order to be objective, it is also good to mention the good side of bio-piracy. After talking about the negative impact of bio-piracy, it is important to note that thanks to the introduction of certain medicines, the health standard of many societies around the world has been drastically improved. Anyway, this should not be any form of justification for bio-piracy, because such positive effects could be accomplished while at the same time, the negative consequences of what is deemed as unacceptable could be avoided.

It is also good to know that bio-piracy has not only got to do with the pharmaceutical industry. It also has a tremendous effect on agriculture, an area in which big companies claim patent rights to particular seeds that have been cultivated for centuries by local farmers and served as a source of food as well as a source of income. An example of such an activity is the issue surrounding the Basmati rice. In the 90s of the twentieth century, the Rice Tech company placed a cross on a variety of Basmati rice seeds with the aim of cultivating it under American climatic conditions. On the 8$^{th}$ of June 1994, the named company filed in an application in order to obtain patent rights for this particular type of rice. Four years later, patent rights were issued to rice Tech on the second of September 1997. The Basmati Rice 'produced' by Rice Tech looked and tasted the same as its original version in India. As a result of the patent rights issued to Rice Tech, certain payments were put in place which in turn brought negative consequences to the income of the Indian farmer[506].

Returning to pharmaceutical industry, it is good to assemble a series of activities that could be taken as an act of bio-piracy. One of these activities was the use of Catarantus from rose flower, also known as rose pigment which grows in Madagascar[507]. This was highly used by the natives for healing purposes. In the 50s of the twentieth century, Eli Lilly a big American pharmaceutical company carried out a test on the plant and discovered that it possess a chemical substance that could be used for the healing of leukemia. It is true that the natives of Madagascar did not use the plant for leukemia healing but the pretext of carrying out the test was an initiative which resulted from the universal knowledge of the local folk about its healing properties[508].

Another example of bio-piracy was the attempt to patent Turmeric also known as curcuma. It is a plant which has been used in India from time immemorial to heal wounds (although its uses are of a much more wider range). Luckily, Turmeric or curcuma ended up not to be patented[509].

Furthermore, another example of bio-piracy which ended up in the gaining of a definite but minimum material benefit by the Khoisan tribe who from time

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[506] http://www.zm.org.pl/?a=biopir (15.12.2013).

[507] Gawryś, W.'Słownik roślin zielnych łacińsko-polski', Officina Botanica, Krakow 2008, p. 50.

[508] Słojewska, A.'Biopiractwo na oczach świata', Rzeczpospolita, text of 18 May 2013.

[509] Matacz, M. 'Biopiractwo', Wprost 2003, item. 21.

immemorial has been using the properties of the Hoodia plant for healing purposes. It is ideal for healing wounds, although it has a lot more uses of a wider range such as: minimizing the effect of hunger and thirst and eventually the effects of obesity. In exchange for their whole knowledge, the Khoisan tribe received a minimum benefit of one and half million dollars within a stipulated period of four years[510].

This sum could be seen as not much, as far as a pharmaceutical company is concerned, but nevertheless, it means something at least for the khoisan tribe. This sum of money is a lot more less than money spent to carry out scientific test over a short period of time. For instance the drug called Tramadol used for the killing of strong pains without much side effects by way of getting addicted to it. The same properties are found in the nature of Nauclea Latifolia. The extract from the roots of this plant had been in use from time immemorial by the inhabitants of modern day Cameroun.

This situation gives us a clear picture on how the local folk and pharmaceutical companies could be useful to each other if some form of corporation is established. Although any kind of corporation should be based on partnership. This could have proven more beneficial for both parties. The local folk possess a great deal of knowledge about the healing properties of certain plants that they could make readily accessible in return for material benefit as in the case of the Khoisan Tribe. Such benefit is not a lot for a giant pharmaceutical company but for the case of the local folk it is a necessary element for survival and even for further development.

### 4. Legal regulation in the sphere of bio-piracy

Bio-piracy could be categorized in two aspects under the point of view of the legal system, namely: national and international law. The rules should have been centered within the parameters of international law. Nevertheless the regulations are been hampered for certain reasons. Firstly, there is a serious lack of national law to cover this area. Secondly, companies that commit the act of bio-piracy have a characteristic nature of been above national regulation. Even though the problem of bio-piracy has been pursued over a very long period of time, there is still lack of uniform and effective regulations. The existing regulations have so far failed to fully fulfill their role which should be on one hand, protecting the knowledge of the local folk and on the other hand not to hamper the progress of the medical and pharmaceutical industry.

Analyzing the existing regulations with regards to the problem of bio-piracy, it is important to take into consideration the Convention on Biological Diversity[511]. This action was the result of the meeting of a group of experts which started in May 1989. The aim was to work out an international package of legal instruments which will pave the way for the protection of the knowledge of the local folk as well as assuring the even

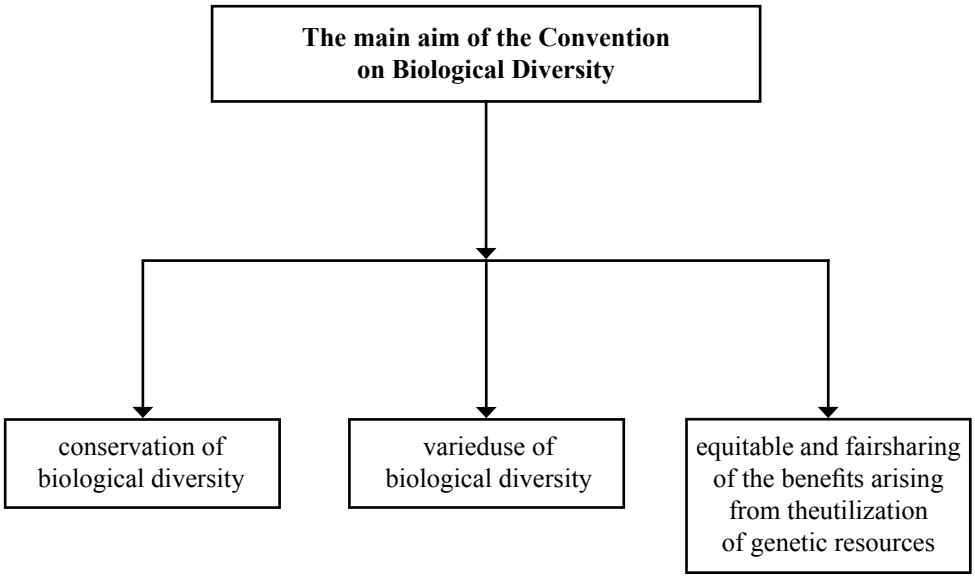
[510] 'Wiedza szamańska za miliony dolarów', Rzeczpospolita, text of 7 April 2003.

[511] Journal of Laws from 2002 No. 184 item. 1532.

exploitation of biodiversity. Among other facts taking into consideration, the division of cost between developed and developing countries as well as ways which could allow the support for innovation inspired by the local folk. In 1991, the group was called the International Committee of Negotiation. This resulted in the drafting of a text known as the Convention on Biological Diversity[512].

The convention on biodiversity adopted a resolution at the UN convention in Rio de Janeiro in 1992. This act was ratified by 193 states, almost all countries in the world. Also, on the side of the convention were European countries and all EU member states[513]. An agreement was stated in the document among others that for the good sake of biological diversity, richer countries should be able to come up with adequate funds for demands of the objects from which they earn commercial benefit. This makes a lot of sense but anyway did not go far enough to precisely state in which way and to what extent of use and for which procedures this could be accomplished. This was one of the main criticisms towards the Convention on Biological Diversity. The main aim of this convention is revealed in diagram 2.

**Diagram 2. He main aim of the Convention on Biological Diversity**




*Source: own study based on: Convention on Biological Diversity.*

[512] http://www.cbd.int/history/default.shtml (30.12.2013).

[513] Have not signed the Convention: Andorra, Vatican City, South Sudanand the United States of America.

The most important regulation concluded at the Convention on Biological Diversity is article 15 in which among others called for the recognition and respect of the sovereign rights of states over their natural resources, the authority to determine access to genetic resources rest with the national government and is subject to national legislation. Each contracting party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other contracting parties and not to impose restrictions that run counter to the objectives of this convention.

That regulation stood as a matter of fact the basis which make possible of precise regulations by individual states that should enable the right to protect biological diversity. However, the so called resolution was not put in full use by the signatories of the convention. Above all, article 15 of the Convention on Biological Diversity met a series of problems in relation to the competent legal necessity of regulation pertaining to the up keeping of biodiversity.

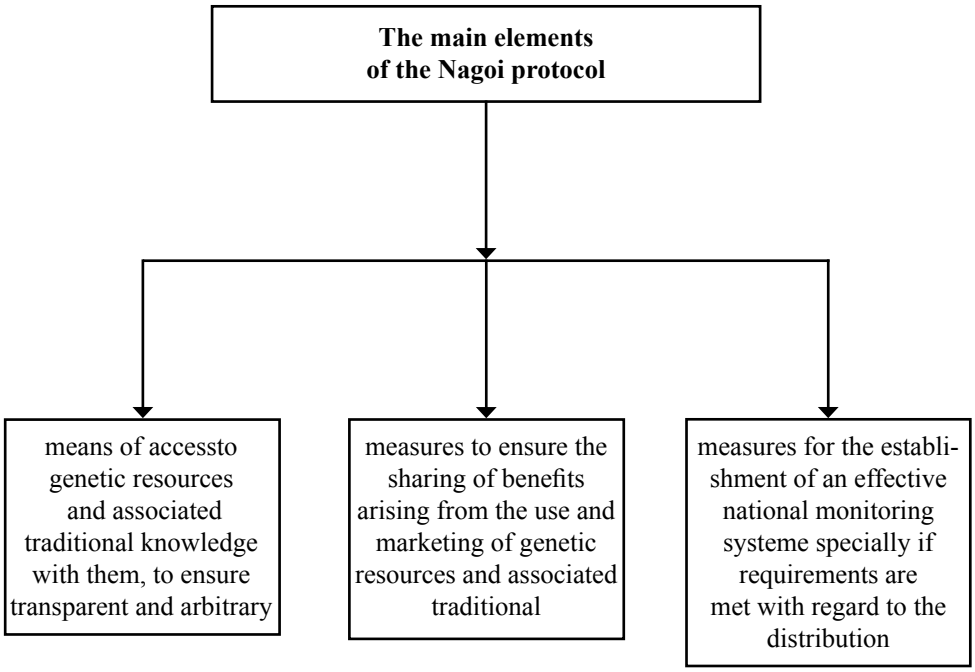
Another important event which took place in the formulation of precise regulations with regards to bio-piracy as well as the protection of biodiversity was the world summit on sustainable development which took place in August 2002. It was decide at that summit that it is necessary to start negotiations in other to establish an international system which determines access as well as the division of eventual benefit within the frames of the convention. Finally on the 29$^{th}$ of October 2010, Nagoi protocol was accepted at the Convention on Biological Diversity. It mentioned biodiversity and access to genetic resources and also justified an equal share of benefit that comes from the use of natural resources. The Nagoi protocol was open for signing at the UN in New York from the 2$^{nd}$ of February 2011 to the 1$^{st}$ of February 2012. Apart from Latvia, Malta and the Slovak Republic, all EU countries were signatories of the protocol[514]. At the same time, the European Parliament and the EU Advisory Commission issued a joint statement to quickly hasten up the process of the ratification of the Nagoi protocol[515].

In this article, there are no specific details about the decisions concluded at the Nagoi protocol. It is only enough to indicate the basic elements which embrace the protocol. These are presented in diagram 3.

[514] Nagoya Protocolh as been signed by 150 countries.

[515] Conclusions Council of Europe on 20 December 2010 in points 1 and 21; Conclusions Council of Europe on 23 June 2011 in point 14; Resolution of the European Parliament on 20 April 2012 in point 101.

**Diagram 3. The main elements of the Nagoi protocol**




*Source: own study based on Nagoi protocol.*

The Nagoi protocol in a certain way gave details of the regulation concluded at the Convention on Biodiversity with regards to the protection of biodiversity. In the general sense, it was meant to make possible the justified division and uses of commercialized natural resources, and the knowledge of the folk between exploited resources and the profits. The regulation stated that the local folk should receive material and non material benefit from the profit that is acquired from the use of such resources. It is important to note that this does not only refer to money benefit but the benefit could come by awarding scholarships for instance (which is of great significance for developing countries). It could also be access to technological know-how (which is of great significance for developing countries). The aim is to improve conditions and facilitate development for the local folk.

According to the author, the mentioned regulations failed to fulfill their role. There is lack of effective mechanism that will be able to execute the law put in place to protect the rights of the local folk. The giant companies are quiet aware of these facts and still continue to exploit the knowledge of the local folk as well as the biological biodiversity for commercial purposes and continue to make huge profits. There is a warning from the EU which signalizes the necessity to take legal actions in this issue. In order to take appropriate action against the issue of bio-piracy, it is important to reveal the origin of

the genetic resources as well as the traditional knowledge that is used. It is also necessary to put in place an agreement with the country supplied with resources and knowledge to give access to the benefit they acquire from these resources. This would have been an additional condition that would have enable the acquisition of patent rights[516].

## 5. Summary

Bio-piracy remains one of the threat which requires a quick and skilful legislative action at the moment. The existing regulations are not enough to fully protect and secure the rights of the local folk. On the other hand, they fail to provide a justified share of the benefit that comes from the biological biodiversity. This problem is not popular in the mass media and it is always pushed to the edge by the ruling elite. This approach is unacceptable and it is necessary to apply all effort in order to change this situation. A proper use of the folk's knowledge could be accomplished in three ways. In the first place, big pharmaceutical companies should be given access to definite knowledge which they have to effectively compete for. Secondly, the local folk should gain relative benefit from what he possess. This will enable him to develop in the socio-economic sphere in line with better developed countries. Finally, the average citizen should have access to medicines or medical facilities acquired from these resources.

The question is what sort of procedures are to be undertaken in order to achieve the above mentioned advantages? In the first place it is important to make use of public opinion of various societies. If societies realized that products are obtained through dishonest attitudes, that is detrimental to the local folk, then the societies could be able to exert some form of pressure on the pharmaceutical companies in order to effect changes. In the same way, the folk should be aware of the worth of his knowledge. When it comes to legal solutions, the Conference on Biodiversity has to decide on further legislative measures. It is necessary to come up with a universal and effective system that will oversee the regulations undertaken as well as a system of executing the law within this scope. It is good to be optimistic that a definite solution could be worked in the near future.

[516] Report No 5/2013 of the European Parliament session in Strasbourg, 14-17 January 2013.

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