

PROTECTION OF CHILDREN'S RIGHTS IN THE HEALTH CARE: PROBLEMS AND LEGAL ISSUES

OCHRONA PRAW DZIECKA W OPIECE ZDROWOTNEJ: PROBLEMY I KWESTIE PRAWNE

Vitaliy Pashkov, Andrii Olefir

POLTAVA LAW INSTITUTE OF YAROSLAV MUDRIY NATIONAL LAW UNIVERSITY, POLTAVA, UKRAINE

ABSTRACT

Introduction: Among all categories of patients children (minors) must be protected first. It is caused so by the specificity of the treatment, their vulnerability, the need of further protection and supervision. Providing of medical care services for children are often connected with the risks of the process of treatment, and of the drug usage.

The aim: To identify the problems associated with the protection of the rights of minors and, on the basis of this, the basic guarantees of their rights, as well as mark the trends in the practice of ECHR.

Materials and Methods: The study is based on its own theoretical and empirical basis. The theoretical basis include scientific articles, expert reviews of legislation and communications of non-governmental organisations, and empirical – decisions of the ECHR, international legal acts and directives of the EU.

Results: The main violations of the rights of minor children include the following: - legal representatives of children do not take to the account their interests (refusal of medical intervention or the choice of certain method of interference); - medical intervention under the influence of coercion; - providing of unwarranted medical care without the corresponding testimony; - providing of inadequate medical care: when the patient was only examined and ineffective treatment was prescribed, and others. As for mentally ill children, the following rights are usually violated: for life, for a fair trial. It has been proved that defects in the provision of health care are often predetermined by the poor state logistics of hospitals, lack of financing and appropriate pediatric medicines, outdated methods of treatment, and incompetence of some doctors.

Conclusions: From the point of view of protecting the rights of minors, the rights of children in medicine can be classified into universal and special. The rights correspond not only to the corresponding duties of medical staff, but also of their parents (legal representatives). Violations of their rights are usually related to improper representation of the interests of children and disadvantages of providing medical services (defects in their provision), in particular, regarding the treatment of mentally ill, as well as in clinical trials. It has been proven that the practice of the ECHR on the protection of the rights of the child in the field of health is of particular importance.

KEY WORDS: children's rights, patient, health care, the right to life, defects in medical care, psychological disorders, European Court of Human Rights, pediatric medicines.

Wiad Lek 2017, 71, 6 cz. I, 1122-1132

INTRODUCTION

The protection of human rights and freedoms is a main task of any democratic state. After all, in a civilized society the highest social value is a man, his/her life and health, honor and dignity, inviolability and safety. In the human rights system a special place is occupied by a patient's complex of rights: health care rights are of a vital importance. Among all categories of patients children (minors) must be protected first. It is caused so by the specificity of the treatment, their vulnerability, the need of further protection and supervision.

Despite that there are approximately 94 million children and young people aged 0-18 living in the European Union (EU), Yet too often children's interests are ignored, and their voices go unheard in the public arena, though they experience difficult circumstances, for example: (1) many children suffer violence within the family, in the community, in residential care and in other settings; (2) some groups of children suffer discrimination, for instance, access to healthcare of Roma children frequently may be poor; (3) many disabled children regularly experience prejudice or lack of awareness, and are

routinely excluded from participating in decisions that affect them [1]. Providing of medical care services for children are often connected with the risks of the process of treatment, and of the drug usage. Risk factors that predispose children to develop an adverse reaction to a medicine can be physiological, indirect or iatrogenic: (1) physiological causes for increased risk: (1.1) young age, e.g. neonates and infants with the greatest physiological differences from adults; (1.2) continuous changes of medicine dispositional parameters during maturation in all age classes; (2) indirect causes for increased risk: (2.1) greater prevalence of polypharmacotherapy, e.g. in the neonatal intensive care unit; (2.2) greater length of hospital stay, e.g. children with congenital or chronic diseases; (2.3) critically ill children, e.g. those who have neoplastic diseases; (3) iatrogenic causes for increased risk: (3.1) use of unlicensed and off-label medicines with very little information regarding appropriate dose, e.g. medicines used in orphan diseases such as cystic fibrosis; (3.2) insufficient number of well-trained health-care professionals to treat seriously ill children. The following problems occur with the use of medicines in the

treatment of children and adolescents: - often, medicines used are unlicensed; - over-the-counter, traditional and herbal medicines are readily available, but their use is generally not evidence-based and is often inappropriate; - counterfeit and substandard medicines are widespread; - abuse by teenagers occurs with non-medical prescription of legal medicines and illegal drugs [2].

THE AIM

To identify the problems associated with the protection of the rights of minors and, on the basis of this, the basic guarantees of their rights, as well as mark the trends in the practice of ECHR.

MATERIALS AND METHODS

The study is based on its own theoretical and empirical basis. The theoretical basis include scientific articles, expert reviews of legislation and communications of non-governmental organisations, and empirical – decisions of the ECHR, international legal acts and directives of the EU.

REVIEW AND DISCUSSION

International law states that children – including adolescents – enjoy the same human rights as adults. Thus, international human rights documents and treaties – such as the 1948 Universal Declaration of Human Rights and the 1966 International Covenants on Civil and Political Rights, and on Economic, Social and Cultural Rights – benefit all persons. The 1989 Convention on the Rights of the Child (CRC) makes that clear by enumerating the political, civil, economic, social and cultural rights of children (defined to be under 18 years of age) [3].

The rights of children in the health care can be classified into two main groups: - universal, which are inherent both for children and adults; - specific, which belong only to children, besides they are reinforced with guarantees of their legal status.

The first ones include: - the right to life and development; - the right to the highest level of health as possible and to access to health services [1]; - to receive treatment on the basis of clinical need; - respect for privacy and dignity [4]; - right to accurate information about their illness and symptoms; - prohibition of discrimination on the grounds of age; - right to express their views on treatment decisions, and for those views to be given appropriate weight, depending on their age and stage of development; - freedom from torture, that no child shall be subjected to torture or other cruel, inhuman or degrading treatment or punishment, such as denial of pain relief [5]; - the right to an individual approach to treatment; - the right to available medical services; - the right to consent o medical intervention (on personal integrity); - the right to choose a health care institution and a doctor; - the right to respect for the patient's time; - the right to receive qualitative and safe medical care; - the right to innovations; - the right to a complaint (compensation). Others include the following: - the right of disabled children to special care; - the right of children placed in the care of the State to periodic review of treatment; - the right to protection from

the use of narcotic and psychotropic drugs [1]; - the right to be treated in a children's hospital, unit or ward with a special medical condition, play and education available; - nursing care by appropriately trained children's staff; - hospital staff and parents have a special duty of care to children and a legal responsibility to protect the child's rights, interests and wishes [4]; - the best interest of the child must be a primary consideration in the provision of health care. For example, treatment decisions for aggressive cancers must consider both the child's physical and emotional well-being, as well as his or her views; - right to development: children need support for physical, emotional, intellectual, social, cultural, and spiritual development [5].

The risks related to protection of medicine consumers' personal data are beyond the buyer's control and they are difficult to overcome with the help of regulatory mechanisms [6]. For example, minors have a limited right to privacy in regard to family planning matters. The US Supreme Court extended the right to privacy to include the right of minors to seek contraceptive care without parental consent. States realize that minors may not seek contraception if parental notification is required and therefore allow physicians to provide birth control services to minors. Most states also provide prenatal services to minors without parental notification. Abortion on a patient of any age is a very controversial topic. However, adolescent abortion presents additional ethical and legal dilemmas. States vary in their interpretation of parental consent and notification requirements as to adolescent abortion. The US Supreme Court has allowed mature minors to consent to abortions without parental approval based on constitutional privacy rights. Most states, however, have laws requiring notification and/or permission of a parent except in circumstances such as incest or rape. All states allow a minor older than 12 years to seek confidential testing or treatment of sexually transmitted disease. Some states allow a physician to notify a parent if it is determined that this information is necessary to the parent, especially in HIV testing. Treatment of substance abuse is another area where minors 12 years and older may consent. Healthcare providers are encouraged to involve family members if such involvement does not impede the treatment and/or counseling of the minor. However, they may not inform family members without the consent of the minor unless it is necessary to protect the minor or others from harm [7].

So, certain limitations (responsibilities) are relied on the parents or legal representatives of the children, in order to exercise their rights as patients. Among these responsibilities are the following: - to give staff full information about your child's condition and to let the staff know if your child has any physical or learning disabilities, allergies, sensitivities, conditions or changes in their health and of any medicines they are taking, including over the counter remedies; - to tell staff if your child is being, or has been, treated by other healthcare professionals that might be relevant to present treatment; - to tell staff if you do not understand or are uncertain about any part of the diagnosis or treatment and ask for more information or clearer explanation (in

writing if it helps); - to follow the instructions given to you on the care of your child before going into hospital for an operation; - to make sure that your child follows the advice on what to do after the operation (eg exercise, diet, etc); - to take any medicine as instructed; - to seek medical advice before stopping or changing treatment; - to ensure that your child attends follow-up appointments and that all appointments are attended on time or that cancellation (with reasonable notice) is arranged; - to make sure you, your child and all accompanying visitors follow all the hospital and ward rules; - to be with your child during treatment, unless it puts either of you at risk, and to stay overnight if you wish; - to take part in all decisions about treatment and aftercare and to have the pros and cons, including any risks, side effects and alternative methods of treatment fully explained to you; - to complain if you are unhappy with the treatment you or your child receives; - to choose whether or not your child may be seen by medical students etc. [4].

PROBLEMS OF PROVIDING INFORMED CONSENT FOR MEDICAL INTERVENTION

Informed consent and the right to refuse treatment has been viewed by the courts as a basic right, besides they are protected by the right to privacy. In some jurisdictions, the right to informed consent arises from the law of battery in that the patient has a right to be free from unconsented touching of their person. Informed consent presumes respect for patient autonomy and the provision of full and accurate information to a patient to enhance decision making. These mandates apply to both the acceptance and the refusal of treatment. Informed consent must include the following: (1) an understandable explanation of the condition, the recommended treatment, the risks and benefits of the proposed treatment, and any alternatives; (2) an assessment of the person's understanding of the information provided; (3) an assessment of the competence of the minor or surrogate to make medical decisions; and (4) assurance that the patient or surrogate has the ability to choose freely between alternatives without coercion [7].

At the same time, problems with the implementation of this right may be encountered by persons with disabilities or incapacitated ones, as well as by minors, due to a possible improper behavior of their legal representatives. The Convention on Human Rights and Biomedicine provides the following clarification in the context of this issue: «Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law. The option of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity» [8]. So, the decision on a newborn child is entirely dependent on his/her parents (legal representatives), but in case of refusal of parents from treatment, how to coordinate this decision with the interests of the child?

Pediatric healthcare providers may face problems with surrogate decision making. Although the law provides parents and guardians discretion in raising their children, their religious and social beliefs may interfere with the best interests of the child. When this occurs, healthcare providers must look to the state and the legal system for answers. When a minor is deemed incompetent and unable to give informed consent, giving assent allows the adolescent's voice to be heard and promotes the perception of empowerment via participation in medical decision making. The assent process should include the following: (1) a developmentally appropriate explanation of the medical condition and the treatment, (2) an assessment of the minor's understanding of the information and how his or her decision was made, and (3) an expression of the minor's willingness or unwillingness to allow treatment [7]. So, does a minor have the right or ability to refuse medical treatment, lifesaving or otherwise, based on his or her religious beliefs or values? Adolescents are in the process of developing a "moral self," and their ability to form values and religious beliefs varies. In the case of *In re E.G.* (1989) the court determined that E.G. was mature enough (based on a standard of proof of clear and convincing evidence) to make the decision to refuse treatment based on the common law right to consent. In this landmark case involving E.G., a 17-year-old minor, the Illinois Supreme Court reversed the trial court decision, which forced E.G. to undergo life-saving blood transfusions. They further determined that E.G. was a "mature minor" and capable of appreciating the consequences of foregoing medical treatment of leukemia based on her religious beliefs as a Jehovah's Witness. In short, they determined that she had the right to refuse treatment. The Supreme Court also reversed the finding of a lower court that held that E.G.'s mother had been a neglectful parent in refusing blood transfusions for her daughter. The Supreme Court looked instead at E.G.'s status as an autonomous individual rather than the parent's behavior [7].

According to the judgment of the European Court of Human Rights (ECHR) in the case of «Religious Community of Jehovah's Witnesses in Moscow against the Russian Federation» [9], the activities of the religious community of Jehovah's Witnesses were forbidden in Moscow for a number of reasons, such as: incitement to religious hatred, coercion to the destruction of families, suicide and rejection of medical care by those who are in a danger conditions of life, namely, the transfusion of blood by adult members of the organization, as well as the refusal of parents to transfuse the blood of a newborn child. These provisions were religiously motivated. However, as the ECHR has pointed out, no evidence has been provided to the negative consequences for the health of individuals due to the refusal to transfuse blood, because the refusal is an example of the exercise of the right to choose treatment methods, even when hemotransfusion is considered to be necessary to prevent irreparable harm to the patient's health.

Therefore, we can identify the contradiction between the duty of health workers to provide medical care to citizens

in order to save their lives, on the one hand, and the right of patients to personal autonomy and physical integrity (pursuant to religious beliefs), on the other. The court has recognized the priority interests of patients to define his/her own life path. That is why state should not influence on them, with exception of certain cases specified by law. As for the protection of children's rights, their parent's decision to refuse the treatment can be appealed to the court to verify the actual risks and consequences of such a refusal. The teaching of Jehovah's Witnesses does not oblige believers to give up blood transfusion, but gives them the opportunity to decide on this occasion on their own. A person who refuses blood transfusion can give a consent to the use of blood substitutes.

Moreover, the point of view that the right to life is absolute and includes the entire range of derivative rights regarding the disposal of his body, including the right to death, is widespread in science. Some experts advocate the idea that each individual owns oneself, as well as own property, so only he/she can decide what will happen to his/her body, dead or alive. Therefore, a potential organ donor can decide how to dispose of his/her body [10].

In the case of «V.K. vs Russia» [11] ECHR recognized that physical coercion of a child in a kindergarten for the purpose of medical intervention – the use of antibiotic eye drops, without the consent of the child's parents and without a preliminary diagnosis, is an appropriate manifestation of inhuman treatment. The court emphasized the violation of the patient's right to an individual treatment approach, since the ophthalmologist did not detect a boy's infection after the incident. This circumstance may indicate even harm to a person's health, which is a violation of the right to security.

Even violations of the patient's rights take place in opposite situations. An example is the ECHR judgment in the case of «Kornevikova and Korneevkov v. Ukraine» [12]. In the case a woman with a newborn child were given into inappropriate conditions of imprisonment, where they had a lack of necessary medical care. According to the applicant, the child was not vaccinated, she did not receive proper and regular medical supervision: the pediatrician had not inspected her with the necessary periodicity, and the administration did not take into account the diagnosed problems with the child's health. Instead, the Government argued that minor health problems could be described as a normal health condition for a newborn who does not need treatment. The ECHR suggested: «Only the fact that the prisoner was being inspected by a doctor, who appointed a particular type of treatment, can not automatically lead to the conclusion that medical care was appropriate». In this regard, the ECHR has developed criteria-requirements to ensure the right to appropriate medical care during detention. In particular, the ECHR entrusts the authorities with the obligation to ensure the complete fixation of the health of the person and the process of treatment, the prompt and accurate diagnosis and provision of assistance, and, when this is caused by a medical condition, regular and systematic supervision according to the plan of therapeutic

measures. But an elimination of symptoms only is insufficient. It is the duty of the state authorities to prove the existence of the proper conditions that are necessary for the actual implementation of the prescribed treatment. The fact that the child was not under the proper supervision of the pediatrician the ECHR considers as a violation of the right to appropriate medical care.

Somewhat special legal status has minors, who are caught in a limbo-like state between the dependency of childhood and the autonomy of adulthood. Their cognitive ability and capacity to reason are similar to those of an adult. However, adolescents may lack the moral responsibility, judgment, and experience to understand the outcome of their actions and decisions. Determination of a minor's competence for medical decision making should include evidence that the minor has the ability to understand the purpose of treatments, risks, both long- and short-term consequences, benefits, and alternatives to treatments [7]. There are circumstances where the law allows an "emancipated minor" to receive treatment without parental consent, including the following: (1) status: (a) a pregnant minor (for medical care and surgery); (b) a married minor; (c) a minor in the armed services; (d) a minor with a child (for medical and dental care, or surgery for the child); (e) a minor living apart from parents and financially self-reliant; (f) a victim of sexual assault or abuse may consent to medical care or counseling; (2) service that is sought: (a) venereal disease treatment or HIV testing; (b) contraception, prenatal care, or abortion; (c) mental health treatment; (d) emergency care; (e) alcohol or drug abuse (after age 12 years). Because there is no definitive line in the sand that is crossed when a minor becomes competent to make treatment decisions other than those listed, the courts have recognized an exception to the common law rule of parental/guardian consent for medical treatment of a minor called the "Mature Minor Doctrine." Circumstances in which the mature minor doctrine permits minors to consent to treatment are the following: (1) the minor is an older adolescent (14 years or older); (2) The minor is capable of giving informed consent; (3) the treatment will benefit the minor; (4) the treatment does not present a great risk to the minor; (5) the treatment is within established medical protocols. However, recognition of the mature minor concept is an emerging trend that promotes the autonomy of the minor and places value on their input [7].

DETERMINATION OF DEFECTS IN MEDICAL CARE DURING THE TREATMENT OF CHILDREN

The following rights of minors are violated as usual: (1) right to be protected from all forms of physical and mental abuse; (2) right to seek, receive and impart information. In the name of tradition, culture or religion, adults routinely deny children, including adolescents, vital information and education on their sexual and reproductive health, and on the means of protecting themselves against unwanted pregnancy and sexually transmitted diseases, including HIV/AIDS; (3) right to health facilities. Children and young

people seeking sexual and reproductive health services are often turned away from health facilities because they are not married or because of their age. Legal provisions or health providers often require the consent of parents or, in the case of married girls, of the husband before care is provided; (4) right to the highest attainable standard of health. Lack of health care, education and information leads to an estimated 330 million new sexually transmitted infections annually, at least half of these among young people (aged 15 - 24). HIV/AIDS alone accounts for 6 million new infections every year, including about 2.6 million infections in the 10-24 age group. Adolescent girls are twice as likely to die from pregnancy and childbirth than women in their twenties, and their children face a higher risk of infant and child death [3].

According to the previous classification we can state, that the violations of children's rights as patients are often accompanied by defects in the provision of medical care. As you know, medical errors have received a great deal of attention in recent years. The phrase "medical error" is an umbrella term covering all errors that occur within the health-care system. Medication errors are probably one of the most common types of medical error, as medication is the most common health-care intervention. In the USA, it is estimated that medication errors kill 7000 patients (both adults and children) per year. In UK hospitals, the incidence and consequences of medication errors appear similar to those reported in the USA – with prescribing errors occurring in 1.5% of prescriptions. While the majority of all errors (61%) originated in medication order writing, most serious errors (58%) originated in the prescribing decision [2]. The most important causes of the defects are as following: - insufficient qualifications of medical staff (24, 7 %); - inferior examination of patients (14,7 %); - inattention to the patient (14,1 %); - shortcomings in the organization of medical processes (13,8 %); - underestimation of the severity of the patient's condition (2,6 %). Improper performance of professional duties most often occur in surgery and gynecology. Such data must be taken into account from the point of view of the investigation and insurance of professional liability for healthcare professionals.

However, it is advisable to dwell briefly on the nature of the defects in medical care, since «medical errors» are not quite a good term for such generalization. The most acceptable definition of the defects is an inadequate diagnosis, treatment of the patient, and the organization of medical care, which led or could lead to an adverse result of medical intervention. Causes of adverse results in medicine can be different: from the untimely treatment of the patient to an ending with incurability of the pathology. It is necessary to distinguish defects in the provision of medical care from an accident. The last one is a defect in medical care, associated with accidental coincidence of circumstances, which the doctor, acting lawfully, within the limits of professional descriptions and in accordance with accepted methods of treatment (diagnosis) in medicine, could not predict and prevent. Accident usually means lawfulness of doctor's actions, who does commit any falsehood activity. Therefore,

the negative consequences for the person's life (health) are always independent of his/her activities. Causes of the accidents can be: - allergic reactions of the patient to drugs; - atypical course of illness; - atypical placement of organs in a body; - atypical response to treatment; - patients do not inform physician about certain information, which significantly affects diagnosis and treatment.

Defects in medical care can be classified as follows: (1) depending on the intention: (1.1) deliberate defects, consisting of the direct intention of the doctor to cause harm to the patient's health, when there is a cause-and-effect relationship between the act and the consequence; (1.2) involuntary defects, when the doctor caused an adverse events, but the doctor knew or should have known about it, however, due to his incompetence or other factors, without foreseeing such effects; (1.3) cases, when the doctor has taken all necessary actions (in accordance with the standard of medical care and the actual conditions of the patient), but he/she could not predict the occurrence of adverse effects, because of the patient's health anomalies. In the latter group, can be distinguished medical errors (honest deceit with the absence of negligence, negligence or frivolous attitude to professional duties, when the adverse effects are caused by factors that are medically dependent on the doctor) and accidents (the actions of doctors when there is an objective inability to predict their consequences); (2) Depending on the kind of medical services: (2.1) defects in medical tactics: - groundless refusal of hospitalization; - late referral to inpatient treatment; - premature discharge of patient; - inadequate selection of forces and means of evacuation; - incorrectly chosen method of diagnosis, treatment or their sequence; - other defects; (2.2) defects in medical evacuation: - improper transportation of the patient (wounded person); - other defects; (2.3) defects in diagnostics: - the minimum obligatory diagnostic studies required in this particular case were not conducted; - the necessary additional diagnostic tests in the case of differential diagnostics were not made; - incorrect interpretation of the results of diagnostic studies (physical, laboratory, instrumental) and the possible result of this: (a) the underlying disease was not recognized; (b) late diagnosis of the underlying disease or leading complication; (c) incorrect assessment of the severity of the patient's condition; (g) hyperdiagnosis of diseases; - technical defects in conducting diagnostic researches; - other defects; (2.4) defects in treatment: - untimely or not fully medication; - excessive drug treatment; - contraindicated treatment; - incorrect methodology of medical treatment (inadequate type and dose of influence or ways and procedure of administration, failure to take into account the possibility of adverse reactions, incompatibility of drugs); - contraindicated surgical treatment; - ungrounded indications for surgical intervention; - technical defects at the stage of preparation for the operation or during the surgery itself, or in the period of postoperative treatment (improper dressings and other surgical manipulations); - other defects; (2.5) defects related to various violations of the sanitary-epidemic regime: - internally hospitalized infection of the patient; - other de-

fects; (2.6) technical defects (errors during diagnostic and medical procedures); (2.7) organizational defects (mistakes in the organization of medical care, absence of necessary conditions for the functioning of it); (2.8) deontological defects (mistakes in the behavior of the doctor, their communication with patients and relatives, colleagues, nurses); (2.9) defects in the filling of medical records, which occur quite often, especially among surgeons (incomprehensible records of operations, postoperative period, so it is difficult to understand what happened to the patient). Diagnostic defects are the most widespread group.

Medication errors are not uncommon in paediatrics: potentially harmful medication errors may be three times more common in the paediatric population than in adults. This in turn indicates that the epidemiological characteristics of medication errors may differ between adults and children [2].

Paediatrics pose a unique set of risks of medication errors, predominantly because of the need to make dosage calculations, which are individually based on the patient's weight, age or body surface area, and their condition. This increases the likelihood of errors, particularly dosing errors. For potent drugs, when only a small fraction of the adult dose is required for children, it becomes very easy to cause dosing errors of 10-fold or greater because of miscalculation or misplacement of the decimal point. For example, there was a case of a 10-month-old baby who had received 10 times the correct dose of intravenous theophylline as a result of miscalculation of the drug dosage. Furthermore, incorrect recording of patients' weights and the difficulties health-care professionals have in making arithmetical calculations could also contribute to incorrect dosing. As discussed above, many drugs used to treat children are either not licenced (unlicenced) or are being prescribed outside the terms of the product licence (off-label prescribing). This poses an additional risk to children from medication errors as doses must be calculated on an individual patient basis, often in the absence of appropriate dosing information from the pharmaceutical manufacturer. In addition, adult dosage formulations often have to be manipulated at ward level by nursing staff, or suitable products prepared extemporaneously in the pharmacy, to meet the need for small doses in paediatric patients. Such manipulations may involve, for example, cutting or grinding up tablets or dispersing or mixing drugs with such agents as food or drinks before administration. These practices are associated with a high risk of errors as the bioavailability of the drugs following such manipulations is often unknown and unpredictable. Compatibility and stability information is often lacking. Furthermore, the lack of standardization has caused confusion in parents resulting in serious medication errors. An example is the case of a child who received his regular supplies of diazoxide suspension made as an extemporaneously prepared suspension at 10 mg/ml, from a local community pharmacy. He was given a 50 mg/ml solution on his visit to a paediatric hospital. His parents did not read the label and gave the same volume of the suspension resulting in

a five times overdose. Consequently, the child required hospitalization [2].

Reasons for medical errors in general medicine are as follows: - lack of information and awareness among most stakeholders in our present health system (most likely a consequence of non-inclusion of pharmacovigilance as an important issue in the undergraduate (medical, pharmacy and nursing) curriculum; - lack of training programmes for health-care professionals; - absence of formal pharmacovigilance systems in many countries and, if present, limited efforts made to inform health-care professionals regarding the systems in place in a given country or region; - problems with diagnosis of ADRs; - problems with the clinical workload for most health-care professionals, especially in developing countries (i.e. no time to make reports); - problems with the reporting procedure (too bureaucratic); - problems related to potential conflicts (legal liability) and fear of punitive consequences including unfavourable media coverage; - absence of a feedback system. In addition, there are even more obstacles related to the reporting of ADRs in paediatric patients: - Children, particularly small children, may be unable to express their sensations and complaints; - A high proportion medicines used are off-label and unlicensed (see above); - Many poorly evaluated phytotherapeutic, ayurvedic, anthroposophic, traditional and homeopathic medications are popular because they are perceived as "soft" and less toxic medicines by many parents, caretakers and even health professionals; - There is irrational use of medicines, e.g. antibiotics; - Clinical trials are lacking and experience and skills in reporting ADRs and AEs are insufficient; - A paediatric essential medicine list (pEML) has yet to be developed; - Appropriate medicine formulations and administration devices for children are lacking; - No paediatric list of laboratory values giving rise to a laboratory filter signal is available; - There is incompatibility of some excipients in the medicine formulations and in poorly defined mixtures of traditional medicines for paediatric use, e.g. diethylene glycol. However, the health administrators in developing countries cannot depend solely upon data generated in western countries for predicting ADRs and assessing medicine safety in their own paediatric population [2].

PROBLEMS OF PROTECTION OF THE RIGHTS OF MENTALLY ILL CHILDREN

Presently growing violations of the rights of a children, who suffer from mental illness (illness), is relevant to national human rights institutions and international organizations. According to the World Health Organization, at the end of 2015 in Europe 20 – 30 % of children had mentally disorders. Recent years have seen substantial increase in mental health problems among young people, ranging from mild forms of depression, emotional and behavioural problems through to complex psychiatric disorders. According to a Commission report on health status within the EU15: "Between 15 % and 20 % of adults and from 17 % to 22 % of teenagers under 18 suffer some form of mental health

problem. Eating disorders, such as anorexia and bulimia, seem to be increasing among adolescents” [1].

Main reasons of violation of the rights of mentally ill persons, in particular, are: they can be applied to coercive measures, and doctors in psychiatric hospitals often neglect the rights of patients. An example is the decision of the ECHR in the case of «Centre for Legal Resources on behalf of Valentin Câmpeanu v. Romania» [13]. V. Campenau died at the age of 18 while he was treated at a psychiatric hospital, where he was hospitalized in an early age because he was recognized incapacitated by a serious mental illness. The court found that the lack of proper medical equipment, as well as professionals, nutrition and heating, in a psychiatric hospital endangered patient's health, so a sick person was deprived of medical care. In addition to the violation of the right to life, the Court emphasized the violation of the right to an effective remedy and made the recommendation to the Romanian Government to ensure the representation of persons with disabilities. In Ukraine there are also systematic violations of the rights of orphan child and children deprived of parental care. The reason for these is the inability of children to protect themselves from unlawful acts. Therefore, the person who has been hospitalized to a psychiatric institution sometimes becomes a «property» of psychiatrists. Quite often the rights of mentally ill children are violated in criminal proceedings. In the case of «X and Y v. the Netherlands» [14] the applicants were a minor mentally ill girl and her father. The subject of the complaint was the behavior of a son of the director of the home for mentally retarded children: a coercion of children to enter into sexual relations with him. Another example is the ECHR judgment in the case of «T and V v. United Kingdom» [15]. In this case the right to a fair trial was violated. The post-traumatic stress disorder suffered by the applicant, combined with the fact that, after committing an offense concerning him, no treatment measures were applied to him, decreased his ability to instruct lawyers and adequately protect his interests. Given the inconveniences during the trial (the lobby of the defendants was raised), he was not able to follow the trial or make relevant decisions. Another example is the judgment of the ECHR in the case of «S.C. v. the United Kingdom» [16], in which the Court concluded that the applicant was unable to participate effectively in the trial, because he did not assess his conditions (threat of sentence in a form of imprisonment). Moreover, after the sentence was passed, the applicant had a confused appearance, hoping he would be able to go home with his father.

Some experts consider the spread of mental illness among children in the context of inadequate medical treatment. With regard to the three ADHD (diagnosis Attention Deficit Hyperactivity Disorder) behavioural categories of hyperactivity, impulsivity and inattention, sometimes these behaviours may be part of typical behavior of childhood. Other times, they may result from boring and poorly disciplined classrooms, lack of grade level educational skills, emotional problems generated from problems at home or in school, issues relating to

poverty such as hunger or poor nutrition, or insomnia and fatigue and a variety of chronic illnesses, including diabetes and head injury (e.g. sports concussions). Stimulants are the most commonly prescribed drugs for ADHD. Most are either amphetamines (e.g. Adderall or Dexedrine) or methylphenidate (e.g. Ritalin or Concerta). Amphetamine and methylphenidate belong to controlled substances list, which is the highest risk of addiction and abuse. Lambert (2005) conducted a 28-year prospective study of children-diagnosed Amm. She found that children treated with methylphenidate were much more likely to abuse cocaine in young adulthood compared to those diagnosed with ADHD without drug exposure. Children treated with stimulants often develop atrophy of the brain. Stimulants have also been found to induce depression and apathy in children. A study of children age 4-6 given methylphenidate found that two-thirds developed symptoms of depression and withdrawal. Older children also may become 'tired, withdrawn, listless, depressed, doxy, dazed, subdued and inactive [17].

That is, the data of these groups of drugs are potentially dangerous for children. The psychiatric drugs used to 'treat' children do not address the underlying problems; at best they can only temporarily suppress their manifestations, while adding brain impairments. Children exposed to psychiatric diagnoses and drugs can suffer iatrogenic effects that impair, rather than improve, their physical, mental and emotional well-being. Prescribing drugs to children enforces physical dependency on psychoactive substances. There are circumstances when psychoactive substances have a legitimate medical purpose in the treatment of children, such as surgical anaesthesia, relief of physical pain and control of seizures. These medical drugs (in contrast to psychiatric drugs) are not intended for the control of behaviour and emotions, or the treatment of psychiatric disorders. Nonetheless, even in these cases, grave caution should be exercised if and when children are exposed to chemicals that affect the brain and mind. [17].

So, there is an urgent need to change the approaches of medical treatment of psychiatric diseases in pediatrics. Authors recognize that at the presence we are a long way from changing the current positive attitude towards psychiatrically diagnosing and drugging children. In addition, any significant reduction in the widespread drugging of children will also cut deeply into the authority, power and profits of the entire psychopharmaceutical complex from drug companies and medical societies to individual researchers and prescribers. Rather than prematurely seeking a legal ban on psychiatric drugs at this time, we should view this as an ideal and an ultimate goal as we work towards a future when society, including healthcare providers and parents, will view psychiatric drugs as an abuse of children, and be ready to prohibit it the same way. This should become a goal for children's rights advocates. Meanwhile, individual parents should avoid putting their children on psychiatric drugs and, if already on drugs, parents should seek help in withdrawing them as soon and safely as possible. Physicians and other prescribers should

resist pressure to put children on psychiatric medications and instead work towards withdrawing them as soon and safely as possible [17].

PROTECTION OF CHILDREN'S RIGHTS IN CLINICAL TRIALS

According to the art. 24 of the Convention on the Rights of the Child [18], children have the right to use the most sophisticated health care services and rehabilitation measures, and also medicines. However, at the present stage there is a shortage of pediatric medicines intended for children. More than 50 % of the medicines used to treat children have not been tested and authorised for use by children. This means a doctor writing a prescription for a child for an untested, unauthorised product, cannot be sure the medicine will be truly effective, what dosage is appropriate, or exactly what the side effects may be [1]. According to the WHO data, the death rate from irregular and uncontrolled administration of medicines occupies the fifth position in the world among death causes [19].

Pediatric drugs have specific characteristics. In the Regulation (EC) no. 1901/2006 of the European Parliament and of the Council «On medicinal products for paediatric use» [20] were identified the important features of the use of pediatric medicines, particularly: - human growth from birth to adulthood is accompanied with specific physical, metabolic and psychological processes. As a result, clinical trials involving children of all ages can be required in many cases to confirm the safety and efficacy of the medicinal product in all target age groups; - children may experience pharmaceutical problems that are not observed in adults and whose occurrence may be age-related. For example, young children are simply not able to swallow tablets of a traditional size; newborns may require very small volumes of parenteral medication to avoid volumetric overload and so on. Therefore, children should use medicines, the pharmaceutical design of which is tailored for use in the target age group; - the primary pharmaceutical design of the pediatric medicinal product should focus on the minimum number of acceptable dosage forms that will meet the needs of most children in the target age group. Consequently, dosage forms that facilitate application of a wide range of doses, and which are acceptable to children of different ages, will satisfy the whole complex of their needs [20].

Even when a new and innovative medicines are available with a paediatric indication, there are no evidence of long-term benefit and risk, e.g. the biological agents used as disease modifying antirheumatic medicines, such as etanercept. Additionally, in resource-poor countries the following may apply: - no treatment may be available, particularly during times of war and civil strife; - medicines may be available through illegal street vendors; - medicines are used in public health driven programmes e.g. for the treatment of endemic infectious diseases such as HIV/AIDS, malaria, tuberculosis and for parasitic diseases [2]. The consequences of the current status of the use of medicines in children include the following: - wrong dosage

causes short-term toxicity or treatment failure. For example, a standard dose of phenobarbital of 15 mg/kg daily will most likely be inappropriate for a newborn with seizures as often a loading dose of more than 20 mg/kg is needed and a maintenance dose of 5 mg/kg might already be more than enough; - non-availability of appropriate paediatric formulations forces health care providers to resort to administering crushed tablets, dissolving tablets in solvents or administering the powder contained inside the capsule. Consequently, these formulations are administered without any data regarding their bio-availability, efficacy and toxicity; - formulations of strengths suitable for administration to neonates, infants and young children are not always available. Adult formulations therefore need to be diluted or administered in miniscule volumes over a period of time. This leads to administration errors (intravenous drips running fast, errors in dosage calculation and dilution), especially in circumstances that require urgent action (as in emergency units, premature units and paediatric and neonatal intensive care units); - inappropriate packages and lack of awareness among parents and caregivers about the methods to be used for prevention of injuries, accidents and poisoning lead to accidental poisoning in infants and small children; - medicines can interact with traditional and herbal medicines; - medicines may have long-term safety problems. For example, etanercept may increase susceptibility to tuberculosis, or long-term use of inhaled corticosteroids in early infancy may increase the risk of growth retardation and/or osteoporosis; - in public health programmes in resource-poor countries, co-morbidity or malnutrition may exacerbate the toxicity. Dehydration is frequently associated with ibuprofen-induced renal failure and malnutrition with paracetamol hepatotoxicity [2].

As a general rule «universal» drugs are used in pediatric. Market forces alone have proven insufficient to stimulate adequate research into, and the development and authorization of, medicinal products for the paediatric population. That is why the Regulation (EC) no. 1901/2006 of the European Parliament and of the Council «On medicinal products for paediatric use» contains specific measures to promote the development and availability of medicines for use in the pediatric population [20].

Firstly, before a medicinal product for human use is placed on the market in one or more Member States, it generally has to have undergone preclinical tests and clinical trials in the paediatric population [20].

Secondly, it is a requirement for new medicinal products and for authorised medicinal products covered by a patent or a supplementary protection certificate to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of filing a marketing authorization application or an application for a new indication, new pharmaceutical form or new route of administration. The introduction of the paediatric investigation plan in the legal framework concerning medicinal products for human use aims at ensuring that the development of medicinal products that

are potentially to be used for the paediatric population becomes an integral part of the development of medicinal products, integrated into the development programme for adults. Thus, paediatric investigation plans should be submitted early during product development, in time for studies to be conducted in the paediatric population, where appropriate, before marketing authorisation applications are submitted. As the development of medicinal products is a dynamic process dependent on the result of ongoing studies, provision should be made for modifying an agreed plan where necessary. The paediatric investigation plan should be the basis upon which compliance with that requirement is judged [20].

However, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the *well-established medicinal use procedure*, nor to homeopathic medicinal products and traditional herbal medicinal products authorised through the simplified registration procedures [20].

Thirdly, free scientific advice should be provided by the competent authority as an incentive to sponsors developing medicinal products for the paediatric population [20].

Fourthly, to provide healthcare professionals and patients with information on the safe and effective use of medicinal products in the paediatric population and as a transparency measure, information on the results of studies in the paediatric population, as well as on the status of the paediatric investigation plans, waivers and deferrals should be included in product information [20].

Financial incentives are extremely important to enter new drug markets. From world experience it is known that a dynamic growth of the economy is possible only on the basis of an innovative growth model and intensive technological renovation of production. For this, first of all, it is necessary to reorient state policy on financial supporting of individual enterprises and industries [21]. Although there are reciprocal examples in the healthcare sector, for example, we should raise a question at UN level of adopting a single imperative conventional act that prohibits commercial relations in the field of transplantology, optimizes organ and tissue transplantation. You should also raise a question of responsibility, not only persons who are engaged illegal transplantation, but also transplant tourists [10].

Experts invoke to strengthen surveillance over the circulation of new drugs to increase the information available from ADR monitoring and to organize and communicate this information to the medical community and the public. Additional reasons for monitoring post-marketing medicine safety in children include the following: - the use of unlicensed and off-label medicines is highly prevalent in children (see above); - children may not voice complaints and ADRs may remain unnoticed; - long-term follow-up is essential in a population with a long lifespan/lifeexpectancy and medicines may have a specific impact on development and maturation of the skeletal, neural, behavioural, sexual and immune systems; - accidental ingestion in small children and suicidal ingestion in adolescents are not

uncommon; - routinely available safety data may not adequately capture events arising in the paediatric population and only in exceptional circumstances can safety data in the paediatric population can be extrapolated from data obtained in adults. This is because certain ADRs may only be seen in the paediatric population, irrespective of effects on growth and development. Thus ADRs from specific ingredients/excipients may be expressed differently in adults and children. A good example for this kind of poisoning is the life-threatening gasping syndrome seen in infants exposed to benzyl alcohol; - in the case of life-long treatment for chronic diseases, the total duration of treatment is longer if started in childhood. This may expose the patient to increased risk of medicine toxicity and adverse events, e.g. chronic use of amphetamines and methylphenidate to treat ADHD carries the possible risk for cardiovascular events such as myocardial infarction, stroke and sudden death later in life [2].

There is an urgent need to facilitate legal protection of minor volunteers in the relations of clinical trials. In the international acts [22; 23] a lot of attention are fixed at the ethical standards for conducting clinical trials, in particular: (1) a clinical trial can be initiated and extended only if the expected benefit justifies the risk; (2) the rights, safety and welfare of experimental subjects are more important than the interests of science and society; (3) before the subject is included in the clinical trial, it is necessary to obtain his voluntary informed consent.

Clinical trials must not endanger children, so it is important to adhere to the principle of «non nocere» («do not harm»). A child in terms of age, lack of psychological and social experience can't express his/her attitude to clinical research. Patients who are not able to provide informed consent are included in a clinical trial only when there is a reason to expect that the use of the investigational medicinal product will directly benefit the patient and the risk will be exceeded. Besides, a written consent of children's parents is compulsory, and as for minors (about 14 – 18 years) they may receive appropriate information in an accessible form, and even express their will in addition to parent's decision.

In this aspect, attention should be drawn to the ECHR judgment in the case of «Charles Gard and Others against the United Kingdom» [24]. Charlie Gard – a 11-month-old kid who suffered from a rare genetic disorder – a mitochondrial DNA exhaustion syndrome. He's became the sixteenth in the world with this diagnosis. With the development of the disease, the boy had been becoming unable to breathe on his own, so he was sent to London's «GreatOrmondStreet» Hospital. After some time, the doctors came to the conclusion that changes in the brain of the baby are irreversible and no treatment will help him. But as doctors did not have the right to turn off the life support system without permission from Charlie's parents, the medical facility turned to the court. National courts have found that it is better for the child to die, because he probably suffers from pain and torment. Besides, the proposed by American specialists experimental treatment will not make sense, as it has not been tested on

any person, or even animal, as the ECHR emphasizes, even rats, and therefore the efficacy and safety of such treatment is very doubtful. In addition, the disease caused an extensive atrophy of the muscle, and it was concluded that the proposed treatment is no longer able to have a positive effect.

The ECHR stated that there is a contradiction between such human rights as «the right to life» and «the right to prevent pain and torment when receiving medical care». The ECHR has noted that in exceptional cases even the right to life may be less important than the interests of the patient. Prolonged life is very important, but it is not an absolute, decisive right that can be overrated, if the quality of life is rather low and the pain and torment or other difficulties in the life of the patient are significant enough. The ECHR has emphasized that special attention should be paid to the pain that a child will feel in a future. The court concluded that Charlie's interests in the context of the release of torment and pain prevail over a seemingly fundamental but not absolute right to life. So, the Court gave a consent to a passive euthanasia, referring to the judgment in the case of «Lambert v. France» [25]. In the last one the ECHR identified three criteria for which passive euthanasia might be applied, namely: (1) national laws may provide a possibility of euthanasia; (2) opinions of relatives and nurses will be taken into account; (3) the possibility to go to the court, if there are doubts regarding the optimal solution of the issue, taking into account interests of the patient. The boy's parents decided to listen to the court's findings and agree to disable Charlie from life support vehicles. So, the court decided to disconnect the child from the devices of artificial respiration and life support, therefore an experiment that gave at least a small chance to save the boy's life was banned.

CONCLUSIONS

Children as patients have additional guarantees of their rights protection. Therefore, these rights can be classified into universal (they spread their action to all age groups) and special. The rights of the child correspond not only to the duties of medical workers, but also to the duties of their parents (legal representatives). Given age characteristics and limited capacity, children are significantly restricted in the ability to independently exercise the rights of patient, in particular with regard to the right to privacy. Violations of children's rights are usually related to the improper representation of their interests by parents and legal representatives, disadvantages of providing medical services (various defects), in particular, this concerns the treatment of mentally ill persons and in clinical trials. Defects in medical care are often connected with an inadequate logistic support of hospitals from the state, and with a lack of financial and medical support, even with an outdated treatment methods, and incompetence of some doctors. Due to the existence of objective difficulties in determining of medical defects, it is advisable to legislatively define the definition of the defects in medical care and their classification.

In the aspect of protection of children's rights in the health care, the practice of the ECHR is very important. At the same time, there is the tendency in resolving of controversial cases: the Court gives priority to the protection of the right to personal integrity and the right to prevent suffering and pain, than the right to life of the patient. Another important legal point is that the facts of medical examination and appointment of a certain type of treatment can not automatically mean that the person has been given appropriate medical care.

REFERENCES

1. Ruxton, S. (2005). What about us? Children's Rights in the European Union: next steps. The European Children's Network. Retrieved from http://www.crin.org/en/docs/Ruxton%20Report_WhatAboutUs.pdf.
2. Promoting safety of medicines for children // WHO Library cataloguing-in-publication data, 2007. Retrieved from http://www.who.int/medicines/publications/essentialmedicines/Promotion_safe_med_childrens.pdf.
3. The Human Rights of Children and their Sexual and Reproductive Health // Prepared by IWHC, In consultation with ACPD, CEDPA, CFFC, CRLP, FCI, Ipas, IPPF, Latin American and Caribbean Youth Network for Sexual and Reproductive Rights, NAPY, and Youth Coalition for ICPD. Retrieved from https://www.reproductiverights.org/sites/default/files/documents/pub_fac_adoles_rtschildren.pdf.
4. Child patient rights and responsibilities: Patient Liaisons Group // The Royal College of Surgeons of England, 2003. Retrieved from <http://www.ouh.nhs.uk/paediatricorthopaedics/information/documents/childrens-rights.pdf>.
5. Children's Palliative Care and Human Rights: Public Health Fact Sheet // Open Society Foundations. Retrieved from http://www.ifhro.org/images/stories/ifhro/Books_reports_articles/palliative-care-human-right-20110524.pdf.
6. Pashkov, V., Hrekov, Y., Hrekova, M. (2017). European experience of regulating distance selling of medicines for Ukraine. *Wiadomości Lekarskie*, 70, 1, 96-100.
7. Hickey, K. (2007). Minors' Rights in Medical Decision Making. *Journal of Nursing Administration Healthcare Law, Ethics, and Regulation*, 9, 3, 100-104.
8. 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. Council of Europe. Retrieved from <https://rm.coe.int/168007cf98>.
9. Case of Jehovan's Witnesses of Moscow and Other's v. Russia (Application no. 302/02). European Court of Human Rights: Judgment, 22.11.2010. Retrieved from <https://www.jw.org/en/news/legal/by-region/russia/echr-judgment-freedom-of-religion/>.
10. Pashkov, V., Golovanova, I., Noha, P. (2016). Principle of serviceability and gratuitousness in transplantation? *Wiadomości Lekarskie*, LXIX, 3 (II), 565-568.
11. Case of V.K. v. Russia (Application no. 9139/08). European Court of Human Rights: Judgment, 28.09.2017. Retrieved from [https://hudoc.echr.coe.int/eng#{"itemid":\["001-172462"\]}](https://hudoc.echr.coe.int/eng#{) ECHR.
12. Case of Kornevikova and Korneevkov v. Ukraine (Application no. 56660/12). European Court of Human Rights: Judgment, 24.06.2016. Retrieved from http://zakon2.rada.gov.ua/laws/show/974_b56.
13. Case of Centre for Legal Resources on behalf of Valentin Câmpeanu v. Romania (Application no. 47848/08). European Court of Human Rights: Judgment, 14.07.2014. Retrieved from [https://hudoc.echr.coe.int/eng#{"appno":\["47848/08"\],"itemid":\["001-145577"\]}](https://hudoc.echr.coe.int/eng#{).
14. Case of X and Y v. the Netherlands (Application no. 8978/80). European Court of Human Rights: Judgment, 26.03.1985. Retrieved from http://www.coe.int/t/dg2/equality/domesticviolencecampaign/resources/x%20and%20y%20v%20the%20netherlands_EN.asp.

15. Case of T and V v. United Kingdom. European Court of Human Rights: Judgment, 16.12.1999. Retrieved from <https://www.crin.org/en/library/legal-database/t-and-v-v-united-kingdom>.
16. Case of SC v. the United Kingdom. European Court of Human Rights: Judgment, 15.07.2004. Retrieved from <http://swarb.co.uk/sc-v-the-united-kingdom-echr-14-sep-2011/>.
17. Breggin, P.R. (2014). The Rights of Children and Parents In Regard to Children Receiving Psychiatric Diagnoses and Drugs. *Children & Society*, 28, 231-241.
18. Convention on the Rights of the Child // United Nations Human Rights Office of the High Commissioner. Retrieved from <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CRC.aspx>.
19. Pashkov, V., Olefir, A., Bytyak, O. (2017). Legal features of the drug advertising. *Wiadomości Lekarskie*, 70, 1, 133-138.
20. Regulation (EC) no. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) no. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) no. 726/2004. Retrieved from https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2006_1901/reg_2006_1901_en.pdf.
21. Pashkov, V., Olefir, A. (2017). Innovative partnership as new form of public procurement in the European Union. *Socrates*, 2 (8), 66-80.
22. Declaration of Helsinki (World Medical Association Declaration of Helsinki) «Ethical Principles for Medical Research Involving Human Subjects» // Bulletin of the World Health Organization, 2001, 79 (4). Retrieved from <http://www.who.int/bulletin/archives/79%284%29373.pdf>.
23. ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6(R1) // Current Step 4 version, 10.07.1996. Retrieved from https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf.
24. Case of Charles Gard and Others against the United Kingdom (Application no. 39793/17). European Court of Human Rights: Judgment, 03.07.2017. Retrieved from http://thaddeuspope.com/images/Inadmissibility_decision_in_the_case_Gard_and_Others_v_the_UK_-_decisions_by_UK_courts_endorsed.pdf.
25. Case of Lambert and Others v. France (Application no. 46043/14). European Court of Human Rights: Judgment, 05.07.2015. Retrieved from http://www.giuffreroma.it/attachments/article/127/PP_INTER_15lambert_milizia_s.pdf.

ADDRESS FOR CORRESPONDENCE

Vitalii Pashkov

Department of Civil, Commercial
and Environmental Law,
Poltava Law Institute, Poltava, Ukraine
tel. +380-532-560-148
e-mail. poltava_inst@nulau.edu.ua

Received: 02.08.2017

Accepted: 05.12.2017