

## Medical-Legal Aspects of Confidentiality in the Field of Pharmaceutical Health Care

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**Abstract** The field of pharmaceutical health care is becoming increasingly established. Modernly, pharmacists learn more from patients about their prescriptions and other very personal, sensitive information. However, having access to an ever-increasing amount of sensitive, personal information raises serious issues pertaining to patient secrets and confidentiality. The term professional secrecy (hereinafter confidentiality) as well as any other form of discretion connected with a professional activity is construed broadly. However, the precise scope of confidentiality is not strictly defined in legislation. Obligation of professional secrecy has been diminished partly due to the general progress in a society and the progress of medical professions. The development of the protection of human rights is a continuous process.

**Keywords:** • pharmaceutical services • privacy • confidentiality • professional secrecy • liability •

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## 1 Introduction

The goal of this article is to explore medical-legal issues involving patient confidentiality in the field of pharmaceutical health care, as such issues are becoming increasingly important and yet are often overlooked in the general field of health services. Namely, there is always a relationship between the physician and the patient, and therapies, ie medication treatment, are in the second plan. This is also the case today from the point of view of the Law of the Republic of Serbia, because a public debate on new legislation is taking place. There is a question of protecting the rights of individuals as users of medicines in this context and, in particular, the right to privacy and confidentiality of their data used in connection with their pharmaceutical health care. This article also explores these issues through a discussion of some of the foreign sources and relevant case law that plays an important role in the national court practice. The first part of this article discusses valid regulations; the second part of the article focuses on professional practices in the field of pharmaceutical health care services and the requirements for respecting patient/consumers' rights of confidentiality; and, the third part of the article explores controversial cases in judicial practice and the protection of the right to privacy/confidentiality. It is concluded that the area of handling and use of medicines is accompanied by numerous data and information about patients - consumers. These data are very sensitive and should be recognized as having the meaning of medical documentation. The privacy and trustworthiness of users includes both advices from pharmacists when issuing medicines. These tips today have the character of wider services according the standards of best professional practice, diferrent than it was in the past. The protection of the rights of a pharmaceutical patient is in this manner gaining more importance.

Generally, the necessity of keeping a professional "secret" (confidentiality) came about due to the nature of certain professions that render services or assistance in highly personal matters where confidentiality is expected (physicians, lawyers, psychologists, priests, social workers, etc.). Indeed, the physician-patient privilege, or confidentiality of information between physician and patient, is one of the oldest forms of professional secrets. Privacy and confidentiality in the medical profession is very important from both an ethical and legal standpoint.

It is a well-known fact found in medical literature that a physician's obligation of maintaining the confidentiality of patient information has been considered holy since *Hippocrates*: ... "and whatsoever I shall see or hear in the course of my profession, as well as outside my profession in my intercourse with men, if it be what should not be published abroad, I will never divulge, holding such things to be holy secrets" (Beauchamp, Childress, 2001: 113).

Maintaining confidentiality (i.e., keeping a secret) had long been exclusively a moral obligation. Transforming the previously moral obligation into a legal one came much later, e.g. a lawyers' obligation (Radišić, 2008: 155). In prior times, private information about individual sphere kept secret for reasons of morality or courtesy and not under compulsion of the law. Keeping secrets (maintaining confidentiality of information) was

expected in everyday life and was common. Today, unlike that period, the privacy rights of people and their personal data is part of the general protection of human rights. With further advancements in the field of electronic data transfer the patient/consumer will be able to check his/her personal health status on-line, electronically. These developments have privacy/confidentiality implications.

When we examine the pharmaceutical profession, and pharmacies in particular, it is necessary to consider how the pharmacist's services to his or her customers (i.e. medication consumers) impacts issues pertaining to trust, privacy and confidentiality. The pharmacist's essential activity is no longer the production of medicines, nor sales, but primarily the delivery of the medicines. Therefore, the pharmacist's focus is very often on the advice relating to the patient's needs, and also on confidentiality and proper management of the consumer/patient's information (Fasset, 2007: 1265). When dispensing medicines, the pharmacist has the responsibility to make decisions that are of a legal character. The pharmacist's dispensation of medicines is essentially an independent analysis and a process for which the pharmacist carries his or her own professional and legal responsibility, personally and unmodified, with due respect for the physician and the patient (Dukes, Mildred, Swartz, 1999: 381–382).

## 2 Legal framework

Establishing a legal, regulatory framework in the field of protection of privacy interests has a long tradition. Numerous international and local legal instruments emphasize as their central tenets the notions of both the protection of private life and the right to be informed. The European Convention on Human Rights and Fundamental Freedoms<sup>1</sup> stipulates that every individual has the right to the full respect of their own private life. This basic principle embodies the idea that governments will not interfere with this right unless prescribed differently by law or unless some degree of interference is necessary in order to protect the health, morals and rights of other people. Promoting this right to privacy in turn justifies the existence of professional confidentiality. The protection of medical data falls under the scope of Article 8 of the European Convention on Human Rights (ECHR).

The European Convention on Human Rights and Biomedicine<sup>2</sup> is a crucial document that helps enshrine the principle of privacy of medical information. In particular, this law provides that everyone has the right to the full respect of their private life, including protection of data about their health. Additionally, the law gives individuals the right to have access to all of the facts collected concerning their health. The law also protects an individual's rights not to be informed regarding issues pertaining to their health. The law can limit these rights for the benefit of a patient but only as an exception. Every individual has the right to privacy of personal data, including the data connected with their health condition, including for example information gathered for a potential diagnostic procedure and treatment, as well as the protection of privacy during diagnostic procedures, regarding services by specialists and medical and surgical procedures in general. All of the data containing information about the health of an individual, including medical and surgical interventions, must be considered private and thus protected. In

short, individual privacy must be respected. Medical and surgical procedures (diagnostic procedures, examinations by medical specialists, consumption of medications) must be organized in suitable fashion and in the presence of those who are supposed to be there (only in case when a patient gives his/her explicit consent or has alternative requests). The goal of the European Charter on Patients' Rights,<sup>3</sup> and also numerous related directives, is to guarantee a high level of the protection of people's health (Turk, Leyshon, Pytte, 2015: 79).

The EU, together with supranational legislation both regard privacy as a fundamental requirement under European human rights law. The data protection reform package entered into force in May 2016 and will take effect in May 2018. This reform package includes the general data protection regulation which updates and modernizes the principles enshrined in the 1995 Data Protection Directive<sup>4</sup> to guarantee privacy rights. The process of implementing some of the main data protection directives under this regulation is currently a high priority.<sup>5</sup>

Concerning Serbia's legal system, the basic notion of respecting a professional secret originates from one of the most important guarantees of the Constitution, namely the stipulation regarding the right to respect one's private life.<sup>6</sup> Personal data protection is guaranteed. Collecting, storing, processing and using personal data is regulated by law. In accordance with law, everyone has the right to be informed about personal data collected, and the right to legal protection in the case of abuse or breach of the law. The confidentiality of the contents of letters as well as the means of communication is based on their inviolability. Deviations from the law are allowed only for a short period of time, and with a court decision, for the purpose of criminal procedures and for protecting the safety of the Republic of Serbia as prescribed by law.

Storing and dealing with data that are of public but not private importance is regulated by The Act on Free Access to Information of Public Importance.<sup>7</sup> This law stipulates that competent authorities must deny a requestor's access to information of public importance if there is a risk that disclosure will violate someone's right to privacy, reputation or any other right of a person that the requested information refers to. The exceptions to this provision are as follows: 1) if an individual gave his/her consent to disclosure; 2) if the requested information pertains to a person or a situation that is of some public interest, particularly if it is about a state official or someone with a political background; and 3) if the requested information pertains to a person whose behavior was the reason for requesting information.

The Criminal Code of Serbia governs situations where there is an abuse or unauthorized disclosure of confidential information.<sup>8</sup> An unauthorized person, who discloses confidential information that he/she discovered while doing their job (lawyers, physicians, etc.), will be fined or sentenced to up to one year imprisonment. A person, who discloses confidential information that is of general interest or in the interest of some other person whose interest in having the information outweighs keeping the information confidential, will not be punished. Besides this criminal offence, unauthorized access to an encrypted computer, computer network or electronic data processing (EDP) subjects

the offender to a fine or up to six months' imprisonment. The use of downloaded data subjects the offender to a fine or up to two years' imprisonment. If the violation causes an interruption or a serious problem in functioning of EDP, data transmission or network or there are some serious consequences, an offender will be sentenced to three years' imprisonment (Milošević, 2010: 1–11).

Both the Health Care Act<sup>9</sup> (HCA) and the Patients' Rights Act<sup>10</sup> (PRA) apply to regulate the medical professions and the staff working in the field of health care systems. These regulations ensure that every patient is entitled to the privacy of their personal health care information including their medical condition, potential and actual diagnostic procedures and all medical treatment. The law strictly forbids medical staff to convey personal information about a patient to other persons. A patient can be examined and medical treatment rendered only in the presence of medical staff and their associates. A patient can, however, give his/her consent to allow the presence of other persons during medical examinations and treatment.<sup>11</sup> Regulations that refer to medical documentation itself, and to the collection of data through the records in the health care system, prescribe that managing documentation within the health care system is a part of professional medical work, and therefore is given public importance, whereas the field of data protection is not regulated in any particular way. In that sense, collection, use and data protection from the records in the field of health care system should be in accordance with the law that regulates the protection of personal data.<sup>12</sup>

Currently, the Serbian Parliament is preparing to adopt the Draft on the Pharmaceutical Affairs Act.<sup>13</sup> This is an important step because the Republic of Serbia previously lacked legislation that would regulate this field, with the exception that the HCA contains only general provisions. This indeed will be historical legislation, and long awaited since the time of the Kingdom of Yugoslavia.<sup>14</sup> The new Act outlines the main principles in this field and governs documentation management. However, a severe limitation or deficiency in the Act is that it does not r the issue of pharmaceutical secrecy or confidentiality. Namely, the principle of respecting human rights and values in the pharmaceutical field implies the highest possible standard in carrying out pharmaceutical business. That is, the right to life, physical and mental integrity as well as the integrity of human dignity, respect of moral, cultural, religious and philosophical beliefs of people (HCA, Article 4). Managing medical documentation and records in the pharmaceutical field is performed in accordance with this law, as well as the law that regulates medical documentation and records and refers to medications and medical equipment (HCA, Article 4). The law prescribes that a pharmaceutical inspector must act in accordance with a duty of care and impartially when carrying out supervision and must maintain data that he or she came across during his/her inspection as a professional secret, especially the data that refer to medical documentation of a patient (HCA, Article 55).

Legal procedures in Serbia point to the seriousness of possible problems due to the unlawful disclosures of professional secrets and breaches of confidentiality and the sensitivity of jobs that health care professionals and pharmacists perform.

There is still the need for greater professional behavior by all participants in the health care system. Concerning current health care there is a tendency to respect dignity and individual rights to a greater extent, where consequently a patient as a consumer of different services in medical and pharmaceutical care should also enjoy more specific legal protection. But in the same time the Serbian legal authorities show deficit in control and processing the cases of confidentiality malpractice. Namely, for a long period there has only been a few cases where the courts have awarded damages because of the disclosure of the information about HIV status of a female patient (Petrović-Škero, 2004: 28).<sup>15</sup> Besides, court practice is still clearly undeveloped concerning the pharmaceutical health care issues.

### 3 Importance of privacy

Determining privacy of data can be evaluated from both the normative and factual point of view. Namely, data privacy implies that protections stem from law, other regulations, general act or any other act passed according to the law and thus pronounced confidential: documents, contents and attachments, subjects, objects, measures or acts as well as official announcements or confidential information presented in the work of state officials or other legal entities (McHale, Fox, 2007: 623). Depending on the kind of privacy, data can be qualified as a state, military, official, business and professional secret. Depending on the level of privacy, data can be qualified as constituting a state secret, classified or strictly confidential data. A professional secret, on the other hand, refers to the data pertaining to the personal and family life of clients that medical and social workers or other officials discover while performing their jobs. The concept of secret data or information refers to everything that a professional discovers about an individual in direct communication, which should not be made available to others, especially those that could endanger him/her (Radišić, 2008: 157). Confidentiality is vitally important in professions connected with individuals that have psychological, psycho-pathological or social problems. These especially sensitive cases are regulated by special codes mandating strict obligations of maintaining professional confidentiality except in rare cases involving exceptional reasons or a court order (Mujović Zornić, 2011: 187).

The concept of confidentiality is deeply rooted in the right to privacy, just as the concept of the right of privacy is deeply rooted in the notion of the autonomy of an individual (Nassar, 2009: 228). Starting from the concept of self-autonomy, it follows that being truly autonomous means having the freedom of thoughts and actions without any interference or limitations by others. Absolute autonomy is abstract. For example, a person cannot act freely in a way that endangers others. No law is necessary to prescribe that. Privacy is not one particular ethical principle by itself. To the contrary, it is interconnected with a number of principles. The concept of privacy reveals respect for autonomy of an individual and his/her right to control personal information. The health care professional that learns of a patient's secret during the course of the professional relationship is working for the patient's benefit, and is working in the patient's best interest. True autonomy insists on the right to a certain level of privacy. It could be best described as an absolute and irrevocable right to enjoy and have control over oneself (Beauchamp/Childress, 2001: 294–295). Everyone should have the right to keep private

the things i.e. information, they do not want others to find out. The obligation of keeping a professional secret (that is, maintaining confidentiality) refers to the facts that are known only to a limited circle of people. Private or confidential information is that information coming from a private sphere of a particular person, which does not have to be of paramount importance. Moreover, information that is subject to confidentiality does not necessarily have to be the data that can be objectively identified. Instead, the true test of confidentiality is whether a patient has a reasonable interest in the privacy of the information deserving of legal protection. That prerequisite is met in a situation where, for example, the disclosure of those data could endanger a patient in any way or it could hurt his/her psychic integrity. It prevents the situations to make wrong, relative, or false the criteria used to describe a secret. It means that everyday information are excluded, e.g. somebody had a cold or broke his/her leg when skiing. Disclosing such information does not interfere with the interest that deserves protection (Radišić, 2008: 158). On the other hand, the benefit of maintaining confidentiality is not valued objectively. Instead, subjective criteria are used without any legal or moral evaluation as the person the information refers to should insist on making it unavailable to the third party.

## **4 Confidentiality in the health care system**

### **4.1 The obligation of maintaining confidentiality**

Health care services employ measures to ensure that healthcare professionals respect the privacy interests of every patient by fulfilling their duty to properly maintain the information they gather during patient treatment. In the past, when care was somehow less complicated, professionals did not think of exchanging data about a patient except with other medical experts directly involved in his/her care without previously discussing it with a patient. Today, however, medical insurance and public awareness about people's health demand the collection and maintenance of very rigorous records of diseases and patients, systematic reporting and informing. Officials working in the field of health insurance are obliged to keep the data about a patient confidential. To help ensure the confidentiality of patient information encrypted medical diagnoses and reports are often used. EDP and medical documentation present serious obstacles for the obligation of keeping patient information confidential. Research has shown, for example, that users either do not know much or they do not think about how many people have legitimate access to what they consider confidential information. The case usually quoted is about a patient worried about the number of people who could have access to his medical documentation while he was hospitalized. His concern was such that he threatened to discontinue treatment. Research revealed that a number of medical staff had a justifiable need and responsibility to access and review the patient's medical chart. In fact, the chart was accessed 75 times (Nassar, 2000: 226). In practice, this implies that personal information presented to other medical professionals or the one officially acquired during the treatment, in its essence, stay confidential. For example, medical information presented to a clinical physician in order to prescribe a tranquilizer is personal information and it would be reasonable to expect of a physician to keep it confidential. That is why a legal platform was adopted requiring that medical professionals and even pharmacists should start from the premise that a patient is not willing to have his/her

personal information disclosed but that in a specific case this premise can become a rebuttable presumption based on the patient's statements or actions.

The patient has absolute autonomy over the own health's information and his/her decision is based on the physician - patient relation that has been developing for centuries. Neither medical professionals nor pharmacists should forget that the patient's autonomy is a matter of trust.

#### **4.2 Specificities of a pharmaceutical profession**

Patients expect pharmacists to be competent in terms of their compliance with professional standards and with the standards of duty of care adopted in pharmaceutical practice. These expectations are present as well when it comes to the issue of the protection of privacy. Generally speaking, in this sphere, legal issues and professional ethics overlap. Very often, professional organizations like chambers are asked for help. The Pharmaceutical Chamber of Serbia passed the Ethical Code of Pharmacists in 2006. Principle no. 4 is the rule governing professional secrecy at work.<sup>16</sup> A decree has been enacted according to which a pharmacist should keep all information about an individual that he/she gathered during work confidential, as that information is considered by law a professional secret. The law mandates that in addition to personal information about an individual, a professional secret of medical workers includes the following: the history of the disease, lab results, prescribed medications as well as medical equipment.

The obligation of maintaining confidentiality extends not only to pharmacists but also to all employees working in a pharmacy, including also anyone who encounters any confidential information while performing their job. A pharmacist has a moral obligation to minimize the risk of unauthorized and unnecessary access to confidential information (computer data encoding, etc.). A responsible pharmacist in any health care institution (hospital, clinic and/or pharmacy) is supposed to take steps to ensure that anyone who has access to confidential information should be aware of the importance of respecting it. Confidential information may be disclosed only in strictly specified cases. In order to prevent serious consequences or endangering a patient's health, the health of a third party or the public health in general, the amount of information disclosed and the number of those it is disclosed to should be limited to the maximum extent possible. A pharmacist should also make sure that services rendered to adolescents should not be disclosed to their parents given the legitimate concern about building and maintaining trust between a pharmacist and an adolescent. Information about a physician's habit of prescribing some medications or physician's work in the sense of his experience or knowledge is also considered confidential. For that reason, a pharmacist is obliged to respect the physician's right to confidentiality even in that sense. Other pharmaceutical codes, when examining the comparative law, mostly refer to the work of pharmacists in a pharmacy setting, and indicate that pharmacists are obliged to: 1) respect a contractual relationship between a patient and a pharmacist, 2) promote welfare of each patient in an attentive, conscientious way full of trust, 3) respect autonomy and dignity of each patient.<sup>17</sup>

Understanding the importance of legal terms (autonomy, privacy and confidentiality) in specific working environment could be at stake due to the dynamics of the health care system. For example, a pharmacist involved in the treatment of a patient with contagious/infectious diseases faces situations where rights are treated differently from those when they treat patients in some other wards. There are also legal requirements to record certain information about contagious/infectious diseases that are not obvious. A pharmacist involved in the long-lasting treatment and care of less capable patients, for example, who can hardly be seen in most health care institutions, is in a position to cooperate with other staff members depending on the medical institution he/she works in. With his/her personal involvement in the protection of the patient's right to autonomy, privacy and confidentiality, a pharmacist can be an example to other medical professions and associates responsible in their mutual care for a patient.

Sometimes the health care institutions are engaged in the practice of communicating with family members about a patient's care, especially with a spouse, although a patient did not previously show any personal interest in it. The reasons for that could be found in therapeutic excuse, which is in the best interest of the patient. Besides, information about a patient undergoing lengthier treatment is regularly shared with other members of the medical team, regardless of their need to know it. Pharmacists are asked to apply *Good Pharmacy Practice* and form their own approach with an aim to protect the patient's privacy when it comes to delivery of medications. For example, in many clinical procedures it is noticeable that information about a patient does not correlate with physician's duties in order to protect personal data. Also the most pharmacists-consultants can confirm the fact that information about patients with institutional and long-lasting care is often easily accessible, even to the public. That kind of practice should not be tolerated. Focusing attention on these shortcomings is just one of the examples of how a conscientious and careful pharmacist can influence his/her working environment with an effect to respect and protect the patient's basic rights.

The law of confidentiality has developed through case law and is supported by various statutes. Practice in question points out as well to the situations in developed countries where health insurance companies disclose information about the number of patients with certain diagnoses or some pharmaceutical companies pay directly to pharmacies in order to obtain access to patients' personal data. Comparative practice shows, for example, some similar cases: 1) A patient was convinced that the information about psoriasis treatment he had shared with a pharmacist and a physician was confidential because, a few months later, he started getting internet messages about the same treatments;<sup>18</sup> 2) The Supreme Court of the USA decided in favor of privacy when prescribing medications and their consumption and also in favor of the integrity of the physician - patient relation. According to this decision it is unacceptable for pharmacists to give information about which physician prescribes which medications and to which patients judging by gender or age;<sup>19</sup> 3) A patient at a high-security psychiatric hospital who was suffering from mental illness was not entitled, under the Data Protection Act 1998, to full disclosure by an NHS trust of a psychology report or disclosure only to his legal representatives. There were clear and compelling reasons based on cogent evidence to support the decision not to disclose, and no injustice had been caused as the patient had had a fair opportunity of

presenting his own psychological evidence. The court rejected both grounds of the application. It was also held that R would suffer no injustice from the non-disclosure. While Article 6 required that R receive a fair trial, this did not give him an absolute or unqualified right to see every document. In any event, as the Trust was not obliged to provide a report, the MHRT did not have any power to compel disclosure.<sup>20</sup>

### 4.3 Release from obligation of maintaining confidentiality

The right to privacy and confidentiality does not necessarily imply an absolute right. To the contrary, there are certain exceptions to the idea of complete confidentiality, which is confirmed in both medical and judicial practice. Medical confidentiality arises from both the nature of the information concerned and the fiduciary character of the pharmacist - patient relationship. There has been a movement towards greater patient, as opposed to professional, control of health information. Decisions about disclosing information should be made on a case-by-case basis and only after fully considering all relevant factors. Disclosure can be made in several forms: disclosing information with consent; disclosing information without consent; disclosures required by law; and, disclosures made in the public interest.

Legal literature quotes an example of where a psychotherapist made a mistake because he kept information about a patient as a secret that he was obliged to disclose (Nassar, 2000: 230). In the case in question, a patient with a mental disorder told his psychiatrist that he was intending to kill his ex-girlfriend. The psychiatrist found out the girl's name and he had the possibility of warning her or reporting those threats to the police but he failed to do so. The tragedy happened as the patient had carried out his threats and killed his girlfriend. The court pronounced the psychiatrist liable since he failed to take any steps to warn the victim. The court explained that the protection of the relation based on trust is favored only until it is necessary, but not when disclosure of information becomes of greater importance in order to protect other people who are in danger. In other words, the privilege has limits, and the privilege of privacy ends where there is general, public interest that requires disclosure of otherwise confidential information in order to prevent or eliminate danger to the larger public. It is more than obvious that the psychiatrist should find a moral and legally based logical reasons for it. Similar to that, many laws contain jus cogent/peremptory provisions norms insisting on reporting, like in the situations of contagious/infectious diseases or with at least some suspicion of abuse. The same are in general legal norms which clearly focus on the protection of corporal or mental integrity of other people from criminal acts.

According to the opinion of the majority of lawyers, the term of unauthorized disclosure of a secret should be equated to the term of unjustifiable i.e., unlawful disclosure. Exceptions to unlawfulness are strictly prescribe by law (requests by the court or any other body or jus cogent/peremptory norms e.g. the norms about mandatory reporting and registration of certain diseases), or they stem from general circumstances that exclude unlawfulness as follows: consent of an authorized person; implied consent of an authorized person; the state of absolute necessity; the defense of his/her justifiable interests (Radišić, 2008: 160-4). The patient's consent is the reason that releases him/her

from maintaining confidentiality and it stems from the patient's right to self-determination, which is of paramount importance. Consent from the patient's statement, or the statement of his/her legal representative (a parent, a guardian, an adoptive parent), that he/she does not want something to be a secret any more. Third persons are not authorized to give that kind of consent, not even in the case when they personally communicated the secret about a patient to a medical professional. However, if the secret refers to a third person, his/her consent is also necessary; the statement of will, which means consent, can be given in any form, expressed by words or conclusive acts. Implied consent is considered to be the reason for release from keeping a secret and it is not just a sub-type of the state of necessity. Implied consent is important in cases when a patient is not capable of giving his/her consent (because he/she died, lost consciousness or is mentally ill) or we can conclude from certain circumstances that a patient has no interest to keep a secret. The contents of implied consent can be assumed from a patient's personal circumstances, interests, wishes, needs and attitudes that imply the standard of a reasonable patient (Radišić, 2008: 162). If there is no firm ground to believe that a patient would object to it, there is always a state of absolute necessity when, because of general interests, either public or private, the only way to avoid danger is to reveal a secret.

The foregoing explains why an example of contagious/infectious diseases is taken when the law allows a medical worker to communicate the information about a patient's health condition to a major member of his/her family, in cases when it is necessary in order to avoid health risks for a family member. The right to reveal a professional secret can be, under certain circumstances, reversed into an obligation of disclosing a secret.<sup>21</sup>

#### **4.4 Breach of confidentiality**

Threats to confidentiality i.e., protection of classified information can be found in the whole health care system. On the one hand, electronic information has become more wide-spread. On the other hand, it has become rather difficult to limit access based on the criterion of necessity, i.e., authority to have information about some data. Thus, if a company is asked to organize with corporate physicians regular medical check-ups for its employees, documents are computerized and connected with other browsers. Most employees suspect that, in that way, copious documentation found in two places, and the part connected with medications, can be used against them. Employees also point out that, in cases like this, a physician has a greater interest to disclose confidential information to the company as an employer than to respect the patient's right to privacy. For example, a patient is in charge of some work that demands critical attention and full concentration and the absence of which can cause damage to him/her as well as to the others. A physician, who finds out that a patient is taking antidepressants, which affect cognitive functions, should not in these circumstances give priority to the patient's right to privacy. Instead, here the priority should be given to the society in order to protect the public good and welfare. However, a definite solution may be in better protection of employees who could also be the subject to an inspection at their private, elected physician as a counselor in this matter. The elected physician takes in account patient's interests and could make a better balance whether to tell or not to tell employer some sensitive health information.

There is a difference between a violation of confidentiality and breach of privacy rights, at least in the sense these issues are considered here (Nassar, 2000: 228). As previously stated, confidential information is the one given freely or collected by professionals during the treatment. If a patient previously gives his/her consent that that information can be communicated to others (a spouse, an employer, an insurer, etc.), there is no violation of confidentiality that is owed to him/her. A violation is obvious only in cases when information about a patient or his/her treatment is given to those who have no authority to get it and there was no good reason to justify that violation of primary health care. A violation of confidentiality supposes that it is performed by those who are authorized to have that information. It is quite different if a person who violates this right is not authorized. If an unauthorized person comes into possession of the information (in a specific situation or any other way), then we can talk about breach of privacy and unauthorized dissemination of information, which is totally unacceptable and thus punishable. This breach can be done by any other person employed in a medical institution. Any ethical discussion would emphasize the importance of confidentiality and the right to privacy should be protected. Trust is an important condition of civilized behavior so the health care service could hardly work well without it. When there are duty-based ethics either towards an individual or a group and they become really crucial, it gets its legal form in legal acts provisions. Since there is no particular provision regarding trust that develops between a physician and a patient, data protection is derived from administrative and general legal solutions: 1) priority given to confidentiality in the communication with a patient means introduction of encrypting official records by means of codes; 2) tort law protects information privacy through court proceedings for the compensation in case of the damage caused by unauthorized disclosure of a patient's secret. Civil and legal protection is widely accepted as a means of clarifying a dispute that involves a clearer explanation of information privacy. An issue of confidentiality in a dispute is always a very concrete question where it is necessary to identify if the information acquired can be freely shared with others or it is reasonable to consider it classified and protected.

There is a lot of discussion in the pharmaceutical business concerning the parameters of when information about a patient may be disclosed and disseminated (Nassar, 2000: 229). In all areas of their practical work, there is a rule for pharmacists providing that, since they have learned about a patient's diagnosis, they are allowed only to give information which is necessary and relevant for the patient's treatment, but nothing more than that. Also, legal issues may be raised concerning how best to handle electronic transmission of medical data with an aim of the protection of patient's privacy. Privacy and safety of the data of this kind of confidentiality is taken into consideration in comparison to the data gathered through public health care system data processing. Many are of the opinion that all the data, which are considered sensitive for a patient, should be sent to health care agencies in order to provide continuity of the treatment. Take for example, a potential treatment of a patient with multiple resistance to TB medications. Each patient from this group is firstly monitored as someone who can be cared for in different facilities, including an emergency department, a clinic for an HIV treatment, homeless shelters, even prisons. Patients with the highest level of risk may be the ones with the least probability of coming back and asking for help or even for the treatment that suits them

better. Continuity of treatment and care can be improved if there is a possibility for institutions to share sensitive information about a patient. With an idea that health care will improve if information is shared, one of the suggestions is, also, to adopt common standards of protection regarding privacy and data safeguards. In the other words, all information users (receivers) are expected to have the same standard of requests for privacy and safety just as the initiator of information does. Some state agencies, for example, may have a developed electronic system for the protection and keeping sensitive information about a patient but they gladly share it with other agencies with an aim of providing patients with better medical care. The agency that receives information has a legal obligation to protect and keep it the way that is equal to or more developed than the sender's. This rule, wherever it is adopted as an official standard, refers to pharmacists as well. In practice, it means that, if a clinical pharmacist or the one working in the production, comes across some data about a patient, who uses a certain medication, should provide the same level of protection provided to patients in authorized pharmacies. The issue of privacy regarding medical records refers to the each part of health legislation and includes different levels of care. Team work in the health care system, especially in long-lasting and institutional care, is a proper way of managing a limited budget and its allocation in order to reduce medical costs. Necessary as it is, team work enables access to medical information to a greater extent than it can be found in some other forms of care and treatment. Actually, it is fundamental to make sure that all team members, and staff members who are in direct contact with a patient, understand the importance of patient's privacy, what is implied by it and their obligation to protect it respecting patient's individuality.

Concerning the European court practice the protection of medical data falls under the scope of Article 8 of the European Convention on Human Rights (ECHR).

In the *case Elberte v. Latvia* the European Court of human rights held that there had been a violation of Article 2 (right to life) and of Article 8 (right to *confidentiality*) for personal information concerning health which had been sent to a German *pharmaceutical* company. Following the death of the applicant's husband in a car accident, tissue was removed from his body during an autopsy at a forensic center and sent to a pharmaceutical company in Germany with a view to creating bio-implants, pursuant to a State-approved agreement. The domestic authorities' failure to secure the legal and practical conditions to enable the applicant to express her wishes concerning the removal of her deceased husband's tissue constituted an interference with her right to respect for private life.

In the case of *Mr and Mrs Campbell*<sup>22</sup> the Court stated that there was no indication that Mrs. Campbell's life expectancy had been reduced by the decision of the health authority. What is clear, however, is that the new drug was effective in Mrs. Campbell's case and had improved her quality of life. In this type of situation, arguments based upon Article 8 may be appropriate (right to respect for private and family life). The decision of the health authority in restricting the prescribing of the drug with the result that some people in the area are being prescribed it, and others are not, could be held to be discriminatory if there is no objective reason for the policy, and so Article 14 could also be engaged. In

the postcode prescribing type of situation, the courts would be more likely to find in a patient's favor, if there was evidence that the restricted medication would be.

One of the cases is *Wretlund v. Sweden decision*<sup>23</sup> where the applicant complained that her obligation to undergo drug testing, as laid down in the Labour Court judgment, interfered with her right to respect her private life under Article 8.1 of the European Convention. She claimed that there was no Swedish legislation giving employers the right to conduct drug tests on their employees and that, consequently, the Labour Court's judgment had no basis in law. Thus, the interference in the case was not 'in accordance with the law' as required by Article 8.2 of the Convention. Further, even assuming that the interference was lawful, she argued that the compulsory drug test could not be considered a justifiable measure having regard to her duties as an office cleaner. The ECHR thus found that the measure challenged by the applicant had a sufficient basis in Swedish law and thus was 'in accordance with the law' within the meaning of Article 8.2. The ECHR also concluded that the operation of a nuclear power plant obviously required a very high level of security and that it was necessary to apply various procedures, including control measures. It was evident to the Court that the use of drugs among the employees might jeopardise the security at such a plant. A drug policy programme involving regular drug testing of staff must be considered as justified.

Court practice notes that all members of healthcare staff are bound by a duty of confidentiality. In 2010, the European Court of Human Rights decided the case *I v. Finland*.<sup>24</sup> Ms. I was a nurse at a hospital in Helsinki who was HIV positive. The systems at the hospital enabled every clinician to see every patient's notes, and in consequence her colleagues discovered her HIV status, and hounded her out of her job. She sued for compensation, and the ECHR found that Finland had breached her right to privacy by failing to provide an environment in which she could keep her medical information confidential: What is required in this connection is practical and effective protection to exclude any possibility of unauthorized access occurring in the first place.

## 5 Conclusion\*

It is essential that pharmacists take steps to protect the confidential information they are given either in the course of their professional practice or because they are a pharmacy professional. As the concept of pharmaceutical care is getting more grounded, there are an increasing number of situations when pharmacists are obliged to collect patients' data, not only to dispense medications, but also because they have to deal with some very sensitive pieces of information. It is often a very serious problem for them.

The concept of professional secrecy, as any other form of discretion regarding different professions, is widely conceived. The duty of confidentiality applies to information about any person, whatever their age, and continues to apply after a person's death. The scope of protection is not solely determined by legislation, e.g. legal standards regarding rendering professional services, but also the idea to reach the level of individual rights of every person in general. There are no clear laws or professional rules in pharmaceutical practice to direct them in this field. Consequently, the private sphere of the patient is

increasingly endangered. It cannot be said in advance that something is in the scope of privacy because it often depends on the specific case, its circumstances, its sides and relations, both in factual and legal sense.

The duty of keeping the secret is undermined by the general social progress and progress of medical activity, which makes health insurance more massive and the distribution of work in medicine is more complete, the private sphere of the patient is increasingly endangered. The two-way relationship between a pharmacist and patient is sometimes transformed into a multiple-party relationship, and the duty of keeping professional secrets is significantly relativized. Compulsory health insurance has transformed the two-way relationship with the patient into a three-way relationship. This is the same reason why the obligation of professional secrecy in the area of pharmaceutical health care has been significantly re-evaluated as well. Namely, health insurance and public health care require rigorous records of illness and patients through systematic reporting and disclosure. The health and social security providers also have the obligation to keep the information on the patient secret and often use the so-called digitized diagnoses and reports. In the long run, electronic data processing and medical documentation make more risk to professional secrecy obligation. The health care system and in this regard aspects of pharmacy care can put a private sphere of the patient at a greater risk. In this situation the obligation of professional secrecy could become quite indefinite.

Regarding the above issues, the development of law as a system is a necessity. Thus, the development and implementation of human rights' standards should always be a continuous process that improves over time and has its own tradition in the field of privacy. Endangered in many ways, the obligation of secrecy, however, is somewhat maintained and lasts.

## Notes

<sup>1</sup> Convention for the Protection of Human Rights and Fundamental Freedoms (1950). Serbia ratified it in December 2003 with legal effect since March 2004. Article 8. Official Gazette of Serbia and Montenegro International agreements. 2003: 9 and 2005: 5.

<sup>2</sup> Convention on Human Rights and Biomedicine Oviedo (1997) Article 10. Serbia ratified it in December 2010; Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997, in force 1 December 1999, ETS No. 164, <http://conventions.coe.int/treaty/en/treaties/html/164.htm> Signed in the moment of adoption by 17 states: Denmark, Estonia, Finland, France, Greece, Italy, Latvia, Lithuania, Luxembourg, Holland, Norway, Portugal, Romania, San Marino, Slovakia, Slovenia and Spain, and later by 18 states more (Turkey, Switzerland, Serbia, Moldova, Montenegro, Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Georgia, Hungary, Iceland, Poland, Sweden, Macedonia and Ukraine).

<sup>3</sup> European Charter on patient's rights, Roma (2002), available at: [ec.europa.eu/health/archive/ph.../co.../health\\_services\\_co108\\_en](http://ec.europa.eu/health/archive/ph.../co.../health_services_co108_en) (March 19, 2017)

<sup>4</sup> Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23. 11. 1995, p. 31).

<sup>5</sup> Council of Europe Data Protection Convention (1981); Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45); Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA

<sup>6</sup> Constitution of the Republic of Serbia (2006) *Official Gazette of the Republic of Serbia*, 83, articles 41-42

<sup>7</sup> Article 14, The Act on Free Access to Information of Public Importance, *Official Gazette of the Republic of Serbia*, No.120/2004, 54/2007, 104/2009 and 36/2010

<sup>8</sup> Article 141 and Article 302 Criminal Code of the Republic of Serbia, *Official Gazette of the Republic of Serbia*, 85/2005 am. 72/111/2009

<sup>9</sup> The Health Care Act, *Official Gazette of the Republic of Serbia*, 107/2005...93/2014, 96/2015 and 106/2015

<sup>10</sup> Patient Rights Act, *Official Gazette of the Republic of Serbia*, 45/2013

<sup>11</sup> Article 30, *ibid.*

<sup>12</sup> Article 3, The Act on Health Records and evidence in the Field of Health Care, *Official Gazette of the Republic of Serbia*, 123/2014, Article 7. See also: The Medicines and Medical Devices Act, *Official Gazette of the Republic of Serbia*, 107/2012, Article 31 and Article 137.

<sup>13</sup> Available at:

[http://www.zdravlje.gov.rs/downloads/2017/Januar/Nactr\\_zakona\\_o\\_apotekarskoj\\_delatnosti.pdf](http://www.zdravlje.gov.rs/downloads/2017/Januar/Nactr_zakona_o_apotekarskoj_delatnosti.pdf) and <http://www.parlament.gov.rs/akti/zakoni-u-proceduri/zakoni-u-proceduri.1037.html> (November 25, 2017).

<sup>14</sup> Zakon o apotekama i nadzoru nad prometom lekova (1930) ZBIRKA zakona, uredbi, pravilnika i propisa o apotekama sa izvodima iz ostalih zakona, koji su u vezi sa apotekarskim radom i pozivom, Apotekarska komora Kraljevine Jugoslavije, Beograd. pp. 6-240.

<sup>15</sup> District court in Požarevac Gz. 83/1996; verdict based on the reversed decision of the Supreme Court of the Republic of Serbia, REV.392/2003.

<sup>16</sup> Ethical Code of Pharmacists of Serbia, *Official Gazette of the Republic of Serbia*, 6/2007

<sup>17</sup> A good example sets Ethical Code of Pharmacists adopted by ASCP in 1992, Nassar, quotation described, available at: [www.asqh.org/threads/](http://www.asqh.org/threads/) (January 28, 2017)

<sup>18</sup> Available at: [www.nepanet.wordpress.com/2011/02/03/](http://www.nepanet.wordpress.com/2011/02/03/) (April 11, 2017).

<sup>19</sup> Decision from March 2011. Since 2003 in USA, there have been new laws that created to prevent illegal disclosure of Confidential Patient Information, known as the HIPPA Act; Available at: <http://www.resource4pharmacy.com/disclosure.html> (November 25, 2017).

<sup>20</sup> Roberts v Nottinghamshire Healthcare NHS Trust [2008] EWHC 1934 (QB).

<sup>21</sup> Article 37, paragraph 6 The Health Care Act, *op.cit.*

<sup>22</sup> Chaos over funds for Alzheimer's drugs', BBC News on line, 11 October 2000.

<sup>23</sup> *Wretlund v. Sweden decision* The European Court of Human Right (ECHR) application no.46210/99.

<sup>24</sup> *I v. Finland* ECHR Application no. 20511/03.

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