

PATIENTS' RIGHTS IN PHARMACY LEGISLATION

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Abstract

The objective of the paper is to present the reflection process and the research carried out by the authors in order to create modern provisions for the pharmacy law, starting from the principle of respecting the ethics of patients' rights within the pharmacy activity as key element in quality assurance. Official European documents and national healthcare laws were studied and provisions referring to patients' rights were created. The result included proposals for the development of an ethical Romanian pharmacy oriented towards providing quality patient services. The proposals were submitted to the Chamber of Deputies, the co-financier of the research. However the Pharmacy Law does not include provisions regarding patients' rights. In order to ensure that the ethics of patients' rights is respected in the pharmacy activity, as part of the national policy of quality assurance in the health system, the pharmacy law must advocate patients' rights in relation to this important health institution, at the same time specifying the means of monitoring that these rights are respected.

Rezumat

Lucrarea de față are ca scop prezentarea cercetării realizate pentru elaborarea unor prevederi moderne pentru legea farmaciei, pornind de la principiul respectării eticii drepturilor pacienților, ca element esențial pentru asigurarea calității în activitatea farmaciei. S-au studiat documente oficiale europene și legislație națională în domeniu și s-au elaborat prevederi referitoare la drepturile pacienților în relația cu farmacia. Au rezultat propuneri pentru dezvoltarea farmaciei românești etice, orientate spre furnizarea de servicii de calitate către pacienți. Propunerile au fost înaintate Camerei Deputaților, care a contribuit la finanțarea cercetării. Totuși, Legea farmaciei nu cuprinde prevederi referitoare la drepturile pacienților în farmacie. Pentru a asigura respectarea drepturilor pacienților în activitatea farmaciei, ca parte a unei politici naționale de asigurare a calității în sistemul de sănătate, este necesar ca Legea farmaciei să proclame drepturile pacienților în relație cu această importantă instituție de sănătate și să prevadă modalitățile de monitorizare a respectării acestora.

Keywords: patients' rights, pharmacy law.

Introduction

Romanian researchers and practitioners in the pharmaceutical field are increasingly concerned with ethical issues in the pharmaceutical care [9, 10, 17, 18]. Unfortunately, provisions concerning the ethics of patients'

rights in pharmaceutical care were not included in the Pharmacy Law [16]. The “Partnership with the Civil Society” Program, a modern tool for creating and developing legislative projects, was initiated by the Chamber of Deputies in 2007 and the project “Modernizing Romanian Pharmacy Legislation for Healthcare Services at European Standards” has been approved and financed in the frame of this program [11, 12]. A pharmacy law proposal was created within the project and a section on patients’ rights in pharmaceutical care was included. The paper presents the research carried out by the project authors in order to: support the need to include provisions on patients’ rights in pharmaceutical care into the law; write these provisions; create the premises for the dynamic adaptation of the law in accordance with developments of the practice.

Materials and Methods

The research on patients’ rights in pharmacy was carried out using the following documents: European Community (EC) and European Union (EU) Fundamental Treaties; Charter of Fundamental Rights of the EU; Declaration of the World Health Organization (WHO) on the Promotion of Patients’ Rights in Europe; Council of Europe Resolution ResAP(2001)2 concerning the Pharmacist's Role in the Framework of Health Security; Council of Europe Recommendation Rec(2006)7 of the Committee of Ministers to Member States on Management of Patient Safety and Prevention of Adverse Events in Health Care; Romanian Constitution; Law no. 46/2003 on patients’ rights and Law no. 95/2006 on healthcare reform. The methods used were: the interpretation methods, crucial for an updated grasp of the legislation, from both the lawmaker’s and researcher’s perspective [6], and the comparative method, extremely effective in the study and development of the legislation [2].

Results and Discussion

The concept of patients’ rights has legal, ethical and social implications, being strongly related to the quality of the healthcare. The main policy instrument employed to implement public policies in this field in Romania is the law [11]. The article 34 of the Romanian Constitution, states that the right to the protection of health is guaranteed, while measures to protect the physical and mental health of a person shall be established in accordance with the law [13]. In accordance with article 152 of the Treaty Establishing the EC, a high level of human health protection shall be ensured in the definition and implementation of all Community policies and

activities. The article also states that Community action in the field of public health shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care [8]. Article 35, on Health Care, of the Charter of Fundamental Rights of the EU mentions that everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices [7]. The Law no. 95/2006, by including chapter VI, entitled Pharmaceutical Care, in the Title I, Public Health, acknowledges the concept of pharmaceutical care and includes it, for the first time after the Revolution of 1989, in public healthcare [15]. This legislative context, meaning a new law on the health care system, and the political one, mainly a Ministry of health willing to reform the healthcare system in Romania, including the pharmaceutical care, were perceived as very favourable to the project. Thus, the authors considered that the right to healthcare includes components related to pharmaceutical care and that it is the State's responsibility to ensure by law that patients benefit from this right within the national health care system, at the same time respecting EU principles. Therefore, provisions concerning pharmaceutical components within the right to healthcare were included in the pharmacy law project.

In accordance with the WHO Declaration on the Promotion of Patients' Rights in Europe, the patients' rights to health care are as follows: the right to treatment and care; the right to information and informed consent regarding health interventions; the right to privacy and confidentiality; the right to quality health services. The first component, the right to treatment and care includes: the right to receive the most adequate health care in accordance with patients' needs, fair access, without discrimination and the right to continuity of services; the right to choose and change the health care provider or health institution; the collective right to a form of representation at every level of the health system; the right to dignity in the health system, i.e. the right to be respected as human beings, including the respect for human integrity and identity [19]. In Romania, most of these rights are stipulated by the Law no. 46/2003 [14], which was created in accordance with the structure and content of the WHO Declaration. Since these rights are, in the national legislation, particularly formulated for medical care [14], the project authors decided to formulate patients' rights within pharmaceutical care. Thus, articles 3-8 of the law project were created.

Article 3: The patient has the right to choose and change pharmacy or the pharmacist providing pharmaceutical care.

Article 4: (1) The patient has fair and non-discriminatory right to medicines or other health products or pharmaceutical services in accordance with their health needs. (2) The right to medicines and other health products in accordance with the patient's health needs includes: the right to medicines and other health products of the quality level stipulated by law; accessibility of medicines and other health products; timely and continuous availability of medicines and other health products; a wide range of medicines in accordance with the patient's health needs. (3) The right to pharmaceutical services in accordance with the patient's health needs includes: information and counseling for disease prevention and a healthy lifestyle; information, informed consent and counseling for the correct use of medicines and other health products throughout the entire duration of treatment; continuity of pharmaceutical services; quality pharmaceutical services.

Article 5: The patient has the right to dignity in pharmaceutical care.

Article 6: The patient has the right to privacy and data confidentiality in pharmaceutical care. All the above-mentioned rights are valid also for the self care (right to self determination), with the help of the pharmacist.

The WHO Declaration also stipulates that patients are entitled to their rights, which means that, in case of failure to respect them, the law must ensure that patients' rights are enforced through appropriate procedures [19]. The general principles of right enforcement are mentioned in the WHO Declaration. This part of the Who Declaration does not have a correspondent in the Law no. 46/2003. The authors considered that these provisions are crucial for ensuring patients' rights and have therefore formulated the article 8 of the law project: the pharmacy must have a procedure for ensuring and monitoring patients' rights, in accordance with the guidelines elaborated by the Romanian College of Pharmacists.

Article 7 of the law project, in accordance with which the patient has the right to safety within pharmaceutical care, was formulated based on Council of Europe documents. Thus, the Council of Europe Recommendation Rec(2006)7 recommends that Member States make sure that patient safety is the cornerstone of their health policies, especially as far as improved quality in the field is concerned [3]. Council of Europe Resolution ResAP(2001) recommends that Member States make full use of the pharmacist's competencies for patient safety as pharmaceutical care is regarded as a key element in preventing and limiting iatrogenic risks [4].

The provisions of the project, concerning patients' rights in pharmaceutical care, include broad principles, which are appropriate for a

law, and send to regulations with less juridical power, as far as their application and monitoring are concerned.

Thus, in accordance with the second part of article 8, the College of Pharmacists has the task of creating guidelines for implementing a procedure to ensure that patients' rights are respected. The College of Pharmacists has listed some patients' rights within pharmaceutical care in the Deontological Code [1]; however, a procedure for monitoring that these rights are respected has not been enforced. This objective, together with the inclusion of omitted rights in the Deontological Code should be part of the policy of the Romanian College of Pharmacists for improving the quality of pharmaceutical care.

Also, the College of Pharmacists should take into account, in his policy, the most recent European act in the field, the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. The Directive provides a legal framework for patient mobility, for reimbursements, for a high level of quality and safety in healthcare, establishing responsibilities for the Member States [5]. The recognition of prescriptions issued in another Member State will have an important impact to the pharmacy practice; the Romanian pharmacists should be prepared to provide pharmaceutical care at European standards for European patients.

Conclusions

The Romanian legislation and official European documents were used to research and to formulate proposal of provisions on patients' rights in pharmaceutical care: the patient's right to choose a pharmacy or pharmacist; the fair and non-discriminatory right to health products and quality pharmaceutical services in accordance with the patient's needs; the right to dignity in pharmaceutical care; the right to privacy and data confidentiality in pharmaceutical care; the right to safety in pharmaceutical care; the right to request that rights be respected when they are not; the obligation of the College of Pharmacists to ensure and monitor that patients' rights are respected. The Pharmacy Law must be completed so that patients' rights and the means of monitoring that these rights are respected be clearly specified, as part of a national policy of quality assurance in the health system. At the same time, Romania must adopt national legislation to comply with the Directive on patients' rights in cross-border healthcare, with impact to the quality of pharmacy services.

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