

## ROMANIAN CODE OF PHARMACEUTICAL DEONTOLOGY – A NEW CONCEPTION

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### Abstract

Professional ethics of pharmacists can be optimized by developing the code of deontology. The purpose of this paper is to present a new approach to the Romanian Code of Pharmaceutical Deontology. The paper has examined codes of ethics for pharmacists from Western countries, using the interpretation and the comparative methods. The Romanian Code in force relates mainly to pharmacists of the community pharmacy. But practicing the pharmacist profession implies also activities in the fields of research, manufacturing, wholesale distribution, education, laboratory or administration. In all these areas, the pharmacist's work may impact on the safe and effective provision of professional services to the population. This is why the project of a new code covers principles that are common as well as specific to all and each such field of activity. The common principles reflect basic values and professional standards, which stand at the core of the code. The new and specific principles relate to compliance with the highest standards of quality and ethics in research, marketing, pharmacovigilance, pharmacy advertising, education, communication and publishing, supervision and inspection. The project was handed over to the Romanian College of Pharmacists. Its role is to adopt a code adapted to the evolution of the pharmacist profession and to make it known and observed in practice.

### Rezumat

Etica profesională a farmaciștilor poate fi optimizată prin dezvoltarea codului deontologic. Scopul lucrării este de a prezenta o nouă concepție asupra codului deontologic al farmacistului din România. S-au cercetat coduri deontologice ale farmaciștilor din state occidentale, folosind metodele interpretării și metoda comparativă. Codul românesc în vigoare se referă în special la farmaciștii din farmacia comunitară. Dar exercitarea profesiei de farmacist se realizează și prin activități în cercetare, industrie, distribuție *en gros*, învățământ, laborator sau administrație. În toate aceste domenii, activitatea farmacistului poate avea impact asupra furnizării sigure și eficiente a serviciilor profesionale către populație. De aceea, proiectul unui nou cod include principii comune și principii specifice domeniilor de activitate. Principiile comune exprimă valori esențiale și standarde profesionale, constituind fundamentul codului. Principiile specifice noi se referă la respectarea celor mai înalte standarde de calitate și de etică în cercetare, marketing, farmacovigilență, publicitatea farmaciei, educație, comunicare și publicare, supervizare și inspecție. Proiectul a fost predat Colegiului Farmaciștilor din România, rolul său este de a adopta un cod adecvat evoluției profesiei, de a-l face cunoscut și respectat în practică.

**Keywords:** code of deontology, pharmacist, Romanian College of Pharmacists

### Introduction

Many practitioners and researchers in the medical and pharmaceutical field in Romania are deeply concerned with healthcare quality and ethics problems, that seemed to have become more numerous in recent years [6, 7, 14, 16, 26, 27, 32, 33].

The code of deontology is recognized as an important tool for the development and promotion of ethical professional behaviour [6, 7, 13, 26, 27]. The Code of Pharmaceutical Deontology has been adopted in Romania by the College of Pharmacists, which, by law, the role of monitoring the compliance of the pharmacy professionals with the applicable principles of ethics [20, 28]. Some of the problems facing the pharmaceutical practice today in Romania

are not sufficiently addressed by the Code of Pharmaceutical Deontology and in particular issues dealing with cooperation between pharmacists and physicians, state authorities and representatives of the Romanian College of Pharmacists, compliance with the quality standards in providing professional services, involvement in pharmacovigilance, pharmacy advertising, including online advertising, and purchase of medicines *via* the Internet [6, 7, 14, 26, 27, 32, 33].

To address all these issues, a draft new code of pharmaceutical deontology has been developed under a research project funded by the Romanian College of Pharmacists. The purpose of this paper is to show the rationale behind the draft code, by describing and substantiating the proposed structure

and its contents, with examples of the most relevant new provisions.

### Materials and Methods

To achieve the purpose of the study, we have analysed the Romanian Code of Pharmaceutical Deontology, currently in force, along with the following standards and codes of ethics of pharmacists in several Western countries: Standards of Conduct, Ethics and Performance, adopted by the General Pharmaceutical Council, the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales [12]; Professional Standards for Hospital Pharmacy Services, adopted by the Royal Pharmaceutical Society, relevant to providers of pharmacy services in or to acute, mental health, private, community service, prison, hospice and ambulance settings in England, Scotland and Wales [30]; Pharmacists' Code of Deontology, adopted by the National Order of Pharmacists in France [19]; Code of Pharmaceutical Deontology, adopted by the Belgian Order of Pharmacists [17]; Code of Deontology, adopted by the General Association of Medicines Industry, Belgium [4]; Code of Deontology, adopted by the Swiss Society of Pharmacists [31]; Code of Ethics for Pharmacists, adopted by the American Pharmacists Association [3]; Code of Ethics, adopted by the Alberta College of Pharmacists [2]; Pharmacists' Code of Deontology, adopted by the Québec Order of Pharmacists [18]; Code of Ethics for Pharmacists, adopted by the Pharmaceutical Society of Australia [22]; Code of Ethics, adopted by the Society of Hospital Pharmacists of Australia [34]; Code of Ethics, Competence Standards for the Pharmacy Profession and Advertising Guidelines, adopted by the Pharmacy Council of New Zealand [23-25].

These codes have been investigated using the methods of interpretation and the comparative method [5, 8]. The main criteria for analysis and comparison were: code structure, general principles and specific principles applicable by different fields.

For the definition of some of the principles of the code, the research has also taken into account the following documents: European Charter of Patients' Rights, adopted by the Active Citizenship Network [1], relevant for the development of some of the general principles of the code; Code of University Ethics and Deontology, adopted by the Senate of the "Iuliu Hațieganu" University of Medicine and Pharmacy in Cluj-Napoca, Romania [15], with relevance for the definition of some principles governing the pharmacists' research and education activities; Code of Conduct adopted by the European Federation of Clinical Chemistry and Laboratory Medicine [9], of relevance for laboratory analysis;

The European Medicines Agency Code of Conduct [11], relevant for management and inspection activities.

### Results and Discussion

#### *The conception and the structure of a new code*

The Code of Pharmaceutical Deontology, currently in force in Romania, includes general principles, deontology standards and final provisions [5]. The analysis of its provisions has revealed that the Code refers in particular to pharmacists in the community pharmacy. But the practice of pharmacy as such, according to Law no. 95/2006, Titles XIV and XVIII, also covers activities in various other fields, such as: scientific research, manufacturing, import and export of medicines, wholesale distribution, retail distribution, lab tests, education and health administration. Beside these activities, the law also provides that pharmacists may also engage in providing information and advice on medicines, cooperation with the physician in establishing and monitoring the therapy applied to the patient, pharmacovigilance, management and marketing activities and also activities covering other health products [20]. All these activities are usually carried out in an organized setting, in one of the general areas of activity mentioned above. In all these areas, the pharmacist's work is oriented towards providing quality healthcare services and products to the public. Therefore, even from the beginning of the research study, the idea was to devise a draft code to include both common principles and principles dedicated specifically to every activity within the scope of the pharmacist profession.

To take into account other relevant concepts in the field, the deontological codes of pharmacists from eight Western countries have been examined and it has been found that these codes can be grouped into the following two broad categories: Deontological codes that establish only general conduct principles, accompanied by a brief interpretation for application purposes, such as, for example, the codes in the United States of America and in Switzerland [3, 31]; Deontological codes setting out general conduct principles and principles that are specific either to certain areas of pharmaceutical activity, or to particular aspects of the pharmacist's work; these principles are accompanied, in general, by application rules, sometimes in the form of a set of standards or guidelines for the fair conduct in practicing this profession in general or of some specific activities in particular, including examples, while also specifying the role played by the competent authorities, as it is the case with the codes in Belgium, Canada and France [2, 4, 17-19] and of the codes, standards and guidelines in Australia, Great Britain and New Zealand, respectively [12, 22-25, 30, 34].

Having analysed these various options, it was felt that a code of deontology containing clear provisions

for pharmacists in each specific area of pharmaceutical activity provided for by the law would be the most appropriate content of such a code in Romania. In fact, in this regard, the Romanian College of Pharmacists has expressed its desire to develop their activities for pharmacists in other areas than that of community pharmacy.

Given the fact that we are dealing with a regulatory document on the proper practice of the pharmacist profession, the draft code starts with general provisions and ends with transitory and final provisions. As such, the draft new code of deontology is structured as follows:

- Chapter I General provisions
- Chapter II Common principles to all pharmacists
- Chapter III Specific principles by field of activity
  - o Section 1 Scientific research
  - o Section 2 Manufacture, importation, exportation
  - o Section 3 Wholesale distribution and brokering
  - o Section 4 Retail supply of medicines and other health products
  - o Section 5 Laboratories
  - o Section 6 Pharmaceutical education
  - o Section 7 Health administration
  - o Section 8 Pharmacist's relationship with the Romanian College of Pharmacists and the governing bodies of the Romanian College of Pharmacists
- Chapter IV Transitional and final provisions [29].

#### *General provisions*

The first chapter of the draft code of deontology contains provisions defining its content, purpose, scope and the role of the Romanian College of Pharmacists to examine and deliver decisions in cases of violation of the provisions of the Code.

Compared to the existing code, the revised version has enlarged, in particular, the purpose of the code, with: "protection of public confidence in the profession of pharmacist and of the dignity and prestige of this profession in the society;" and "stimulate reflection of pharmacists on ethical quality standards and promote the monitoring of the quality of their own professional activities" [29].

A source of inspiration in defining the purpose of the new code was the Code of Ethics for Pharmacists in New Zealand, according to which the code is for pharmacists and in particular for those entering the profession, "a source of education and reflection" [24]. The Code of Ethics for Pharmacists in Australia says that "To practice as a pharmacist means undertaking any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist. Practice is not restricted to the provision of direct clinical care" [22].

Reflecting on these considerations, which are in harmony with the provisions of Law no. 95/2006, Title XIV, referring to the scope of the pharmacist practice, the proposed draft code of deontology under consideration has defined the professional activities of the pharmacist as including "any activity, whether remunerated or not, in which a pharmacist uses his or her skills, knowledge and professional abilities, no matter whether he or she is in direct or indirect relationship with a certain patient, a community of individuals or with the public at large and irrespective of the status of the institution or unit where he or she works as a pharmacist" [29]. The definition had to be expanded to include any field of activity, any pharmaceutical activity and any category of professional role.

#### *Common principles to all pharmacists*

The second chapter of the draft new code has maintained many of the principles of the code that is in force at present, reformulating some of them. The most important new provisions refer to the patients' rights in relation to the pharmacy practice. These rights have been formulated by adapting to the pharmaceutical field the rights established under the European Charter of Patients' Rights. Although the Romanian Law no. 46/2003 regulates the patients' rights, it refers in particular to the medical field [21] and is incomplete in relation to the content of the European document mentioned. Thus, under the proposed draft code, "the pharmacist shall respect the following patients' rights: the right of patients to health services and products for disease prevention, including to education appropriate for this purpose; the right of access to services and products suited to the patient's health, including the innovative ones; the right of patients to information about their health condition, health services and products and research and innovation in the field of health; the right to informed consent on the use of health services and products; the right to choose the healthcare provider, the healthcare professional and the health services and products appropriate to their health; the right to privacy during the delivery and use of health services and products; the right to confidentiality of personal information and information about their health condition and the health services and products they use; the right to respect for their time in the delivery of the health services and products required; the right to quality health products and services, in accordance with the statutory standards in force; the right to safety in relation to health facilities, healthcare professionals and the health services and products used; the right to reject any unnecessary suffering and pain related to their health condition; the right to complain about health services or products, the right to settlement of their complaints and the right to be informed about the resolution to their complaints;

the right to compensation for physical, moral or psychological damages suffered in connection with the use of health services or products" [29].

A principle enshrined in the codes of ethics of pharmacists in Australia and Canada-Alberta is that concerning the pharmacist's engagement in the development and evolution of the profession [2, 22, 34]. This principle was formulated in the proposed draft code for Romanian pharmacists in the form of provisions containing the guidance for future pharmacists: "The pharmacist has a moral obligation to engage in the development and evolution of the profession, in particular through participation to professional education and training of future pharmacists. The pharmacist who guides students or residents in practice or during internship should allow sufficient time for their proper training and involve them in all his professional activities. The pharmacist should share his professional skills to students and residents and provide them with all relevant documentation for a high-level practical education and training. The pharmacist has a duty to inspire students and residents with respect and dedication to the profession, being himself a professional and ethical role-model" [29]. Also, based on the same principle and having also regard to the principle of the transmission of good quality professional information [4, 34], provisions have been formulated regarding the ethical obligations of pharmacists who communicate and/or disseminate professional and scientific materials on various occasions. "Pharmacists participating with presentations at scientific or professional events and those who publish professional materials should make sure that the whole content of such materials is honest, balanced, objective, based on scientific information that can contribute to improving the knowledge and services provided to patients and the use of medicines" [29].

#### *Specific principles by field of activity*

*Scientific research* is an area that has not been addressed so far by the Romanian Code of Pharmaceutical Deontology. Other codes, however, recognize it as one of the fields of activities of the pharmacist and, as such, regulate it accordingly. It is the case of the Codes of Ethics of the pharmacists in Australia, Canada, Great Britain and New Zealand [2, 12, 18, 22, 24, 25, 30, 34].

Another source of inspiration for this activity was the Code of University Ethics and Deontology of the "Iuliu Hațieganu" University of Medicine and Pharmacy in Cluj-Napoca, Romania, in its provisions relating to the support and promotion of honest and high quality research [15]. The section referring to scientific research, in the draft new code of deontology, proclaims the principles of compliance with the standards of quality and ethics applicable to research activity, including the principle of protection of animal and human subjects participating in

research, in accordance with the applicable laws and the internationally accepted practices.

A provision of this section states that "pharmacists, who are authors of inventions, innovations, scientific or professional publications, as well as those in charge with their evaluation, editing or publication, are required to abide by the internationally accepted ethical principles and practices dealing with protection of intellectual property rights and ensuring the quality of publications" [29].

Particular importance was given to the principle of compliance with the ethical standards not only for the function of research of discovering and creating new knowledge, but also for its function of capitalising upon their results, in the form of publications or new industrial products such as medicines or other health products.

*Manufacture, importation, exportation* are other new areas addressed by the new proposed code. Other codes that include provisions in this field are the codes of pharmacists in Australia, France, Great Britain and New Zealand and the Belgian Code of Deontology for the Medicines Industry [4, 12, 19, 22, 24]. The section dealing with manufacture, importation and exportation enshrines the principles of respect for legal, quality and ethical standards governing these activities, as well as the role of the Romanian College of Pharmacists in supporting the development of "a responsible pharmaceutical industry that is capable to manufacture and to place on the market quality medicines and satisfy the demand for medicines of the Romanian market" [29]. Having regard to the new legislation on pharmacovigilance [20], special provisions have been formulated, relating to "involvement of pharmacists in pharmacovigilance activities carried out by marketing authorisations holders and by the National Agency for Medicines and Medical Devices [...], while protecting the patients' rights to quality medicines, including innovative ones, personal data protection and safety in the use of medicines" [29]. The most interesting provisions are those relating to the ethical behaviour required from the pharmacist working as a medical sales representative of the manufacturer or of the importer of medicines, in relation to any healthcare personnel and in the use of financial and material sources put at his disposal by the employer. "These means can be used in relation to health professionals only for the purpose of promoting health or research in the field, respectively as symbolic courtesy gestures, and not for the purpose of stimulating, recommending, prescribing, purchasing or selling, supplying or administering the drugs. Any practices such as the promise, offering or providing, directly or indirectly, bonuses, pecuniary, material or other advantages to healthcare professionals or

the acceptance or encouragement of such practices in order to prescribe, recommend, purchase or sell, or for the supply or administration of the medicines promoted, are contrary to pharmaceutical ethics" [29].

*Wholesale distribution and brokering* are pharmaceutical areas that are not addressed by the codes of ethics for pharmacists. Only the French code contains requirements for pharmacists practicing in the field of wholesale distribution of medicinal products [19]. Brokering is a field that has been more recently regulated in the European Union and in Romania, and which does not require the presence of a pharmacist, like the other activities involving medicines. However, given the broker's duty to know the European and the national legislation in the field of medicines [20], pharmacists may constitute a very useful category of personnel in this area, too. The draft of the new code of deontology stipulates the responsibility of pharmacists practicing in these areas to ensure the quality of their work. "They shall ensure that all legal and ethical requirements are met for the proper running of the wholesale distribution and brokering of medicines, to avoid the entry into the legal circuit and the use by patients of defective, falsified or counterfeited products. The rights of patients in Romania concerning the availability, accessibility and quality of medicines must be safeguarded at all times by pharmacists involved in medicine wholesale distribution or brokering, through fair and non-discriminatory supply of all pharmaceutical retail suppliers" [29].

*Retail supply of medicines and other health products* is the area that includes the services provided by pharmacists in a community pharmacy, a hospital pharmacy and a drugstore. All the Western codes of ethics specified herein contain provisions on the work of the pharmacist in a pharmacy. The most interesting provisions are those contained in the Belgian, French and the New Zealander codes, dealing with pharmacy advertising [17, 19, 23], in the American, Australian and New Zealander codes, regarding the duty of the pharmacist to ensure the good management of resources in the health system [3, 22, 24], in the Belgian code, relating to environmental protection and the pharmacist relationship with the Internet [17], and in the Australian and the British codes, dealing with hospital pharmacy [30, 34]. All these have been used as important sources of inspiration for developing this section of the Romanian new code. The proposed draft code has preserved, however, many provisions of the code in force at present, some of them being reformulated. The new provisions of the proposed draft code are mainly covering issues such as pharmacovigilance, unfair association and collusion between pharmacists and physicians, pharmacy advertising and display, online pharmacy services,

environmental protection, specific obligations of hospital pharmacists and of those involved in humanitarian initiatives.

Given the evolution of the legal framework and the increasing concerns for pharmacovigilance [14, 20], it was considered necessary to establish a set of ethical principles designed to guide the retail supply of medicines carried out by the pharmacists, as follows: "In order to meet the patients' rights to a safe use of medicines, pharmacists in the retail supply have the ethical obligation to participate in pharmacovigilance. To this end, pharmacists have the duty to provide patients and other healthcare professionals with appropriate information, support and expertise, to prevent, document, report and/or manage adverse reactions to medicinal products. They should encourage patients to report adverse reactions to medicinal products, either through them or through other healthcare professionals, directly to the National Agency for Medicines and Medical Devices or to the marketing authorisations holders" [29].

In recent years, cases of unethical practices and collusions between pharmacists and physicians have increased the risk of decline in the public confidence in these professionals, who should otherwise serve as role models by their professionalism [6, 16, 26]. Therefore, the draft code has further developed the provisions of the current Code, by incorporating obligations dealing with the good management of resources in the health system and in particular in the social health insurance system. "In their collaboration with doctors, the pharmacists working in community pharmacy shall refrain from any actions or arrangements that would result in a violation of the patient's right to free choice of the pharmacy or the pharmacist, or the gaining of undue material benefits. Such actions and arrangements are deemed to include, without limitation, the following: providing material benefits to the prescribing physician in exchange of recommendation for the patient to go to a specific pharmacy or specific pharmacies; providing and/or storage of medicines or other health products to/on the premises of the health centre where the prescribing physician works; providing medical prescription forms with the identification details of a specific pharmacy.

Any agreements between pharmacists, between pharmacists and physicians or other healthcare professionals, which are likely to jeopardize the proper functioning of health institutions and/or social security systems or the good management of their resources, or which are aimed at obtaining material benefits at the expense of the financial resources available for treatment or prevention of diseases are contrary to the pharmaceutical deontology and are prohibited" [29].

Pharmacy advertising is an issue much debated today in the Romanian pharmaceutical community,

especially because this field is not addressed by Law no. 266/2008 - the pharmacy law. It was therefore considered useful to establish ethical rules for this activity, given its considerable impact on patient decision-making. The most important rule is that regarding the obligation of the chief pharmacists to "submit, in advance, for approval by the Romanian College of Pharmacists, any advertising material that relates to pharmacists and/or their practice in the pharmacies or drugstores they are managing" [29]. The Romanian College of Pharmacists is required to ensure that the advertising of pharmacies "is ethical, for the purpose of this Code of Deontology, and in compliance with the profession's role in promoting and protecting human health" [29]. The advertising practices that are "contrary to pharmaceutical deontology and are prohibited include: any reference to the identity of the patients of the pharmaceutical units; use of commendatory words or comparisons; use of names of scientific, professional, cultural, political or any other notorious personalities; any reference to providing material benefits to patients, including any reference of a promotional nature regarding discounts applied to the prices of medicines or other health products, giving gifts, bonuses, special offers or additional services for the purchase of medicines or other healthcare products or the like" [29].

As one can see, these provisions have a preventive purpose, allowing the College of Pharmacists to exercise its role as a professional and ethical authority [20] in this field of pharmacy practice. In full consonance with this principle and with the rules on advertising, several rules were established, covering pharmacy display. Thus, "it is forbidden to display information on discounts applied to medicines, special offers, gifts, bonuses or additional services for the purchase of medicines and any other similar messages designed to attract patients and/or influence the patient's right to a free choice of the pharmacy and pharmacist" [29].

At European level there is a particular concern for establishing appropriate rules to prevent the use by patients of falsified medicines, sometimes purchased via the Internet, rules that have to be transposed into the Romanian legislation as well [10]. In anticipation of such transposition and given the rapid growth of online business, the draft code has established that, if the pharmacy wants to supply services on the Internet, "its website should contain at least the following information: pharmacy name, certified logo, number of the operating license issued by the competent authority and the hyperlink to its website, the contact details of the pharmacy (address, telephone number, e-mail address) and the categories of products and professional services provided" [29].

For all the fields of activity of the pharmacist, the draft code has incorporated provisions establishing

the ethical obligation of this professional to contribute to environmental protection through specific actions, depending on the type of activity he or she is involved in. For example, the pharmacist in the pharmacy is required to "collect, store and dispose of the waste resulted from pharmaceutical activity, in accordance with the laws in force. He has a duty to contribute to the education of the patient and of the general public with regard to the conservation and management at home of medicines and other health products, including those expired or degraded, so as to prevent contamination of the environment" [29].

Most of the provisions of this section are applicable equally to pharmacists in the community pharmacy and in hospital pharmacy. The specificity of the practice of the hospital pharmacist is given by the belonging of the pharmacy to a medical facility and by the pharmacist's relationship with the hospital management, hospital doctors and possibly with the hospitalized patients. Therefore, "taking into account the affiliation to a hospital or to other type of health facility with beds, hospital pharmacists have, in particular, the following ethical obligations: to ensure under the best conditions the required pharmaceutical care within the healthcare facility to which the pharmacy belongs, including by ensuring the presence of at least one pharmacist during the opening hours of the pharmacy; to ensure and monitor the quality of medicines and other healthcare products they are managing within the healthcare facility the pharmacy belongs to; to make sure that medicines and other healthcare products reach safely the relevant departments of the healthcare facility the pharmacy belongs to and the patient's bedside; to ensure that medicines and other healthcare products are properly preserved and used within the departments of the healthcare facility the pharmacy belongs to; to engage in the proper management of the expired, degraded or unused medicines within the healthcare unit the pharmacy belongs to, for their proper disposal; to provide appropriate information and advice in the field of pharmaceuticals, where appropriate, to the management of the healthcare facility the pharmacy belongs to, to heads of departments, physicians, other healthcare professionals in the hospital and to patients who are hospitalized or who resort to the healthcare services provided by the healthcare facility; [...]" [29].

These provisions "shall apply also to the pharmacists who exercise their profession in hospitals without a pharmacy of its own" [29]. It is, more exactly, the case where a pharmacist works in a medical unit as, for example, a clinical pharmacist and performing specific professional duties as a member of the medical team caring for the patient. In this case, the medical centre purchases medicines and other health products from a community pharmacy, and the most qualified professional to manage the medicines so purchased is still the clinical pharmacist. Although

there are many pharmacists specialized in clinical pharmacy, a title obtained by graduating the residency training programs, hospitals and other medical facilities in Romania do not have in their organization charts the position of clinical pharmacist.

*The pharmacist's laboratory work includes*, in accordance with Law no. 95/2006, Title XIV, tests in laboratories for the testing of medicinal products, biochemistry (medical or clinical laboratory), toxicology, environmental and food hygiene [20]. This specific activity has not been so far approached by the Romanian Code of Pharmaceutical Deontology. In preparing the provisions contained under this section of the proposed draft code, the sources of inspiration were the French Code of Deontology, which contains special provisions for pharmacists engaged in laboratory work [19] and the Code of Conduct adopted by the European Federation of Clinical Chemistry and Laboratory Medicine, which establishes the ethical principles to be observed by laboratories in the health system [9]. The draft code establishes the obligations of laboratory pharmacists to meet the applicable quality and ethical standards and to safeguard the rights of individuals in relation to laboratory work. It also stipulates that "laboratory pharmacist has the duty to fulfil his mission by using the most up-to-date information sources and the most adequate scientific methods. He should carry out at the highest possible technical level the laboratory analyses he is in charge of, with the greatest care for the quality and integrity of the results" [29]. The end of this section is dedicated to chief laboratory pharmacist, who has specific ethical obligations related to his leader position, including those of "maintaining good working relations with all authorities and institutions involved in protecting life, public health and the environment and responding to their request to participate in interventions, programs or projects that require his expertise" [29]. Laboratory work is a field less accessed by pharmacists in Romania, even if they have the possibility to specialize in this field as residents and in spite of the fact that there are many laboratory pharmacists in Romania, who are not only qualified to practice this activity, but even to lead such a unit.

*Pharmaceutical education* is another field of activity newly approached by the proposed code. This field is recognized as a pharmaceutical field in the codes of pharmacists in Australia, Great Britain and New Zealand [12, 22, 24].

An inspiration for the drafting of the provisions of this section was the Code of University Ethics and Deontology of the "Iuliu Hațieganu" University of Medicine and Pharmacy in Cluj-Napoca, Romania, which contains specific provisions relating to the right to quality education [15]. The section on pharmaceutical education in the draft code

proclaims the principles of respect for the standards of quality and ethics governing this activity, as well as the support by the Romanian College of Pharmacists for "publication and dissemination of treaties, manuals and other teaching materials, which are useful for the initial and continuous training of pharmacists, subject to compliance with the laws on copyrights" [29]. This section enshrines the principle of commitment and responsibility for the development and progress of the profession, through initial and continuous training in pharmacy, in the case of pharmacists practicing as teachers. The principles that should govern the work of these pharmacists are: cooperation with pharmacy practitioners, regular updating of curricula, the culture of ethics, fostering active participation of students to educational programs, evaluation of students based on their knowledge, skills and competences acquired. In the context of current discussions about the decline in education quality in general, we believe that such provisions could be an important source of ethical reflection, because pharmacist-teachers, involved in delivering lectures, seminars and in other educational activities, should act as "intellectual trainers and expert advisers of the participants, with due respect for their legitimate rights and interests related to their education" [29].

*Health administration* is an area which mainly includes pharmacists working within public institutions, where they are mostly in charge with handling pharmacy-related administrative, regulatory and inspection tasks, as, for example, pharmacists from the Ministry of Health, National Agency for Medicines and Medical Devices, territorial public health authorities, health insurance institutions, etc. These types of activities are defined by the Code of Ethics of the Australian pharmacists [22] as activities falling within the scope of the code. In Romania, Law no. 95/2006, Title XIV, provides that pharmacists practicing within public institutions may also work with private pharmaceutical units, such provisions being also incorporated in the current Code of Pharmaceutical Deontology [5, 20], yet only schematically. Under these circumstances, the draft code considered it necessary to define some ethical principles specifically dedicated to the work of pharmacists engaged in health administration.

The European Medicines Agency Code of Conduct was used, in this case, as an inspirational source, such code establishing a very strict set of ethical rules for its own officers, designed to warrant a professional, objective, serious professional activity and combat corrupt practices [11].

Thus, the draft code proposed establishes that pharmacists practicing in health administration "shall not have financial or other interests, direct or indirect, that are likely to affect their impartiality in relation to pharmaceutical units or to their representatives, whom they come in contact with

during their work. Any potential conflict of interest shall be declared before engaging in the conflicting activity, to allow for its resolution at institutional level” [29]. In the context of the extensive debate on corruption in Romania today, we consider that such provisions are very instrumental, and so are those according to which “pharmacists in health administration should actively discourage any practices such as the promise, offering or providing, directly or indirectly, of gifts, favours or other pecuniary, material or any other benefits from pharmaceutical units or their representatives whom they come into contact during their work” [29].

This section also incorporates provisions regarding compliance with the legal standards of quality and ethics, the responsibility of the pharmacists in leading positions in administration to monitor compliance with these standards, the proper guidance of pharmacists for the adequate implementation of the relevant laws, regulations and health policies, the cooperation with other competent institutions.

*The Pharmacist's relationship with the Romanian College of Pharmacists and the governing bodies of the Romanian College of Pharmacists* represents a novelty brought about by the new draft code of deontology, this chapter being dedicated to all the pharmacists who are members of the professional association, and in particular to those who are elected by their fellows, as members of the governing bodies of the association.

The codes of ethics of British, Australians and New Zealander pharmacists and the European Medicines Agency Code of Conduct were the inspiration for the development of the provisions of this section of the draft code, in particular of those referring to maintaining the professionalism, integrity and objectivity in the pharmacist practice, prevention of corrupt practices [11], avoiding the abuse of professional position or of public trust and respect, namely the avoidance of exploitation of the vulnerability and lack of information of others [12, 22, 24].

The section contains behaviour principles and values that should govern the relations between pharmacists who are members of the College of Pharmacists and those who are elected members of its governing bodies or in managerial positions within the association, as well as between them and the employees thereof, such as respect, courtesy, dignity, honesty, participation in the proper running of the association and in strengthening its role in the society, respect for the purpose of the profession and for its honour and dignity in Romania.

“The duties under-taken as a member of the governing bodies of the Romanian College of Pharmacists or as an employee thereof shall be fulfilled in good faith, actively, timely and for the

smooth running of the organization. [...]Pharmacists who are members of the governing bodies of the Romanian College of Pharmacists and the employees of the College have an ethical obligation to keep confidential the personal information and data of other pharmacists, patients and third parties, including the internal information of pharmaceutical units, to which they have access in the normal course of their mission of representation in the meetings and debates of such governing bodies” [29].

This section of the draft code defines the role of pharmacists in managerial positions within the College of Pharmacists in the monitoring and in the correct information and guidance of member-pharmacists and in maintaining and promoting at institutional level of good cooperation relationships with all authorities and institutions involved in healthcare.

### Conclusions

Professional ethics of pharmacists in Romania can be optimized by developing their code of deontology. A research project initiated by the Romanian College of Pharmacists has examined codes of ethics and professional standards of pharmacists from eight Western counties and European documents of relevance for the topic of research, and a new text for the Romanian Code of Pharmaceutical Deontology has been drafted.

In the new conception, the code contains general provisions, principles that are common to all pharmacists, specific principles applicable by different fields of activity, as well as transitional and final provisions.

The newest of the general provisions of the proposed draft code are those defining the purpose of the code, the professional activities governed by the code, the patients' rights in relation to pharmaceutical activities, the role of the pharmacist in the development and evolution of the profession and in disseminating high quality professional information.

The sections dedicated to each specific field of the pharmaceutical practice define the principles and ethical standards applicable to each of them, in line with the official texts of relevance at national and European level, using as sources of inspiration the experience and reflection on professional ethics as expressed by other associations of pharmacists in their codes of ethics.

The newest special provisions relate to: compliance with internationally recognized standards and practices in the field of scientific research, including those relating to intellectual property rights; the ethical obligation of pharmacists involved in pharmacovigilance to act and protect the patients' rights to safe use of medicines; ethical use of resources made available by employer to the pharmacist who



works as its medical sales representative; the responsibility of pharmacists engaged in wholesale distribution to ensure fair and quality supply of products to pharmacies; prevention of unfair advertising of pharmacy services to the public at large; exposure of any collusions and association for purely mercantile purposes among pharmacists to the detriment of patients and of the resources of the public health system; provision of laboratory services aligned to European ethical standards; provision of quality and ethical pharmaceutical education and training; monitoring and control of ethical exercise of the profession by pharmacists who work within public authorities or as members of the governing bodies of the Romanian College of Pharmacists.

The draft code was handed over to the Romanian College of Pharmacists, for consideration and in view of adopting a new code of deontology for pharmacists in Romania.

The role of the Romanian College of Pharmacists is to subject the draft code to debate to its members, to adopt a code harmonised to the latest international developments in this profession and to make it known and respected among its members, including by appropriate strategies for continuous training, promoting ethical behaviour.

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