



# Teaching human rights at the doctoral school in Romania

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#### **Abstract**

The doctoral curriculum of the Iuliu Hatieganu University of Medicine and Pharmacy of Cluj-Napoca comprises the course "European Legislation on Research". The chapter "Human rights in health" includes a study on health legislation, which analyses the right to health protection and its components—the recognition within the Romanian legislation with reference to international documents, the respect in the health system and health research. For example, the principle of informed consent in health research is established. The final part of the course highlights the need to correct shortcomings of the legislation, and the importance of professional and human training, by studying and applying the ethics of patients' rights. Evaluation of the course shows good results from the doctoral students, and their appreciation for the course and the teacher's performance. Future plans include continuous updates and improvement of the evaluation system.

Keywords: Doctoral school, human rights, research, future plans

#### Context

In Romania, the government regulations state that doctoral studies should include two to three semesters of advanced university training and three to four semesters of research (Hotărârea Guvernului nr. 567/2005). Based on this regulation, Iuliu Hatieganu University of Medicine and Pharmacy in Cluj-Napoca created a new department for the academic year 2005/6, called the Doctoral School. During advanced university training doctoral students in medicine and pharmacy attend the following courses: Conferences of Scientific and Cultural Personalities; Scientific Documentation; European Legislation on Research; Scientific Research Methodology; Publishing Rules and Scientific Publishing Ethics; Scientific Research Ethics; and Planning and Grant Management.

The purpose of the paper is to describe the *European Legislation on Research* course and the experience of the Romanian doctoral school students'.

## Course description

The European Legislation on Research course aims to teach legislation on research within the European

Union and Romania, with a thorough study of human rights in the field of health.

The course comprises 18 lectures, with the following themes:

- 1. European Union (three lectures): brief history; basic principles; institutions; law sources; and accession criteria and the impact of the accession on the Romanian judicial system.
- 2. Research within the European Union (three lectures): legal framework; general principles; instruments; European research; European researchers; and, health research.
- 3. Research in Romania (three lectures): legal framework, principles and objectives; education and research; good research practice; and existing research.
- 4. Human rights in health (six lectures): international documents; national legislation; studies of human rights within the health field; and, health research contracts.
- 5. The researchers' responsibility within the health field (three lectures): general conditions for

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ISSN 1560-2214 print/ISSN 1477-2701 online © 2007 Informa UK Ltd. DOI: 10.1080/15602210701751096

commitment; forms of responsibility; responsibility for the research activity; and research practice and jurisprudence.

#### Human rights in health

The fourth part of the course, "Human rights in health", focuses on the right to health protection, regarding treatment and care, information and informed consent, confidentiality and privacy, quality of health services, and the exercise of rights.

Taking into consideration that health professionals are often not up to date in the field of human rights, especially within their field of practice, it was important for the university to provide this training, if only for the moment in the doctoral school.

The course consists of an analysis of patients' rights regarding the following aspects:

- Recognition of patients' rights in Romanian and international legislation, and discussing the need for completion in the case of retraction;
- Respect within the health system and in the case of it lacking, analyzing the causes and possible solutions, especially ones which have an impact on the professional training of specialists;
- Importance of respecting patients in health research.

An example of informed consent. The World Health Organization declaration on the promotion of patients' rights in Europe (1994) and the European convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine (convention on human rights and biomedicine 1997) states that the patient must be informed prior to any medical investigations, which he might agree to or not (WHO The Declaration on the Promotion of Patients Rights in Europe 1994, Legea nr. 17/2001).

Although the Romanian law no. 46/2003 on patients rights has undertaken most of the WHO recommendations, it is only partially enforced, having failed to undertake the core principle: that informed consent of the patient is a prerequisite for any medical intervention. In the case of declining any medical intervention, Law no. 46/2003 states that the patient

must declare in writing that he is taking on full responsibility and that he/she is ready to support the consequences; there is no regulation to prove that the patient has been, prior to his consent, well informed (Legea nr. 46/2003).

However, Law no. 95/2006 on health field reform introduces new stipulations in this field that oblige the health professionals to fully inform their patients prior to providing any prevention, diagnosis or treatment method and requires the written consent of the patient for any medical intervention. There is, however, a limitation on this right, for those situations when the method to be applied is, as the law states, "a potential risk to the patient" (Legea nr. 95/2006). This is not in compliance with international documents because the principle of the right to information is valid for all the situations regarding the health of an individual. From experience and discussions with students it has been concluded that in practice patients are informed and their consent is indeed required by the physicians only for medical interventions, which are considered to be of higher risk. The pharmacist provides information and advice when the patient requires this type of service, but not necessarily for other interventions, despite it being his professional duty (Decizia Colegiului Farmaciștilor din România nr 1/2005).

Concerning participation in health research, the principle of informed consent is stated in the international documents, such as the WHO declaration, The Helsinki declaration of the World Medical Association, Ethical principles for medical research involving human subjects, as well as in national documents. The principle of informed consent is proclaimed in Law no. 46/2003 and the principles of the declaration of Helsinki are established in the medical deontology code and good clinical practice, except that which refers to the consent of a person who is already dependent on the researcher (WMA The Declaration of Helsinki Colegiul Medicilon din Romania Codul de Dentologie Medicala).

In practice, these rules are respected, perhaps because this activity is better regulated and reviewed by bodies such as ethics committees, state authorities, and the National Drug Agency.

The final part of the course emphasizes the need to correct the shortcomings of Romanian legislation and the need for continuous training of health professionals in the field of legislation and the ethics of patients' rights.

Table I. Doctoral students' assessment.

School year/number of students	Results				
	9-10/10 very good (%)	7-8/10 good (%)	5-6/10 poor (%)	Under 5/10 very poor (%)	
2005/6:155 students	59.4	30.3	6.5	3.9	
2006/7:130 students	68.5	22.3	1.5	7.7	

Criterion	Results				
	Very good (%)	Good (%)	Poor (%)	Very poor (%)	
Content	57.8	37.8	4.4		
Teaching materials and methods	57.8	35.6	4.4	2.2	
Lecturers' performance	84.48	15.6	_	_	
Assessment system (Imatest)	51.1	35.6	11.1	2.2	

#### **Evaluation**

The doctoral students' knowledge was assessed through multiple-choice examinations. In the academic year 2005/6, when 155 students attended the course, the assessment also included an essay based on one of the topics discussed in the course, the final grade being the average between the exam and the essay. In the academic year 2006/7, when 130 students attended the course, the essay assessment was not included because the Doctoral School implemented an online evaluation system with the Imatest autotesting and evaluation software, formulated within a research program at the University. The results of the doctoral students' assessments are presented in the Table I.

The content of the course, the teaching methodology and the assessment system also underwent an evaluation in 2006/7, based on a questionnaire sent to the doctoral students via email, to which 35% answered. The results of the course evaluation are presented in Table II.

# Discussion

The assessment suggests that the course provides a very good preparation for doctoral students, both in 2005/6 and 2006/7 academic years. In the year 2006/7, both the number of doctoral students with very good results and the number of the doctoral students with poor results increased, from 59.4 to 68.5%, and from 3.9 to 7.7% respectively. One of the reasons could be the discontinuation of the essay component, leaving assessment only via multiple-choice examinations. Questions with frequently wrong answers will be analyzed and re-written if needed.

The course and the teachers' performance were positively appraised by the students in the school year 2006/7. However, students particularly drew attention to the technical difficulties in accessing and use of the Imatest software, and the vastness and complexity of the course.

#### Future plans

The course content will be updated and restructured, according to the evolution of legislation, doctrine and

practice in the field. In response to students' opinions, it is acknowledged that the course needs some improvement, such as a more appropriate structure in order for students to more easily follow the course, and provision of more examples from practice in order to facilitate better understanding. The Imatest software will be further implemented, its usage being expanded to other courses, but it will be improved in order to avoid technical difficulties highlighted by the students. Further, the essay on a chosen topic might be reconsidered as an evaluation criterion, because it allows a more comprehensive assessment of the students.

#### References

Colegiul Medicilor din România, Codul de Deontologie Medicală (College of Physicians of Romania, The Medical Deontology Code) http://www.cmr.ro/images/stories/pdf/cod\_deontologic\_final\_verificat06\_04\_05pdf.

Decizia Colegiului Farmaciștilor din România nr, 1/2005 privind adoptarea Statutului și Codului deontologic al farmacistului, Monitorul Oficial nr. 752/2005. (Decision of the College of Pharmacists of Romania no. 1/2005 on the Statute and the Pharmacist's Deontological Code, Official Journal no. 752/2005).

Hotărârea Guvernului nr, 567/2005 privind organizarea şi desfăşurarea studiilor universitare de doctorat, Monitorul Oficial nr. 505/2005. (Decision of the Government no. 567/2005 on the Organization and Unfolding of Doctoral Studies, Official Journal no. 505/2005).

Legea nr, 17/2001 privind ratificarea Convenției europene pentru protecția drepturilor omului și a demnității ființei umane față de aplicațiile biologiei și medicinei: Convenția privind drepturile omului și biomedicina, semnată la Oviedo la 4 aprilie 1997, Monitorul Oficial nr. 103/2002. (Law no. 17/2001 on the Ratification of the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, signed at Oviedo on April 4th 1997, Official Journal no. 103/2002).

Legea nr, 46/2003 privind drepturile pacienților, Monitorul Oficial nr. 51/2003. (Law no. 46/2003 on the Patients Rights, Official Journal no. 51/2003).

Legea nr, 95/2006 privind reforma în domeniul sănătății, Monitorul Oficial nr. 372/2006. (Law no. 95/2006 on the Health Field Reform, Official Journal no. 372/2006).

WHO. Regional Office for Europe, The Declaration on the Promotion of Patients' Rights in Europe, Copenhagen. (1994).
WMA, The Declaration of Helsinki, http://www.wma.net/e/policy/b3.htm