

**AN OVERVIEW OF THE PHARMACY SECTOR IN ROMANIA  
POST-1989**

**ROSALYN C KING, PHARM D , MPH\***

**and**

**MARIUS T BOJITA, PH D \*\***

**Submitted to  
USAID/BUCHAREST  
PROGRAM OFFICE**

---

\* **Howard University Continuing Education (HUCE), PACE Center, Director**  
\*\* **University of Medicine and Pharmacy, Vice-Rector**

## TABLE OF CONTENTS

### **ACKNOWLEDGMENTS**

### **ACRONYMS**

### **LIST OF FIGURES**

### **LIST OF TABLES**

### **1 0 INTRODUCTION**

- 1 1 Background
- 1 2 Purpose and Methods

### **2 0 PHARMACY SECTOR**

- 2 1 Context of Post-1989 Changes
  - 2 1 1 Selected Issues of Transition
  - 2 1 2 Rules and Regulations Regarding Pharmacies
  - 2 1 3 Summary of the Practice of Pharmacy
  - 2 1 4 Overview of Pre-Service Education and Training for Pharmacists
  - 2 1 5 Selected Projects Focusing on Pharmacist Training
  - 2 1 6 Review of Training under the PROFIT Sub-Project
- 2 2 Issues Regarding Drugs
  - 2 2 1 Governmental Decision Making
  - 2 2 2 Distribution of Drugs
  - 2 2 3 Profit Margins

### **3 0 PHARMACISTS & USAID/ROMANIA STRATEGIC OBJECTIVES**

- 3 1 An Approach to Interventions
- 3 2 Decreased Dependency on Institutions for Children
- 3 3 Increased Use of And Access to Women's Health Services
- 3 4 Recommendation

### **APPENDICES**

- A Good Pharmacy Practice (GPP), September, 1996
- B Law on the Organization and Function of Pharmacy, Ordinul M S nr 2234/1994
- C The Curriculum of the Faculty of Pharmacy at the University of Medicine and Pharmacy at Cluj-Napoca, 1998
- D "Iulu Hatieganu" University of Medicine and Pharmacy and Howard University Continuing Education PACE Center Course Syllabus The Role of the Pharmacist in Primary Health Care
- E "Dear Patient", *LUMEA FARMACEUTICA* , Year 4, Number 2 (16), February, 1999

## ACKNOWLEDGEMENTS

The authors wish to recognize some of the many colleagues who facilitated and contributed to the work outlined in this Overview. A special thanks to is given to the Rector of the University, Dr. Oliviu Pascu, and to the Dean of the Faculty of Pharmacy, Dr. Cornelia Tarmure, for backing the project under which this work was conducted. Dr. Felicia Loghin, UMF-Cluj Faculty of Pharmacy, International Affairs Coordinator, reviewed the manuscript.

Ministry of Health, Department of Pharmacy and the Center for Health Statistics were very timely in providing up to date information.

We are grateful to Ms. Randal Thompson and her staff at USAID/Bucharest for their invaluable insights.

Many thanks are due to our respective office staff, especially Ms. Daniela Pipas, UMF-Cluj, and Mr. Charles Hamidu, HUCE/PACE for their tireless assistance.

## ACRONYMS

<b>ARAS</b>	<b>Asociate Romana Anti-SIDA</b>
<b>CT</b>	<b>Contraceptive Technology</b>
<b>FP</b>	<b>Family Planning</b>
<b>GMP</b>	<b>Good Manufacturing Practice</b>
<b>GOR</b>	<b>Government of Romania</b>
<b>GPP</b>	<b>Good Pharmacy Practice</b>
<b>HUCE</b>	<b>Howard University Continuing Education</b>
<b>IMAS</b>	<b>Institute of Marketing and Survey</b>
<b>ISCDPR</b>	<b>Institute for State Control of Drugs and Pharmaceutical Research</b>
<b>IR</b>	<b>Intermediate Result</b>
<b>MOE</b>	<b>Ministry of Education</b>
<b>MOH</b>	<b>Ministry of Health</b>
<b>NPA</b>	<b>National Pharmacy Association</b>
<b>OIP</b>	<b>Office of International Programs</b>
<b>PACE</b>	<b>Pharmacists and Continuing Education</b>
<b>PHC</b>	<b>Primary Health Care</b>
<b>PSI</b>	<b>Population Service International</b>
<b>QS</b>	<b>Quality Service</b>
<b>RH</b>	<b>Reproductive Health</b>
<b>SOE</b>	<b>State-Owned Enterprises</b>
<b>SO</b>	<b>Strategic Objective</b>
<b>TOT</b>	<b>Trainer of Trainers</b>
<b>UMF-Cluj/Napoca</b>	<b>University of Medicine and Pharmacy-Cluj/Napoca</b>
<b>USAID</b>	<b>United States Agency for International Development</b>

**LIST OF FIGURES**

**Figure 1 AN OVERVIEW OF THE PHARMACY SECTOR IN ROMANIA, 1999**

## LIST OF TABLES

TABLE 1	Number of Pharmacists in the Public and Private Sectors, 1994-1998
TABLE 2	Number of Pharmacy Points in the Public and Private Sectors and Warehouses in the Private Sector, 1994-1998
TABLE 3	Number and Gender Of Pharmacists In The Public And Private Sector 1994-1998
TABLE 4	Response To Questions Do Customers Ask For Advice Concerning Medicines? And Do Customers Ask For Advice Concerning Contraceptive Methods?
TABLE 5	Response To Question In What Year Was The Pharmacy Privatized?
TABLE 6	Response To Question What Are The Reasons For Starting The Private Pharmacy?
TABLE 7	Response To Question What Is The Prior Work Experience?
TABLE 8	Pharmacy Faculties, Their University Affiliation, Number Of Students & Authorization Status, 1998
TABLE 9	Percentage Distribution Of Pharmacists In Target Judets By Willingness To Participate In Training
TABLE 10	Percentage Distribution Of Pharmacists In Target Judets By Timing Of Last Training
TABLE 11	Training Needs And Willingness To Pay
TABLE 12	Response To Question Does The Pharmacy Sell Contraceptives?
TABLE 13	Response To Question How Do Your Clients Ask For Contraceptives?
TABLE 14	PROFIT Subproject – Contraceptive Technology And Quality Services Seminars For Pharmacists – Sept 1996-June 1997
TABLE 15	Final Evaluation Of PROFIT Private Sector Subproject (Romania)
TABLE 16	Input Goals, Indicators, Data Sources, And Results Of The PROFIT Subproject

# AN OVERVIEW OF THE PHARMACY SECTOR IN ROMANIA POST-1989

## 1 0 INTRODUCTION

### 1 1 Background

This report updates information presented to the United States Agency for International Development (USAID), Bucharest, Romania, under an award to Howard University Continuing Education, Office of International Programs (HUCE/OIP). USAID awarded a grant in 1998 to HUCE's Pharmacist and Continuing Education Center (PACE) in support of its collaborative efforts with the Faculty of Pharmacy at "Iuliu Hatieganu" University of Medicine and Pharmacy (UMP), Cluj/Napoca, Romania.

The focus of this institutional collaboration—begun in 1996—is the expansion of the pharmacist's role in primary health care (PHC) in Romania through the introduction of sustainable, University-based training interventions, which could complement an already strong curriculum.

The intended results of this 1998 award were

- Collaboration on the development of a detailed model for a Faculty of Pharmacy PHC curriculum which complements health service delivery, supports the ongoing reforms in the Romanian system and includes the wise use of pharmaceuticals for PHC.
- An outline of a process for the continuing education, via telecommunications, for faculty, professionals in the workforce, students, graduates and postgraduates so that they may, over the long-term, increase or maintain their effective role in Romanian health care.

Results of this award are also intended to support the current strategic objectives of USAID's Mission to improve women's and children's welfare by advancing institutional and human capacity development for the training of pharmacists in support of their role in primary health care.

### 1 2 Purpose and Methods

The purpose of this report is to present data that could serve as a background and a summary on key activities and projects in the Pharmacy Sector of Romania, post-1989, in response to a request of USAID's Program Development Office. The request emphasized those projects that addressed ways to increase the involvement of pharmacists in meeting USAID's strategic objectives in health. For this reason the overview of the entire pharmaceutical sector was amended to provide an overview of the pharmacy sector.<sup>1</sup> The pharmacy sector encompasses

---

<sup>1</sup> The pharmaceutical sector—a term in common usage—refers to that segment of health care delivery most closely related to the industry which seeks to provide research, development and production of drug products for populations. Business and economics are more often highlighted.

the professional of pharmacy who has major responsibility for the art and practice of preserving, storing, compounding and dispensing medicines as a part of therapy or prevention to help improve a patient's health outcome

Data for this report were collected between April, 1998 and June, 1999. The approach used by the authors was to organize key interviews with government and agency officials and practitioners and use source documents from USAID, the World Bank, the Ministry of Health and NGOs. An earlier draft, included in a trip report presented to USAID in June, 1998 was updated and revised for this report.

## **2 0 PHARMACY SECTOR**

### **2 1 Context of Post-1989 Changes**

After Poland, Romania is Central and Eastern Europe's most populated state with some 23 million people. It is also larger than 10 of the present 15 members of the European Union. The capital, Bucharest [2.4 million pop.], and the next 25 most populated judets, including, Constanta [350,000 pop.], Iasi [345,000 pop.] and Cluj [330,000 pop.] make up about 30 percent of the total population. As a result of pronatalist policies, Romania's population has a large proportion of both young and elderly people. In 1990, 10.1 percent of the population was age 65 or older, and 23.5 percent were under the age of 15. The Romanian infant mortality rate is 24 infant deaths per 1000 births, compared to 8 per 1000 in the Czech Republic.

Despite its land and population advantages, Romania is ranked as a lower middle-income country. As with most of its neighbors, which comprise the New Independent States (NIS), Romania's present situation emanates from socialist policies enacted during the post-World War II era. Following the popular 1989 revolution that toppled the Communist Ceausescu regime, Romanians chose the path toward multi-party democracy and economic liberalization. However, politico-economic exigencies contributed to official adoption of a halting and parsimonious approach to the process of market reform. Disenchantment by the electorate with the slow pace of economic restructuring led in November 1996 to the election of a government committed to a strong program of reform.

In 1996, Romania's GNP per capita [\$1510] was less than half that of the neighboring Czech Republic, whose population stands at 10 million. As a proportion of GDP, total drug expenditures were less than 1% in Romania in 1996 and about 23% of total health expenditures. The proportion of public and private health expenditures spent on drugs is 19% and 31%, respectively, as compared to 25.8% in the Czech Republic in 1995 and 28.5% in Hungary or 16.6% in the United Kingdom.

---

and may or may not include the segment relating to the profession of the pharmacy in its many aspects. This report gives greater focuses to the pharmacy sector and less to the pharmaceutical one.

A number of fiscal regimes and legislative measures have been put in place since the last election to promote macroeconomic stability, one of which is privatization of state-owned businesses. The process of privatizing state-owned pharmacies has proceeded briskly as shown by a study of 597 pharmacies in 1998 that will be discussed later in this report.

### 2.1.1 Selected Issues of Transition

The pharmacy sector is a complex component of the Romania health system (See Figure 1). Although the Government of Romania (GOR) retains organizational and financial control of the Romanian health system, the pharmacy sector is experiencing a rapid rate of privatization since 1989.

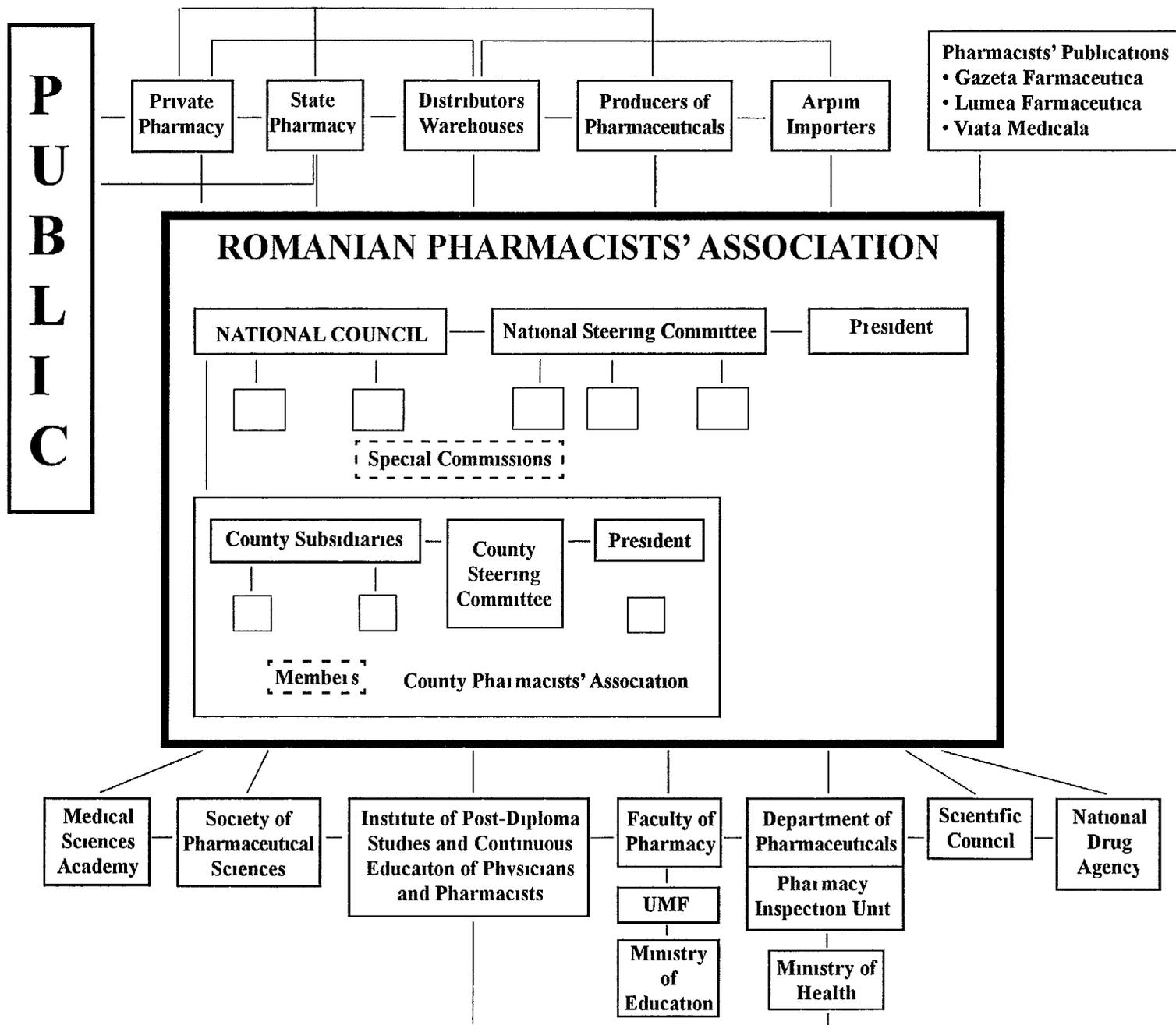
In 1996 there were 3603 pharmacies in Romania (2680 pharmacies in the private sector and 923 in the public sector), according to the records of the MOH Center for Statistics (See Table 1). Of the 923 public sector pharmacies, 675 were in urban areas, and 248 were in rural areas. By 1998, the total number of pharmacies stayed about the same, 3593 pharmacies with 3049 privately held and 544 held by the government. Of those in the public sector, 474 were in urban areas and 70 in rural areas. These figures indicate the decrease in the number of public sector pharmacies during this period was about equal to the increase in the number of private sector pharmacies. The most notable shift, however, was the decrease in number of the pharmacies in rural areas with no equal gain in private rural pharmacies. This means that the primary gain in the number of pharmacies was mostly in urban areas. Further, the concomitant shift in number of pharmacy points, Table 2, points out the growing maldistribution of pharmacies in Romania over the last few years.

Whereas the MOH continues to encourage privatization in all its sectors, structural and financial problems abound and act as constraints upon the sustained growth of the services of private pharmacies. From an economic perspective, high inflationary rates, artificial pricing mechanisms, high taxation and slow reimbursements by government all--contribute to cash flow problems for private pharmacies and their ability to expand services. For example, privatized pharmacies face major budgetary problems with the three-month or longer lag time between the dispensing of a medication eligible for reimbursement and the actual reimbursement by the government for dispensing products. Also, the lack of adequate credit facilities for the purchase of drugs as well as uncertainty about the stability of retail store leases are all symptomatic of the routine challenges which have faced private pharmacies in Romania.

The Center for Statistics in the Ministry of Health also reports that there are some 5557 pharmacists in Romania serving a population of 23 million (as compared to a ratio of 64 per 100,000 in the United States). Moreover, pharmaceutical expenditure, estimated at \$15 per capita in 1996, was \$18 per capita in 1997 (as compared to \$193 for the Czech Republic and \$152 for Hungary, countries of Eastern Europe).

However, these shifts illustrate some of the challenges facing economies in transition. The new government has indicated a desire to further the privatization and overall reform process.

FIGURE 1 AN OVERVIEW OF THE PHARMACY SECTOR IN ROMANIA, 1999



SOURCE PROFIT PROJECT, 1998, UPDATED BY MINISTRY OF HEALTH, 1999

TABLE 1

Number of Pharmacists in the Public and Private Sectors 1994-1998

		1994	1995	1996	1997	1998
<b>I</b>	<b>FARMACII IN SECTORUL PUBLIC</b>					
	<b>Total</b>	<b>951</b>	<b>972</b>	<b>923</b>	<b>550</b>	<b>544</b>
	Urban	685	689	675	481	474
	Rural	266	283	248	69	70
<b>1</b>	<b>CLUJ</b>					
	<b>Total</b>	<b>36</b>	<b>37</b>	<b>37</b>	<b>25</b>	<b>25</b>
	Urban	32	33	33	24	24
	Rural	4	4	4	1	1
<b>2</b>	<b>CONSTANTA</b>					
	<b>Total</b>	<b>22</b>	<b>22</b>	<b>11</b>	<b>11</b>	<b>11</b>
	Urban	19	19	9	10	10
	Rural	3	3	2	1	1
<b>3</b>	<b>IASI</b>					
	<b>Total</b>	<b>43</b>	<b>42</b>	<b>42</b>	<b>19</b>	<b>19</b>
	Urban	31	31	31	18	18
	Rural	12	11	11	1	1
<b>II</b>	<b>FARMACII IN SECTORUL PARTICULAR</b>					
	<b>Total</b>	<b>2077</b>	<b>2360</b>	<b>2680</b>	<b>2839</b>	<b>3049</b>
	Urban	1563	1817	2060	2211	2425
	Rural	514	543	620	628	624
<b>1</b>	<b>CLUJ</b>					
	<b>Total</b>	<b>54</b>	<b>66</b>	<b>82</b>	<b>77</b>	<b>93</b>
	Urban	45	57	69	62	80
	Rural	9	9	13	15	13
<b>2</b>	<b>CONSTANTA</b>					
	<b>Total</b>	<b>82</b>	<b>106</b>	<b>123</b>	<b>125</b>	<b>148</b>
	Urban	70	93	103	108	130
	Rural	12	13	20	17	18
<b>3</b>	<b>IASI</b>					
	<b>Total</b>	<b>21</b>	<b>28</b>	<b>54</b>	<b>58</b>	<b>93</b>
	Urban	21	27	45	49	88
	Rural	-	1	9	9	5

Source Reteaua si activitatea unitatilor sanitare 1994 1995 1996 1997 1998 lucrare editata de Comisia Nationala pentru Statistica

**TABLE 2**

Number of Pharmacy Points in the Public and Private Sectors and Warehouses in the Private Sector 1994-1998

		1994	1995	1996	1997	1998
<b>III PUNCTE FARMACEUTICE IN SECTORUL PUBLIC</b>						
	<b>Total</b>	<b>270</b>	<b>245</b>	<b>191</b>	<b>27</b>	<b>27</b>
	Urban	56	46	38	11	10
	Rural	214	199	153	16	17
<b>1</b>	<b>CLUJ</b>					
	<b>Total</b>	<b>4</b>	<b>3</b>	<b>3</b>	<b>-</b>	<b>-</b>
	Urban	2	1	1	-	-
	Rural	2	2	2	-	-
<b>2</b>	<b>CONSTANTA</b>					
	<b>Total</b>	<b>8</b>	<b>7</b>	<b>-</b>	<b>-</b>	<b>-</b>
	Urban	1	-	-	-	-
	Rural	7	7	-	-	-
<b>3</b>	<b>IASI</b>					
	<b>Total</b>	<b>18</b>	<b>11</b>	<b>11</b>	<b>2</b>	<b>2</b>
	Urban	3	3	3	2	2
	Rural	15	8	8	-	-
<b>IV PUNCTE FARMACEUTICE IN SECTORUL PARTICULAR</b>						
	<b>Total</b>	<b>170</b>	<b>288</b>	<b>348</b>	<b>445</b>	<b>556</b>
	Urban	112	175	193	232	276
	Rural	58	113	155	213	280
<b>1</b>	<b>CLUJ</b>					
	<b>Total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
	Urban	-	-	-	-	-
	Rural	-	-	-	-	-
<b>2</b>	<b>CONSTANTA</b>					
	<b>Total</b>	<b>3</b>	<b>11</b>	<b>14</b>	<b>21</b>	<b>30</b>
	Urban	1	7	8	10	17
	Rural	2	4	6	11	13
<b>3</b>	<b>IASI</b>					
	<b>Total</b>	<b>4</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>3</b>
	Urban	2	3	3	3	3
	Rural	2	-	-	-	-
<b>V DEPOZITE FARMACEUTICE IN SECTORUL PARTICULAR</b>						
	<b>Total</b>	<b>-</b>	<b>295</b>	<b>376</b>	<b>420</b>	<b>463</b>
	Urban	-	287	369	407	450
	Rural	-	8	7	13	13
<b>1</b>	<b>CLUJ</b>					
	<b>Total</b>	<b>-</b>	<b>22</b>	<b>27</b>	<b>30</b>	<b>46</b>
	Urban	-	22	27	30	46
	Rural	-	-	-	-	-
<b>2</b>	<b>CONSTANTA</b>					
	<b>Total</b>	<b>-</b>	<b>6</b>	<b>8</b>	<b>7</b>	<b>12</b>
	Urban	-	6	8	7	12
	Rural	-	-	-	-	-
<b>3</b>	<b>IASI</b>					
	<b>Total</b>	<b>-</b>	<b>2</b>	<b>2</b>	<b>6</b>	<b>10</b>
	Urban	-	2	2	6	9
	Rural	-	-	-	-	1

Sursa datelor Reteaua si activitatea unitatilor sanitare 1994 1995 1996 1997 1998 lucrare editata de Comisia Nationala pentru Statistica

Although Romania is struggling with the implementation of a National Drug Policy, steps have been taken toward the enactment of regulations on Good Pharmacy Practice (GPP), Appendix A, and Good Manufacturing Practices (GMP)

In the related area of pharmaceutical production, there has been limited private sector activity. The World Bank 1996 report indicates that this area is still dominated by state-owned enterprises (SOEs) that have a 42 percent market share. Despite being poorly managed, heavily in debt, and producing drugs of questionable standards, these SOEs continue to enjoy state protectionism. Nevertheless, privatization efforts have contributed to an overall accelerated growth in the medicines market, valued in 1995 at a wholesale price of US \$275 million, which represents a 23 percent growth over 1994 figures.

Recently, a law was passed which devolved much regulatory authority to the National Pharmacists' Association (NPA), also called the College of Pharmacists. Under this law, the NPA is government-mandated as an equal partner with the Ministry of Health to craft pharmacy policy. With the appropriate levels of funding and professional input, the NPA should be able to make a substantial contribution in addressing many of the fundamental issues afflicting private and public pharmacies and take many of the above points into consideration.

#### 2.1.2 Rules and Regulations Regarding Pharmacies

The staffing, size, location, stock, supply system and pricing issues regarding pharmacies in Romania are regulated by the Law on the Organization and Function of Pharmacy, Ordinul M S nr 2234/1994, Appendix B, of this report. This law is being revised, and Ordinul M S nr 201/5-4-99 was in the legislative process at the time this report was prepared.

The government has a "Certificate of Need" regulation which attempts to control the number of private pharmacists by designating one private pharmacy per every 7,000 citizens. A gray area of the law can be found with respect to rural areas where the 7,000-population requirement is not enforced. Another stipulation is that applicants seeking private pharmacy licenses must be first approved by the College of Pharmacy. Whereas these laws may appear restrictive to pharmacists seeking entry into the market, for those pharmacies already established, they are a reprieve from the threat of further competition.

Private pharmacies in Romania are established either as completely new businesses or as privatized SOEs. Those located in the most densely populated areas—particularly in the cities—are more likely to be new than privatized SOEs. A 1996 sample survey by the Institute of Marketing and Survey (IMAS) of 597 pharmacists revealed that 71.9 percent of them cited a desire for ownership and independence as motivation for working in a private pharmacy. In reality, though, at least half of the new pharmacy facilities [50.2 percent] were established under the ownership of a large company. About 29.2 percent rented space from the state, and 20.6 percent rented space from a private individual.

To some, these facts are bothersome. For example, in 1994 the President of the NPA expressed his concern about the potential chain operations that privatized state distributors

could create by evicting private pharmacists who lease their retail sites from the distributor or contract-manage a pharmacy owned by the distributor

Like all health care facilities, private pharmacies are under the authority of the MOH and as such require an MOH license and local Sanitary Commission approval as well as the local branch of the NPA. The NPA at the local level plays a major role in establishing new pharmacies. The local NPA must give its approval to the MOH in Bucharest in order for a new pharmacy to be opened. Once opened, a pharmacy is re-authorized to serve the public every two years by the Ministry of Health.

Staff size in the IMAS survey was closely associated with a pharmacy's location—those in rural areas tended to have a staff of no more than three whereas pharmacies in cities with populations of 50,000 or more were likely to have four or more full-time staff. All staff members are required to have specialized and officially attested studies in their field, corresponding to their position. The private pharmacist and the assistant must each have a license of "free practice," and the former is required by law to have a graduate degree in pharmacy. Furthermore, the law forbids that a pharmacy function in the absence of a pharmacist.

The physical facility regulations governing private pharmacies in Romania are similar to Western European standards. These include separation and control of narcotics, enforcing prescription requirements and keeping a record of prescriptions, no sale of unregistered drugs, reporting of drug reactions, retaining a copy of the official price list, and appropriate labeling of containers. Community pharmacies generally consist of 4 rooms. There is the "officina," where prescriptions are received and dispensed to patients. This room is usually the entry to the pharmacy and the waiting area. A second room is the "receptura" in which prescriptions are compounded. The third is the warehouse, where excess stock is kept, and the fourth is the laboratory in which solutions, suppositories and ointments are prepared in bulk form.

Requirements for the location and size of pharmacies are quite specific. If the pharmacist's living quarters is located in the same building as the pharmacy, it must be completely separate. Except for balneary hospitals that are permitted to have their pharmacies on the first floor, all urban and rural-based pharmacies with pharmacist's living quarters restrict their pharmacies to the ground floor. Urban pharmacies are to be approximately 50-sq meters area with rooms of the pharmacy at least 2.5m in height and separated by no other structures than built walls.

All pharmacies are required to open every working day, excluding Sundays and legal holidays. Their hours of operations are regulated by the local judet (county) College of Pharmacists (or by the Bucharest College of Pharmacists in the case of the capital city, Bucharest) in agreement with the local health department's Board of Pharmacy and Medical Apparatuses.

Although a wide range of products are available, inventories are kept low for several reasons, among them the lack of credit facilities for drug purchases and cash flow constraints resulting from slow reimbursement for state-subsidized products. When stock-outs occur, they seem to be caused by both cash flow constraints and poor inventory management systems. The

preservation, storage, labeling and dispensing of medicines is to be preserved under the guidelines of the Romanian Pharmacopoeia and international standards

Regulatory barriers to the establishment of private sector drug distributorships are minimal — the warehouse must be supervised by a licensed pharmacist and meet minimal physical standards. Moreover, there also appears to be no regulatory barrier to the importation of drugs either by public or private distributors. A 1994 study of marketing for contraceptives reported that a US \$1,000 fee was required to license any new drug before entry into the market. It usually took three to six months from the date of filing for registration to occur. Basic chemical and therapeutic data and clinical trials are also required prior to approval of registration by the MOH upon receipt of the Drug Commission's (now called the Scientific Council) recommendation.

Government regulations limit the total wholesale and retail profit margins on products, preventing pharmacists from increasing prices to generate greater revenue. The allowable markup in 1997 depended on import prices and ranged from 14 to 25 percent. The lack of hard currency also means that both private and public wholesale distributors face difficulty guaranteeing essential drug stocks at competitive prices. The prices on all imported drugs must be negotiated with the MOH.

### 2.1.3 Summary of the Practice of Pharmacy

In Romania, the pharmacy is regarded as a health facility that has as its object the preparation, preservation and dispensing of pharmaceutical products. There are two types of pharmacies: open-circuit and closed-circuit. Open-circuit pharmacies—urban and rural—assure the population access to ambulatory services. Closed-circuit pharmacies are in hospitals and other institutions to which patients are admitted.

All pharmacies, closed or open, must operate under the authority of a pharmacist in charge—a master pharmacist—who may also hire an accountant, clerks, caretakers, etc., as auxiliary personnel. By law, the general responsibilities of the pharmacist include:

- the overall supervision of the activities and function of the pharmacy
- the relationship between the patient and the pharmacy with a view toward patient education on the wise use of medicines
- establishing good relations and cooperation with physicians
- pharmaco-vigilance
- maintaining professional and scientific currency
- keeping current copies of the Romanian Pharmacopoeia and other appropriate literature on hand in the pharmacy
- supervision of residents and students in the pharmacy
- representing and defending the principles of the profession

The extent to which each and or all of these functions exist in an individual pharmacy varies

Pharmacy assistants work under the direct supervision of the pharmacist and are non-degreed. They perform those functions that do not imply a professional responsibility on the preparation, dispensing and use of medicines which is restricted to the pharmacist only.

Most of the pharmacists in practice are female (See Table 3). Pharmacists see themselves and are recognized as health specialists who help solve problems of "medicine assistance" and who are to collaborate in the medical management of the public health (in the case of open-circuit pharmacies) and in the institution (in the case of closed-circuit pharmacies). In the Sherpick and Hopstock study of pharmacists in Romania, 597 pharmacists were interviewed, one-on-one, to determine pharmacists' business, knowledge, attitudes and practices about family planning and their level of interest in receiving training and promotional materials. Pharmacists are asked for advice on medicine use and side effects, general medical advice, medicine substitutes, expiration dates and prices of products, as well as other matters (Table 4).

Results of the Sherpick and Hopstock study indicate that privatization of pharmacies peaked between 1991 and 1993 (See Table 5). The process of privatization afforded pharmacists employed in state-owned pharmacies with the opportunity to work on their own (See Tables 6 and 7). There are anecdotal reports that now that the business issue of privatization has been addressed, it is now time to return to the health professional role of the pharmacist.

#### 2.1.4 Overview of Pre-Service Education and Training for Pharmacists

In 1998, there were eight institutions in Romania that granted degrees in Pharmacy (See Table 8). Most of them require a five-year curriculum in undergraduate pharmaceutical education. The curriculum of the Faculty of Pharmacy at the University of Medicine and Pharmacy at Cluj-Napoca, Appendix C, is a sample of the content found at a leading Faculty of Pharmacy in Romania. There is a competitive examination, and all that pass are granted admission, tuition free, to enter the Faculty of Pharmacy. Students who do not pass may consider pursuing a two-year pharmacy assistant program at a local technical college. There is a preliminary preparatory year for foreign citizens to enable them to learn Romanian. Foreign citizens who pass this year are granted a certificate confirming their ability to enter the first academic year. At the end of the course of studies and the successful defense of an undergraduate thesis, students are granted a diploma from the Ministry of Education.

After undergraduate training, students may elect to pursue a two-to three-year residency in general pharmacy, clinical pharmacy, industrial pharmacy or laboratory research. They may also elect to pursue the Doctor of Pharmacy degree. Students who pursue the Doctor of Pharmacy degree may take up to six years to complete additional coursework, pass a theoretical exam, present and then defend a dissertation. Upon completion of postgraduate training, they receive either a residency certificate or a doctoral diploma that is validated by the Ministry of Education (MOE). This constitutes a license to practice pharmacy.

Continuing Education is not required for continued licensing. Practitioners have several informal mechanisms open to them to maintain their skills: arranged continuing education.

TABLE 3

Number and Gender of Pharmacists in the Public and Private Sector – 1994-1998

		1994	1995	1996	1997	1998
IX	<b>NUMAR FARMACISTI IN SECTORUL PUBLIC</b>					
	<b>Total</b>	<b>2814</b>	<b>2661</b>	<b>2578</b>	<b>1690</b>	<b>1642</b>
	Urban	2660	2532	2463	1658	1611
	Rural	154	129	115	32	31
	<b>1 CLUJ</b>					
	<b>Total</b>	<b>191</b>	<b>233</b>	<b>251</b>	<b>134</b>	<b>148</b>
	Urban	188	231	248	134	148
	Rural	3	2	3	-	-
	<b>2 CONSTANTA</b>					
	<b>Total</b>	<b>100</b>	<b>97</b>	<b>44</b>	<b>40</b>	<b>36</b>
	Urban	96	93	41	39	35
	Rural	4	4	3	1	1
<b>3 IASI</b>						
<b>Total</b>	<b>169</b>	<b>189</b>	<b>189</b>	<b>137</b>	<b>128</b>	
Urban	160	180	181	137	128	
Rural	9	9	8	-	-	
X	<b>NUMAR FARMACISTI IN SECTORUL PARTICULAR</b>					
	<b>Total</b>				<b>3579</b>	<b>3915</b>
	Urban				2956	3302
	Rural				623	613
	<b>1 CLUJ</b>					
	<b>Total</b>				<b>131</b>	<b>169</b>
	Urban				126	164
	Rural				5	5
	<b>2 CONSTANTA</b>					
	<b>Total</b>				<b>222</b>	<b>302</b>
	Urban				206	283
	Rural				16	19
<b>3 IASI</b>						
<b>Total</b>				<b>117</b>	<b>176</b>	
Urban				106	160	
Rural				11	16	
XI	<b>FARMACISTI -SECTOR PUBLIC</b>	<b>2814</b>	<b>2661</b>	<b>2578</b>	<b>1690</b>	<b>1642</b>
	MASCULIN		284	319	146	189
	FEMININ		2377	2259	644	1453
XII	<b>FARMACISTI- SECTOR PARTIC</b>				<b>3579</b>	<b>3915</b>
	MASCULIN				277	308
	FEMININ				3302	3607

Sursa datelor Reteaua si activitatea unitatilor sanitare 1994 1995 1996 1997 1998 lucrare editata de Comisia Nationala pentru Statistica

**TABLE 4**

**RESPONSE TO QUESTIONS**

**Do customers ask for advice concerning medicines?**

**Do customers ask for advice concerning contraceptive methods?**

Type of Advice	Q 28 (medicines)		Q43 (contraceptive methods)	
	N	%	N	%
Usage	417	69.8	168	28.1
Side Effects	245	41.0	87	14.6
What to use			133	22.3
Thorough Medical Advice	154	25.8		
Medicine Substitutes	106	17.8		
Other	66	11.1	22	3.7
Expiration Date	31	5.2		
Price	27	4.5		
No Advice	21	3.5	220	36.9
Send to the Physician	14	2.3	60	10.1

Source A R Sherpick & Paul J Hopstock, "Study of Romanian Private Pharmacists,"  
The PROFIT Project, November 1996

**TABLE 5**

**RESPONSE TO QUESTION**

**In what year was the pharmacy privatized?**

	N	%	CUM %
1990	18	3.0	3.0
1991	132	22.1	25.1
1992	130	21.8	46.9
1993	140	23.5	70.4
1994	82	13.7	84.1
1995	70	11.7	95.8
1996	19	3.2	99.0
Don't Know	6	1.0	100.0
Total	597	100.0	
Average	Year Opened 1993	# of Years in Private Sector	3.3

Source A R Sherpick & Paul J Hopstock, "Study of Romanian Private Pharmacists,"  
The PROFIT Project, November 1996

**TABLE 6**

**RESPONSE TO QUESTION**

**What are the reasons for starting the private pharmacy?**

	<b>N</b>	<b>%</b>
<b>Will to Work on Own</b>	<b>429</b>	<b>71.9</b>
<b>Privatization</b>	<b>309</b>	<b>51.8</b>
<b>Higher Salary</b>	<b>188</b>	<b>31.5</b>
<b>Other</b>	<b>102</b>	<b>17.1</b>
<b>Low Costs</b>	<b>17</b>	<b>2.8</b>
<b>Don't Know</b>	<b>17</b>	<b>2.8</b>
<b>Total</b>	<b>1,062</b>	<b>177.9</b>

**Source**            **A.R. Sherpick & Paul J Hopstock, "Study of Romanian Private Pharmacists," The PROFIT Project, November 1996**

**TABLE 7**

**RESPONSE TO QUESTION**

**What is the prior work experience?**

	<b>N</b>	<b>%</b>
<b>State-owned Pharmacy</b>	<b>543</b>	<b>91.0</b>
<b>Private Pharmacy, Employer</b>	<b>25</b>	<b>4.2</b>
<b>Private Pharmacy, Owner</b>	<b>5</b>	<b>0.8</b>
<b>My First Try</b>	<b>10</b>	<b>1.7</b>
<b>Other Situation</b>	<b>14</b>	<b>2.3</b>
<b>Total</b>	<b>597</b>	<b>100.0</b>

**Source**            **A R Sherpick & Paul J Hopstock, "Study of Romanian Private Pharmacists," The PROFIT Project, November 1996**

TABLE 8

PHARMACY FACULTIES, THEIR UNIVERSITY AFFILIATION, NUMBER OF STUDENTS & AUTHORIZATION STATUS,  
1998

Location	University	Affiliation	Approximate Number of Students	Authorization Status
	University	Faculty or Section		
1 Bucharest	University of Medicine and Pharmacy "Carol Davila"	Faculty of Pharmacy	800	Authorized
2 Iasi	University of Medicine and Pharmacy "Grigore T Popa"	Faculty of Pharmacy	500	Authorized
3 Cluj-Napoca	University of Medicine and Pharmacy "Iuliu Hatieganu"	Faculty of Pharmacy	500	Authorized
4 Targu-Mures	University of Medicine and Pharmacy	Faculty of Pharmacy	200	Authorized
5 Timisoara	University of Timisoara	Section of Pharmacy in Faculty of Medicine	150	Authorized
6 Craiova	University of Craiova	Section of Pharmacy in Faculty of Medicine	20-25 Students/yr (yrs 1-2)	Authorization in process
7 Oradea	University of Oradea	Section of Pharmacy in Faculty of Medicine	20-25 Students/yr (yrs 2-5)	Authorization in process
8 Constanta	University of Constanta	Section of Pharmacy in Faculty of Medicine	20-25 Students/yr (yrs 2-4)	Authorization in process

SOURCE University of Medicine and Pharmacy, Cluj-Napoca, June 1998 -- Dr F Loghin

courses at universities, product seminars sponsored by pharmaceutical manufacturers and information direct from manufacturer's representatives. There is also an Institute for Post-Diploma Studies and Continuous Education of Physicians and Pharmacists within the MOH that approves residency training programs. This segment of the MOH has issued draft CE programs, one of which was for specific medical training of physicians and pharmacists in FP.

## 2.1.5 Selected Projects Focusing on Pharmacist Training

As of 1997 the MOH had established a list of goals but had not yet fully articulated a comprehensive Health Sector Reform Strategy with the input of the health sector constituency. This list of goals included making improvements in Primary Health Care (PHC) and Family Planning services (FP). A better-trained cadre of health care providers would be a fundamental step in the health reform process especially toward improving PHC and FP delivery.

Beginning in 1996, the MOH collaborated with World Bank and USAID projects, especially World Vision Relief and Development (WVRD) and Deloitte and Touche's PROFIT project, to improve, strengthen and sustain, at the highest level, the role of the pharmacist in the PHC/FP delivery process. Additionally, the collaboration between the University of Medicine and Pharmacy and Howard University, which began in 1996, has evolved into the current TrainPharm Project. USAID has also funded separate studies that provide background on the role of the pharmacist in selected PHC efforts. One was undertaken by PSI, and the other is under the aegis of ARAS with the collaboration of Case Western Reserve School of Medicine. These are the *Pharmacist Survey of Contraceptive Availability, Knowledge and Practices, Romania, 1998* by PSI Romania, and the other is the *Pilot Pharmacy-Based HIV Prevention Intervention Study*. The former is completed, and the latter is in progress. The goals, objectives and key results of each of the above projects are summarized below.

Under the World Bank's Health and Rehabilitation Loan, a report of a fact-finding mission identified issues facing the pharmaceutical sector in general and the impact of this sector on the Loan. The report pointed out that within the retail sector (which had reached 74% privatization in Romania by 1996) the overall pharmaceutical market should receive attention because it experienced a rapid rate of privatization and tremendous growth (23% between 1994 and 1995). Recommendations put forward in the report included, among others, promotion of the rational use of drugs through an information, education and communication campaign directed to pharmacists, doctors and consumers on the rational use of essential generic drugs and Good Pharmacy Practices, the training of drug inspectors, curricula reform for medical and pharmacy schools and the development of a National Drug Policy. The report suggests that greater attention should be given to the drug reimbursement system and the resultant financial pressure placed on pharmacists who own or manage pharmacies.

The WVRD's Primary Health Care Project I was designed to improve the responsiveness, sustainability and effectiveness in the delivery of PHC through a mutual partnership with the University of Medicine and Pharmacy in Cluj and the Ministry of Health. A segment of Project II focused on designing a PHC framework for the Faculty of Pharmacy. As a result of this

framework, pharmacy students were to have a greater awareness of their potential role as a provider of primary health care, would focus on preventive as well as curative care and communities and would begin to see themselves as a part of a comprehensive and integrated health care delivery system. The project resulted in some 31 hours of lectures on aspects of primary health care that were themes in several classes in the 4<sup>th</sup> and 5<sup>th</sup> year of the curriculum in the Faculty of Pharmacy, but students lacked an integration point on PHC within the curriculum.

The Promoting Financial Investments and Transfers (PROFIT) project, funded by Deloitte and Touche, will be described in detail in the section below. The Sherpick and Hopstock study, referred to earlier in this report, was conducted under this project. The study contained data and information from 597 pharmacist interviews from six regions of Romania and six focus groups that had a total of 49 pharmacist members from Bucharest, Cluj and Iasi. A few questions in the study focused on business training for pharmacists (Table 9) and results showed that pharmacists in the sample were willing to receive (76/0%) and pay for training (60.3%) to acquire knowledge of new supplies and products.

In 1998 under the UMF/PACE Center collaboration, a 12-hour integration course on Primary Health Care was developed and taught. Course topics, Table 10, were presented, using various instructional methods (lecture, mini-case development, presentation and analysis, interactive discussion), some of which were not in the mainstream of the usual and ordinary university-level method. A 4-hour patient-centered demonstration on the monitoring of drug therapy in a community pharmacy supplemented the lecture. Some 115, 5<sup>th</sup> year students, graduate residents and pharmacist practitioners took the course and received a joint certificate from the "Iuliu Hatieganu" University of Medicine and Pharmacy and Howard University Continuing Education PACE Center.

The course syllabus in Appendix D, The TrainPharm Project, funded to begin in July, 1999, continues the collaborative effort between UMF and the PACE Center. The purpose of the project is to support USAID/Romania Strategic Objective 3.2 "Improved Welfare of Women and Children in Romania" with primary emphasis on Women's Health Services - Reproductive Health and Family Planning (RH/FP). The project will assist the UMF-Cluj to develop, organize and conduct a training process for up to 300 pharmacist practitioners from Cluj, Constanta and Iasi during which current and relevant Primary Health Care (PHC) delivery information, knowledge and skills, specifically as they relate to RH/FP, will be imparted. It will also assist UMF-Cluj to develop a sustainable capacity to plan, implement and evaluate Continuing Education services for pharmacist practitioners.

The PSI of Romania conducted a rapid assessment of 263 pharmacists in Cluj, Constanta and Iasi (1) to assess the situation and needs of pharmacists and pharmacies and to recommend ways to improve reproductive health activities in these 3 judets, (2) to determine participation in past training on contraceptives as well as (3) interest and willingness to participate in future to show training on contraceptives. The study examined rural and urban judet differentials on these points. Table 11 presents data from the study that related to the training needs of pharmacists. Well over 70% of pharmacists across all 3 judets, urban or rural, were willing to

TABLE 9

Percentage Distribution of Pharmacists in Target Judets by Willingness to Participate in Training

	Percentage of Pharmacists who are willing	Percentage of Pharmacists who are not willing for the following reasons					
		Unable to leave	No interest	No need	Too old	Other	N (100 %)
Cluj	71.4	10.0	1.4	1.4	14.3	1.4	70
Constanta	80.9	12.8	4.3	1.1	1.1	0.0	94
Iasi	80.4	6.2	4.1	0.0	4.1	5.2	97
Rural	77.4	11.3	5.7	1.9	3.8	0.0	53
Urban	77.9	9.1	2.9	0.5	6.7	2.9	208
<b>Total</b>	<b>78.2</b>	<b>9.6</b>	<b>3.4</b>	<b>0.8</b>	<b>5.7</b>	<b>2.3</b>	<b>261</b>

SOURCE Judith Heichelheim, Michael Holscher, Dominique Meekers and Mihaela Pirvulescu  
 Pharmacist Survey of Contraceptive Availability, Knowledge and Practices, Romania 1998  
 Population Services International - Romania

TABLE 10

Percentage Distribution of All Pharmacists in Target Judets by Timing of Last Training

	Percentage of Pharmacists with Last Training in the Following Timeframe				
	Never	<1 Year	2-3 Years	3+ Years	N
Cluj	79.7	11.6	7.2	1.4	69
Constanta	93.4	4.4	1.1	1.1	91
Iasi	79.6	11.2	6.1	3.1	98
Rural	94.3	1.9	1.9	1.9	53
Urban	82.0	10.7	5.4	2.0	205
<b>Total</b>	<b>84.5</b>	<b>8.9</b>	<b>4.7</b>	<b>1.9</b>	<b>258</b>

SOURCE Judith Heichelheim, Michael Holscher, Dominique Meekers and Mihaela Pirvulescu  
 Pharmacist Survey of Contraceptive Availability, Knowledge and Practices, Romania 1998  
 Population Services International - Romania

TABLE 11

Training Needs And Willingness To Pay

<b>Training Needs and Willingness to Pay</b>		
	<b>Need to improve Knowledge (%)</b>	<b>Willing to pay for Training (%)</b>
<b>New Suppliers and Products</b>	<b>76 0</b>	<b>60 3</b>
<b>Marketing</b>	<b>35 5</b>	<b>23 6</b>
<b>Finance</b>	<b>30 5</b>	<b>21 8</b>
<b>Human Resources</b>	<b>26 8</b>	<b>17 4</b>
<b>Advertising</b>	<b>25 0</b>	<b>14 2</b>
<b>Stock Management</b>	<b>19 8</b>	<b>10 2</b>

Source A R Sherpick & Paul J Hopstock, Study of Romanian Private Pharmacists The PROFIT Project November 1996

TABLE 12

RESPONSE TO QUESTION Does the pharmacy sell contraceptives?

	<b>N</b>	<b>%</b>
<b>Yes</b>	<b>572</b>	<b>95 8</b>
<b>No</b>	<b>25</b>	<b>4 2</b>
<b>Total</b>	<b>597</b>	<b>100 0</b>

Source A R Sherpick & Paul J Hopstock "Study of Romanian Private Pharmacists ' The PROFIT Project, November 1996

TABLE 13

RESPONSE TO QUESTION How do your Clients ask for Contraceptives?

	<b>N</b>	<b>%</b>
<b>Not Embarrassed</b>	<b>427</b>	<b>71 5</b>
<b>Embarrassed</b>	<b>64</b>	<b>10 7</b>
<b>Other</b>	<b>67</b>	<b>11 2</b>
<b>Don't Know/Not Applicable</b>	<b>39</b>	<b>6 5</b>
<b>Total</b>	<b>597</b>	

Source A R Sherpick & Paul J Hopstock, "Study of Romanian Private Pharmacists The PROFIT Project November 1996

participate in training on contraceptives. Some 80% to 93% of pharmacists across the 3 judets had not ever participated in any training program on contraceptives. This finding is consistent with the Sherpick and Hopstock study results noted above.

The Asociate Romana Anti-SIDA (ARAS) in conjunction with the Case Western Reserve School of Medicine mounted a Pharmacy-Based HIV Prevention Intervention study in pilot pharmacies in Iasi to provide preliminary information on

- whether pharmacists are key individuals in the community opinion formation change and, if not, can they be supported to assume such a role,
- does the involvement of pharmacists in HIV prevention information efforts result in increased sales in condoms, and
- will locals accept HIV prevention information through pharmacies

The projects that, to date, can be said to focus most directly on the training of pharmacists are the WVRD's PHC II project, the PROFIT Subproject and the new TrainPharm Project.

#### 2.1.6 Review of Training under the PROFIT Sub-Project

USAID/Romania has asked that this review provide a special focus on the PROFIT project. Of the projects listed above, the PROFIT project is likely to have a significant impact on advancing a focus in Romania on the issue of pharmacist training. In October 1995, G/PHN/POP obligated US \$1.1 million from USAID/Romania funds to implement a sub-project under the PROFIT umbrella that was aimed at increasing use of modern contraceptives through the commercial sector with a specific emphasis on pharmacies. Following an assessment of opportunities to expand usage of modern contraceptives through Romania's private sector that was completed in August, 1994, a subproject was initiated under USAID's sponsorship the following year to improve family planning knowledge and business skills of pharmacists. The project was operational from October 1995 through September 1997.

The 1994 assessment recommended that key structural changes were needed at the level of the MOH and NPA to help create a more professionally competitive environment for pharmacists. Key structural reform should also ensure that at least 25 percent of the total number of pharmacists were trained in not only the principles of contraceptive technology and quality service but also in business and communication. This approach would enable them to improve how they manage and market their pharmacies as well as strengthen their service to women and children.

One of the earlier activities was the April 1996 study of Romanian pharmacists, the Sherpick and Hopstock study. The goal of this study was to explore the business knowledge, attitudes and practices (KAP) of pharmacists with regard to family planning and to determine their level of interest in receiving training and promotional materials. In addition to the results mentioned in Section 2 of this report, the study found that

- The interview sample was 92.3% female
- Most of the pharmacies managed by respondents were privatized between 1991 and 1993

- Typical customers in the pharmacies sampled, as described by respondents, were older or retired clients (69%)
- The median number of employees in private pharmacies was three, two of whom were involved in selling medications
- Virtually all of the pharmacies (92.1%) employed fully educated pharmacists who had experience with a pharmacy assistant (69.8%)
- Oral contraceptives and condoms were widely available, but IUDs and diaphragms were less available
- Pharmacists reported being comfortable with selling contraceptives and confident in answering questions from customers even though they are not asked for advice on contraceptives as much as for advice on other medicines
- Nearly all respondents (91.2%) were willing to display promotional materials about contraceptives in their pharmacies and were also willing to learn about new products

Above all, the study found that 96% of the sample pharmacies stocked and sold contraceptives, and pharmacists stated that of customers who asked for contraceptive products, (72%) were not embarrassed to ask for them (Tables 12 and 13)

The PROFIT sub-project had two objectives. The first objective was to increase the knowledge and use of modern contraceptive methods among young adults, 15-24, who use private pharmacies as a product source. The second was to increase the use of private pharmacies as a source for a range of modern contraceptive methods.

To achieve its first objective, PROFIT planned

- 3 waves of audience research
- 78 media appearances (TV, radio, print media)
- printed materials (flyers, brochures, posters, newsletters, T-shirts)
- special events
- direct mailings

To accomplish the second objective, PROFIT planned to

- conduct market research
- engage in curriculum-based training
- select and train five trainers
- organize seminars in towns
- train 100 pharmacists
- develop and distribute 2,000 copies of a Contraceptive Technology Guide for Pharmacies

The project worked in partnership with the NPA to provide training to private pharmacists in Contraceptive Technology (CT) and Quality Service (QS). The latter included a focus on communication and business principles. Pharmacist training was a four-phase process.

During Phase I, training of trainers (TOT), October-November 1996, PROFIT developed a cadre of 14 trainers. They comprised a mix of pharmacists from the private and academic

sectors as well as physicians from the NGO sector, all well versed in the content, principles and skills covered. The PROFIT group had initially planned to select five trainers.

Phase II (December, 1996 through February, 1997) involved the training of pharmacists (TOP) in CT and QS. PROFIT initially planned 10 training workshops in five major towns—Bucharest, Iasi, Cluj, Timisoara and Targu Mures to train 100 pharmacists. There were actually 11 workshops held in eight cities (as listed in Table 14), and 195 pharmacists from 15 different counties were trained, each of whom received a certificate signed by the NPA president.

The third phase involved the distribution of a handbook “Pharmacists’ Guide in Contraceptive Technology and Quality Service,” based on the original training materials. Some 2,000 copies were slated for distribution to private pharmacies. In fact, the end-of-project report indicated that 5,000 copies were distributed.

Phase IV involved monitoring and evaluation from March to May, 1997 to assess the impact of the training and the materials and handbook. Project activities were evaluated, using a telephone interview of a total of 169 pharmacists. Of these, 67 were trained through the project, and 102 were not. Areas of evaluation included:

- use of knowledge gained and its effect on performance
- receipt and use of the PHARMACISTS’ GUIDE
- stock level of contraceptives
- stock and availability of educational leaflets
- the pharmacists’ attitude (toward providing contract information)
- the pharmacists’ knowledge (accuracy of information content)

Table 15 gives key results from the quantitative survey. Results were reported in all areas except stock and availability of educational leaflets. Results of this evaluation with regard to pharmacist training indicate that, when compared to the control group, sales growth of oral contraceptives [nine percent], condoms [12 percent] and spermicides [15 percent] were respectively higher in the trained group than in the control group. Another major difference between the trained and the control group was that trained pharmacists were more able to implement quality of service to patients by explaining side effects and effectiveness of contraceptives.

Table 16 presents the input goals, indicators, data sources, and outputs key results of the Subproject. Overall the Subproject:

- developed a core group of trainers familiar with the pharmacist’s situation,
- developed a curriculum which can be used and/or modified for continuing education of pharmacist practitioners,
- developed reference materials for future training of pharmacists,
- helped to raise awareness of the potential role pharmacists can and do play in PHC, especially care of women and children,

TABLE 14

PROFIT PROJECT  
CONTRACEPTIVE TECHNOLOGY AND QUALITY SERVICES TRAINING  
Seminars for Pharmacists  
Sept 1996 – June 1997

No	SEMINAR CITY	Date	NUMBER OF PHARMACISTS TRAINED
1	BUCURESTI	12/21/96	21
2	CLUJ	1/25/97	21
3	CLUJ	1/26/97	19
4	TIMISOARA	1/31/97	14
5	TIMISOARA	2/1/97	18
6	TARGU MURES	2/15/97	17
7	TARGU MURES	2/16/97	18
8	IASI	3/1/97	15
9	CRAIOVA	4/5/97	15
10	FOCSANI	5/16/97	20
11	CONSTANTA	5/24/97	17
	TOTAL PHARMACISTS		195
	TOTAL TRAINERS		14
	TOTAL PERSONS TRAINED BY PROFIT		209

SOURCE PROFIT Project

TABLE 15

## FINAL EVALUATION OF PRIVATE SECTOR SUBPROJECT (ROMANIA)

Key Results From Quantitative Survey of Romanian Pharmacists					
Variable		Experimental Group (N = 67)	Control Group (N = 102)	Variance	
Mean Age (years)		41	42	1	
Gender (percent)	Female	99	99	-	
	Male	1	1	-	
Mean Years of Experience		16.7	18.3	1.6	
Increase in Contraceptive Sales over the Past Year (percent)	Oral Contraceptives	82.1	73.5	8.6	
	Condoms	83.6	71.6	12	
	Spermicides	85.0	69.6	15.4	
Lack of Supply (i.e. number of clients who requested Contraceptives that were not in the Pharmacy at the time)		43	59	16	
Knowledge (indicator question "What would you tell a client who misses two Oral Contraceptives?")		Percent Correct	64.2	51.0	13.2
Quality Client Care (i.e. explained mechanism of action, how to use, side effects, and effectiveness rates) percent	Mechanism of Action	47.8	40.2	7.6	
	Use	61.2	55.9	5.3	
	Side Effects	38.8	18.6	20.2	
	Effectiveness	59.7	39.2	20.5	
Availability of Educational Materials	For Self	64.3	61.8	2.5	
	For Clients	47.7	41.3	6.4	

SOURCE J M Weinman, Private Sector Subproject, Romania, Final Evaluation Report, September 1997

TABLE 16

INPUT GOALS INDICATORS DATA SOURCES AND OUTPUTS OF THE PROFIT SUBPROJECT

Input Goals, Indicators, Data Sources and Outputs			
Goal/Objective	Measurable Indicator	Source of Information	Outputs
Through an IEC campaign to educate consumers (aged 15-24) about modern methods of contraceptives and motivate them to use them and to obtain them through private providers especially pharmacists	<ul style="list-style-type: none"> <li>Issue Terms of Reference</li> <li>Select firm to implement</li> <li>Conduct formative research</li> <li>Implement work plan</li> <li>Evaluate reach of campaign and effectiveness of its messages</li> </ul>	<ul style="list-style-type: none"> <li>Country staff monthly reports</li> <li>CDC pre-survey of youth completed in September 1996</li> <li>Mid-term survey of youth completed in September 1996</li> <li>Mid-term survey to be completed by April 1997</li> <li>Post-survey completed in September 1997</li> </ul>	<ul style="list-style-type: none"> <li>In August 1996 contracted with firm to conduct IEC campaign</li> <li>Campaign was launched October 28 1996</li> <li>Mass media including TV radio and print materials were used 323 times</li> <li>Mid-term and final evaluation completed</li> </ul>
To train trainers to conduct training of pharmacists	Training 12 trainers	Training report	Thirteen trainers trained October 25-27 1996
To train staff from 50 private pharmacies in contraceptive technology management and quality client-care skills	Train staff from 50 private pharmacies by June 30 1997	<ul style="list-style-type: none"> <li>Training report</li> <li>Post-training survey with trained and untrained pharmacists for comparison completed in September 1997</li> </ul>	<ul style="list-style-type: none"> <li>Eleven training workshops held from December 1996 to May 1997 training 195 pharmacists from 92 pharmacies and 8 physicians</li> <li>Post-training survey completed with trained and untrained pharmacists for comparison</li> </ul>
To develop a guide for pharmacists on contraceptives management and quality patient care skills	<ul style="list-style-type: none"> <li>Develop guide</li> <li>Distribute guide to 2 000 pharmacies</li> </ul>	<ul style="list-style-type: none"> <li>Country staff monthly reports</li> <li>Post-training survey completed with pharmacists to assess recall of receiving guide</li> </ul>	<ul style="list-style-type: none"> <li>In March 1997 the guide was printed and distributed to 3 000 private pharmacists another 1 500 copies were distributed to university pharmacy departments NGOs and government agencies</li> <li>In September 1997 a marketing and management guide was developed and distributed to the same groups</li> </ul>
To improve availability of commodities in private pharmacies by facilitating communication between distributors and pharmacists	Recruit at least one distributor to serve as a resource at each training workshop	<ul style="list-style-type: none"> <li>Country staff monthly reports</li> <li>Training reports</li> </ul>	<ul style="list-style-type: none"> <li>Representatives from various distributors provided information at 11 training workshops</li> </ul>

SOURCE J M Weinman Private Sector Subproject Romania Final Evaluation Report September 1997

- established a base of pharmacists across the country who have been equipped with CT information and have been trained to improve the quality of their patient interactions especially around counseling on the use of contraceptives

The PROFIT Project's activity in the Romanian health sector has served to highlight many positives and raise certain questions. It has emphasized the important contribution training can make to strengthening the role pharmacists play in reproductive health. However, the questions it raises include: Was the number trained sufficient to promote the needed service in reproductive health care delivery, what information did the trained pharmacists use most frequently and what mechanism is there to provide an update on the information pharmacists most use and most need?

One of the major shortcomings of the project was the absence of association with an institution for project continuance at the end of technical assistance. When the project ended, no formal mechanism was in place to continue to use the products and reinforce the training started. To overcome some of these drawbacks, training of pharmacists should be more geographically focused and should extend over a critical mass, and the curricula for training practitioner pharmacists should be institutionalized so as to increase the likelihood of sustainability.

## 2.2 Issues Regarding Drugs

### 2.2.1 Governmental Decision Making

The MOH's Pharmaceutical Directorate regulates Romania's entire pharmaceutical sector. The Directorate is divided into three divisions:

- Inspection and Organization
- Programs with World Bank and PHARE and Drug Distribution (for these specific programs)
- Registration, Drug Distribution, Pricing and Narcotics

The latter division is most responsible for formulating and implementing all aspects of pharmacy policy. Until recently, the Pharmaceutical Directorate collaborated with all other Directorates, the ISCDPR and the central state warehouse, UNIFARM. The ISCDPR, formerly responsible for undertaking quality assessments and registering all drugs that enter the Romanian market, has been replaced by the National Drug Agency. The Drug Commission, now called the Scientific Council, is responsible for the pre-selection process of drugs that will be registered on the market.

Responsibility for the formulation of the National Drug Policy (NDP) has been largely limited to staff in the Pharmaceutical Directorate. Although there has recently been the development

of regulations for Good Manufacturing Practices (GMP) and Good Pharmacy Practice (GPP), political, human resource and financial investments are needed to enforce them. There have been limited efforts to promote the rational use of drugs. Moreover, the World Bank 1996 fact-finding mission reports that this weakness is contributing to the uncontrolled supply of over-the-counter and prescription drugs at pharmacies.

Although regulations on advertising exist, impartial drug information is not being disseminated. Education, formal and informal, and widespread communication on the wise use of drugs, particularly contraceptives, are urgently needed. The 1997 report of Ionescu and Mitchell revealed that the greatest obstacle to the use of modern contraceptive methods available through available commercial channels was the lack of correct information.

## 2.2.2 Distribution of Drugs

Before the changes in the political system in 1989, the government had designated 18 pharmaceutical areas throughout Romania. Each area included a warehouse, community pharmacies, hospital pharmacies, quality control laboratories and production units. Romania was considered to be self-sufficient in the production of raw materials and finished pharmaceutical products. After 1989 and the move toward privatization, warehouses were privatized, hospital pharmacies were given to each hospital to operate, and community pharmacies were privatized. Pharmaceutical inspection remained under the state drug control unit and territorial laboratories.

A review of Table 2 shows that there were no records of private warehouses before 1995 and that the number has increased by 57% by 1998. At the same time public pharmacy points - small distribution units - decreased by tenfold while more than tripling numerically in the private sector during the same period. However, in the three target judets, the number of pharmacy points has dwindled to 0 in Cluj and Constanta with only 2 urban ones in Iasi. In the private sector in 1998, Constanta alone reports a sizable number of them, Cluj has none, and Iasi only 3 urban ones. With post-1989 shifts, it is clear that channels to distribute pharmaceutical products in rural areas are sparse because of a maldistribution of community pharmacies and pharmacy points.

Regulatory barriers to the establishment of private sector drug distributorships are low. According to MOH data, licenses have been granted to 340 private wholesalers. The national drug distributor, UNIFARM, is seen as a competitor by some as it takes a lower share of the authorized wholesale/retail market, Romania. It was documented in 1996 that private wholesalers supplied 58 percent of the total pharmaceutical market, and UNIFARM and the 17 regional wholesalers accounted for the remaining 42 percent.

Theoretically, the structure of these 17 wholesalers—referred to as “commercial companies” since the transition towards a market economy—are 51 percent state-owned and 49 percent privately owned although the figures may vary. These commercial companies, together with hospitals, public and private wholesalers, hospitals, public and private pharmacies, were

supplied with drugs imported by UNIFARM under the World Bank/Ministry of Health Reproductive Health Loan. However, the majority of products destined for the private pharmacies are imported through a network of private distributors.

The public pharmaceutical production industry was developed solely to supply the major needs of the population and provide for self-sufficiency. However, during the pre-'89 era, public pharmaceutical production was always subordinated by the priority placed on heavy industry, energy and investment sectors. Isolation from international innovations in pharmaceutical development, high debt, mismanagement and low quality standards led to an overall structural weakness, but the industry is a part of the privatization efforts in Romania. Some drug producers, such as Europharm, a Romanian-American company, are comparatively better off financially and operating under more efficient systems. In fact, Europharm merged with the multinational Smith Kline Beecham in 1998.

There appears to be no regulatory barrier to importation of drugs by either the public or private distributors. The central public warehouse and parastatal, UNIFARM—which until 1989 enjoyed a monopoly on drug imports into Romania—is now facing competition from private importers. International producers have also entered the Romanian market heavily through imports and also by way of licensing their products for local production. Some of these international producers have quickly penetrated the market through a variety of marketing strategies.

Many private distributors and importers had until recently placed limits on the quantity of imported essential drugs because of the instability of the Romanian currency, the lei. The recurrent instability of the lei led in January/February, 1997 to a halt by importers of all shipments to protest crippling price controls. In response to that development, new regulations were adopted by the MOH to overcome this problem. They permitted importers to charge up to a 20 percent commission above the fixed import price to offset the exchange rate risk. Once the currency is stabilized, the plan is either to lower or lift the premium.

Within the context of health reform, the MOH is structuring a health insurance strategy, but the manner in which drugs are to be reimbursed is being worked out.

### 2.2.3 Profit Margins

The government fully reimburses commercial pharmacies for providing drugs to patients who have certain diseases (e.g., tuberculosis). There are other drugs for which a co-payment of 20% is required. All drugs to hospitalized patients are free. Reimbursement systems have been a problem for many in privatized pharmacy. There is an inability to adjust for inflation, frequent changes in the list of reimbursable drugs and payment delays.

Part of government's health policy is to subsidize health care for the average Romanian. In the pharmaceutical sector this is done through the Drug Fund. Government reimbursements to private pharmacies for drugs issued to the needy public are mainly drawn from a two

percent payroll tax from commercial companies, one to 10 percent through “sin” taxes, with the remainder provided by the general budget [30 percent] However, reimbursements to private pharmacies have been late because of the inability of the MOH to collect promptly payments from commercial companies A new regulation enacted in 1996 made it mandatory for commercial companies to pay the tax, and a punitive 0.13 percent interest per day charge was imposed on the delinquent tax However enforcement of the tax is minimal because of potential political fall-out

Previous regulations limited the combined wholesaler/retailer markup to 12 to 33 percent of the import price Later, it was changed slightly to between 14 to 25 percent of the import price of which the distributor can receive from 4 percent to 9 percent However, it is the retail pharmacist who has minimal control over her selling price, she must settle for whatever margin is left after paying the distributor This has made for an undue manufacturer’s and distributor’s influence on the selling price as well as an incentive to structure and obtain hidden margins

Despite the distortions in the pharmaceutical market brought on by price restrictions, high inflation, high taxation and government delinquency in reimbursements, pharmacists seem to accept the rules governing profit margins In fact, they are concerned about enforcement actions for violation of the rules This pervasive attitude negates the reality that government controls on sales margins limit potential profits for private pharmacists, and it may stem from the fact that private pharmacists view themselves as health care professionals rather than as business people Moreover, they do not see themselves as being in competition with each other Yet, the shortcomings of the system and the concomitant cash flow constraints do incur a detrimental impact on the ability of most private pharmacies to improve their services and management systems, to reinvest in and expand their businesses

### **3.0 PHARMACISTS & USAID/ROMANIA STRATEGIC OBJECTIVES**

This section contains responses to USAID/ROMANIA questions on the wider role pharmacists can play in support of strategic health sector objectives The current strategy of the USAID Romania Mission is designed to achieve specific results related to quality partnerships which facilitates local action, encourages local advocacy for development and fosters synergy at local levels through increased community organization The following recommendation builds on the USAID strategy and proposes an approach that seeks to integrate pharmacists in their pharmacies as partners in this progress and reform effort The framework for the USAID/Romania health strategy is Strategic Objective 3.2 “Improved Welfare of Children and Women” This objective seeks to achieve two intermediate results (IRs)

- decreased dependency on institutions for children
- increased use of women’s health services

This strategy supports health sector reforms in Romania and builds a basis for sustainable services Under this strategy, USAID intends to build models of service in three target judets

Iasi, Cluj and Constanta USAID will work with judet leaders and organizations and use lessons learned from past projects

### 3.1 An Approach to Interventions

As in most countries, sizable numbers of populations flow through pharmacies each day that they are open. One does not need to set an appointment or pay a fee to receive information or assistance from a pharmacist to help solve a health problem. However, it is also a fact that many pharmacists worldwide also focus on the entrepreneurial side of their practice and less on the professional in order to use this access to populations for financial gain. In Romania, with the increased interest in privatization, many pharmacists did focus, necessarily so, on the business side of their practice. But now there is evidence of a return to a health care delivery role. In 1999 in one of the major trade magazines, the local Cluj College of Pharmacists included their recently developed brochure on the health care advice role of the pharmacist. This brochure was developed and used by the local College of Pharmacists and shared with others around the country as the centerfold of *LUMEA FAEMACEUTICA* (Appendix E). In the PSI survey, pharmacists were asked if customers asked for advice concerning medicines and contraceptive methods.

In the recent past, USAID has supported several projects that acknowledge the health service role of pharmacists with emphases on family planning (FP) and improved management of the pharmacy. This was a focus of the PROFIT Subproject. The WVRD PHC II project also acknowledged a broader PHC role that pharmacists could play. However, while achieving their stated goals and objectives, neither of these projects focused on vertical and/or horizontal integration of pharmacist's services.

Given the realities described above and the lessons learned from past USAID projects, it would be prudent for USAID to suggest in its discussions with the GOR that it consider supporting interventions that maximize the GOR's investment in these professionals. Such support will benefit the local populace, improve the delivery of local services for the benefit of the country as a whole, and give greater emphasis to the professional aspect of the pharmacist's contribution to the country's health and welfare.

In concert with its focus on three judets and as a part of achieving objectives in child welfare and women's health, USAID projects should

- enhance recognition of the role that pharmacists and pharmacies play in projects,
- specify activities that pharmacists can perform to enhance their recognition in their pharmacy site, be acknowledged within the wider community and serve as a vital resource and component of an integrated child welfare and women's health model,
- focus assistance on education and training in support of these designated activities.

In general, interventions should use **the pharmacy as a health message, information and referral center** as well as **a source of pharmaceutical products**. Pharmacists and their staff would promote healthy behaviors and healthy solutions to priority health problems by first promoting rational use of pharmaceuticals and partnering with physicians on rational prescribing efforts. The pharmacy is viewed as a community service facility, and with minimal training its pharmacists can participate in and/or lead efforts designed to achieve specific results. In addition to having a role as disseminators of medicines, pharmacists could also disseminate information on steps that the populace can take to address health problems or efficient ways to utilize local health facilities and programs. In some communities, pharmacists also serve as business and community leaders. In this way, pharmacists can be highly committed health service delivery collaborators in building sustained community-based programs. This approach is discussed below.

### 3.2 Decreased Dependency on Institutions for Children

Activities would focus on reducing the institutionalization of children, and pharmacists/pharmacies would be viewed as a part of the continuum of care within the community. The pharmacist, as a professional and community leader, could be integrated into the policy and reform process within a judet. The purpose would be to help improve child welfare policies and administrative procedures. Also, the pharmacy could be a place where brochures and other general information literature can be obtained on child welfare issues (family support, parent education, family preservation, parental assistance, temporary care facilities, appeals for foster care and adoption).

Further, when pharmacists participate in innovative training such as case-finding and referral, this contributes to increasing the number of professionals helping to improve the quality of child welfare services. It also lends itself to a wider number of citizens participating in child welfare activities.

### 3.3 Increased Use of And Access to Women's Health Services

Since research in Romania has shown that 54 percent of contraceptives used in selected areas are purchased in pharmacies, projects designed to increase the access, quality and demand of women's health should include a role for pharmacists in their pharmacies. Pharmacists could refer women to local facilities that provide FP services as well as pregnancy counseling and assistance in dealing with abuse, leading to an increased number of women using women's health. An increased number of pharmacists in community practice would also have their knowledge of contraceptive products updated. Then they would be trained in the application of that knowledge in their communications with patients and other health professionals. This would help to increase both the numbers of pharmacies providing contraceptive products as well as the number of professionals trained in counseling women on their use. With minimal effort, an intervention could be structured to encourage and use pharmacists who could be trained to use their syndromic approach to counsel women who seek to purchase drugs to deal with HIV/AIDS prevention and sexually transmitted diseases. They could also apply the same techniques toward the appropriate use of prescribed drugs or for self-medication. This

entire intervention should take into consideration a natural coincidence most pharmacists in Romania are women

### 3.4 Recommendation

To ensure the availability of the human capacity necessary to sustain this approach at the end of specific projects, it is recommended that USAID train current and future pharmacists to serve as partners in this integrated approach. One way to build sustainability is through individual empowerment and institutional partnership that translate into empowerment. There were several programs that emphasized the training of pharmacists. However, the ones in collaboration with Romanian educational institutions seem to have the greatest potential for continuance as educators can be enthusiastic about achievements and incorporate accomplishments even after a project has ended.

Accordingly, it is suggested that within the three target judets, USAID establish centers for the training of pharmacists in collaboration with the Faculty or section of pharmacy as the program anchor. The local College of Pharmacists and community pharmacists in the three judets would be called upon to be participants in this training program. These centers could have goals to

- develop a program that focuses on the training needs and skills enhancement for current practitioners. These include pharmacists, pharmacist technicians and others who are working in pharmacies. For instance, improved management of pharmacies, family planning services [contraceptive products, counseling, referral, etc ], and recognizing and handling the presentation of adverse drug events,
- develop and integrate PHC modules and topics—especially on children's and women's health—into the curriculum for undergraduate and graduate pharmacy students
- document the process so that it may serve as a reference point should other institutions of higher learning seek to replicate the process

Those funded efforts that focus solely on products - that is to promote the rational use of medicines and/or rational prescribing - should support conceptual coordination of the contribution both physicians and pharmacists, as well as other health professionals, make to improved prescribing and use of pharmaceuticals. Education and training interventions should build upon available resources, benefit from lessons learned in other projects and seek to increase the potential for sustainability.

## REFERENCES

- 1 Tarus V Drug Distribution in Romania How Important, How Efficient? In Update of the marketing assessment for the sale of contraceptives in the private sector in Romania Ionescu G, Mitchell S, editors Evaluation Report Arlington (VA), 1997 May Contract No DPE-3056-C-00-1040-00 Sponsored by the United States Agency for International Development (USAID)
- 2 National Public Health and Hospital Institute (NPHHI) Central and Eastern Europe Overview of the History, Health System, and Health Status of Romania [serial online] 1994, 1 [6 screens] Available from APC networks and via NISHEALTH list [nphhi@igc.apc.org](mailto:nphhi@igc.apc.org)
- 3 Issued by the World Bank Cohen, JC A review of the pharmaceutical sector in Romania Back-to-Office Report Bucharest (Romania) Human Development Department, 1996 Sept
- 4 MTEEP Monitoring and Evaluation Report Romania Washington State University Vancouver (WA) 1997 Aug, 165
- 5 Issued by USAID The Policy Project Romania work plan Washington/Bucharest 1997 November Sponsored by USAID/Bucharest and USAID Global Bureau
- 6 The World Bank Romania Country Overview [serial online] 1998 Jan [cited 1998 Apr 28], 1 [3 screens] Available from <http://www.worldbank.org>
- 7 Issued by the PROFIT Project Ionescu G, Mitchell S, editors Update of the marketing assessment for the sale of contraceptives in the private sector in Romania Evaluation Report Arlington (VA), 1997 May Contract No DPE-3056-C-00-1040-00 Sponsored by the United States Agency for International Development (USAID)
- 8 Issued by Office of International Programs, Howard University Continuing Education King R Expanding primary health care in the pharmacy curriculum Primary health care project II Report of a Consultation Silver Spring (MD) 1996 Sept Sponsored by World Vision Relief and Development, Inc
- 9 Issued by PROFIT Project Weinman J, Ionescu G Improved quality of FP range of services-products Project Progress Report Bucharest (Romania) 1997 March 17 Contract No DPE-3056-C-00-1040-00 Sponsored by the Office of Population in the Center for Population, Health and Nutrition (G/PHN/POP) of United States Agency for International Development (USAID)
- 10 Issued by the PROFIT Project Mitchell S, Feeley F, editors Marketing assessment for the sale of contraceptives in the private sector in Romania Evaluation Report

Arlington (VA), 1994 Sept Contract No DPE-3056-C-00-1040-00 Sponsored by the Office of Population in the Center for Population, Health and Nutrition (G/PHN/POP) of United States Agency for International Development (USAID)

- 11 Public Law  
The Law on the Organization and Function of Pharmacy of 1994, Pub L No 2234  
The Chamber of Deputies, Parliament of Romania In King R Expanding primary health care in the pharmacy curriculum Primary health care project II Report of a Consultation Silver Spring (MD) 1996 Sept Sponsored by World Vision Relief and Development, Inc
- 12 Issued by the PROFIT Project Sherpick AR, Hopstock PJ, editors Study of Romanian private pharmacists Arlington (VA) 1996 Nov Contract No DPE-3056-C-00-1040-00 Sponsored by the Office of Population in the Center for Population, Health and Nutrition (G/PHN/POP) of United States Agency for International Development (USAID)
- 13 Issued by PROFIT Project Weinman J Private Sector Subproject Romania Final evaluation report Arlington (VA) 1997 Sept Contract No DPE-3056-C-00-1040-00 Sponsored by the Office of Population in the Center for Population, Health and Nutrition (G/PHN/POP) of the United States Agency for International Development (USAID)
- 14 Issued by PROFIT Project IEC campaign and pharmacists training activities sites Arlington (VA) 1996 Contract No DPE-3056-C-00-1040-00 Sponsored by the Office of Population in the Center for Population, Health and Nutrition (G/PHN/POP) of United States Agency for International Development (USAID)
- 15 Issued by PROFIT Project Cogwell L Trip Report Romania, Arlington (VA) 1996 Oct Contract No DPE-3056-C-00-1040-00 Sponsored by the Office of Population in the Center for Population, Health and Nutrition (G/PHN/POP) of United States Agency for International Development (USAID)
- 16 Issued by PROFIT Project Ionescu G Final evaluation of PROFIT IEC campaign Memorandum Bucharest (Romania) 1997 April Contract No DPE-3056-C-00-1040-00 Sponsored by the Office of Population in the Center for Population, Health and Nutrition (G/PHN/POP) of United States Agency for International Development (USAID)
- 17 Issued by the World Bank Romania Health Sector Support Strategy Document Number 18410 RO, June, 1999
- 18 Loue, Sana, Pilot Pharmacy-Based HIV Prevention Intervention Study, 1999

- 19 Issued by Population Services International (PSI) , Judith Heichelheim, Michael Holscher, Dominique Meekers and Mihaela Pirvulescu, Pharmacist Survey of Contraceptive Availability, Knowledge and Practices, Romania, 1998,

**APPENDIX A**

**RULES ON THE GOOD PRACTICE OF PHARMACY  
Romanian and English Versions**

**Source**            **ACTUALITATEA FARMACEUTICA, September 15, 1996, pages 5-6**

# **RULES ON THE GOOD PRACTICE OF PHARMACY**

**(Romanian English Version)**

## **CHAPTER I**

### **GENERAL PRINCIPLES**

- 1 The application of the RULES on the GOOD PRACTICE of PHARMACY has in view the assurance of medicine assistance at the highest levels, from the point of view of supplying pharmaceutical units with medicines, as well as with the whole range of services that the pharmacist has to provide in the patient's employ
- 2 The pharmaceutical services imply the assurance of a good quality, no less than the education of the population with a view to avoiding its falling ill. The rules on the GOOD PRACTICE of PHARMACY also have to pursue the accomplishment of maximum therapeutic benefit, as well as the avoidance of unwanted reactions to medicine. This requires a sharing of the responsibilities and a perfect collaboration among physician, pharmacist and patient for an efficient therapy
- 3 The professional pharmaceutical organizations have to act with a view to the assurance of an exacting professional education of the pharmaceutical staff both before and after they obtain the right of free practice. This implies that the University of Pharmacy should lay stress on the usage of instruction and the action of medicines during students' practice, as well as on the importance of the relationship that must exist between physician and pharmacist

## **CHAPTER II**

### **GENERAL REQUIREMENTS REGARDING THE RULES ON THE GOOD PRACTICE OF PHARMACY**

- 4 The Pharmacist is the unique representative of the institution Pharmacy, upon whom rests the whole responsibility for the medicine, whatever its form, being forced to respect the traditional principles and modern settlements imposed by the national and international forums, to preserve the authority of his/her social function
- 5 In order to fulfill his/her duties, the pharmacist must appropriately complete the principles that promote the ethics of his/her profession and assure the probity and professional independence without which he/she cannot carry the highest level of thinking liberty and professional action
- 6 The pharmacist is a specialist with options of decision, for which he has to establish the pertinent relationship with the subject of the medicine

- 7 The pharmacist must not refuse the pharmaceutical act on a request concerning the health of the sick subject, that is in his competence
- 8 The pharmacist is responsible for the activity of the pharmacy on the whole
- 9 The pharmacist assures the relationship between the patient and the pharmacy in order to educate the public in the matter of medicine and therapy in general
- 10 By his authority as a specialist and in hi/her direct relationship with the public the pharmacist will discourage the tendency to self-medication
- 11 The pharmacist will discern and choose the best means of cooperation with the physician whenever there appears a misunderstanding of the scheme of treatment and mostly in case of associations of medicines under any form, avoiding the subject's discomfort and the feasible accidents caused by medicines
- 12 The pharmacist has to be in keeping with the therapeutic news at the national and international level and must know the sanitary legislation of the country, regarding pharmacy and medicine, including the international norms to which our country adhered
- 13 The pharmacist must have the Romanian Pharmacopoeia and other treaties already included in specialized literature and the valid catalogue of medicines The pharmacist must have among his/her basic concerns supplying the institution with the traditional and modern specialized literature so as to be able to support his/her whole scientific and practical activity
- 14 The pharmacist who supervises students in pharmacy and the residents will keep a record of the individual professional evolution from a scientific and practical point of view, depending on the terms established by the Faculty of Pharmacy and the Health Department
- 15 Through his/her multidimensional formation adjacent to the many disciplines which contribute to obtaining the medicine, the pharmacist must be scientifically informed with recent and very recent data
- 16 The pharmacist must not be in disloyal competition with the other pharmaceutical institutions
- 17 The pharmacist must keep and guarantee the principles of the profession with competence and consistency
- 18 In practicing his/her profession, the pharmacist will comply with the norms of confidentiality in his/her relationship with the patient

## CHAPTER III

### Practical Requirements of the Rules of the Good Practice of Pharmacy

- 19 In pharmacies, the right to prepare, handle and release medicines is restricted to pharmacists, helped by the staff inferior to them
- 20 In storehouses the management of the whole technical activity must be assured by pharmacists
- 21 The space of the pharmaceutical institutions has to correspond from the point of view of its destination, furniture, apparatuses and dishes to the valid norms set by the Health Department
- 22 The conditions of manipulation, storage and preservation of pharmaceutical products, other products of human use, toxic products and intoxicants and inflammable products must correspond to the valid legislation for each group of products
- 23 Pharmaceutical institutions will respect the norms regarding the inception, storage, checking of the expiration date and of the quality of the medicines during their validity
- 24 Pharmacies and medicine storehouses must be provided with the whole range of basic medicines and, according to the Catalogue of medicines of the Health Department, depending on their profile
- 25 Pharmaceutical substances and finite products released by the storehouses must be accompanied by quality certificates
- 26 Pharmacies will assure the technical conditions for the preparation of medicines and of some products of human use, sterile, eye medicines and of those which imply a therapeutic risk when administered
- 27 Pharmacies will respect the operations regarding tax, labeling, enrolling the major prescriptions in the register, the packing of the major laboratory products
- 28 In every pharmacy there will be a standard of products made according to the valid Romanian Pharmacopoeia
- 29 In the rooms of the pharmacy where medicines are prepared or operations intermediary to the preparation take place, only the pharmaceutical staff of the respective pharmacy is allowed
- 30 Pharmacists must control the quality of the pharmaceutical substances in the pharmacy, keeping an exact record of the documents that certify it

# REGULI DE BUNĂ PRACTICĂ FARMACEUTICĂ

## CAPITOLUL I

### PRINCIPII GENERALE

1 Aplicarea REGULILOR de BUNĂ PRACTICĂ FARMACEUTICĂ urmărește asigurarea unei asistente cu medicamente la cei mai înalți parametri din punct de vedere al aprovizionării cu medicamente a unităților farmaceutice, precum și al întinării garanției de calitate pe care farmacistul trebuie să le pună în slujba omului bolnav

2 Serviciile farmaceutice implică asigurarea unei bune calități precum și educația populației în scopul evitării îmbolnăvirii acestora

De asemenea, REGULILE de BUNĂ PRACTICĂ FARMACEUTICĂ trebuie să urmărească realizarea unui beneficiu rapid și sigur precum și evitarea reacțiilor nedorite la medicament Aceasta presupune o împărțire a responsabilităților și o colaborare perfectă medic farmacist - pacient în scopul unei terapii eficiente

3 Organizarea profesiei de farmaceutice trebuie să acționeze în vederea asigurării unei exigente educații profesionale și a nivelului farmaceutic atât înainte cât și după obținerea dreptului de liberă practică Aceasta presupune ca învățământul universitar farmaceutic să pună un accent deosebit în cadrul stagiului practic al studenților pe modul de folosire și acțiunea medicamentelor precum și pe importanța relațiilor care trebuie să existe între medic și farmacist

## CAPITOLUL II

### CERINȚE GENERALE PRIVIND REGULILE DE BUNĂ PRACTICĂ FARMACEUTICĂ

4 Farmacistul este unicul reprezentant al instituției - Farmacie căruia îi revine toată răspunderea legată de medicament sub orice formă s-ar afla el fiind obligat să respecte principiile tradiționale și reglementările moderne impuse de forurile naționale și internaționale în scopul de a-și conserva autoritatea funcției sale sociale

5 Pentru a-și îndeplini îndatoririle el este obligat să-și însușească pe deplin principiile care promovează etica profesiei sale și să-și asigure probitate și independență profesională fără de care nu-și poate obtine gradul maxim de libertate de gândire și acțiune profesională

6 Farmacistul este un specialist cu opțiuni decizionale, performanțele sale trebuie să stabilească relația pertinentă cu subiectul destinatarului medicamentului

7 Este interzis farmacistului să refuze actul farmaceutic sau o cerere legată de sănătatea subiectului bolnav, în cadrul competențelor sale

8 Farmacistul răspunde de toată activitatea farmaciei în ansamblul ei

9 Farmacistul asigură relația bolnav-farmacie în scopul educației publicului față de medicament și terapeutică în general

10 Farmacistul prin autoritatea sa de specialist și în relația directă cu publicul va combate tendința de autotratament

11 Farmacistul va discuta și alege cel mai bun mijloc de cooperare cu medicul ori de câte ori s-ar ivi o neînțelegere a schemei de tratament și mai ales în cazul asocierilor de medicamente sub orice formă, evitând disconfortul subiectului și eventualele accidente medicamentoase

12 Farmacistul este obligat să fie la curent cu noutățile terapeutice pe plan național și internațional și să cunoască legislația sanitară a țării care se referă la farmacie și medicament inclusiv a normelor internaționale la care țara noastră a aderat

13 Farmacistul este obligat să dețină Farmacopeea Romană în vigoare și alte tratate

intrate deja în literatura de specialitate, Nomenclatorul de medicamente în vigoare Farmacistul va trebui să aibă în preocupările sale de bază dotarea instituției cu literatura de specialitate tradițională și modernă pentru a-și putea spijini întreaga lui activitate științifică și practică

14 Farmacistii care au în supraveghere și formare studenții în farmacie și rezidenții vor tine o evidență a evoluției profesionale individuale din punct de vedere științific și practic în raport de tematica stabilită de Facultatea de Farmacie și Ministerul Sănătății

15 Farmacistul prin poliformația sa contingentă cu multe discipline contribuie la obținerea medicamentului, trebuie să fie informat științific cu date recente și să participe la activități științifice

16 Se interzice ca farmacistul să practice o concurență nelegală, în raport cu celelalte unități farmaceutice

17 Farmacistul are obligația să păstreze și să garanteze principiile profesiei cu competență și consecvență

18 Farmacistul în practica profesiei sale se va conforma normelor de confidențialitate, în relația sa cu pacienții

## LEGIȘLAȚIA RECOMENZILE ÎN PRACTICĂ ALE REGULILOR DE BUNĂ PRACTICĂ FARMACEUTICĂ

19 În farmacie, au dreptul să prepare, să mânuiască și să elibereze medicamentele numai farmaciștii, ajutați de personalul mediu de farmacie

20 În depozite, conducerea întregii activități tehnice trebuie să fie asigurată de către farmaciștii

21 Spațiul unităților farmaceutice trebuie să corespundă din punct de vedere al funcționalității, destinației, dotării cu mobilier, aparatură și veselă, normativelor în vigoare emise de Ministerul Sănătății

22 Condițiile de manipulare, conservare și depozitare ale produselor farmaceutice ale altor produse de uz uman, a produselor toxice și stupefiante a produselor inflamabile trebuie să corespundă legislației în vigoare pentru fiecare grupă de produse

23 Unitățile farmaceutice vor respecta normele privind recepția depozitarea urmărirea termenului de valabilitate, urmărirea calității medicamentelor pe perioada valabilității lor

24 Farmaciile și depozitele de medicamente trebuie să fie aprovizionate cu întreaga gamă de medicamente esențiale și în conformitate cu Nomenclatorul de medicamente al Ministerului Sănătății în funcție de profilul lor

25 Substanțele farmaceutice și produsele finite eliberate de depozite vor fi însoțite obligatoriu de certificate de calitate

26 Farmaciile vor asigura condițiile tehnice pentru prepararea medicamentelor și a unor produse de uz uman, a medicamentelor sterile, oxi-mologiilor și a celor care implică risc terapeutic la administrare

27 Farmaciile vor respecta și urmări normele privind taxarea, etichetarea, înscrisura în registrul de copiere al rețetelor magistrale, ambalarea preparatelor magistrale sau oficinale

28 În fiecare farmacie va fi pus la dispoziție un număr de produse elaborate conform Farmacopeei Române în vederea asigurării necesității de produse

29 În încăperea farmaciei unde se efectuează prepararea medicamentelor sau se execută operațiunile intermediare acestea, are acces numai personalul farmaceutic al farmaciei respective

30 Farmaciștii sunt obligați să efectueze controlul calitativ al substanțelor farmaceutice existente în farmacie ținându-se o evidență exactă a actelor care atestă aceasta

**APPENDIX B**

**LAW ON THE ORGANIZATION AND FUNCTION OF PHARMACY  
(Annex to Ordinul M S nr 2234/1994)**

**Romanian and English Versions**

**Source**            **LUMEA FARMACEUTICA, September 1996, pages 29-37**

**Law on the Organization and Function of Pharmacy**  
**(Annex to Ordinul M S nr 2234/1994)**

**Romanian English Version**

**I The Pharmacy - A Sanitary Institution**

- 1 The pharmacy is the sanitary institution that has as its object of activity the preparation, preservation, release of medicines and other pharmaceutical products for human use, hygienic, cosmetic and technical medical products
  
- 2 According to the nature of the pharmaceutical activity, there are
  - a public pharmacies (open-circuit pharmacies), urban or rural, which assure the ambulatory medical assistance of the population,
  - b hospital pharmacies (closed -circuit pharmacies) which assure the medicine assistance of the patients hospitalized in sanitary institutions (hospitals, sanitariums, etc ) of the Health Department, of other ministries, having their own sanitary network, other institutions or associations

The pharmacies of sanitary institutions - hospitals or polyclinics - are integrated in their organizational structure as departments of the sanitary units The pharmacies belonging to various associations will function independently under the conditions of open-circuit pharmacies

**II Objective of Activity**

The objective of activity of the pharmacy is the preparation, storage and release of medicines of any type and under any form, according to the stipulations of the valid *Romanian Pharmacopoeia* and the international standards, The release of medicines of other pharmaceutical products, technical-medical hygienic sanitary parapharmaceutical authorized and/or recorded by the Health Department will be made, according to its valid provisions

Medicines and other pharmaceutical products which are released by the pharmacy will be accompanied by quality certificates and bulletins of analysis, printed by the laboratories of analysis acknowledged by the Health Department

**III The Pharmacy Staff**

- 1 The staff admitted to work in the pharmacy is
  - a The master pharmacist, and
    - pharmacist,
    - resident pharmacist,
    - student of the Faculty of Pharmacy in practice,
    - pharmacy assistant

The pharmacist must have the valid Romanian Pharmacopoeia and other treaties already included in the literature of this field and the valid catalogue of medicines

The pharmacist supervises students in pharmacy and residents For each of them, according to the themes established by the Faculty of Pharmacy and the Health Department, the pharmacist will keep a record of the evolution and the individual capacities from a scientific and practical point of view The master pharmacist or his/her deputy is responsible for the strictly professional aspects and the representation of the institution to any authorized control, the pharmacist cannot be replaced by another person of another profession

- 7 Through his multiple formation, adjacent to many disciplines that contribute to the obtaining of a medicine, the pharmacist must be scientifically informed with recent and very recent data
- 8 The pharmacist must not practice a disloyal competition
- 9 The pharmacist has the obligation to defend the principles of the profession, to exercise his authority and skills

#### **V Pharmacy Assistant - Duties**

Pharmacy assistants represent the staff subordinate to the pharmacist (they do not hold a degree) He/she is part of the execution in the laboratory, fulfilling a limited number of operations under the pharmacist's supervision (divisions, supervision of the distillery, the kneader, etc , bookkeeping and primary recording, checking of the order and the manufacture series of the medicines in the storehouse, the circulation speed of the medicine and other functions entrusted to him/her by the pharmacist, functions that do not imply the direct responsibility for the consequences of the use of the medicine

#### **VI The Space of the Pharmacy**

- 1 The space of the pharmacy must be adequate from the point of view of the dimensions of the rooms, and its division into compartments must ensure fluency of activity in order to increase the efficiency of the institution
- 2 The public pharmacies must be situated in accessible streets, in adequate buildings with entrance from the thoroughfare
- 3 Since the day these rules came into operation it is forbidden to place pharmacies in blocks of flats, in other unsuitable buildings such as wooden or aluminum booths, garages, etc , as well as to place the open-circuit pharmacies in the precincts of sanitary institutions that have their own pharmacy departments
- 4 The pharmacy must be situated on the ground floor of the buildings

- 5 The rooms of the pharmacy will be functionally linked among them, the dispersion of the rooms inside the same building is not allowed
- 6 The pharmacist's house - in case it is in the same building -- will be completely separate from the rooms of the pharmacy
- 7 The balneary hospitals, in case the pharmacy cannot be situated on the ground floor, it can be placed only on the first floor
- 8 The rooms of the pharmacy will be at least 2.5m in height, and they will be separated by built walls and not by French doors or curtains, etc
- 9 A public pharmacy in urban area will be at least 50 sq meters area, not including the toilets
- 10 The pharmacy in an urban area will have the following rooms
  - a the office - accessible to the public, in which medicines are released, it will be at least 16 sq meters in area, well naturally lighted, air-conditioned and dry,
  - b the reception-room - it is the room for preparation of major prescriptions, it will contain the table for analysis,
  - c the laboratory - it is the room for the preparation of galenic products and the divisions. In this room the apparatuses used for the preparation of medicines will be placed: the kneader, filtration, forms of molding ovules or suppositories, the tablet compressing machine, etc ,
  - d the storehouse - the room in which the medicines will be stored. Separately there will be storing spaces for pharmaceutical substances and inflammable products,
  - e a room of at least 2 x 2 m for preparing the distilled water
- 11 The pharmacy in urban area must be connected to plumbing, sewerage, sinks
- 12 The following rooms, reception, laboratory, distillery, toilets, will have their walls painted in oil or covered with paper (preferably white)
- 13 The floors of the rooms in the pharmacy will be covered depending on their destination, with mosaic, gritstone, parquet, linoleum
- 14 In a rural area the pharmacy will carry on its activity on the ground floor of some buildings adequate for the pharmaceutical activity, organizing its number of rooms and its functionality like the pharmacies in an urban area
- 15 In the pharmacy tidiness and cleanliness will be kept permanently

## **VII The Necessary Minimum Supply**

### **1 Furniture**

The pharmacy will have furniture adequate for the activity in it, according to the destination of each room. In the laboratory and the reception room there will be wooden lockers, continuing the tradition of the profession.

In the reception room there must be a table suitable for the preparation of the major medicines.

The tables for preparation of the galenic products will be papered or covered with stainless steel.

In the storehouse the shelves will be made of wood or metal, obligatorily painted.

### **2 Apparatuses and Necessary Material**

The pharmacy will have a distillery, a refrigerator, a cooker or Bunsen gas burner, containers for measuring volumes, scales for reception, weighing machines or scales for weighing 5 - 10 kg, apparatuses for measuring density, alcohol molds for the preparation of ovules and suppositories, graduated cylinders, test tubes, mortars, porcelain, capsules, Erlenmeyer and Berzelius glasses, funnels, wands, metallic and bone pestles, asbestos sieves, a set of sieves, litmus paper, as well as other utensils necessary for the preparation of the major or galenic medicines.

## **VIII Preservation, Storage Labeling, Release of Medicines**

- 1 Medicines will be preserved according to the stipulations of the Romanian Pharmacopoeia and the international standards.
- 2 Medicines will be stored in therapeutic groups, pharmaceutical forms, according to physical - chemical features and in the order of the manufacture series. Those that have a date limit of validity (an expiring date) will be stored separately. The toxic products and drugs will be stored, according to the stipulations of the valid legislation.
- 3 When conditioned medicines are released, the usage instructions must be specified. Medicines prepared in pharmacy will be released in adequate packing, according to their pharmaceutical form and the characteristics of the medicine. The medicines which are prepared will be labeled according to the indications of Romanian Pharmacopoeia, specifying the way of administration: internal, external, and other necessary precautions: "stir before use", "deadly substance", "expiring date", etc.

## **IX The Timetable of the Pharmacy**

The pharmacy as a sanitary institution for public use must function every working day. The function hours will be established by the County College of Pharmacists or by the Bucharest College of Pharmacists in agreement with the Health Department - The Board of Pharmacy and Medical Apparatuses. On Sundays and legal holidays, the public pharmacies will be closed, excepting those which are on duty, according to the program established by the same college. The county colleges or the Bucharest college will appoint the pharmacies that will keep a permanent program by turns and will establish their schedule.

The timetable established by the College of Pharmacists and approved by the Health Department - the Board of Pharmacy and Medical Apparatuses must be visibly posted and abided.

## **X The Closed-Circuit Pharmacy**

- 1 The closed-circuit pharmacy is part of the sanitary institution within which it exists, and it has, as its objective of activity, the insurance of medical assistance of the hospitalized patients.
- 2 The organization of the space of the pharmacy and its supply with furniture and utensils can assure the rational course of activity, taking into account the destination of each room, the way of communications among them, as well as the conditions imposed by the nature of the activity.

The closed-circuit pharmacy includes the following rooms

- ♦ a space with a desk and adequate supply for the delivery and reception of the registers containing the medical prescriptions
- ♦ a room for the preparation of the registers containing the conditioned medicines
- ♦ a room (the reception room) for the preparation of the major prescriptions
- ♦ a laboratory-room for the preparation of the galenic medicines
- ♦ at least two rooms for the storage of medicines
- ♦ an office for the master pharmacist
- ♦ toilets with showers, locker rooms

In closed-circuit pharmacies, the spaces for the preparation of the sterile solutions will be separated from the rest of the institution, ensuring the functionality of the activity specific for the preparation of the sterile solutions, according to the stipulations of the disposition of the Health Department No. 120/1980.

- 3 The staff of the Closed-circuit pharmacy will include
  - graduate staff (pharmacist)
  - pharmacy assistant
  - auxiliary staff (caretaker, etc.)

The duties of the closed-circuit pharmacy staff are those stipulated by the present rules in the chapter "Responsibilities of the Pharmacist and Pharmacist Assistant"

As a special mention for the master pharmacist or his deputy from the closed-circuit is that of participating and contributing to the report on duty for the permanent improvement of the therapeutic act. He/she will also look after the use of the medicine at the patient's bed, making personal observations related to the patient's reaction to the administered medication.

The master pharmacist will collaborate with the medical management of the sanitary institution to solve the problems of medicine assistance, he is part of the management of the sanitary institution, of the pharmaceutical vigilance, keeping in touch with the Board of Pharmacy and Medical Apparatuses from the Health Department.

- 4 The timetable of the closed-circuit pharmacy is established by the master of the institution together with the manager of the sanitary institution. The medicine assistance in the closed-circuit sanitary institutions is ensured only by the pharmacy of the institution, not allowing inside it the establishment of any branches or working units that have the authority to release medicines for ambulatory treatment.

## **XI General Provisions**

- 1 Being the unique representative of the pharmacy upon whom the whole responsibility concerning the medicine is incumbent, the pharmacist must comply with the traditional and modern settlements imposed by the national and international forums.

The pharmacist is a specialist with abilities to decide, that is why he/she has to re-establish the pertinent relationship with the patient.

The pharmacist is not allowed to refuse for reasons of superficiality, indolence, or lack of skill, a prescription on the request concerning the health of the patient within his competence.

The pharmacist is technically subordinated, in his whole activity, to the Health Department - the Board of Pharmacy and the Medical Apparatuses and the Pharmacy Inspection.

In the rooms of the pharmacy where operations intermediary to the obtaining of the medicine are prepared, stored or carried on, nobody except the hired staff is allowed.

In the window of the public pharmacy nothing can be displayed except for inscriptions that help in protecting the public health, ornamental medicinal plants, traditional objects that highlight the evolution of the profession.

In the pharmacy the carrying on of activities other than those stipulated in the rules on the function of pharmacy is forbidden.

The medicines, cosmetics, technical - medical items, medical optics and other sanitary materials -- are delivered only by detail

- 2 The public pharmacy can release medicines and sanitary materials on registers for medical health units, factories or schools

The working clothes of the staff, sanitary regulated by the Health Department, overall or white suit - must be decent and clean

The tidiness and the hygiene of the premises of the pharmacy must be kept according to the norms established for the sanitary institutions by the Health Department

The recording and legislative documents of the domain of pharmaceutical activity will be perfectly worked up and made known by all the staff of the pharmacy, depending on the training and responsibilities of each member. There will be special records for registration of the prescriptions in the register, the registration of compilations, analysis records for the pharmaceutical substances, of the medicines having an expiring date, of the release of sedatives, which will be initially numbered and sanctioned by the pharmacy Inspection, the registers for the recording of the drugs will be sanctioned by the special division in the home affairs department, and the register for the recording of toxic substances will be sanctioned by the local sanitary Police

The documents and the archives of the pharmacy must be kept in order in the place for this purpose

# REGULAMENTUL DE ORGANIZARE ȘI FUNCȚIONARE

Anexa la Ordinul M S nr.2234/1994

## I FARMACIA - INSTITUTIE SANITARĂ

1 Farmacia este instituția sanitară care are ca obiect de activitate prepararea, conservarea, eliberarea medicamentelor și a altor produse farmaceutice de uz uman, produse igieno-cosmetice și tehnico-medicale

2 După specificul activității farmaceutice sunt

a) farmacii publice (de circuit deschis), urbane sau rurale, care asigură asistența în ambulatoriu cu medicamente a populației

b) farmacii de spital (de circuit închis) care asigură asistența cu medicamente a bolnavilor internați în instituțiile sanitare (spitale, sanatorii, etc) ale Ministerului Sănătății, ale altor ministere cu rețea sanitară proprie, alte instituții sau asociații

Farmacile unităților sanitare - spitale sau policlinici - sunt integrate în structura organizatorică a acestora ca secții ale unităților sanitare. Farmacile aparținătoare diferitelor asociații vor funcționa independent, după regimul farmaciilor de circuit deschis

## II OBIECTIVUL DE ACTIVITATE

1 Farmacia are ca obiect de activitate prepararea, conservarea și eliberarea medicamentelor de orice natură și sub orice formă, în conformitate cu prevederile Farmacopeei Române în vigoare și cu standardele internaționale, eliberarea medicamentelor, a celorlalte produse farmaceutice, tehnico-medicale, igieno-sanitare, parafarmaceutice autorizate și/sau înregistrate de Ministerul Sănătății se va face în conformitate cu dispozițiile în vigoare ale acestuia

Medicamentele și celelalte produse farmaceutice care se eliberează la nivelul farmaciei vor fi însoțite de certificate de calitate și buletine de analiză, emise de laboratoarele de analiză recunoscute de Ministerul Sănătății

## III PERSONALUL FARMACIEI

1 Personalul admis să lucreze în farmacie este

- a) - farmacist diriginte,
- farmacist,
- farmacist rezident,
- studenții facultăților de farmacie în practică,
- asistent de farmacie

b) La libera opțiune a farmacistului diriginte mai pot lucra

- contabil,
- casier,
- îngrijitor, etc

2 Personalul prevăzut la punctul 1 lit "a" va trebui să îndeplinească condițiile de studii de specialitate atestate oficiale corespunzătoare funcției pe care îndeplinesc. Farmacistul și asistentul să poată obține Avizul de liberă practică

3 Farmacistul asigură prepararea și eliberarea medicamentelor, răspunzând de calitatea acestora

4 Farmacia va fi condusă de farmacistul diriginte

5 Încadrarea cu farmaciști și personal auxiliar face la libera apreciere a farmacistului diriginte, asigurându-se în vedere volumul de lucru al unității, precum și capacitatea valorică a fiecărui cadru în parte, pentru buna funcționare al unității

6 Farmacia nu va funcționa nici un moment în lipsa prezenței unui farmacist. În absența farmacistului, farmacia se închide

## IV RESPONSABILITĂȚI FARMACIST

1 Farmacistul răspunde de toată activitatea farmaciei în ansamblul ei

2 Farmacistul asigură relația bolnav-farmacie, scopul educației publicului față de medicament și farmaceutică în general

3 Farmacistul, prin autoritatea sa de specialitate, relația directă cu publicul, va combate tendințele de automedicație

4 Farmacistul va discerne și alege cel mai bun mijloc de cooperare cu medicul ori de câte ori există o neînțelegere a schemei terapeutice și mai ales în cazul asocierilor de medicamente sub orice formă, evitând disconfortul subiectului și eventualele efecte medicamentoase

5 În ideea că fiecare bolnav are sau va avea familia (farmacistul) familiei, se impune o repartizare cazuistică pentru o contribuție reală a farmacistului la aspectele de farmacovigilență

6 Farmacistul este obligat să urmărească noile terapii terapeutice pe plan național și internațional, precum și să cunoască partea din legislația sanitară a țării în care se referă la farmacie și medicament, inclusiv normelor internaționale la care a aderat țara noastră. Farmacistul are în preocupările sale preponderantă dotarea instituției cu literatura de specialitate

nală și modernă pentru a-și putea sprijini întreaga lui activitate științifică și practică

Este obligat să dețină F R în vigoare și alte tratate intrate deja în literatura de specialitate, nomenclatorul de medicamente în vigoare

Farmacistul are în supraveghere și formarea studenților în farmacie și rezidenților, pentru fiecare dintre aceștia, în baza tematicii stabilite de Facultatea de Farmacie și Ministerul Sănătății, va ține o evidență a evoluției și capacităților individuale din punct de vedere științific și practic

Farmacistul diriginte sau farmacistul locuitor, răspunde pe lângă aspectele strict profesionale și de reprezentarea instituției sale față de orice control autorizat, farmacistul nu poate fi substituit de o altă persoană de altă profesie

7 Farmacistul pnn poliformația sa, contingentând cu multe discipline ce contribuie la obținerea medicamentului, trebuie să fie informat științific cu date recente și foarte recente

8 Se interzice ca farmacistul să practice o concurență neloială

9 Farmacistul are obligația să apere principiile profesiei în vigoare, să dovedească autontate și pricepere

## V. ATRIBUȚII ASISTENT DE FARMACIE

Asistentul de farmacie este personal mediu subordonat farmacistului. Este cadru de execuție în laboratorul farmaciei, îndeplinind un număr limitat de operațiuni sub supravegherea farmacistului (diviziuni, supraveghează aparate distilator, malaxor etc, efectuează operațiuni de casă, operațiuni de contabilitate și evidență primară, urmărește ordinea și sena de fabricație a medicamentelor din depozit, urmărește viteza de circulație a medicamentului și alte atribuții încredințate de farmacist, care nu atrag după sine răspunderea directă asupra consecințelor utilizării medicamentului)

## VI SPATIUL FARMACIEI

1 Spațiul farmaciei trebuie să fie corespunzător din punct de vedere al dimensiunii camerelor, iar compartimentarea acestuia să asigure fluenta activității în scopul creșterii randamentului instituției

2 Farmaciile publice trebuie să fie situate pe străzi accesibile, în clădiri adecvate cu intrare din artera de circulație

3 De la data intrării în vigoare a prezentului regulament este interzisă amplasarea farmaciilor în aparta-

mente din blocuri de locuințe, în alte localități vate de tipul barăcilor din lemn, aluminiu, garaje ca și amplasarea farmaciilor de circuit deschis, cina unităților sanitare care au secții de farmacia pni

4 Farmacia va fi situată în mod obligatoriu la parterul clădirilor

5 Încăperile farmaciei vor fi legate funcțional, nefiind permisă dispersarea încăperilor farmaciei în interiorul aceleiași clădiri

6 Locuința farmacistului - în cazul în care se află în aceeași clădire, va fi complet separată de încăperile destinate farmaciei

7 În complexe de sănătate, în cazul în care nu este posibil a fi amplasată la parter, farmacia poate fi amplasată numai la etajul 1

8 Înălțimea încăperilor farmaciei va fi de cel puțin 2,5 m, camerele vor fi separate prin pereți construiți din cărămidă sau perdele, etc

9 Suprafața totală a unei farmaciei publice în mediul urban va fi de minim 50 m<sup>2</sup> excluzând din această suprafață grupul sanitar

10 Farmacia în mediul urban va avea următoarele încăperi

a) oficina - accesibilă publicului, în care se efectuează eliberarea medicamentelor, oficina va avea o suprafață de cel puțin 16 m<sup>2</sup>, va fi bine luminată și aerisită, ventilată și uscată,

b) receptura - este încăperea în care se vor efectua prescripțiile magistrale, în această încăpere se va organiza masa de analize

c) laborator - pentru prepararea produselor și efectuarea diviziunilor. În această încăpere se va amplasa aparatura folosită la prepararea medicamentelor malaxor, filtrare, forme de turnat și dispozitive, mașina de comprimat etc

d) depozit - camera în care se vor conserva medicamentele aflate în stoc. Separat se vor organiza de depozitare a substanțelor farmaceutice inflamabile

e) o încăpere de cel puțin 2x2 m pentru prepararea distilată

11 Farmacia în mediul urban va fi racordată la rețeaua de apă curentă, canalizare,

12 Încăperile cu destinația receptură, distilator, grup sanitar vor avea pereții vopsiți sau după caz acoperiți cu faianță (de preferință)

13 Pardoselile încăperilor farmaciei vor fi realizate în funcție de destinația fiecăreia, cu mozaic sau parchet, linoleum

(continuare din pag 14)

2 In județele cuprinse în Experimentul de Reformă sanitară punctele speciale pentru eliberarea medicamentelor în sistem gratuit și compensat se vor organiza de asemenea ca subgestiuni a celor mai apropiate farmacii din spitale sau policlinici

Directorii de spitale tentonale, împreună cu farmaciștii diriginți respectivi propun direcției sanitare dispensarele unde se vor organiza puncte speciale de eliberare a medicamentelor în regim de gratuitate

3 In comunele în care nu funcționează farmacii sau drogheni și nu se poate organiza punct special de eliberare a medicamentelor compensate, populația se va adresa celei mai apropiate unități farmaceutice care eliberează medicamente compensate

4 Punctele special organizate pentru eliberarea de medicamente în sistem gratuit sau compensat nu vor elibera medicamente contra cost sau pentru bolnavii internați în unități sanitare

5 Direcția de specialitate din Ministerul Sănătății va elabora precizările financiar-contabile necesare aplicării prezentului Ordin

Intarea autontaților (produsă de opinia generala de repudiere a ordinelor aberante) a fost așa de mare încât s-a recurs la tentativa de scoatere a farmaciștilor din sistemul național de asistență cu medicamente. A ieșit în evidență lipsa donției de rezolvare a problemelor și s-a remarcat donția de a pedepsi exemplar (?) o comunitate profesională care a îndrăznit să combată cu argumente pertinente hotărârile guvernamentale și ministeriale

O asemenea perspectivă, în care se încerca substituirea asistenței cu medicamente prin rețeaua farmaceutică existentă cu asistența printr-o rețea paralelă, încadrată cu personal necalificat, este poate cea mai sumbră pentru profesia noastră și este extrem de greu de crezut că un medic, nu un ministru, oricât de rau intenționat, ar putea crede în viabilitatea acestei structuri. Și totuși emiterea unor asemenea stupidități care anulează dreptul farmaciștilor de a-și exercita profesia a fost posibilă

Reunit de urgență în ședință extraordinară, Consiliul Național al Colegiului farmaciștilor redactează următoarea scrisoare deschisă adresată Președintelui României, Parlamentului, Guvernului și opiniei publice

#### SCRISOARE DESCHISA

Farmaciștii din Romania luând act de H G nr 590 din 19 iulie 1996, prin care se stabilește ca farmaciile de circuit închis din spitale și policlinici să elibereze medicamente în regim compensat și gratuit către populație, precum și de normele metodologice de aplicare aprobate cu Ordinul Ministerului Sănătății 1610 din 19 iulie 1996 care permit crearea unei rețele de distribuție a medicamentelor inexistente până în prezent în care vor lucra cadre ce nu au

pregătirea necesară și să se organizeze un sistem național de alarmă asupra pericolului pe care l-ar reprezenta punerea în aplicare a acestor reglementări

Motivul pentru care ne exprimăm îngrijorarea dezacordul sunt următoarele

\* Rețeaua de unități farmaceutice a apărut cu legilor în vigoare prin curajul și inițiativa farmaciștilor necesitate a îmbunătățirii asistenței cu medicamente reprezintă în prezent peste 80% din totalul farmaceutic. Această rețea, până în prezent, a asigurat necesarul de medicamente pentru bolnavii din ambulatoriu farmaceutic depunând eforturi financiare importante, sprijinind cu talul propriu politica de protecție socială a Guvernului

\* Conform H G nr 590 din 19 iulie 1996 activitatea farmaciilor particulare este obstrucționată prin modificarea statutului de organizare și funcționare a farmaciilor de stat și policlinici, care, în concepția actuală vor avea și activitate publică, contrar legilor sanitare și comerciale în vigoare. Considerăm că organizarea unei rețele paralele de unități speciale, care să fie deservite de asistenți medicali și să respecte toate normele profesionale recunoscute pe plan național și internațional

\* Prin aplicarea acestei hotărâri va aduce la cunoștință că bolnavului i se îngrădește dreptul de a și de a primi medicamentele necesare din orice farmacie pe dreptul de a beneficia de recomandările competente ale medicului profesionistului

\* În același timp este îngrădit și dreptul farmaciștilor ca unic specialist în domeniul medicamentului de a și de a exercita profesia pentru care a fost pregătit

Atragem atenția că aplicarea hotărârii menționate din perspectivă, creează mari probleme pentru sănătatea populației care fiind asistați în eliberarea medicamentelor din ambulatoriu necalificat în acest domeniu poate aduce mari probleme de sănătate publică. În aceste condiții, medicamentul devine un pericol pentru bolnav, în loc de remediu

Vă aducem la cunoștință faptul că începând cu Ordinul Ministerului Sănătății din 16 mai 1996 și cu toate celelalte reglementări apărute cu maximă celeritate pe unitate de timp până la H G nr 590 din 19 iulie 1996 Ordinul Ministerului Sănătății 1537 din 15 iulie 1996 Ordinul Ministerului Sănătății 1610 din 19 iulie 1996 Ordinul Ministerului Sănătății 1611 din 22 iulie 1996 și prin normele de aplicare, se distrage atenția populației de la dificultățile de plată către farmaciile pentru eliberarea medicamentelor în regim gratuit și compensat în ultimele luni

În conformitate cu cele expuse, cerem următoarele

\* Abrogarea H G 590 din 19 iulie 1996 și Ordinul Ministerului Sănătății nr 1537 din 15 iulie 1996, 1610 din 19 iulie 1996, 1611 din 22 iulie 1996 și a normelor de aplicare

\* Renunțarea la organizarea de licitații pentru eliberarea de medicamente în regim compensat și gratuit incompatibile cu grija pentru sănătatea omului și cu drepturile de farmaciști

\* Transformarea convențiilor încheiate între unitățile sanitare în contracte ferme cu drepturi bine stabilite pentru ambele părți și în conformitate cu legislația în vigoare

Vă informăm că în condițiile în care nu vom beneficia de audiență directă farmaciștii din România sunt hotărâți să apeleze la forurile internaționale considerând că prin aplicarea H G nr 590 sunt puse în pericol sănătatea populației și profesia de farmacist

23 iulie 1996  
Colegiul Farmaciștilor din Romania

De asemenea nu trebuie uitată tentativa de excludere a Colegiului Farmaciștilor de la autorizarea farmaciilor, realizabilă prin Ordinul Ministerului Sănătății nr 1053/1996, care deschide o porțiță pentru înființarea unor farmacii mai mult sau mai puțin independente (vezi ideea farmaciilor direcțiilor sanitare), care să servească drept pseudosoluție în disputele cu Colegiul Farmaciștilor în problemele controversate

Considerăm că nu mai este cazul să analizăm declarații de genul „așa-zisa asociație a farmaciștilor, condusă de miliardari și oameni politici”, care denotă că dl ministru nu cunoaște nici măcar titulatura asociației profesionale a farmaciștilor

La aproximativ o lună de la momentul efervescenței care a dus la emiterea avalanșei de ordine, cu o înverșunare demnă de o cauză mai bună, ministrul Iulian Mincu își dădea demisia „din motive personale”. În momentul redactării acestui articol, lucrurile nu sunt pe deplin lămurite, iar specialiștii vor fi nevoiți să muncească serios pentru a repara „operele” Ministerului Sănătății din epoca Mincu

După consumarea acestor evenimente, câteva lucruri au reșit în evidență

1 Profesia de farmacist și membrii acesteia vor fi confrunțați în continuare cu provocări și presiuni crescânde din partea difentelor grupuri de interese,

2 Poziția și prestigiul profesiei nu pot fi apărate decât de farmaciști printr-o solidaritate profesională ireproșabilă. Așa cum am mai spus, acest lucru nu este posibil în mod individual, ci doar într-o formă organizată și anume prin intermediul Colegiului Farmaciștilor, la nivel regional și central

Sarcinile grele care revin Colegiului Farmaciștilor nu pot fi lăsate numai pe seama câtorva persoane, bazându-ne doar pe abnegația și devotamentul acestora

Colegiul Farmaciștilor trebuie să devină o structură mult mai puternică din punct de vedere administrativ, organizatoric, profesional, dar mai ales financiar

3 Poziția presei scrise și audiovizuale a fost în general corectă, aceasta relatând cu obiectivitate deru-

larea faptelor și dezavuând în final atitudinea Ministerului Sănătății, unele abordări jurnalistice denotă totuși insuficiența cunoaștere a problemelor din domeniul farmaceutic

Problema principală, care după părerea noastră va exista și în următorii ani va fi decalajul dintre fondurile alocate pentru compensarea / gratuitatea medicamentelor și necesarul corespunzător pentru aceste medicamente. Situația va putea fi controlată doar în momentul în care vom avea asigurări de sănătate funcționale, până atunci transformarea convențiilor în contracte ferme, cu obligații clare pentru ambele părți (inclusiv penalizări pentru întârzierea decontărilor) pare a fi soluția cea mai rezonabilă

Având în vedere numirea unei noi echipe ministeriale căreia îi dorim mult succes ne permitem să sugerăm următoarele

- anularea H G nr 590 din 19 iulie 1996 și Ordinului M S nr 1537 din 15 iulie 1996, nr 1610 din 1 iulie 1996 și nr 1611 din 22 iulie 1996, ca măsuri imediate pentru revenire la normalitate,

- alocarea unui procent corespunzător din PI (de minimum 6%) pentru sănătate,

- alocarea fundamentată de resurse financiare pentru medicamentele eliberate în sistem compensat gratuit,

- readucerea Direcției Farmaceutice la statutul de direcție distinctă, care să se ocupe exclusiv de problema medicamentului în România,

- colaborarea și consultarea Colegiului Farmaciștilor în problemele specifice, ținând cont că acesta reprezintă interesele farmaciștilor ,

- elaborarea unei politici coerente pe termen lung în domeniul medicamentului

Considerăm că îndeplinirea acestor cerințe reprezintă o necesitate obiectivă indiferent de orientarea politica a celor care vor conduce destinele domeniului medical și farmaceutic

Opinia publică și factorii de decizie trebuie să înțeleagă rolul pe care farmacistul îl deține în calitatea asistenței cu medicamente. Fără a ne feri de cuvinte credem că este necesară o campanie susținută pentru a lămurii definitiv pe toată lumea despre monopolul legal pe care farmacistul îl deține în acest domeniu. În toate țările civilizate, monopolul este constituit și este garantat pentru pacient ca asistența cu medicamente este asigurată la cel mai înalt nivel posibil

**APPENDIX C**

**THE "TULIU HATIEGANU" UNIVERSITY OF MEDICINE & PHARMACY CLUJ-NAPOCA**

**INFORMATION ON THE FACULTY OF PHARMACY**

## **FACULTY OF PHARMACY**

The Faculty of Pharmacy was founded in 1948 with a complex structure including teaching staff and laboratories for all fundamental and speciality study disciplines. As an academic institution with training and research competence, it has continued to develop according to the exigencies of the profession and requirements of the pharmaceutical community. After 1989, with the lateral opening of relations with the West, through Tempus, Socrates and Erasmus programs, recognition of the value and European character of our medical and pharmaceutical educational system became evident. New targets were initiated: the computerization of the education process, restructuring of the curricula, the recognition of the importance of quality management, the orientation towards clinical pharmacy and other biomedical disciplines with the aim of the complete integration of the pharmacist within the medical team. Another objective was the alignment of the Romanian education system to contemporary European standards, by adapting the curricula and adopting the transferable credit system as a basis for international mobility grants and prizes for students.

The Faculty of Pharmacy trains specialists for public and hospital pharmacies, drug analysis laboratories, clinical biochemistry, toxicology and sanitary chemistry laboratories, medicinal plant units, drug industry, as well as for market prospecting and launching of new drugs. In the end of the five years of study, after the license examination, graduates obtain a pharmacist degree. At present, there are approximately 500 students, Romanian and foreign citizens.

An important aspect of this faculty is the postgraduate study, which has developed and diversified a major part of it being the residency. Special efforts are made to promote research as a priority in order to ensure the progress of pharmaceutical science including professional improvement. An integral part of this approach is the readiness to extend interdisciplinary cooperation, inclusively with similar teams from abroad. Other goals are the involvement of students and residents in research teams as well as the active support of young people training for their doctorate. The faculty also contains a Department of Analysis and Production, which serves as an education basis as well. In the latter years, didactic and scientific cooperation programs have been established with pharmacy faculties in France, Belgium and Spain. By preserving its valuable national traditions and following a constant process of renewal, the Cluj Faculty of Pharmacy is consistent with

modern initiatives, consolidating its international prestige

## **POSTGRADUATE EDUCATION**

The Medical and Pharmaceutical Postgraduate Education Department at the "Iuliu Hatieganu" University of Medicine and Pharmacy, Cluj-Napoca is part of the Medical Education Center belonging to the Didactic Vice-Rector's Office. Its role is to liaise with doctors, dentists and pharmacists within the university, to ensure continuing professional education, to assist specialization and/or higher specialization by the attainment of competency in specific specialties and also to offer constant personal development in medical fields by short term training courses or advanced studies (master's degree)

The activity of continuing medical education embraces all medical, surgical branches and specialties, preventive and laboratory medicine, dental and pharmaceutical specialties. It is open to doctors, pharmacists and other specialists who want to complete their professional and scientific education, such as biologists, chemists, physicists, informaticians etc. The teaching staff, associated teaching staff from Romania and abroad, as well as reputed specialists from the health network or pharmaceutical industry are all involved in these activities. Access to all university clinics and laboratories, the microproduction workshop and all their equipment - apparatus, multimedia audiovisual aids-, is ensured throughout the education process. The Central University Medical Library provides extensive bibliographic tools, as well as Internet facilities for communication and access to outside information in order to obtain necessary material.

## **RESIDENCY**

Residency is the standard form of postgraduate training in order to become a specialist doctor. The admittance examination for residencies is organized every year at national level. The duration of residency studies is 2 to 7 years, depending on the speciality. The educational programs and the curricula are unique for the whole country and are approved by the Postgraduate Training Center for Doctors and Pharmacists, a body authorized for this purpose by the Ministry of Health. All curricula have been adapted in accordance with the requirements of Higher Education Reform in Romania and its integration with the standards of Western European universities and also in order to create the possibility of applying for training abroad. Over 1452 residents attend this form of postgraduate training.

## **COMPETENCY COURSES**

These are designed as short specialization programs in a more restricted branch derived from a basic specialty or as programs for acquiring medical equipment techniques, which confer the right

and accreditation to practice the acquired knowledge. In order to obtain these, specialists attend a program of courses and practical training with duration of 6 months to 1 year, depending on the competence required.

### **POSTGRADUATE TRAINING COURSES**

These are organized every year, aiming to improve and update professional knowledge acquired during the faculty and the period of training in a specific specialty. The duration of these courses is short, between 1 and 6 weeks. Their subjects and bibliography include various fields, as well as the latest results of medical scientific research, which are transmitted both as theoretical information and practical applications, using the top-level medical equipment of the university. The annual selection of courses attempts to meet the needs of doctors and pharmacists and the actual requirements of current medical care. At the end of this theoretical and practical program, the specialists pass an examination and receive a certificate attesting both their course attendance and their competence.

### **MASTER'S DEGREE**

The master's degree in medical computer science is intended to be a 1 year program of theoretical and practical training, in order to train specialists with interdisciplinary skills (medicine, informatics, epidemiology and biostatistics), necessary for the achievement of the health system reform in Romania.

### **DOCTORAL DEGREE**

As a higher form of specialty education and research, the doctoral degree is organized in two ways: with attendance (4-year duration) and without attendance (6-year duration). In the end of the doctoral program (4-6 years), after the oral presentation of the doctorate thesis and the confirmation of the scientific title by the National Board for the Attestation of University Certificates, Degrees and Titles of the Ministry of National Education, the degree of "Doctor in Medicine" or "Doctor in Pharmacy" is given. In our University there are 56 scientific directors in 36 specialties (30 in medicine and 6 in pharmacy). Over 570 doctors from Romania and abroad are undertaking this training curriculum.

### **HONORARY TITLES - UNIVERSITY AWARDS**

The Senate of the university has the power to award the title of *Doctor Honoris Causa*, *Honorary Member of the Teaching Staff* and *Visiting Professor*. Every year in the Open Days of the Cluj University of Medicine and Pharmacy, these university awards are given including the following: "Iuliu Hatieganu", "Iuliu Moldovan", "Teodor Goina" and "Gheorghe Bilascu".

### **INTERNATIONAL RELATIONS**

The "Iuliu Hatieganu" University of Medicine and Pharmacy, Cluj-Napoca has developed over the years an extensive international cooperation through existing European programs: Tempus, Erasmus, Socrates and Phare, by initiating regional or European mutual research projects, and by introducing the transferable credit system to facilitate student mobility. The Tempus program has evolved at our University in three directions:

THE "IULIU HATIEGANU" UNIVERSITY OF MEDICINE & PHARMACY, CLUJ-NAPOCA

FACULTY OF PHARMACY – CURRICULUM

1st year

1		General and inorganic chemistry
2		Analytical chemistry
3		Pharmaceutical botany
4		Biophysics and radiopharmacy
5		Advanced mathematics and biostatistics
6		Pharmaceutical administration informatics
7		Introduction to pharmaceutical legislation and techniques
8		Foreign languages
9		Physical education
10		Summer electives
11		Botanical fieldwork
12	Optional	Medical terminology

2nd year

1		Analytical chemistry and instrumental analysis
2		Organic chemistry
3		Physical chemistry
4		Microbiology, virology parasitology
5		Pharmaceutical administration informatics
6		Cell biology
7		Hematology - immunology
8		Anatomy, physiology, physiopathology
9		Foreign languages
10		Physical education
11		Summer electives
12	Optional	Introduction to research and documentation Mycology

3rd year

1		Pharmaceutical chemistry
2		Pharmacognosy and phytotherapy
3		Pharmaceutical technology
4		Pharmaceutical biochemistry and clinical laboratory
5		Environmental chemistry and hygiene
6		Marketing
7		Technical-medical products
8		Psychology and interpersonal relations
9		Foreign languages
10		Summer electives
11	Optional	Protein products

**4th year**

- |   |          |   |
|---|----------|---|
| 1 |          | Therapeutical chemistry                                       |
| 2 |          | Industrial pharmaceutical technology                          |
| 3 |          | Biopharmacy and pharmacokinetics                              |
| 4 |          | Toxicology  |
| 5 |          | Pharmacodynamics  |
| 6 |          | Biological drugs and biological drugs control                 |
| 7 |          | Clinical pathology and drug therapy                           |
| 8 |          | Summer electives  |
| 9 | Optional | Drug metabolism<br>Toxic plants<br>Nutrition and diet therapy |

**5th year**

- |   |          |  |
|---|----------|--|
| 1 |          | Drug industry and pharmaceutical biotechnologies   |
| 2 |          | Drug control   |
| 3 |          | Pharmaceutical legislation and management  |
| 4 |          | Clinical pharmacy  |
| 5 |          | Dermopharmacy and cosmetology  |
| 6 |          | Technology of homeopathic remedies and veterinary drugs  |
| 7 |          | Advanced course in pharmaceutical sciences   |
| 8 |          | Practical seminar  |
| 9 | Optional | Electives in drug stores, pharmaceutical industry, laboratories<br>Pharmaco-vigilance<br>History of pharmacy |

**APPENDIX D**

**ROLE OF THE PHARMACIST IN PRIMARY HEALTH CARE**

**COURSE SYLLABUS**

# COURSE SYLLABUS

"TULIU HATIEGANU"  
UNIVERSITY OF MEDICINE AND PHARMACY

*IN COLLABORATION WITH*

HOWARD UNIVERSITY CONTINUING EDUCATION  
THE PACE CENTER

**PRIMARY HEALTH CARE DELIVERY AND THE ROLE OF THE PHARMACIST**  
COURSE DATE April 20 – 30, 1999

Faculty Dr Marius Bojita, Dr Rosalyn C King, Dr Felicia Loghin,  
Class Dates & Hours (2 hours per session, 3 sessions per week, 12 hours )

## CONTENTS OF SYLLABUS

Course Description and Goal  
Course Learning Objectives  
Core Competencies Stressed  
Instructional Strategies  
Required & Reference Texts and Periodical Readings  
Course Organization and Grading  
Study Hours  
Week and Topic Outline

## COURSE DESCRIPTION AND GOAL

This is an integration course for the senior pharmacy student. It provides students with the requisite knowledge and skills to understand the concepts of health care system delivery and facilities, health care service, health care policy, disease prevention, health promotion and health education, health care outcomes, the rational use of drugs in health care systems, communications with health professionals on drug therapy, communication with patients on the wise use of medicines, and operations research in health care delivery. Students will have the opportunity to explore the potential of the role of pharmacists in primary, secondary or hospital based care.

The goal of this course is to provide the student with knowledge of the structural features and operational characteristics of a dynamic health care system including key concepts in organized care, models, and jargon, along with relevant social, economic, cultural and historical contexts.

## **COURSE OBJECTIVES**

At the end of this course, the student is expected to be able to

- 1 analyze the current services that pharmacists provide in health care delivery and health care facilities in Romania,
- 2 delineate the decision-making processes of health care organizations,
- 3 compare and contrast primary health care (PHC) approaches used in Romania to those of the World Health Organization (WHO), Western Europe, North America, and systems from various other regions of the world, including developing countries,
- 4 list the components and general themes of PHC (including health promotion, disease prevention and health education),
- 5 define the roles, responsibilities, and functions of the pharmacist in community pharmacies and organized health care delivery settings,
- 6 indicate skills that pharmacists need for selected PHC interventions,
- 7 define the terms "medication history," "monitoring drug therapy," "referral" and "drug information" and "rational drug use,"
- 8 develop a pharmacy-based, PHC intervention project for a community pharmacy or an organized health care setting,
- 9 structure medicine-related communications which are supportive of PHC goals (including drug-related health information) to individual patients, community groups and other members of the health team – especially, physicians and nurses,
- 10 outline how pharmacists can contribute to operations research via drug use investigations, data collection and analysis,
- 11 communicate health needs of patients – especially women and children – to other segments of the health delivery system via a referral process, and
- 12 discuss and rate interventions presented in class

## **CORE COMPETENCY STRESSED**

Knowledge and Understanding of the Dynamics of the Health Care Delivery Environment in Romania and Approaches for Greater Involvement of Pharmacy Personnel in Achieving Health Outcomes

## **INSTRUCTIONAL STRATEGIES**

This course is designed to enhance the development of strategic thinking skills by helping the student to understand the challenges and opportunities that pharmacists face in attempting to define and contribute to health care services and patient outcomes

The method of instruction for this class will be lecture, lecture-discussion, case analysis, role play and in-class student presentations. Students are encouraged to participate in all related classroom discussions and to be punctual in their regular class attendance. Each student is responsible for all required readings and other assignments

**REQUIRED READING**

- F Mullan, "The 'Mona Lisa' of Health Policy Primary Care At Home and Abroad," Health Affairs - Volume 17, Number 2
- V Moffat, "Health for All and The Pharmacist," International Pharmacy Journal vol 2, No 2, 1988
- Declaration of Alma-Ata, International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978, World Health Organization
- (WHO TEXT ON PRIMARY HEALTH CARE - IN ROMANIAN)

**REFERENCE READINGS**

- *(Insert here full title of proceedings from UMF- World Vision PHC Conference of 1996)*
- Additional Materials Will Be Given In Class As Handouts

**COURSE ORGANIZATION & GRADING**

The course will be organized into 2 hour sessions which will be held 3 times per week During the third session, the class will be divided into Project Groups Each group will participate in preparing a pharmacy-based PHC intervention that will be presented in class during the fifth session

The grade for this course will be based upon the following

Class Participation	15%
Examination	50
In-class group presentation	30
Other Exercises (Written and Oral)	<u>5</u>
Total	100%

The course examination will be given in class on the last session The University plans to give credit to those students who successfully complete the course according to University policy A joint certificate will be given to those non-students who complete all requirements including turning in assignments

**STUDY HOURS** It is estimated that each student will spend a minimum of one to two hours of study time per class hour for this course

UMF Course Number  
HUCE Course Number 175-040-01 SP 99

**PRIMARY HEALTH CARE (PHC) DELIVERY AND THE ROLE OF THE PHARMACIST**  
(April 20 - 30, 1999)

SESSION #	TOPIC OUTLINE – <i>Perspectives on Primary Health Care</i>	
1 (2 Hrs)	<b>Bojita (1 Hr)</b>	Introductions and Course Overview Organization of Health Services in Romania The System and its Policies The Process
	<b>King (1 Hr)</b>	Overview, Definitions and Approaches to Primary Health Care The WHO View Western Europe including EU and PHARE initiatives North America (United States and Canada) Other World Regions and Developing Countries
2 (2 Hrs)	<b>King (2 Hrs)</b>	Integrating the Knowledge and Functions of the PHC Team Members Strategies and Approaches in Health Education Strategies and Approaches in Health Promotion Strategies and Approaches in Disease Prevention  <i>Overview of Selected Tasks of the Pharmacist in PHC</i>
3 (2 Hrs)	<b>King (2 Hrs)</b>	Medication History & Monitoring Drug Therapy, Providing Drug Information to Patients via Counseling, Providing Drug Information to Community Groups & to Other Health Professionals
4 (2 Hrs)	<b>Loghin (1 5 Hrs)</b>	Drug Use Investigations, Data Collection and Analysis



	<b>King (0.5 Hr)</b>	Referral Process Developing Interventions
5 (3 Hrs)	<b>Bojita, King, Loghin</b>	In-class Presentation of Interventions (Community or Organized Health Care Pharmacy) Monitoring Drug Therapy Maternal and Child Health/Family Planning Health Education, Health Promotion/Disease Prevention Campaign Assuring Compliance in Chronic Disease Therapy Drug Use Investigations
6 (1 Hr)	<b>Bojita, King, Loghin</b>	Examination and Closing



APPENDIX E

LUMEA FACMACEUTICA

"DEAR PATEINT" BROCHURE

2



# INDUCTION

Anul IV • nr. 2 (16) • februarie 1999

L 4 11 18 25  
M 5 12 19 26  
M 6 13 20 27  
J 7 14 21 28  
V 1 8 15 22 29  
S 9 16 23 30  
D 3 10 17 24 31

## Dragă pacientule,

**F**armacia, ca ștună medicală și ca instituție sanitară își găsește împlinirea prin a-ți pune la dispoziție produsul farmaceutic de care ai nevoie și prin alte servicii, mai puțin cunoscute de tine, dar care ameliorează starea ta de sănătate

**U**nul dintre acestea este informarea ta asupra medicamentului, fie când îl primești în farmacie, la un moment dat, sau în acest mod, al comunicării scrise

**N**oi, farmaciștii, încercăm astfel să venim în întâmpinarea ta, cu răspunsuri la întrebări pe care ți le pui în legătură cu medicamentul, cu serviciile pe care farmacistul dorește și este dator să ți le ofere, înspre confortul și binele tău

**Î**n acest prim pliant, care deschide seria unei colaborări benefice, ne propunem să-ți prezentăm medicamentul, din punct de vedere al activității sale și reglementările naționale și internaționale pe care farmacistul trebuie să le respecte pentru a-ți proteja sănătatea

**D**acă ai propuneri privind temele viitoare ale pliantului nostru, privind medicamentele sau regimul tău de viață cotidiană, scrie-ne pe adresa Colegiul Farmaciștilor str Pasteur nr 4, 3400 Cluj-Napoca

L 1 8 15 22  
M 2 9 16 23  
M 3 10 17 24  
J 4 11 18 25  
V 5 12 19 26  
S 6 13 20 27  
D 7 14 21 28

L 1 8 15 22 29  
M 2 9 16 23 30  
M 3 10 17 24 31  
J 4 11 18 25  
V 5 12 19 26  
S 6 13 20 27  
D 7 14 21 28

L 5 12 19 26  
M 6 13 20 27  
M 7 14 21 28  
J 1 8 15 22 29  
V 2 9 16 23 30  
S 3 10 17 24  
D 4 11 18 25

L 3 10 17 24 31  
M 4 11 18 25  
M 5 12 19 26  
J 6 13 20 27  
V 7 14 21 28  
S 1 8 15 22 29  
D 2 9 16 23 30

L 7 14 21 28  
M 1 8 15 22 29  
M 2 9 16 23 30  
J 3 10 17 24  
V 4 11 18 25  
S 5 12 19 26  
D 6 13 20 27

### Antibiotice

Numai medicul, în urma consultății și analizelor pe care vi le efectuează poate decide CARE antibiotic vă este potrivit și în ce DOZĂ!

### Somnifere, sedative și calmante

Fiind medicamente care dau dependență și care au numeroase efecte nedorite, medicul decide care anume vă este potrivit și în ce DOZĂ!

### Medicamentele aparatului cardiovascular

Diversitatea mare a medicamentelor existente în acest domeniu și specificul bolii necesită o conducere supravegheată a tratamentului de către medicul dvs

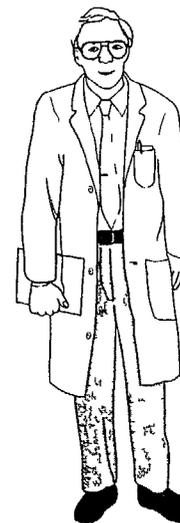
### Hormoni

Sunt medicamente care se adresează unor echilibre sensibile ale organismului dvs, tratamentul se face sub stricta supraveghere a parametrilor biochimici și condus, bineînțeles, de medicul dvs curant

### Analgezice (calmante) puternice

Unele din ele fiind situate la granița dintre analgezice obișnuite și stupefiante, nu apelati la aceste medicamente decât în cazuri extreme și sub stricta supraveghere a medicului dvs, pe toată durata tratamentului recomandat. Atenție!

Dau dependență!



Este în interesul sănătății dvs să colaborați în primul rând cu medicul când aveți nevoie de un astfel de tratament. Nu abuzați de aceste medicamente și nu repetați tratamentul din proprie inițiativă! Medicul vă prescrie cele mai potrivite medicamente bolii și individualității dvs iar farmacistul vă va furniza medicamentele și informațiile referitoare la administrarea lor

între risc și beneficiu-

Substanțele chimice continute în medicamentele moderne sunt foarte active, chiar periculoase, dacă nu sunt utilizate rațional. De aceea, din punct de vedere al riscului pentru sănătate, medicamentele se împart în două categorii:

#### A

Cele care se eliberează numai cu rețetă prescrisă de medic (în regim necompensat sau gratuit). Acestea sunt medicamentele a căror utilizare trebuie supravegheată îndeaproape de medic sau farmacistul dvs. Ele au nu numai beneficiu pentru sănătatea dvs, dar prezintă riscul, prin efectele lor secundare, doze necorespunzătoare, asocierile cu altele medicamente sau nerespectarea duratei de tratament

#### B

Cele care pot fi eliberate fără rețetă, stabilite prin lege în fiecare țară (la noi, pr

L 5 12 19 26  
M 6 13 20 27  
M 7 14 21 28  
J 1 8 15 22 29  
V 2 9 16 23 30  
S 3 10 17 24 31  
D 4 11 18 25

Ordinul Ministerului Sănătății nr 361/1996) și care sunt cunoscute internațional sub denumirea de "OTC". Ele nu reprezintă un risc major pentru sănătatea dvs și farmacistul le poate recomanda în afecțiuni banale și pentru tratamente de scurtă durată



Dacă farmacistul refuză să vă elibereze un medicament din categoria A la simplă cerere, nu vă supărați! Nu o face decât pentru a vă proteja sănătatea în contextul respectării legii. Recomandând consultarea unui medic vă ajută tot în acest sens!

L 2 9 16 23 30  
M 3 10 17 24 31  
M 4 11 18 25  
J 5 12 19 26  
V 6 13 20 27  
S 7 14 21 28  
D 1 8 15 22 29

L 6 13 20 27  
M 7 14 21 28  
M 1 8 15 22 29  
J 2 9 16 23 30  
V 3 10 17 24  
S 4 11 18 25  
D 5 12 19 26

L 4 11 18 25  
M 5 12 19 26  
M 6 13 20 27  
J 7 14 21 28  
V 1 8 15 22 29  
S 2 9 16 23 30  
D 3 10 17 24 31

Antiinflamatoare și calmante usoare (Aspirină, Acid niflumic, Fasconal, Saridon, Algocalmin, Paracetamol)

Dezinfectante usoare pentru uz intern și extern

Antitusive (Bromhexin, siropuri de tuse, Trecid)

Pansamente gastrice

Laxative ușoare

Vitamine

Minerale

Îndulcitori artificiali

Fitoterapeutice (unele preparate din plante, ceaiuri)

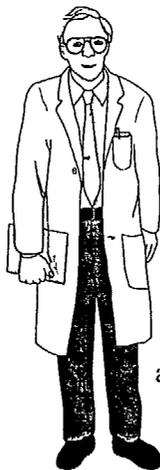
Preparate pentru înlesnirea digestiei (fermenți, coleretice)

L 6 13 20 27  
M 7 14 21 28  
M 1 8 15 22 29  
J 2 9 16 23 30  
V 3 10 17 24 31  
S 4 11 18 25  
D 5 12 19 26

Preparate de uz extern

• unguente și creme (antiinflamatoare, antivaricoase, dezinfectante)

• soluții (picături pentru nas, pentru urechi, pentru ochi)



Aceste medicamente sunt considerate mai puțin toxice pentru sănătatea dvs. Ele nu reprezintă riscuri terapeutice și pot fi solicitate în farmacie, fără rețetă.

Tineți legătura cu farmacistul dvs când urmați un astfel de tratament. Dacă simptomele persistă, adresați-vă medicului dvs!

### Întrebări și răspunsuri despre profesia farmaceutică

V-ați gândit vreodată că farmacia este în primul rând o instituție de sănătate publică și nu comercială?

### FARMACIA = UN SPAȚIU DE SĂNĂTATE

Când luați un medicament, vă întrebați câtă muncă (ceretare, producție, distribuție și eliberare) este înglobată în acest comprimat sau într-o linguriță de sirop?

### FARMACISTUL = SPECIALIST ÎN DOMENIUL MEDICAMENTULUI

V-ați întrebat care este aria preocupărilor farmacistului, ca responsabil de sănătatea dvs, în afara aceleia de a vă elibera medicamentul de care aveți nevoie?

### FARMACISTUL = UN PRESTATOR DE SERVICII DE SANATATE

Conform conceptelor promovate azi de organizații mondiale ale sănătății, în sistemul de sănătate, FARMACISTUL are următoarele atribuții:

informarea pacientului privind utilizarea rațională a medicamentelor  
prepararea și fabricarea la scară mică a medicamentelor

eliberarea medicamentelor cu și fără prescripție medicală, în conformitate cu prevederile legale

supravegherea și raportarea consumului de medicamente

promovarea sănătății în campanii organizate, naționale și proprii al Colegiului Farmaciștilor

*Acest pliant este un început. Un început în comunicarea cu tine, pacientule, pentru sănătatea și binele tău.*

*Acum, când ne apropiem de sfârșitul mileniului, sub deviza internațională "Anul 2000 Sănătate pentru toți", fiecare dintre noi trebuie să știe mai mult despre sine, pentru un mod de viață cât mai sănătos.*

Colegiul Farmaciștilor str Pasteur nr 4  
3400 Cluj-Napoca