

ROMANIAN PHARMACY IN DIFFERENT POLITICAL REGIMES (1948-2013)

VALENTINA SOROCEANU, CRISTINA RAIS*,
ADRIANA-ELENA TĂEREL

*“Carol Davila” University of Medicine and Pharmacy, Bucharest,
Department of Management, Marketing and History of Pharmacy*

**Corresponding author: cristina_rais@yahoo.com*

Abstract

The current study aims to cover two main aspects. First we analyzed the development of the Romanian pharmaceutical legislation. Secondly, we evaluated how the Romanian pharmacy was influenced by these legislative changes.

Two other previously published studies, followed the same theme regarding the progress of the pharmaceutical legislation, from the very first health law (1874) up to 1948. However, the current study aims to analyze the development of the pharmaceutical regulation from 1948 up to present. The results show that the quantity of laws is not important, but the power and the manner in which they are applied into practice. In the same time, a positive evolution is observed with respect to specific quantitative indicators in the pharmaceutical assistance of the population, although a deficit in quality is clearly revealed.

Rezumat

Prin studiul actual ne-am propus pe de o parte să evidențiem evoluția legislației farmaceutice pe teritoriul țării noastre și pe de altă parte să urmărim cum a fost influențată farmacia românească de aceste schimbări legislative.

Având în vedere faptul că două lucrări publicate anterior au prezentat evoluția legislației farmaceutice de la prima lege sanitară (1874) până în 1948, în această lucrare ne propunem să analizăm perioada de la 1948 – până astăzi. Rezultatele demonstrează că nu numărul reglementărilor legale este important, ci tăria lor și modul de aplicare în practică. Deasemenea, se constată o evoluție pozitivă a anumitor indicatori cantitativi privind asistența farmaceutică, dar din punct de vedere calitativ asigurarea asistenței farmaceutice a populației este încă deficitară.

Keywords: nationalization, rural pharmacies, average indicator, hospitals pharmacies, legislation.

Introduction

Along its historical evolution, the pharmacy, as the science of preparation, handling, preservation and distribution of drugs, underwent several stages corresponding to the economic, technological, scientific and social characteristics of those times. It recorded periods of both ascension and stagnation as well as regress.

Regardless of the historical era, the pharmacy represented “a sanctuary of science, a laboratory of research and artisanal production of medicines, a link to the healthcare system, while the pharmacists, bearers of the science and culture of the respective ages, were considered valuable elements of healthcare and society, contributing to the cultural, scientific and socio-economic progress of the latter” [3].

From the first documented authentication of a pharmacy in 1494 in Romania (Sibiu), to the first healthcare law (1874), professionals have striven to meet the most demanding requirements for pharmaceutical practice along with the national and international standards. Pharmacy premises began to get better equipment, most of them being furnished with custom items ordered abroad. After the Second World War and following the change of political regime in Romania, there have been enormous changes in the pharmaceutical domain, some of the consequences of these changes being discussed in this paper. We will also review the way in which the changes produced in the Romanian society by the historical events from December 1989 have influenced the pharmaceutical activity.

The historical and legislative setting of the evolution of pharmacy in Romania from nationalization to present times.

The 119/1948 Law of Nationalization for industrial enterprises, banking, insurance, mining and transport is the law that makes the transition from Romanian capitalist economy to centralized economy. The same law implied that all land and subsoil resources that were not owned by the state at that time were to be nationalized. 1060 enterprises have been given to the state, recorded in the law and listed in its 28 appendices by activity fields. According to this law (Cap I, art 49) enterprises producing perfumery and cosmetics, solvents, fragrances, essential oils and pharmaceutical laboratories have also been nationalized – list 19 (29 entries – 24 in Bucharest, 2 in Arad, 2 in Oradea and 1 in Cluj) [1].

On April 2nd 1949, Decree 13 ratified by law 716-1948, also stipulated the nationalization of deposits, medical analysis laboratories, pharmacies and drugstores. The medical units are owned by the state as “ common goods of the people, free of any charges, being administered by the Ministry of Health” [10].

Ministry of Health Circular No. 47332 in April 26th, 1956 specifies that state pharmacies are factors of national public healthcare and protection, therefore need to take part in the population’s health education, including information about hygiene within communities and the use of pharmaceutical products as well as other sanitary ware.

The 59299/50 Decision of the Ministry of Health approves The Regulation for organization of pharmacies in Romania, which sets out the role of socialist pharmacy and its contribution to public healthcare. The regulation establishes the classification of pharmaceutical units as follows: state public pharmacies; clinic, hospital, nursing and university pharmacies; institutions and enterprises pharmacies and rural pharmacies [3].

The experienced pharmaceutical staff included: chief pharmacist, main pharmacist, urban pharmacist, intern pharmacist and countryside pharmacist.

The same regulation also introduces measures to improve the quality of medicines and adequate supply according to consumption, and separate chapters are reserved for issues management, medicine handling and preservation, preventive controls in order to impend preparation errors.

Another decision 70138/June 1950 founded the Medicines Commission with numerous responsibilities out of which we mention: establishing the therapeutic products list, assessing the therapeutic value of drugs, serums, vaccines, approval of their use in practice etc. Starting with 1960, the endorsement of new medicines introduction on the market is assessed to the State Control of Drug and Pharmaceutical Research (ICSMCF).

The most important regulations influencing the pharmaceutical domain in this period are shown in Tables I and II.

Table I
Health-pharmaceutical legislation in the socialist/communist regime (1948-1990)

Nr. crt.	Regulation	Changes / Additions	Regulation domain
1	Law no.119/11 June 1948 Concerning enterprises regulations – Official Monitor (OM) no. 133 bis/11 June 1948		Nationalization of medicine production
2	Decree 134/1949 regarding the nationalization of urban health-pharmaceutical enterprises Official Bulletin (OB) no. 15 bis/2 April 1949	Official Bulletin no. 20 in 21 April 1949, page 144, and No. 31 in 21 May 1949, page 212.	
3	Decision 59299/1950 for the Organization and functioning of pharmaceutical units	Orders no.174/1953 and 361/1955.	XIII – chapters (105 art.)
4	Decision 70138/1950 of the Ministry of Health		Medicines Commission
5	Decree 418/1953 – Nationalization of rural private pharmacies. Official Bulletin no. 16/1953	Order no. 255/1953 Verification of medicines taken from private pharmacies in order to be nationalized	Nationalization of rural private pharmacies.
6	1978-Law no.3 concerning population healthcare implementation / <i>OB no. 54 10 July 1978</i>	IX Chap. - 189 art.	C.III,(art 72)/ pharmaceutical staff C VII. Medicines (Art.156/172)

Table II
Health-pharmaceutical legislation between 1990 - 2013

Nr. Crt	Regulation – published	Changes	Regulation domain
1.	Law no.31/1990 concerning trading companies O.M. P.I no. 126 /1990	Amended and supplemented by: - Law 164/2006 and 441/2006 - Government Emergency Ordinance (GEO) no. 82/2007, 52/2008, 43/2010 and 54/2010	Partially pharmaceutical
2.	Governmental Decision (GD) no.15/1990 concerning the implementation of pharmaceutical companies SA O.M.PI no.8/1991.		Entirely pharmaceutical
3.	Order of Health Ministry no.560/30.04.1991 Authorization rules on the establishment and operation of pharmaceutical units.		Entirely pharmaceutical
4.	Order of Health Ministry no.141/1992 for the Amending and supplementation of Order of Health Ministry no.560-1991	For the Amending and supplementation of Order of Health Ministry no.560-1991	"
5.	Order of Health Ministry no.2234/1994 1992 for the Amending and supplementation of Order of Health Ministry no.141/1992 <i>M.O.P I no.44/1995 p 4-8</i>	For the Amending and supplementation of Order of Health Ministry no.141 din 1992	"
6.	Order of Health Ministry no.201/1999 1992 for the Amending and supplementation of Order of Health Ministry no.2234/1994 <i>M O, P, I, no. 278 in 17 June 1999,</i>	For the Amending and supplementation of Order of Health Ministry no. 2234/1994	"
7.	Order of Health Ministry no.626/ Authorization rules on the establishment and operation of pharmaceutical units <i>M O. P I no. 629 in 08/10/2001</i>		"
8.	Law no.95/2006 concerning the Healthcare Reform – <i>O.M. of Romania, P I, no. 391 in 5 May 2006</i>	<i>42 changes up to 2013 done through laws or governmental emergency ordinances.</i>	Title XIV-pharmacist profession Title XVII, Medicin
9.	Law no.266/2008 concerning the establishment and operation of pharmacies and drugstores in Romania OM, Part I, no.765/2008	Law no. 236/2009 for amending Law no. 266/2008, published in OM, Part I, no. 404 in 15 June 2009 GEO no.130/2010 , GEO no.18/2011	Pharmaceutical

From the above tables, one can notice that, during the nationalization up until the events in December 1989, there were only few rules for the pharmaceutical practice. After 1990, regulation of this area of activity has

seen numerous rules, especially minister orders, without having a law of pharmacy up until 2008.

In 1948, in Romania there were about 1,110 private pharmacies in cities, a couple of hundreds of pharmacies in rural areas and 236 pharmacies belonging to the Health Ministry and Health Insurance company. The drug market abounded in various trade names, many of which were less justified therapeutically. Following World War II, the situation became unmanageable and medicine exploitation registered a high increase. This situation called for rationalization of drugs and their typing in 1948. The Commission authorized by the Ministry to solve this task eliminated over 90% of more than 4700 specials on the market at that time. There remained in use 407 specialties (264 indigenous products, 52 sera and 91 imported products) [1].

Starting with 1990 up until 2013, anyone wishing can open a pharmacy in Romania under minimum conditions: hiring a chief pharmacist, possessing an area of at least 50 square meters under legal form. It is therefore easy to understand why the number of pharmacies has reached over 7000 nowadays, hospital pharmacies excluded.

Figures 1-3, the situation of pharmacies, pharmacists and residents in counties during the studied period is presented, as well as the evolution of the pharmacy/population indicator from 1948 to present days.

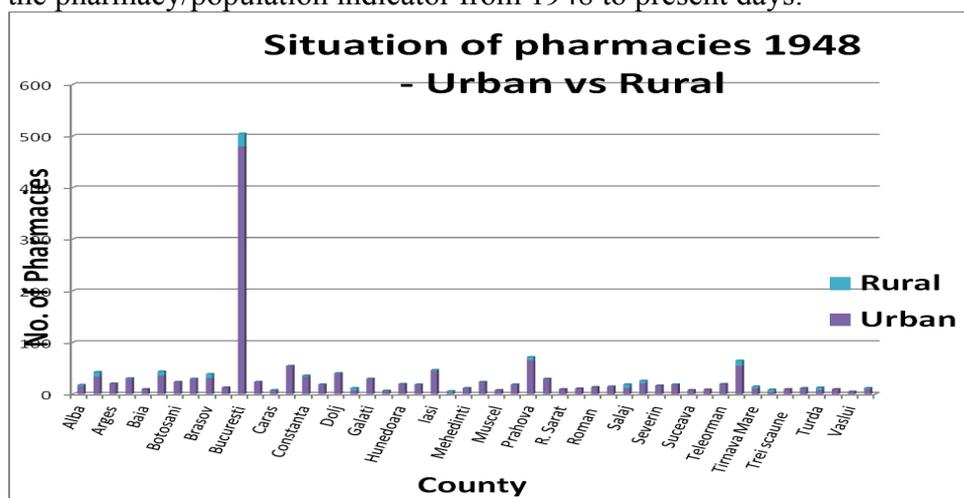


Figure 1

Situation of pharmacies and population in counties in 1948. National average indicator was 1 pharmacy for 14,299 inhabitants. However, there were major differences between urban and rural areas, and some of those areas lacked pharmaceutical assistance (e.g. Ilfov county had only 1 pharmacy for 72,187 inhabitants) [3]. In Bucharest there was 1 pharmacy to approx. 2,000 inhabitants, in the urban environment 1 pharmacy to 2,500 residents, and at the countryside there was 1 pharmacy to tens of thousands of people.

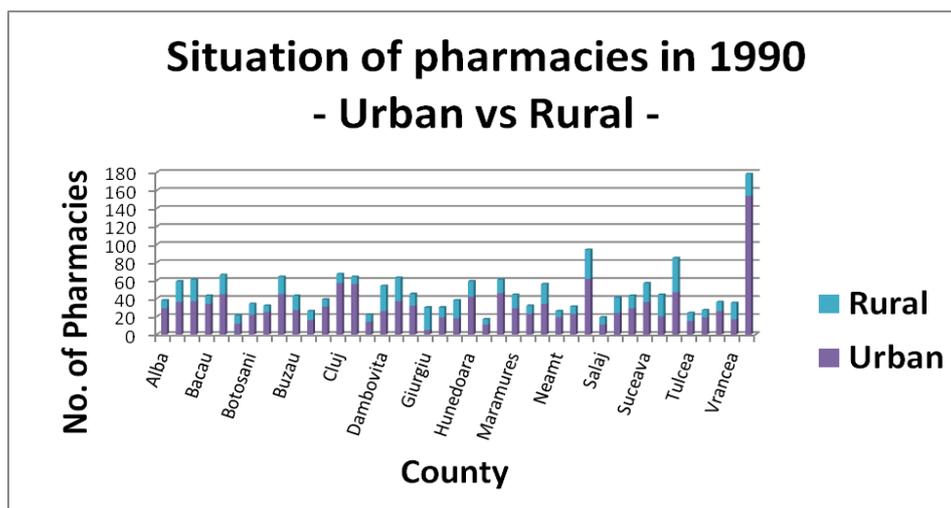


Figure 2

Situation of pharmacies and population in counties in 1990

National average indicator pharmacy/inhabitants was 11,913.

The lowest pharmacy/inhabitants indicator – 1 pharmacy for 17,000 inhabitants in the counties of Ialomita, Neamt, Olt.

The best pharmacy/inhabitants indicator – Arad with 1 pharmacy for 8,615 inhabitants followed closely by Harghita and Hunedoara with 1/9,000.

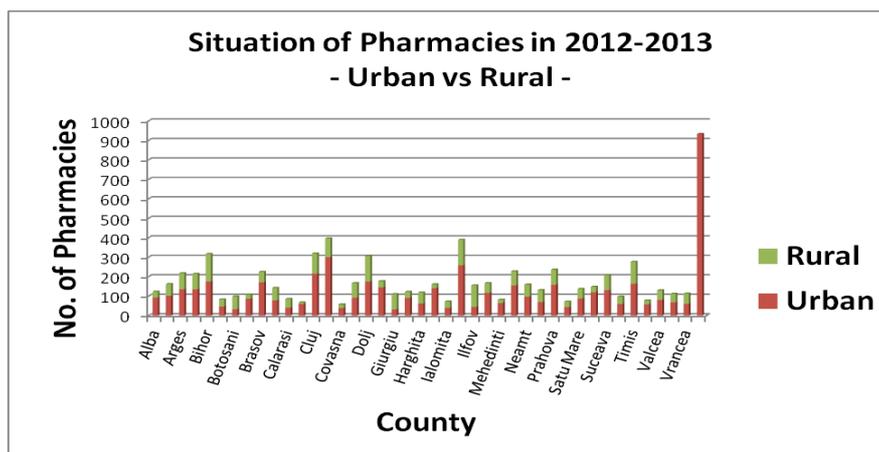


Figure 3

Situation of pharmacies and population in counties in 2012-2013

Current national average pharmacy/inhabitants indicator = 2,781

The best pharmacy/inhabitants indicators, meaning less than 2000 inhabitants/pharmacy were in the following counties: Constanta (1/1,828), Bihor (1/1,869) followed by Bucharest, Ifov, Iasi (approx. 1/2,000 inhabitants).

The lowest pharmacy/inhabitants indicator were in the following counties: Caras-Severin (1/4,618), Botosani (1/4,516), Teleorman (1/4,061) and Vaslui (1/4,014 inhabitants).

Table III

Indicator evolution for the studied period (1948 - 2012/2013) [4,5,6,7,8,9]

Year	Unit No.	Urban	Rural	Pharm.	Population			Ind.
					Total	Urban	Rural	
1948	1110	672	438	2786	15,872,624	3.713.139	12.159.485	14,299
1990	1948	1310	638	6286	23,206,720	12,608,844	10,597,876	11,941
2012/13	7705	5265	2440	16000	21,431,298	11,798,735	9,632,563	2,781

A first analysis of the data in Table III would suggest that Romanian pharmacy has registered steady progress from 1948 to present. The number of pharmacies has increased, as has the number of professionals in the domain, and the indicator pharmacy/population has improved considerably. At a closer look, we notice that, even though the indicator pharmacy/population followed a positive trend, the situation is not uniform throughout the country. Thus, although in 1948 we had an average indicator of 1/14,299, there is an urban-rural discrepancy of 1/5525 vs. 1/27716. The situation is similar in 1990 and 2012/2013, even though both the national average indicator and the urban-rural differences diminish significantly. Thus we have for 1990 in the urban an average of 1/9,625 and in rural 1/16,611, and for 2012-2013 an indicator of 1/2,240 (urban) and 1/3,947 (rural), the average pharmacy/population indicator being 1/11,913 in 1990 and 1/2,781 in 2012.

We mention that in addition to the data presented in the charts, today there are also 563 closed circuit pharmacies (hospitals and clinics).

Conclusions

If one takes these pharmacies into consideration as well during the studied period, one will notice that, from a quantitative point of view, population care conditions have improved, the number of pharmacies and pharmacists has increased and the urban/rural discrepancies has diminished. From a qualitative point of view however, it cannot be said that the situation has evolved positively, since in 1948 there were 2.12 pharmacists per unit, in 1990 there were 2.51 pharmacists per unit and in 2012 there are only 1.81 pharmacists per unit. The coverage is insufficient when it comes to the legal program of pharmacies, the majority of which have opened more than 12 hours a day [11,12]. Note that when we calculated this report we have also taken into consideration the production units authorized by the Drugs National Agency, as well as the *en-gross* distribution units which, according

to legal dispositions, require the presence of a chief pharmacist for authorization.

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