

EVALUATION OF THE INFLUENCE OF ECONOMIC, DEMOGRAPHIC AND LEGISLATIVE FACTORS ON THE DEVELOPMENT OF THE NUMBER OF PHARMACIES IN ROMANIA

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Abstract

At the European level, the evolution in the number of pharmacies differs from case to case. Romania is the 5th among European countries regarding the number of pharmacies, the registered number increased from 5,700 to 7,150 from 2008 to 2011. The aim of this paper was to determine which of the three variables (economical, demographical, and legislative) had an influence on the development of the number of pharmacies in Romania. The design of the study was a longitudinal one, using quantitative data analysis and also methods of qualitative analysis of the European and national legislations regarding regulations on the functioning of pharmacies. As determined after the statistical processing, there is an insufficient correlation between the development of the Gross Domestic Product (GDP) and the growth of the number of pharmacies. When it comes to the demographic argument, Romania presented a demographical decrease in the studied period of time, which justifies even less the significant development of the pharmaceutical market. The third element, legislation, seems to offer a possible explanation for this evolution.

Rezumat

La nivel european, evoluția numărului de farmacii diferă de la caz la caz. România se plasează pe locul cinci în rândul țărilor europene în ceea ce privește numărul de farmacii, numărul înregistrat crescând de la 5700 la 7150 din 2008 până în 2011. Scopul acestei lucrări a fost de a determina care dintre cele trei variabile (economică, demografică, precum și legislativă) au avut o influență în creșterea numărului de farmacii din România. Designul studiului a fost unul longitudinal, folosind analiza datelor cantitative și, de asemenea, metodele de analiză calitativă asupra legislației europene și naționale în ceea ce privește reglementările privind funcționarea farmaciilor. În urma prelucrării statistice, nu există o corelație între valoarea Produsului Intern Brut (PIB) și creșterea numărului de farmacii. Când vine vorba de argumentul demografic, România a prezentat o scădere demografică în perioada studiată de timp, ceea ce justifică cu atât mai puțin dezvoltarea semnificativă a pieței farmaceutice. Al treilea element, legislația, pare să ofere o posibilă explicație pentru această evoluție.

Keywords: number of pharmacies, longitudinal design, economical, demographical, legislative variables

Introduction

The pharmaceutical market is under continuous development, due to organizational and functional regulations. At the European level, the evolution in the number of pharmacies differs from case to case; as for Romania, there is an impression of a particular wellbeing of the market, as there is a large number of pharmacies in all the hectic areas of each city. From 2008 up to 2011, the registered number increased from 5,700 to 7,150 [1]. According to the National Association of Pharmaceutical Distributors and Retailers, Romania is the 5th among European countries regarding the density of pharmacies [2]. In Romania, the pharmaceutical market is regulated according to demographic criteria. According to this, a

pharmacy can be opened and can function with respect to a minimum number of 3.000 (in the capital city)/3,500 (county residence)/4,000 (in other cities) inhabitants [3]. This demographic criterion is applied selectively in Europe, which means that there are states with an unregulated pharmaceutical market, even more, presenting a significant variation regarding the number of pharmacies. The situation becomes even more complex in the context of the online pharmaceutical system [4] and which represents mechanisms of future supplies at a community level [5].

As D. Lakic *et al.* [6] specified, development of the pharmaceutical network responds to the need of access to medication and it is closely related to the financial availability of the health insurance system. In many countries, including Romania, the volume

of financing for health is bound to the taxes collected from the active population and the distribution of these funds is expressed as a percentage from the Gross Domestic Product (GDP). The growth in the number of pharmacies may have an economic justification (the growth of the GDP and implicitly the growth of the funds directed to drugs - pharmaceutical market), utility for the population (growth of the population), or a legislative one, as well as other factors such as investment-related, environmental ones, availability of specialists, requirements for counselling and reporting to authorities [7], level of profitability, etc. The aim of this paper was to determine if the three variables (economical, demographical, and legislative) had an influence on the development of the number of pharmacies in Romania.

Materials and Methods

Study Design

The design of the study was a longitudinal one, using quantitative data analysis and also methods of qualitative analysis of the European and national legislations regarding regulations on the functioning of pharmacies. This combined approach made the testing of the research hypothesis possible, with respect to the three variables (economic, demographic, legislative).

Data and measurement. Data collection and analysis

As for testing the economic variable, the study focused on the evolution of the GDP, using the

National Institute of Statistics data from 2013. For the evolution of GDP we used Eurostat data. For the number of pharmacies, we used data on the active pharmacies according to the IMS Health and Cegedim, starting from 2008 until 2011. We chose this specific timeframe due to the Government Emergency Ordinance no.130/2010 that has eliminated the concept of "exception" and therefore the pharmaceutical market in urban areas was closed. Demographical data has been extracted from the 2011 census results. The necessary qualitative data regarding the legislation have included relevant normative acts (2001-2010), with the purpose of following the patterns of pharmacy regulation.

We used the annual growth for determining the existence or inexistence of correlations between the number of pharmacies, population and GDP. The annual growth is calculated for each indicator individually – GDP, pharmaceutical market, population, number of pharmacies.

Data processing has been performed using Microsoft Office Excel, and for the statistical processing the PRISM 6 software was used.

Results and Discussion

In the context of the economic crisis, the GDP values for Romania have registered a decrease between 2008 and 2011. As for the pharmaceutical market development, it has considerably increased since 2008 up to 2011 (Table I).

Table I

GDP (mil Euros) and pharmaceutical market in Romania

	Yr 2008	Yr 2009	Yr 2010	Yr 2011	Annual growth
<i>GDP (mil. Euros)</i>	139,765	118,196	124,328	131,327	0.9846
<i>Pharmaceutical market</i>	2,422,434	2,432,442	2,917,573	3,259,530	1.1069

The analysis of the two indicators shows that there is a growth in the pharmaceutical market, even if the GDP decreased in the studied period.

Regarding the demographic variable, Romania registered a decrease of over 2 million of inhabitants in the period 2008-2011 (Table II).

Table II

Romanian population between 2008 and 2011

	Yr 2008	Yr 2009	Yr 2010	Yr 2011	Annual growth
<i>Number of inhabitants</i>	21,504,442	21,260,359	21,431,298	19,043,767	0.9618

The evolution of the number of pharmacies presents a significant growth in Romania starting from 2008 up until 2011. Registered data from 2014 can confirm this growth, providing values for every

county. There is no statistical correlation between the number of pharmacies and the three mentioned factors: GDP, market size and population ($p > 0.05$ for all cases) (Table III).

Table III

Total number of pharmacies in Romania and their distribution within counties

	Yr 2008	Yr 2009	Yr 2010	Yr 2011	Development index
Total number of pharmacies	5,700	6,171	6,357	7,150	1.0792
2014					
County	Number of pharmacies (Cegedim Romania)		Number of pharmacies (IMS Health)		
<i>AB</i>	133		135		
<i>AG</i>	229		239		
<i>AR</i>	165		158		
<i>B1</i>	183		178		
<i>B2</i>	235		213		
<i>B3</i>	164		153		
<i>B4</i>	145		136		
<i>B5</i>	84		83		
<i>B6</i>	166		169		
<i>BC</i>	182		197		
<i>BH</i>	294		301		
<i>BN</i>	100		98		
<i>BR</i>	90		110		
<i>BT</i>	103		104		
<i>BV</i>	219		218		
<i>BZ</i>	134		149		
<i>CJ</i>	308		312		
<i>CL</i>	90		90		
<i>CS</i>	60		61		
<i>CT</i>	395		433		
<i>CV</i>	56		55		
<i>DB</i>	151		165		
<i>DJ</i>	293		314		
<i>GJ</i>	125		117		
<i>GL</i>	149		170		
<i>GR</i>	102		105		
<i>HD</i>	171		177		
<i>HR</i>	113		115		
<i>IF</i>	179		174		
<i>IL</i>	79		90		
<i>IS</i>	374		374		
<i>MH</i>	91		89		
<i>MM</i>	171		173		
<i>MS</i>	228		228		
<i>NT</i>	151		164		
<i>OT</i>	135		140		
<i>PH</i>	232		238		
<i>SB</i>	163		167		
<i>SJ</i>	73		84		
<i>SM</i>	134		137		
<i>SV</i>	227		225		
<i>TL</i>	80		85		
<i>TM</i>	261		268		
<i>TR</i>	107		107		
<i>VL</i>	130		136		
<i>VN</i>	117		130		
<i>VS</i>	106		113		

If we pay attention to the conditions of opening and functioning of the pharmacies, we talk about a market controlled by the authorities through legislation and by the authorization process.

In the European Union countries, the legislation provides the information according to which

community pharmacy needs to be present in all areas, taking also into account the geographical distribution of pharmacies. This measure demands the pharmacies that record a relatively high turnover to pay a sales tax while those with low turnover pay less or no tax [8] (Table IV).

Table IV

Annual growth for the studied parameters, detailed for each county

County	Annual growth GDP	Annual growth market	Annual growth Population	Annual growth Pharmacies
Alba	1.009	1.123	0.879	1.026
Arad	1.072	1.090	0.899	1.047
Arges	1.008	1.113	0.925	0.995
Bacau	0.967	1.080	0.817	1.025
Bihor	0.959	1.106	0.928	1.065
Bistrita-Nasaud	1.052	1.067	0.876	1.051
Botosani	1.061	1.106	0.892	1.023
Braila	1.133	1.091	0.853	1.024
Brasov	1.019	1.074	0.845	1.095
Bucuresti	1.127	1.050	0.864	1.054
Buzau	1.019	1.172	0.900	1.049
Calarasi	1.022	1.139	0.914	1.063
Caras-Severin	0.973	1.048	0.855	0.983
Cluj	1.067	1.124	0.954	1.113
Constanta	1.049	1.098	0.871	1.124
Covasna	1.114	1.082	0.927	1.043
Dambovita	1.007	1.104	0.948	0.829
Dolj	1.054	1.101	0.881	1.057
Galati	1.025	1.127	0.833	1.023
Giurgiu	1.024	1.060	0.948	0.987
Gorj	1.054	1.153	0.888	1.080
Harghita	1.071	1.091	0.939	1.010
Hunedoara	1.014	1.094	0.859	1.065
Ialomita	1.117	1.021	0.901	1.035
Iasi	1.019	1.089	0.876	1.015
Ilfov	1.119	0.889	1.135	1.068
Maramures	1.028	1.090	0.904	1.140
Mehedinti	1.044	1.091	0.875	1.041
Mures	1.046	1.053	0.916	1.079
Neamt	1.058	1.183	0.806	1.079
Olt	1.023	1.126	0.898	1.070
Prahova	1.138	1.074	0.905	1.064
Salaj	1.021	1.085	0.904	1.070
Satu Mare	1.045	1.110	0.904	1.113
Sibiu	1.052	1.041	0.884	1.082
Suceava	1.058	1.122	0.867	1.011
Teleorman	1.045	1.117	0.905	1.046
Timis	1.060	1.190	0.957	1.071
Tulcea	1.179	1.030	0.819	1.046
Valcea	1.118	1.095	0.874	1.071
Vaslui	1.038	1.098	0.835	1.074
Vrancea	0.998	1.092	0.829	1.082

The report entitled "Community pharmacy in Europe" argues that deregulation does not bring an increase regarding the competitiveness on the market among pharmacies. Moreover, neither brings record price reductions for over the counter (OTC) drugs. For example, the pharmaceutical industry in Italy is based on demographic-geographic criteria; therefore, the number of pharmacies is proportional to the number of inhabitants. Spain also takes into account the number of inhabitants and the distance between pharmacies, for issuing operating licenses [9]. In

the case of Austria, the demographic and geographic criteria prevail for establishing new pharmacies [11].

Romania has always had a demographic criterion which serves the opening of the pharmacies in the urban area, where the majority of the pharmacies are being placed.

The authority which issued the licenses for functioning (functioning authorizations) was almost in every case the Ministry of Health. Through the Law 266/2008, this responsibility was transferred to the National Agency of Medication, but due to the

modifications brought to the Law 236/2009, the Ministry of Health regained its previous role in this domain. When this material was conceived, the Romanian authorities were preparing the relocation

of the authority to the National Agency of Medication and Medical Devices for issuing the authorizations for functioning and inspection of pharmacies (Table V).

Table V

Evolution of important parameters within legislation regarding opening community pharmacies

Normative act/ Evaluated subject	OMS 626/2001	OMS 1199/2004	L 266/2008	L 236/2009 for modification L 266/2008	Government Emergency Ordinance 130/2010
Who issues the functioning authorization of the pharmacy?	Ministry of Health	Ministry of Health	National Agency of Medication	Ministry of Health	Ministry of health
Validity of the functioning authorization	5 years	permanent	permanent	permanent	permanent
Demographic criteria	5000 inhabitants for a pharmacy in the urban area	3000 inhabitants in Bucharest, 3500 inhabitants in county residences, 4000 inhabitants in other cities	3000 inhabitants in Bucharest, 3500 inhabitants in county residences, 4000 inhabitants in other cities	3000 inhabitants in Bucharest, 3500 inhabitants in county residences, 4000 inhabitants in other cities	3000 inhabitants in Bucharest, 3500 inhabitants in county residences, 4000 inhabitants in other cities The demographic criteria maintained until 31.12.2014 according to the Law 215/2012
Concept of "exception"	No	Yes, without being well defined	Yes, in commercial buildings bigger than 3000 mp	Yes, in commercial buildings, the way they are defined in OUG 99/2000, meaning 1000 mp	No. With the exception of the ones defined in Emergency Ordinance 18/2011, for the locations which are to be built and the contract exists.
Necessity of approval from the College of Pharmacists	Yes	Yes	No	No	No
Possibility of moving the location	In objective conditions, not really well defined	In objective conditions with the approval of the College of Pharmacists	No restriction.	No restriction.	No restriction.
Other regulations		The inspection sheet is being introduced.	According to article 12(3) the Ministry of Health is obliged to announce in a transparent manner the situation of requirements for pharmacy openings	The notion of Pharmaceutical Good Practices is being introduced	

OMS – Ministry of Health Order; L – Law issued by the Romanian Parliament

Since the demographic regulation, starting from 2004 there have been openings of pharmacies through exception. In 2004, this possibility was unclearly defined – in train stations, airports and commercial centres of large surfaces. Later on, through the Law 266/2008, the commercial centre

was defined more specifically as a surface of 3000 mp, without the clear precision that needs to certify this surface. Through the Law 236/2009 the notion of commercial centre was modified in the meaning of which there was a reference to the Government Ordinance 99/2000 and so the minimal surface of

the commercial centre was set to 1000 mp and the certification of this is allocated to the local authorities. At the end of 2010, as a result of a stream of requirements of new pharmacy openings through exception from the demographic criteria, the Ministry of Health promoted a Government Emergency Ordinance which again modified the Law 266/2008 in the meaning of eliminating the previous exception. Practically, this regulation permitted the opening of a number of pharmacies even after 2011. The legislation regarding on-line pharmacies was not considered although this model of pharmacies may emerge also in Romania [10].

Conclusions

As determined after the statistical processing, there is an insufficient correlation between the development of the GDP and the growth of the number of pharmacies. The pharmaceutical market has always enjoyed somewhat better dynamics, but insufficient to present a statistically relevant correlation for this evolution in the number of pharmacies, in this time frame. In conclusion, the economical factor cannot fully explain the development of the number of pharmacies in Romania.

When it comes to the demographic argument, Romania presented a demographical decrease in the studied period of time, which justifies even less the significant development of the pharmaceutical market. However, this presents certain vulnerability, since the number of pharmacies was always regulated by the law and we cannot be certain if the pharmacies were sufficient in 2008.

The third element, legislation, seems to offer some explanation for this evolution. Practically we can say that in the studied period there were a lot of changes in the legislation which allowed the growth of the number of pharmacies, particularly at the end of 2010. We can remind here the possibility of opening pharmacies through exception to the demographic criteria, the constant modification of the concept of "commercial centre", the disposal of the College of Pharmacists from the authorization process.

At the same time, being a regulated market, the authorities through the authorization process controlled the number of pharmacies. Therefore, the pharmacy license itself (the authorization for functioning) represented an asset of the firm and it

permanently had a trading market. Even if some pharmacies generated economic losses or went bankrupt, they didn't close, but they were bought by other operators existing on the market.

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