INTRODUCTION
The pharmaceutical activity in Romania has a considerable history starting from forms of traditional treatment based on the curative effects of plants until the first pharmacy emerged in 1494 in Sibiu [1]. The development of the pharmaceutical sector was based on the social need to obtain the treatment that every patient needed. According to the Article no. 557 of the Health Reform Law no. 95/2006, the profession of pharmacist is an independent profession and is exercised on the basis of the membership certificate of the College of Pharmacists in Romania [2].

Under the Article no. 579 of the Law no. 95/2006 on Health Reform, the Romanian College of Pharmacists is a professional, apolitical organism, with responsibilities delegated by the state authority in the field of authorization, control and supervision of the pharmaceutical profession. Thus, the College of Pharmacists is a guardian of the profession of a pharmacist as a free profession and, at the same time, a guardian of good practice in the field, of observing the legal and moral standards in the exercise of the profession [2].

The Romanian Pharmacists' College is affiliated to the Liberal Professions Union of Romania and to international forums and organizations such as the Euro Pharm Forum [3], the International Pharmaceutical Federation [4], the Pharmaceutical Group of the European Union [5]. These forums create a climate of protection for the profession of pharmacist but impose different standards of professional ethics and a service development program.

The specific of pharmacies is that they are public or private commercial agents with a public interest activity, that ensures the patient's access to medicines and other products established by the Order of the Ministry of Health. This is underlined in the Law no. 95/2006 on Health Reform in several articles like the Article no. 35 [1].

This article presents the evolution of the community pharmacies regulation in Romania in the last 20 years, as well as the evolution of the number of community pharmacies and pharmacy points in the same period in the context of European regulations regarding community pharmacies.

METHODOLOGY:
The present study is a descriptive, transversal analysis of the data reported between 1997 and 2016 on the number of pharmacies and pharmaceutical points registered in Romania. For the legislative analysis, we identified all the pharmacies licensing regulations in the same period.

Keywords: community pharmacies, demographic criteria

According to the World Health Organization (WHO), the main regulatory functions in the field of medicines are: licensing, ensuring safety, efficacy and quality, inspection and surveillance, control and monitoring, at all stages from production to sale, as well as providing information related to medicines, for professionals as well as doctors [6]. In 2013, there was a network of 160,000 Community pharmacies in Europe, with an estimated 46 million people visiting this network daily [7].

In Romania pharmacies are organized according to the Law no. 31/1990 on companies, republished, updated and consolidated [8]. The profession of pharmacist was regulated by the Law no. 81 from 1997 on the exercise of the profession of pharmacist, the establishment, organization and functioning of the College of Pharmacists in Romania [9]. Law no. 81 was repealed with the advent of the Law no. 95 of 2006 of the health reform, which took over the regulation on the exercise of the profession [2].

The Order of the Minister of Health no. 626 from 11th September 2001 on the approval of the Norms regarding the establishment and authorization of the pharmaceutical units, as well as of the Conditions for their organization and functioning was issued based on the Government Emergency Ordinance no. 152/1999 on medicinal products for human use. According to the Article no. 14 of this order, in the urban environment a pharmacy can be established for a population of 5,000 inhabitants. In calculating the number of inhabitants, the population of neighboring or subordinated communes where there are no pharmacies will not count. In rural areas, pharmacies will be set up, preferably near the headquarters of healthcare establishments, and pharmaceutical activity may take place in the pharmaceutical unit serving one or more communes, the authorization being performed by the MoH [10,11].
HOSPITAL MANAGEMENT

By the Order no. 1199 from 23rd September 2004, amending and supplementing the Order of the Minister of Health and Family no. 626/2001 for the approval of the Norms regarding the establishment and authorization of the pharmaceutical units, as well as the Conditions for their organization and functioning, separate regulations for community pharmacies, warehouses and drugstores are introduced, depending on the number of inhabitants, thus [13]:

- In Bucharest =1 pharmacy per 3000 inhabitants
- In the cities of the county residence = 1 pharmacy to 3500 inhabitants
- In other cities = 1 pharmacy to 4000 inhabitants
- Exception in railway stations = If there is no pharmacy in the immediate vicinity
- Exception in large commercial complexes = The area is not specified, but it is taken into account the Government Ordinance no. 99/2000 specifying an area of 1,000 m.
- In the rural areas = Authorized pharmacies can set up work points in rural areas, which will cease to operate when a self-contained pharmacy is licensed in the locality.

The Pharmacy Law no. 266 from 2008 introduces authorization and inspection by the National Medicines Agency, an opportunity notice and increases the areas where pharmacies can be licensed in shopping centers. Thus [14]:

- In Bucharest =1 pharmacy per 3000 inhabitants
- In the cities of the county residence = 1 pharmacy to 3500 inhabitants
- In other cities = 1 pharmacy to 4000 inhabitants
- Exception in railway stations = 1 pharmacy
- Exception in large commercial complexes = If they have a sales area of at least 3000 m.
- In the rural areas = 1 pharmacy per 4000 inhabitants and a maximum pharmacy in towns under 4000 inhabitants

The Ministry of Public Health and the public health authorities have the obligation to publish on their own websites the lists of the localities in the county where community pharmacies can be opened according to the specified conditions. Companies which have established community pharmacies may also set up a local distribution pharmaceutical points in the localities without pharmaceutical services, which are recorded on the authorization to operate of the community pharmacy. It operates in the presence of the pharmacist, according to an established schedule and announced to the public and communicated to the county branch of the Romanian Pharmacy College, but if a community pharmacy is established in that locality, the existing local pharmaceutical points is abolished [14].

The Law no. 236 from 2009 for the amendment and completion of the Pharmacy Law no. 266/2008 amends the provisions as follows [15]:

- In Bucharest =1 pharmacy per 3000 inhabitants
- In the cities of the county residence = 1 pharmacy to 3500 inhabitants
- In other cities = 1 pharmacy to 4000 inhabitants
- Exception in railway stations = 1 pharmacy
- Exception in large commercial complexes = If they have a sales area of over 1000 m, according to Government Ordinance 99/2000.
- In the rural areas = 1 local pharmaceutical point in the communes without a pharmacy or official, passed in the authorization of the holding pharmacy.
- In seaside resorts in the summer season = 1 local pharmaceutical point written in the authorization of the holding pharmacy.

The authorization of pharmacies is moved from the National Medicines Agency to the Ministry of Health. The administration of vaccines in community pharmacies is also introduced [15].

By the Government Emergency Ordinance no.130 from 2010 amending the Pharmacy Law no. 266/2008, Article no. 42, the demographic criterion applies until 31st December 2012. The Law no. 215 from 2012, approving the Government Emergency Ordinance no. 130 from 2010 extends the term of application of the demographic criterion until 31st December 2014, while the Law no. 162 from 2014 leaves the demographic criterion valid indefinitely [16].

As regards the demographic criterion, an essential issue is related to the effects of this criterion on the competitive principles of the market. In practice, this principle limits the number of pharmacies, and therefore competitors, that can appear on the market based on an objective criterion related to the number of inhabitants existing in a geographical area. The fact that this criterion was originally applied in the urban and rural areas and then applied only in the urban environment indicates the legislator's intention to limit the number of pharmaceutical units only in the urban area, where the fight in the pharmaceutical market is higher, the pharmacies being more economically viable. In rural areas, due to low profitability, there are areas where the supply of medicines is difficult and in some places non-existent. For this reason, the repeal of the rural limitations aimed at increasing the number of pharmacies in order to cover the rural area where there are still problems.

In this respect, an important act is the Opinion of the Competition Council of Romania on the legislative initiative to extend the demographic criterion for the establishment of a pharmacy in the urban area. The Competition Council underlines that, in terms of material competition law, the demographic criterion is a barrier on the market, with a negative effect on the competitiveness and efficiency of a market because the number of competitors present is lower than the number of potential competitors. In this way, consumers are also affected, as high competition generates a lowering of prices, an increase in the quality of services and a greater interest of the economic agents in meeting consumer requirements [17].
The Competition Council notes that limiting the number of pharmacies in the urban area will not directly lead to the opening of new pharmacies in rural areas, considering that the solution is to encourage access to those areas, not to hamper urban access. In this regard, there is a reference to the situation in Great Britain that has implemented two solutions in low-access areas: The Essential Scheme for Small Pharmacies that provides financial assistance to pharmacies that are not economically viable due to their location but are considered vital for supplying pharmaceutical services to the local community and the release of medicines by prescription physicians. The release is only provided if there are no pharmacies in the area and only for prescription drugs. This solution is implemented in several countries in order to meet the needs of the rural environment: Austria, Czech Republic, France, Hungary, Ireland, Slovenia, the United Kingdom, the Netherlands. The Competition Council also suggests two solutions: a more permissive legislation for rural pharmacies by stipulating less restrictive conditions and criteria for setting up pharmacies in the urban area (low-duty program, a range of limited products, the elimination of the own laboratory condition, a smaller area, the possibility of being serviced by a pharmacy assistant, etc.) and the introduction of a pilot program for the establishment of mobile pharmacies for hard-to-reach rural areas. [17]

The Competition Council concludes that the measure can only be maintained for a determined period of up to 9 months. [17] Even under these conditions, the Romanian Parliament adopted the Law no.162 from 2014 in order to amend and supplement the Pharmacy Law no. 266 from 2008 in which, by abrogating the Article no. 42, the demographic criterion in the opening of pharmacies remains valid indefinitely. [18]

The Government Emergency Ordinance no. 58 from 2017 maintains the demographic criterion in the authorization of pharmacies, introducing the establishment of local distribution pharmaceutical points in the rural area and in the seaside resorts, which are registered on the functioning authorization of the titular community pharmacy. [19]

Under the European Union (EU) law, competition policy is an exclusive EU competence. Therefore, Romania has to implement and comply with European norms from which it cannot derogate. In the field of public health, the EU only has the competence to support, cooperate or complement the national rules, with States being competent to decide on this matter. [20]

At European level, the European Court of Justice has heard a number of cases relating to the application of non-discriminatory principles for the establishment of pharmacies such as José Manuel Blanco Pérez and Maríadel Pilar Chao Gómez against the Conseil de Salud y Servicios Sanitarios (C-570/07) and the Principality of Asturias (C-571/07). In these cases the Court states that the limitation of the number of pharmacies based on an objective criterion on population density and the distance between pharmacies is not contrary to EU norms but the application of the criterion must be done primarily without discrimination and on the basis of a general interest, of that objective, and secondly without going beyond what is necessary to achieve the pursued aim. [21]

In 2012, the Association of Distributors and Retailers of Pharmaceuticals in Romania (ADFRF) citing the Euromonitor and Eurostat data, presents the following situation at European level as is presented in table 1.

**Table 1. Total No. of Pharmacies, Europe, 2012**

<table>
<thead>
<tr>
<th>State</th>
<th>Total No. of Pharmacies</th>
<th>Average residents / pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grecia</td>
<td>9916</td>
<td>1140</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>3520</td>
<td>2093</td>
</tr>
<tr>
<td>Spain</td>
<td>21470</td>
<td>2149</td>
</tr>
<tr>
<td>Belgia</td>
<td>5032</td>
<td>2186</td>
</tr>
<tr>
<td>Slovacia</td>
<td>2023</td>
<td>2686</td>
</tr>
<tr>
<td>Polonia</td>
<td>13668</td>
<td>2794</td>
</tr>
<tr>
<td>Franta</td>
<td>22795</td>
<td>2853</td>
</tr>
<tr>
<td>Italia</td>
<td>18164</td>
<td>3337</td>
</tr>
<tr>
<td>Portugalia</td>
<td>2870</td>
<td>3706</td>
</tr>
<tr>
<td>Cehia</td>
<td>2781</td>
<td>3787</td>
</tr>
<tr>
<td>Germania</td>
<td>21582</td>
<td>3787</td>
</tr>
<tr>
<td>Ungaria</td>
<td>2502</td>
<td>3986</td>
</tr>
<tr>
<td>Marea Britanie</td>
<td>9677</td>
<td>6458</td>
</tr>
<tr>
<td>Finlanda</td>
<td>812</td>
<td>6619</td>
</tr>
<tr>
<td>Austria</td>
<td>1220</td>
<td>6881</td>
</tr>
<tr>
<td>Suedia</td>
<td>1266</td>
<td>7437</td>
</tr>
<tr>
<td>Olanda</td>
<td>2050</td>
<td>8124</td>
</tr>
<tr>
<td>Irlanda</td>
<td>503</td>
<td>8908</td>
</tr>
<tr>
<td>Danemarca</td>
<td>316</td>
<td>17598</td>
</tr>
</tbody>
</table>

Regarding the evolution of the number of pharmacies and pharmaceutical points authorized in Romania and reported by the National Institute of Statistics, the following data can be observed for the period 1997-2016, in table 2. Of the 7802 pharmacies authorized and reported in 2016, 399 are public property, representing public hospitals and 7403 are private pharmacies. Of the 1693 pharmaceutical points, 68 are public, at the level of public hospitals and 1625 private. This results in pharmaceutical services coverage by a total of 9028 pharmacies and private pharmaceutical points. [22]

The data published by the National Institute of Statistics on the Population of Romania on cities on January 1st, 2016 indicate a total population of 22,224,178, out of which 12546212 are urban and 9695506 in the rural area. [22]

Applying the distribution of the population to the total number of pharmacies and private pharmaceutical points results an average of 2464 citizens served by a pharmacy in Romania in the year 2016.
CONCLUSIONS:

In Romania, the number of pharmacies has increased steadily, although there is a demographic criterion in setting up and licensing pharmacies. Applying and maintaining the demographic criterion in licensing pharmacies has led to an increase in the number of pharmacies and pharmaceutical points open in rural areas and a better coverage of pharmaceutical services at this level.

In Romania, demographic rates vary according to the number of inhabitants of a city and not a single national quota. Thus, coverage in Romania is much closer to the varied needs of a large city than a small one. The deregulation of the demographic criterion, so the liberalization of the market must be accompanied by measures aimed at public health and the interest in the population's access to medicines. Thus, the legislator has to revise the pharmacy law so that rural areas are not deprived of access to pharmaceutical products.

The deregulation of the demographic criterion must be accompanied by measures to increase the profitability of rural pharmacies, so that by economic motivation to increase the pharmacies coverage at national level.

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Conflicts of interest: The authors declare that they have no conflict of interest.

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