

# Legal framework and regulatory requirements for community pharmacies in some Balkan countries

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## Introduction

Community pharmacies are premises that, in accordance with national regulations and definitions, may operate as a facility for the provision of pharmacy services in community settings (OECD, 2021). The main definition of 'community pharmacy' may vary in different countries across Europe, although most define it as a type of health care facility that provides specific services or with a given mission around medicines (WHO, 2019).

Community pharmacies are an important component of the healthcare system. Community pharmacists are recognized within national health systems as key health professionals making a dynamic and evolving contribution to improving the health of the communities they serve (PGEU, 2019).

Cultural, socioeconomic and geographical conditions have required different legislative decisions for community pharmacies in Europe. The legal and regulatory framework for community pharmacies in the countries across Europe is generally determined by a single pharmacy law or by health/medicines laws and additional executive orders or decrees defined by the ministry of health (WHO, 2019). The number of community pharmacies per 100 000 inhabitants varies in different European countries. The statistical data shows that in 2019, 9 community pharmacies in Denmark and 88 community pharmacies in Greece served 100 000 people (OECD, 2021). On the one hand, this contrast may be due to different legal and regulatory requirements and on the other hand, can be explained by differences in distribution channels.

The aim of this study is to outline the similarities and differences in the legal and regulatory framework for community pharmacies in five Balkan countries – Bulgaria, Greece, Romania, The Republic of North Macedonia, and Turkey.

## Materials and methods

For the purpose of the study, a comparison between the legal documents on community pharmacies in the five Balkan countries has been made. The main focus was requirements on pharmacy licence, pharmacy ownership, premises, demographic restrictions, geographical distribution, and restrictions on horizontal and vertical integration.

## Results and discussion

### *Pharmacy licence*

In all five Balkan countries included in our review, a licence is required to open and operate a community pharmacy. The pharmacy licence may be facility-based or associated with a specific responsible pharmacist. In Turkey, the license is linked to a specific location, while in Bulgaria this licence is issued to a responsible pharmacist - it is personal. In Turkey and Greece, an application for a community pharmacy permit must be submitted electronically, while in Bulgaria this is done on-site at the Bulgarian Drug Agency. Another condition for opening a pharmacy in Turkey and Greece is the possession of Turkish and Greek citizenship, respectively.

### *The ownership requirements*

In Romania, community pharmacies are private institutions. Their owners don't need to be pharmacists as long as they hire a pharmacist as the manager (Sandulovci et al., 2018). The similar requirements are observed in Bulgaria, where pharmacy ownership is not restricted to pharmacists (Petkova & Atkinson, 2017). In Greece, ownership is allowed to non-pharmacists with the compulsory participation of a licensed pharmacist at 33 percent (Kalavrezou and Jin, 2021). In the Republic of North Macedonia, ownership of pharmacies is also not limited to pharmacists, so there are many pharmacy chains owned by pharmaceutical wholesalers or local pharmaceutical manufacturers. (Ivanovska, 2011).

### *Premises requirements*

In Romania and Turkey, the minimum area of the community pharmacy is 55 m<sup>2</sup>. In Bulgaria, the requirement is 30 m<sup>2</sup> for a pharmacy without drug compounding and with one workplace. Moreover, depending on the services provided by the pharmacy, additional premises and equipment might be needed in some of the mentioned countries. In Turkey, in areas where a natural disaster has recently taken place, a pharmacy can be opened in smaller premises of 20 m<sup>2</sup> for a period not exceeding two years (WHO, 2019).

### *Demographic restrictions and geographical distribution of pharmacies*

Demographic restrictions are most often determined on the basis of the number of inhabitants in the settlement. In Turkey, the minimum number of inhabitants per new community pharmacy is 3500. In Romania, the demographic restrictions vary in different cities. In Bucharest restriction is one pharmacy per 3000 inhabitants, while in other cities – one pharmacy per 4000 inhabitants. Exceptions from these provisions are the community pharmacies found in railway stations, airports, and large surface commercial centers. However, there are no such criteria in rural areas (Sandulovci et al., 2018). In Greece, only one pharmacy is allowed per 1,000 inhabitants (Kalavrezou and Jin, 2021). In the Republic of North Macedonia for settlements in rural areas with a maximum of 1000 inhabitants, the turnover of retail trade in medicines can be done by car of a health institution – a mobile pharmacy. In Bulgaria, there are no governmental restrictions on the demographic distribution of community pharmacies as a function of population density for instance (Petkova & Atkinson, 2017). Several countries included in the review use minimum distances between new and existing pharmacies as geographical criteria to determine whether a pharmacy licence can be issued. The

distance varies from 100 m in the Republic of North Macedonia to 250 m in Turkey and Greece.

### *Restrictions to horizontal integration*

In Bulgaria, no more than four pharmacies can be owned by the same entity (Petkova & Atkinson, 2017; WHO, 2019). In Turkey, multiple ownership is forbidden (Law on Pharmacists and Pharmacies, 2014).

## **Conclusion**

Despite the above-mentioned legal and regulatory differences between these five Balkan countries, most of the requirements for opening and operating a community pharmacy are similar. This may be explained by the fact that they are all located in the neighboring Balkan Peninsula.

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