Introduction

- 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).

Aim

- 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

- Licence is required
- Facility-based licence
- Licence associated with a specific responsible pharmacist
- Citizenship

The ownership requirements

- In these countries where the owner is not a pharmacist need to have a pharmacist as a manager.
- In Greece, ownership is allowed to non-pharmacists with the compulsory participation of a licensed pharmacist at 33%.

Premises requirements

<table>
<thead>
<tr>
<th>Country</th>
<th>Minimum area of the community pharmacy</th>
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<tbody>
<tr>
<td>Bulgaria</td>
<td>30m²</td>
</tr>
<tr>
<td>Turkey</td>
<td>55m²</td>
</tr>
<tr>
<td>Romania</td>
<td>55m²</td>
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</tbody>
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Demographic restrictions and geographical distribution of pharmacies

- Demographic restrictions
  - Bulgaria: There are no governmental restrictions
  - Turkey: 3500 inhabitants
  - Romania: In Bucharest – 3000 inhabitants
  - In other cities – 4000 inhabitants
  - Greece: 1000 inhabitants
  - 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

Geographical distribution

The minimum distance between new and existing pharmacy 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.

In Turkey, multiple ownership is forbidden.

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.

References

World Health Organization, Regional Office for Europe. The Legal and Regulatory Framework for Community Pharmacies in the WHO European Region, World Health Organization, Regional Office for Europe: Copenhagen, Denmark, 2019; Available online: https://apps.who.int/iris/handle/10665/326394 (accessed on 18 April 2022).