## Policy Briefings



Establishment and distribution of community pharmacies
Models and policy options

## Colophon

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Author:
Gonçalo Sousa Pinto
Editor:
Luc Besançon

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## 1 Introduction

The establishment and territorial distribution of community pharmacies constitute key elements in the definition of national medicines policies that guarantee equitable and continuous access to medicines and associated services to the population. Beyond the professional service of offering quality and safe medicines to the public and dispensing them in a manner that ensures adequate use and optimal outcomes, pharmacies may also be seen as a network of primary health care facilities and professionals that can serve as an entry gate to healthcare systems and are an integral part of healthcare systems.

According to a survey conducted by FIP in 2015, with responses from 71 countries and territories covering approximately $80 \%$ of the world's population, only seven out of 70 respondents indicated that the state does not play a role in regulating the opening of new pharmacies. These were Canada, China Taiwan, Ireland, the Netherlands, Paraguay, Sweden and Switzerland. In all other 63 countries and territories, pharmacy establishment was either regulated through special licences (58 respondents; 83\%), or the definition of demographic criteria ( 18 respondents; 25\%) or geographic criteria ( 25 respondents; 35\%) (1) .

Yet, pharmacy regulatory frameworks around the world may combine different elements and define a wide range of models that play a decisive influence in the accessibility of pharmacies by the public, their sustainability, the professional services they provide and the way they participate in health policies.

Such models can range from highly regulated to highly liberalised, with several in-between situations where some form of regulation, planning or governing criteria apply. This policy briefing aims to offer an overview of different models and policy options in terms of the establishment and distribution of community pharmacies, and to briefly describe the situation in a number of countries or territories that may be used as references when advocating for a given regulatory model.

It should be noted that that the establishment of community pharmacies may be (and frequently is) subject to additional technical requirements and regulations in terms of the premises of the pharmacy, as well as workforce requirements, regardless of the restrictions that may or not be in place to regulate their market entry. This document will primarily focus on the regulation of market entry of new community pharmacies.

The following chapters present an overview of the most frequent policy options in terms of the regulation of the establishment of community pharmacies and their territorial distribution, as well as key advocacy arguments for or against each model and a number of examples of how different countries or territories approach this issue.

## 2 Regulated models

### 2.1 Considerations for regulation

In regulated models for the establishment and distribution of community pharmacies, public administrations consider that the benefits of such regulation justify the application of restrictions to free establishment policies.

The following considerations play a key role in such approach:
a. The establishment and distribution of community pharmacies should ensure equitable and continuous access to safe and quality medicines and the professional services of pharmacists in a timely manner to the entire population of a given jurisdiction, regardless of where they live.
b. The criteria for the establishment of community pharmacies should be in line with a definition of pharmacies as health care facilities that offer a public service by providing products and professional services that are used to prevent disease, promote health and treat or manage disease, as well as optimise medication use and outcomes.
c. Such criteria should be aligned with the missions and roles of community pharmacies within the health care system.
d. Criteria applied for ensuring such distribution need to be objective, i.e., clearly connected with a welldefined goal, so that their relevance can be demonstrated (especially as such criteria can be perceived as a limitation to free enterprise).

### 2.2 Different regulatory strategies

### 2.2.1 Regulating the opening of new community pharmacies

In regulated models, the establishment of new pharmacies is generally determined by public administrations through the application of demographic and/or geographic criteria, following a rationale of ensuring timely access to medicines to all persons and a functional and sustainable network of pharmacies. While such criteria primarily aim to guarantee that there is at least one pharmacy within a reasonable travelling time (on foot or public transports) for everyone, another objective of regulating the opening of new pharmacies is to prevent an unbalanced territorial distribution where a saturation of pharmacies in certain areas could compromise their financial viability and service quality.

Establishing a minimum distance between pharmacies and a minimum number of inhabitants per pharmacy in a specific geographical area (e.g. a city, a county...) also serves the purpose of ensuring that the pharmacy can remain viable without recurring to business practices that diverge from its core mission - such as selling products unrelated to health care or self-care, or adopting marketing tactics to stimulate consumption of (unnecessary) health care products. Such policies follow an understanding that pharmacies, although private, offer an essential public service, and as such, they need to be regulated by the state and preserved from market dynamics in terms of establishment and competition.

Regulated models may also establish a maximum distance and a maximum number of inhabitants per pharmacy, which determine the need to issue a new licence.

### 2.2.2 Regulating the change of ownership of existing community pharmacies

Licences to establish a community pharmacy may be not only bound to a specific location or area, but also to a specific licence holder. As the state issues such licences - usually through a competition system where interested applicants are ranked according to their suitability - it may determine that licences cannot be transferred to another person through inheritance, purchase or other means. In countries like Denmark,

Finland or Luxembourg, pharmacy licences remain property of the state - that is, the pharmacy owner only owns the premises of the pharmacy, and he or she may not sell that licence or pass it on to his or her descendants. When the pharmacist-owner retires, dies or moves to another pharmacy, their licence goes back to the state, who can decide to make it available to other pharmacists or to cancel it. Successful applicants may choose to buy the premises of the existing pharmacy or to establish a new pharmacy in the same area.

In other jurisdictions, however, pharmacy licences become the property of the pharmacist who owns the pharmacy. As such, accessing pharmacy ownership in a specific location can be achieved either by applying for a licence to establish a new pharmacy, or by buying or inheriting a pharmacy and its licence from an existing owner. This is the case of Belgium, China, Croatia, Spain, France, Lebanon, Portugal, Senegal or Uruguay, for example.

When a planned system for the distribution of community pharmacies is implemented, existing pharmacies are usually authorised to continue operating, in consideration of their acquired rights in the previous system. This may result in a higher density of community pharmacies than stipulated by law.

Similarly, when the population of a specific region decreases, the number of community pharmacies may become excessive to serve the needs of the community.

To deal with these cases, some governments have developed specific policies (such as fiscal incentives) for two pharmacies to merge or for a pharmacy to buy another, thus cancelling one of the licences.

### 2.2.3 Providing financial support to low-turnover pharmacies

While demographic or geographic criteria are the most common principles for planning the location of community pharmacies in order to ensure an equitable and continuous access to a pharmacy across the territory, other approaches can be used, either in combination or as an alternative system.

Indeed, some pharmacies in sparsely populated areas may be of high relevance from a public health perspective. However, the absence of competition does not necessarily make them profitable. As such, in several jurisdictions, mechanisms of compensation have been developed. The aim of such mechanisms is primarily to ensure the viability of pharmacies with a low turnover, but also to compensate pharmacy owners who provide a public service in less favourable circumstances from an economic point of view.

In some countries, such as Australia, Denmark, Finland, Spain or the United Kingdom, this has been addressed by means of financial incentives or compensations to low-turnover pharmacies in rural or remote areas. This can be achieved by means of a contribution paid by all pharmacies (based on their turnover) and received only by pharmacies with the lowest turnovers in the rural environment, or by means of fiscal benefits for such pharmacies.

Another possible type of incentive is to reward pharmacists who have practiced in underserved areas with higher marks for the ranking to access a licence for a pharmacy in a more populous area (and expectably more profitable) in the future.

Notwithstanding, not all jurisdictions with planned models for the distribution of pharmacies have such types of mechanisms in place. In some countries and territories, licences for new pharmacies are still attached to a specific location (based on an assessment of needs or the application of the mentioned geographic or demographic criteria), and those pharmacies may experience hardship in terms of their financial sustainability, which in turn limits their capacity to invest in qualified workforce or innovate in terms of technology or professional services. As such, it seems fair to assert that the implementation of compensation mechanisms for such pharmacies is a sound policy to ensure a consistent quality of service by all pharmacies across the territory and to ultimately avoid penalising people living in sparsely populated areas.

### 2.3 Impact of regulated distribution models

According to the 2015 FIP survey, access to community pharmacies varies greatly around the world: although the global average number of inhabitants per pharmacy is 15,546 (which is in itself a high figure), this indicator varied from 1,563 inhabitants per pharmacy in Lebanon, to 356,125 inhabitants per pharmacy in Chad (1).

Only within the European Union (EU), a report from 2014 indicated that "the number of pharmacies goes from one per every ten thousand inhabitants in Denmark, Sweden, Slovenia and the Netherlands to more than five in Malta, Cyprus and Bulgaria, and almost eight in Greece. Most countries however have between two and four pharmacies per every ten thousand inhabitants" (2). The same report further indicates that, as of January 2014, "sixteen EU countries have some form of regulation of pharmacy establishment, often in the form of geographic and demographic criteria to limit the density of pharmacies" (2). It is worth mentioning (especially for EU countries) that pharmacies are not subject to EU directive 2006/123/EC, which established a single market for services in the European Union. This is because this directive excludes services provided by regulated professions in the Member States.

Likewise, directive 2005/36/EC, which regulates the recognition of professional qualifications (and the freedom of movement of professionals in the EU) also states the following:
"This Directive does not coordinate all the conditions for access to activities in the field of pharmacy and the pursuit of these activities. In particular, the geographical distribution of pharmacies and the monopoly for dispensing medicines should remain a matter for the Member States. This Directive leaves unchanged the legislative, regulatory and administrative provisions of the Member States forbidding companies from pursuing certain pharmacists' activities or subjecting the pursuit of such activities to certain conditions." $(3)^{a}$

A comprehensive study conducted in 2012 by Sabine Vogler et al. (4) analysed the impact of pharmacy deregulation and regulation in nine European countries - five with a largely deregulated community pharmacy sector (England, Ireland, the Netherlands, Norway, and Sweden), and four with regulated models (Austria, Denmark, Finland, and Spain). The study concluded the following:

Deregulation in the community pharmacy sector is often connected to certain expectations, in particular to improved accessibility and reduced medicines prices. In reality, these expectations could not be fully met. Liberalisation in the pharmacy sector can even have consequences, which might impede a good and equitable access to medicines, such as:

- An uneven spread of community pharmacies within a country,
- The dominance of some market players, for example wholesalers and
- The economic pressure to increase the pharmacy turnover through the sale of OTC medicines and non-pharmaceuticals. (4)

The study also grouped their findings under different types of impacts:

## A. Impact on the accessibility of medicines

- Deregulation tends to lead to urban clustering.
- Deregulation has not improved the accessibility of pharmacies and other dispensaries for prescription-only medicines in rural areas
- Country-specific approaches ensure accessibility in rural, sparsely populated areas.
- Deregulation may cause limited availability of less frequently prescribed medicines
- Vertically integrated pharmacies may be encouraged to align their product range to the supply of their owners
- Opening hours have, to some extent, been expanded after deregulation.

[^0]B. Impact on the quality of pharmacy services

- The quality of pharmacy services appears to be appropriate in all countries regardless of the extent of regulation
- Counselling is a key task of the pharmacist profession.
- Deregulation might lead to time constraints and an increased workload of the pharmacy staff
C. Impact on savings
- Deregulation in the community pharmacy sector has no direct impact on a country's pharmaceutical, including public, expenditure.
- Deregulation in the community pharmacy sector cannot considerably influence medicines prices
Lower average pharmacy margins are the result of reductions in the statutorily regulated pharmacy remuneration schemes


### 2.4 Coexistence with other regulations

Although regulated models presuppose a stronger role of the state in controlling business practices, such models exist in fact in several countries with free market economies. In such cases, despite overall laissez-faire policies in other sectors of the economy, legislators consider that access to medicines (and particularly prescription-only medicines) and associated services is a fundamental right of individuals that should be safeguarded by the state and cannot be subject to market dynamics alone.

It should also be noted that a regulated model for the establishment and distribution of pharmacies may coexist with a liberal system in terms of pharmacy ownership - that is, ownership may be open to nonpharmacists and corporations, but still be subject to regulations in terms of licensing based on social need and demographic and/or geographic criteria (as is the case of Portugal or the United Kingdom, for example).

On the other hand, in countries like Germany or Turkey, although ownership is restricted to pharmacists and pharmacy chains are not allowed by law, there are no geographic or demographic restrictions to the establishment of community pharmacies.

Moreover, in some countries where the ownership of multiple pharmacies is permitted, there may also be regulations that establish a minimum distance between pharmacies of the same owner(s). This is case of Uruguay, for example, where this minimum distance is 1000 m and ownership is capped to a maximum of 15 pharmacies per individual or corporation.

## 3 Non-regulated models

Although in the majority of the World's countries and territories ( $90 \%$ ), the state plays a regulatory role related to the opening of new pharmacies, the percentage of jurisdictions that have systems in place to plan the territorial distribution of pharmacies and ensure a continuous and equitable access to pharmacies is much lower - only $29(41 \%)$, according to the cited FIP survey (1).

This may be explained by the fact that depending on the characteristics of a given country (including distribution of its population), economic forces are effective to ensure a continuous and equitable access to community pharmacies.

Additional considerations may also explain this, such as a political model or tradition in which the entrepreneurial aspects of market entry and the very nature of pharmacies as business entities are given equal consideration to other types of business establishments. In these cases, any regulations or restrictions to private initiative for the free establishment and location of pharmacies are considered barriers to competition and to economic dynamism, thus limiting customer choice. In such models, it is generally accepted that the market will regulate itself and that the requirements of the population in terms of access to medicines will be met through the entrepreneurial identification of market needs and uncovered niches.

It is also argued that increasing competition in the pharmacy sector brings medicine prices down, thus improving access to medicines.Vogler et al. concluded that there is no evidence that liberalisation has reduced medicine prices since they are influenced by other policies (e.g. statutory framework, strategies of third party payers, generic policies) (4). Whilst this may not be applicable to medicines with regulated prices, it could be true for those with free pricing. Yet, some evidence has indicated that the reduction in medicine prices after market liberalisation may not be significant, if any at all, as was the case in Portugal (5).

In Europe, countries such as Germany, Ireland, the Netherlands, the Russian Federation, Sweden or Switzerland do not regulate where pharmacies are located, i.e., pharmacy owners are free to open a pharmacy at any place of their preference. In Germany, however, a pharmacy owner may establish up to three branch pharmacies, and these must be located in the same or an adjacent district to ensure that the owner can exert his/her personal responsibility.

In South and Central America, except for a few countries or regions that have adopted some degree of regulation or planning criteria for the establishment of community pharmacies, most jurisdictions have liberalised models where no demographic or geographic rules apply. This is the case in most provinces of Argentina, Bolivia, Brazil, Colombia, Chile, Costa Rica (where a minimum distance of 500 m was applicable until 1991) and Venezuela, for example.

In Paraguay, a non-regulated model is in place, but the Government is currently considering introducing territorial planning criteria for the establishment of pharmacies, following heavy inequalities in access to a pharmacy, with the majority of pharmacies being concentrated in city centres and leaving less affluent areas with insufficient pharmacies, especially in the capital city of Asunción.

This is also true for North America, where Canada, Mexico and the United States apply no restrictions to pharmacy location, and the same applies to a significant part of Asia (for example, in China Taiwan, India or Japan) and Africa (Chad, Ethiopia, Nigeria, Sierra Leone, Tanzania, Zimbabwe).

It should be noted that, although several jurisdiction have free establishment and location policies for community pharmacies, pharmacy owners may still be required to request a licence from a regulatory body, which is usually attached to the fulfilment of other requirements in terms of the pharmacy premises, workforce, suitability of the licence holder, presence of a managing pharmacist, etc. As is the case for regulated models, such licences may be transferrable (sold, inherited or otherwise) or non-transferrable. That is, if a new owner wishes to buy or inherit an existing pharmacy, they may be required to apply for a new licence.

Likewise, in some jurisdictions, licences may be perpetual, while others require a periodical renewal of licences, subject to a verification of the stipulated requirements.

Finally, it should be noted that, in some jurisdictions in low- or middle-income countries or territories, the absence of regulations for the establishment and distribution of community pharmacies may be due not to the application of free market principles to this sector, but to the lack of institutional capacity and resources to plan, regulate and oversee the territorial distribution of pharmacies and access to medicines. In such contexts, which often coexist with critical shortages of medicines and pharmacy workforce, different types of medicines retailers may exist, including informal selling points at markets and street vendors.

## 4 Conclusion

As can be inferred from this overview, the territorial distribution and establishment of community pharmacies can broadly follow one of the models indicated in the table below. For regulated models, the main regulatory strategies are indicated.

|  | Regulation by issuing <br> location-bound licences <br> (for pharmacies owned by <br> a corporation or an <br> individual, whether a <br> pharmacist or not). | Geographic criteria |
| :--- | :--- | :--- | :--- |
| Applicable to pharmacies |  |  |
| and their branches. |  |  |$\quad$| Demographic criteria |
| :--- |
| (generally combined with |
| geographic criteria) |

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## Annex 1. Jurisdictions with regulated models

Below is a brief description of how several countries have defined different regulatory models in terms of pharmacy establishment and distribution. It is not the intention of this briefing to provide an exhaustive global overview on the subject but to indicate a range of models or possibilities. Unless otherwise referenced, data was obtained from the survey conducted by FIP in 2015 to its member organisations.

Although national legislation does not specify geographic or demographic criteria for the establishment of new pharmacies, the province of Buenos Aires (the largest and most

## Argentina

 populous) defines pharmacies as part of the health care system and applies territorial planning rules: one pharmacy for every 3000 inhabitants (except in towns with less than 6000 people, where a second pharmacy may be established when the population exceeds 4000 people). In all cases, a minimum distance of 300 metres must exist between two pharmacies.According to the Austrian Federal Constitution, the pharmacy system is not governed by the Industry and Trade Act, but forms part of the health system (6). Thus, the establishment of community pharmacies in Austria is regulated according to geographic (min. 500 m from the nearest pharmacy) and demographic criteria (min. 5,500 users). Since 1998, newly established pharmacies may choose to open even if their population ration is lower than 5,500 , but for existing pharmacies, this criterion must still be observed. The license to operate a pharmacy constitutes a personal right which cannot be transferred from one pharmacist to another. The premises of a pharmacy may be sold or inherited, but the new owner must apply for a new licence. The main prescription-only medicines dispensaries are community pharmacies (approx. 1,300 ), but there are also dispensing doctors (940). Five of the 46 hospital pharmacies also act as community pharmacies. Each pharmacy is allowed to run at least one branch pharmacy (in total there are 23 branch pharmacies). Internet pharmacies are not allowed and there is a very small list of OTC medicines which may be sold outside pharmacies.

[^1]|  | The establishment of pharmacies is regulated through licences issued by the Danish Health <br> and Medicines Authority, based on an independent evaluation of needs. The Ministry of <br> Health may subsidise pharmacies, in exceptional circumstances, located in sparsely <br> populated areas or with a very low turnover through fees paid by pharmacies with a higher <br> turnover across the country (7). |
| :--- | :--- |
| Pharmacy establishment is regulated by the Finnish Medicines Agency (FIMEA) which takes |  |
| a decision based on accessibility aspects and the opinion of the municipality concerned. In |  |
| rural areas, pharmacy service points may be established by a supervising pharmacy but are |  |
| only allowed to dispense a range of OTC medicines. The ownership of multiple pharmacies is |  |
| not allowed, nor is vertical integration. g8\% of community pharmacies are privately owned. |  |

A licence issued by the Pharmacy Council is necessary to establish a pharmacy, and a number
Ghana of requirements must be met, including a minimum distance of 400 metres from the nearest existing pharmacy.

| Greece | No geographic criteria apply, but a minimum population increase of 1,000 people is necessary to the establishment of a new pharmacy since 2014. |
| :---: | :---: |
| Italy | A minimum distance of 200 m from existing pharmacies, and a minimum of 4,000 inhabitants (for towns with over 12,500 people) or 5,000 inhabitants in towns with a population below 12,500. |
| Lebanon | A minimum distance of 200 metres must exist between any two pharmacies, and branch pharmacies are not allowed. Lebanon has the lowest ratio of inhabitants per pharmacy $(1,563)$ in the world. |
| Mali | A demographic criterion (one pharmacy per 7,500 inhabitants) is used in planning the establishment of new pharmacies. |
| Morocco | A minimum distance of 300 metres must exist between any two pharmacies. |
| Nigeria | A minimum distance of 200 metres must exist between any two pharmacies. |

> A minimum distance of 350 m from any new pharmacy to the existing ones, and of 100 m from Portugal the nearest hospital or health care centre; and a minimum of 3500 inhabitants are required to open a new pharmacy.

Establishment rules apply since 2011: a) in urban areas, a community pharmacy may be set up for a minimum of 3,000 inhabitants in Bucharest city and at least 3,500 inhabitants in county seat cities and at least 4,000 inhabitants in the other cities; b) in rural areas, a
Romania community pharmacy may set up for a minimum of 4,000 inhabitants in localities over 4,000 inhabitants and no more than one pharmacy in localities under 4,000 inhabitants. A community pharmacy may also be established in railway stations and airports as well as in shopping centres with a minimum sales area of $3000 \mathrm{~m}^{2}$.

## Senegal

The Ministry of Health issues licences for new pharmacies based on an annual assessment of where they are necessary and using demographic criteria (minimum 5,000 inhabitants) and geographic criteria (200/300/400 metres, depending on the location of the pharmacy).

Slovenia Demographic criteria apply not only to the establishment of pharmacies (5,000-7,000 inhabitants), but also to the number of pharmacists (at least 1 per 2,755 inhabitants).

A thorough assessment is done by health authorities to determine the need for a new South pharmacy in a given area, considering the population, distance to other pharmacies and Africa health facilities, existence of shopping centres or other facilities that may generate a high flow of people, etc. (8).

There are geographic and demographic criteria for the establishment and distribution of pharmacies. The general provisions are a minimum of 2,800 inhabitants per pharmacy and a minimum distance of 250 metres between any two pharmacies. These national regulations may be supplemented or slightly adapted by Autonomous Regions. In fact, the region of Spain Navarra does not apply establishment criteria. There are 21,458 community pharmacies and a population of 46.5 million in Spain - producing an average of 2,167 inhabitants/pharmacy (the 3rd lowest rate in Europe, after Greece and Belgium). $98.9 \%$ of the Spanish population have a pharmacy in their municipality of residence. Since 2000, there is a scale of deductions applicable to pharmacies that compensates pharmacies with a lower turnover (especially in rural areas) in the form of lower taxes and higher margins.

To date, there is no restriction on the establishment of pharmacies. However, in 2013 a discussion was started on new licence conditions for the provision of the wholesale and Ukraine retail sale of medical drugs. The draft version of the document provides for a limitation on pharmacy location, introducing the principle of 'walking accessibility'. In case of adoption, pharmacies would have to be located not closer than 300 meters from each other.

For a pharmacy to dispense medicines under the National Health Services Prescriptions


#### Abstract

United Kingdom (which amount to approximately 80\% of the turnover of an average pharmacy), the owner must obtain a contract with a local NHS Primary Care Organisation (PCO), who will determine if a new contract is necessary to adequately meet the needs of that local community.


Generally, no establishment rules are in place. Yet, since 2013, there must be a minimum distance of $1,000 \mathrm{~m}$ between two pharmacies of the same owner.


International
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## Fédération

Internationale
Pharmaceutique

Andries Bickerweg 5
2517 JP The Hague
The Netherlands

The Policy Briefings is a series of short reports presenting different models, policy options, advocacy arguments and examples from around the world on issues of relevance for FIP member organisations.

T +31 (0)70 3021970
F +31 (0)70 3021999
fip@fip.org


[^0]:    a This directive is originally from 2005 and was amended by directive 2013/55/EU, but the principle of legislative autonomy of the Member States in this regard was preserved.

[^1]:    The number of pharmacy licences in each town is calculated according to their population: for towns below 7,500 people, the population is divided by 2,000 to calculate the number of Belgium pharmacies; for towns between 7,500 and 30,000 , the population is divided by 2,500 ; and for towns above 30,000 people, the population is divided by 3,000 .

