CNMC
COMISIÓN NACIONAL DE LOS MERCADOS Y LA COMPETENCIA

E/CNMC/003/15 STUDY OF THE RETAIL MEDICINE DISTRIBUTION MARKET IN SPAIN

15 October 2015

www.cnmc.es

Contents

EXECUTIVE SUMMARY

This study analyses the various restrictions to competition in the retail medicine distribution market in Spain, from the point of view of efficient economic regulation. The objective is to make recommendations to the competent authorities, both national and regional, for improving economic efficiency in the distribution of medicines while maintaining or improving current levels of public health protection.

The CNMC acknowledges the need to protect the public interest inherent in the regulation of this market, as regards safety and access to medicines. Also, it is essential for the defence of the general interest that the regulation conforms to the principles of necessity and proportionality, avoiding the introduction or retention of unwarranted restrictions to competition that hinder or prevent the attainment of greater efficiency in the distribution of these products which may be required to improve the population's welfare.

The current regulation of pharmacies in Spain imposes restrictions on access and on the exercise of the activity of retail distribution of medicines. These restrictions have a negative impact on competition and consequently undermine patients as consumers, increase the public sector's procurement costs and reduce general welfare.

In Spain, Law 16/1997 of 25 April on the Regulation of Pharmacy Services establishes some basic principles for the organisation of the pharmaceutical sector. It is for the Autonomous Regions to develop the planning criteria for authorising pharmacies, which must take into account the density, dispersion and geographical characteristics of the population. The purpose of the regulation is to ensure accessibility and quality of service and sufficient supply of medicines.

The wide variety of pharmaceutical planning models adopted by the Autonomous Regions allows us on this occasion to carry out a quantitative and qualitative analysis of the effect of the restrictions imposed by each model on competition in the market and on the degree of attainment of the objective of ensuring the population's access to medicines.

The economic analysis shows that setting a maximum number of authorised pharmacies per population module is limiting the opening of pharmacies and impeding the existence of competition in many municipalities. This market access model, adopted in all Autonomous Regions with the exception of Navarre, is not a necessary restriction to competition in order to ensure the required pharmaceutical care of the population. This is proven by the fact that Navarre's limited reform of 2000 reducing the restriction on distances and population modules led to a

significant increase in competition in municipalities with large populations, and at the same time had a positive effect on pharmaceutical coverage in small municipalities, without increasing the cost of drugs for the Autonomous Region.

However, as well as the restrictions in terms of population modules and distances between pharmacies, in all the Autonomous Regions there are other barriers to access and to the exercise of pharmaceutical activity. These unwarranted restrictions limit competition in the retail distribution of medicines and involve a loss of welfare for patients as consumers as well as for the sector itself and its professionals.

The restrictions to competition imposed by the organisational model in force for Spain's pharmaceutical sector have been analysed from the point of view of the principles of efficient economic regulation, which allows the proposal of a number of recommendations to the competent authorities. These recommendations will enable improvements in terms of access to the market and the exercise of the activity and facilitate ownership and organisation of pharmacies, incentivising the beneficial effects of competition on quality, service, prices and innovation.

Firstly, it is recommended to lift the current legal restrictions on access to the market: population modules and mandatory minimum distances, whether between pharmacies or between pharmacies and healthcare centres, do not protect the general interest.

Secondly, it is recommended to remove a number of restrictions affecting the retail dispensing of medicines which, according to Spanish legislation currently in force, is unjustifiably and exclusively reserved to pharmacies.

As regards pharmacies' exclusive right to distribute non-prescription drugs, it is recommended to allow their sale in other establishments provided that these meet a number of minimum health requirements as regards conservation and hygiene. As for the online sale of these medicines, it is proposed that ownership of the websites be liberalised so that they are not limited to physical pharmacies.

As regards pharmacies' exclusive right to dispense prescription drugs, it is recommended to extend the cases in which they can be dispensed in hospitals or healthcare centres, as long as they meet the necessary technical conditions for the conservation of the medicines and they can count on the advice of a competent technician who meets the training requirements set forth in Directive 2005/36/EC.

The online sale of medicines in Spain subject to medical prescription, as it is at EU level, is also recommended. The CNMC points out by way of reminder that this must be done with the indispensable requirement that the medicine be dispensed

by a competent technician, which must include qualified pharmacists, who safeguards the public interest involved, without this person necessarily being the owner of the website or a physical pharmacy.

Thirdly, it is proposed to eliminate the requirement that owners and operators of pharmacies be exclusively graduates in pharmacy and mandatorily belong to an association. It is recommended to allow ownership of more than one pharmacy and eliminating the restriction on vertical integration of pharmacies, for example with wholesale distribution, by amending the corresponding legislation.

Fourthly, it is proposed that alternatives to the current financing system for pharmacies be evaluated, with a view to having the remuneration received by the pharmacies reflect the services effectively provided by them. In particular, alternative systems that provide incentives to improve the quality of the services offered or that remunerate additional services that might be particularly beneficial to patients.

Fifthly, having ensured the appropriate pharmaceutical care of the population with minimum opening hours and the on-call duty, the elimination of the regulatory, administrative and practical obstacles that prevent pharmacies from voluntarily extending their opening hours, should they wish to do so, is proposed.

Sixthly, it is proposed to remove the additional prohibition on advertising by pharmacies, provided that such advertising conforms to the provisions of Article 44 of Law 44/2003, of 21 November, on the organisation of the healthcare professions.

Seventhly, it is recommended that the Autonomous Regions eliminate all the requirements contained in the competitive examinations for the opening of new pharmacies that unnecessarily restrict competition and do not strictly relate to healthcare criteria.

Eighthly, it is recommended that the Autonomous Regions suppress those restrictions to competition in the supply of social healthcare medicines which do not strictly relate to healthcare criteria.

Ninthly, the elimination of the requirement of mandatory membership of an association for owner-operators and pharmacists in pharmacies is proposed, by means of the appropriate legislative amendments, ensuring the voluntary nature of such membership.

Lastly, it is recommended to eliminate the exclusive right of the Official Associations of Pharmacists to invoice and collect prescriptions.

1. INTRODUCTION

The retail distribution of medicines is a tightly regulated activity in Spain, at both state and regional levels. Unlike other countries where doctors and hospitals play a significant role in dispensing medicines, the distribution of medicines in Spain is carried out mainly by pharmacies[1].

The current regulation of pharmacies in Spain imposes restrictions on access and on the exercise of the activity which have an impact on competition in the retail medicine distribution market and consequently on patients as consumers of these products, the public sector's procurement costs and the general interest.

In this case the restrictions on access to the market are legal barriers imposed by the regulation, which determine the requirements laid down by the competent administration for opening a pharmacy. Opening a pharmacy requires administrative authorisation which is subject to certain criteria. Additionally, pharmacies are subject to territorial planning, which means that at present the opening of such a retail establishment is authorised only if it meets certain criteria of minimum distance between pharmacies and subject to a minimum population in the zone in which it is to be opened.

The main restrictions on the dispensing of medicines consist in the obligation to hold a degree in pharmacy and the requirement for the owner of the pharmacy to be a pharmacist in all cases.

To a greater or lesser extent, the majority of EU Member States[2], like Spain, apply restrictions to the freedom of establishment of pharmacies. This situation contrasts with the regulations in place in countries such as Canada and the U.S., where there are no such restrictions and the regulations are aimed at ensuring that pharmacies,

[1] However, hospitals' share in the retail medicine distribution market in Spain has increased considerably in the past few years, to 30% by value. This increase is explained basically by the ageing of the population with the consequent chronification of various illnesses, the high cost of the innovative drugs used to treat them and the fact that the dispensing of the drugs used to treat these chronic ailments in outpatients is reserved to the hospitals.

[2] According to information provided by ÖBIG, the Austrian Health Institute (2006): “Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States", a report commissioned by the European Commission, 17 of the 25 Member States applied restrictions to the freedom of establishment of pharmacies in 2006. Of these 17, seven (Austria, Greece, Hungary, Italy, Portugal, Slovenia and Spain) also had geographical restrictions on the establishment of new pharmacies.

whether established or new, have sufficient resources with which to perform their healthcare function.

The European Union has no common legal framework for the free establishment and opening of pharmacies. The regulation of the exercise of the profession of pharmacist depends on the Member States, since it is connected with the relatively exceptional nature of the national organisation of healthcare services[3].

In Spain, Law 16/1997, of 25 April, on the Regulation of Pharmacy Services establishes some basic precepts[4] for the organisation of the pharmaceutical sector, leaving it to the Autonomous Regions to develop and execute the rules in accordance with their particular needs and conditions.

According to this Law, the planning criteria for the authorisation of pharmacies, to be developed by the Autonomous Regions, must take into account the density, dispersion and geographical characteristics of the population, so as to ensure accessibility and quality of service and sufficient supply of medicines, according to the healthcare needs in each territory.

The wide variety of pharmaceutical planning models adopted by the Autonomous Regions allows us to carry out a quantitative and qualitative analysis of the degree of compliance with the objective of ensuring the population's access to medicines. It also allows us to analyse the effect of the restrictions imposed by each model on competition in the market.

The retail medicine distribution market is an atypical market in which the Spanish National Health System (NHS) plays a fundamental role as buyer. The main social and economic reasons for public financing of medicines are the fact that medicines are essential goods, due to their importance for preserving health, and the positive externalities that their proper consumption can generate for society as a whole.

With a view to ensuring that medicines are accessible to the entire population, the prices of prescription drugs that can be financed by the National Health System (94% of the total[5]) are highly regulated. Other medicines, known as generics or OTC, are not subject to any price controls, although the Ministry of Health must be

[3] Directive 2006/123/EC of the European Parliament and of the Council, de 12 December de 2006 on services in the internal market, establishes the exclusion of pharmaceutical services from its scope of application.

[4] Law 16/1997 establishes, generally, a minimum population module for opening pharmacies of 2,800 inhabitants per establishment and a minimum distance of 250 metres between pharmacies.

[5] Total billings of prescription drugs at manufacturers' selling price compared with total medicines in 2013 according to IMS Health.

informed of all prices[6]. Although it is legally possible to grant discounts of up to 10%, such price reductions have so far been limited.

Even in a market like the present one, with regulated, practically fixed prices, in which no competition is possible on prices or margins, which is a basic economic instrument for achieving efficiency, adopting a less restrictive pharmaceutical planning model as regards various variables could bring significant benefits to the patient as consumer. Among these benefits would be a broader and more varied supply of pharmaceutical dispensing, and there could be a positive effect on variables such as the quality and convenience of the service, opening hours better suited to patients, greater variety of types of pharmacy, including online distribution, as well as on the amount of discounts on prices of OTC drugs.

The CNMC is fully aware of the imperative need to protect the public interest as it relates to the safety of and access to medicines, which is inherent in the regulation of the retail distribution of medicines in advanced countries and in particular in Spain. It is essential to separate this main general interest objective from the protection, which is also legitimate, of private interests (financial viability of pharmacies and wholesale distributors). Efficient economic regulation always takes both aspects into account and is aligned with the basic objectives of the regulation of this sector, namely i) to ensure maximum quality and innovation in pharmaceutical care and ii) to reduce costs of access to suitable medicines for patients and distribution costs for operators.

It is therefore necessary to study the extent to which the restrictions imposed by the regulation inhibit or encourage competition in the retail medicine distribution market, and whether these restrictions benefit consumers or, on the contrary, impose unnecessary costs on them and on the public sector as financier of the system.

The distribution of medicines in Spain has been studied in several reports of the Competition Authority (the CNMC - Spain's National Authority for Markets and Competition - and its predecessors the CNC and the Tribunal for the Defence of Competition)[7]. Due to various local characteristics it has also been the subject of disciplinary proceedings on the part of various regional competition authorities[8].

[6] Prescription drugs that are not financed are also sold on a price notification basis but may not be advertised to the public.

[7] IPN/CNMC/005/15 on the Royal Legislative Decree Law approving the Consolidated Text of the Law on Guarantees and Rational Use of Medicines and Healthcare Products, IPN 110/13 on the Draft Law on Professional Services, IPN 085/13 on the Royal Decree Law on Distribution of Medicines for Human Use, IPN 081/12 on the Draft Law to Amend the Law on Guarantees and Medicines and IPN 018/09 on Omnibus Royal Decree Laws. Healthcare and Pharmaceutical Services and Report of the

However, until now no in-depth analysis has been carried out of the retail medicine distribution market in Spain from the point of view of competition and efficient regulation.

This study is also especially relevant at this time in view of the importance of this market in economic terms and the heavy weight of public expenditure on pharmaceuticals in healthcare spending and the public accounts. Since the onset of Spain's economic crisis, a series of measures have been implemented aimed at boosting the efficiency of expenditure on pharmaceuticals. These measures have focused particularly on the wholesale part of the market[9], without substantial reforms being proposed for the retail market.

Apart from this, the growth of the new technologies in the past few years, and especially the Internet as a means whereby transactions are increasingly carried out for all types of products - including medicines in other countries- constitutes a fundamental innovation in this market. Although still in its infancy in Spain, this innovation shows potential benefits as an instrument for energising competition.

In this context, the basic objective of this study is to analyse the various restrictions to competition in the retail medicine distribution market from the point of view of efficient economic regulation. In other words, to use economic and legal criteria to evaluate the need for and proportionality of the restrictions, bearing in mind comparative experience at home and abroad, in order to draw conclusions and make recommendations as to the configuration that would most favour competition and economic efficiency, while at the same time fully respecting the reasons of imperative general interest referred to.

The study consists of five sections plus the introduction. In the second section we present a legal analysis of European, Spanish and regional regulation on medicines and the organisation of the pharmaceutical sector. The third section contains an economic analysis of the market. The fourth section studies the current organisational model of the pharmaceutical sector from the point of view of

---

Tribunal for the Defence of Competition "Competition in Spain: Balance Sheet and New Proposals" (1995), *inter alia*.

[8] Resolution S/07/2014 on Pharmacies in Andalusia of the Andalusian Council for the Defence of Competition, Resolution (Case 10/2012, Pharmaceutical Services in Homes 2) of the Basque Competition Authority, Resolution R 2/2012-Electronic Prescription of the Galician Council for Competition and Resolution (Case 2/2008 of the Board for the Defence of Competition of Extremadura).

[9] They include the introduction of cost-effectiveness and budgetary impact criteria in the financing of medicines, and price discounts on medicines financed by the NHS.

competition and efficient economic regulation. This section of the study is in turn divided into two parts. The first part consists of a quantitative and qualitative assessment of the main restrictions to competition, and the second one contains an evaluation of the impact of Navarre's 2000 reform on the entry of new pharmacies using econometric techniques. Lastly, we present the main conclusions obtained from the analysis and put forward recommendations to the competent authorities.

In producing this study we were able to rely on the participation of the different market agents: pharmacies, Associations of Pharmacists, the Ministry of Health and also the contribution of academic researchers with expertise in the pharmaceutical sector[10].

2. LEGAL ANALYSIS

2.1. European regulation

The legal framework of the pharmaceutical sector in the European Union in aspects relating to the quality and safety of medicines consists essentially of Directive 2010/84/EU of the European Parliament and of the Council, of 15 December 2010, on pharmacovigilance and Directive 2011/62/EU of the European Parliament and of the Council, of 8 June 2011, on the prevention of the entry into the legal supply chain of falsified medicinal products[11].

However, at European level there is no common legal framework for the requirements for owning the business and free establishment of pharmacies. The regulation of the exercise of the profession of pharmacist depends on the Member States, since it is connected with the relatively exceptional nature of the national organisation of healthcare services[12], which have traditionally included the dispensing of medicines.

[10] Among others, meetings were held with representatives of the Madrid Association of Pharmacy Entrepreneurs (ADEFARMA), The Business Federation of Spanish Pharmacists (FEFE), the Ministry of Health, Social Services and Equality and the General Council of Official Associations of Pharmacists (CGCOF).

[11] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0062&from=EN.

[12] Directive 2006/123/EC of the European Parliament and of the Council, of 12 December 2006, on services in the internal market, establishes the exclusion of pharmaceutical services from its scope of application.

However, in accordance with European Union law[13], restrictions on freedom of establishment are allowed only when: they are justified by reasons of overriding general interest (necessity), are proportionate to said objective, involving as little competitive distortion as possible (proportionality), enable the objective pursued to be attained (suitability) and are applied in a non-discriminatory manner (non-discrimination).

In 2006 geographical and ownership restrictions on pharmacies were the subject of a Reasoned Opinion to several countries, Spain among them, by virtue of Article 226 of the Treaty Establishing the European Community. The Commission considered that quantitative limits on the establishment of pharmacies are not only disproportionate but actually counterproductive as regards attaining the healthcare objectives pursued. Concerning the restriction whereby the owner of a pharmacy must be a pharmacist with a degree, the Commission considered that the objectives of ensuring a quality service to users can be attained by complying with the ethical rules (pharmacists' professional obligations) or through the exercise of a public power of inspection and control, and that therefore this restriction would not be necessary to attain this objective.

Although the European Court of Justice[14] subsequently ruled that Spain's geographical restrictions on the opening of new pharmacies and the restriction of ownership and operation of pharmacies to pharmacists did not violate the principle of free establishment *stricto sensu*, an analysis of these restrictions continues to be entirely relevant from the point of view of the promotion of competition and the principles of necessity and minimal competitive distortion that inform efficient economic regulation.

2.2. Regulation of the pharmaceutical sector in Spain

Spain's pharmaceutical sector is characterised, like that of most neighbouring countries, by being tightly regulated in all activities the length of the medicine chain.

Regulation of the pharmaceutical sector is justified by several reasons: a) the special safeguards required by the vital legal interest protected: people's health; b) the

[13] ECJ Gebhard Case C-55/94. Ruling of the European Court of Justice of 30 November 1995; ECJR of 5 June 2007. Rosengren and Others. Case C-170/04; ECJR of 17 July 2008. Corporación Dermoestética. Case C-500/06. cf. Moral Soriano (2002).

[14] Ruling of 1 June 2010 on combined cases C-570/07 and C-571/07.

existence of market failures[15] due to which free competition would not necessarily lead to economic efficiency in all situations; and c) the strategic importance of the sector in the economy, given the intensity of innovation and the impact of expenditure on pharmaceuticals on the public accounts and, consequently, on taxpayers.

The activities in the medicine chain are, firstly, the research and production of the medicines by the pharmaceutical companies. Secondly, the distribution of medicines to hospitals and pharmacies by wholesale distributors[16] and, lastly, the distribution of medicines to patients by pharmacies, hospitals and primary care centres.

The retail distribution of medicines through pharmacies is therefore the final link in the medicine chain and the nearest one to the patient or the person acquiring the medicine on the patient's behalf when the patient cannot visit the pharmacy in person. Its analysis requires an overall and detailed view of the functioning and the regulation of the pharmaceutical sector in Spain.

Law 14/1986, of 25 April, the General Health Act[17] is one of the basic laws regulating the Spanish pharmaceutical sector, since it established the National Health System and decentralised competences in public health and healthcare, including pharmaceutical services, to the Autonomous Regions[18], as already envisaged in the Spanish Constitution.

Although the Autonomous Regions have legislative competence for the territorial planning of pharmacies, the State has competence for legislation on pharmaceutical products.

The basic legislation on medicines is contained in the Consolidated Text of the Law on Guarantees and Rational Use of Medicines and Healthcare Products (hereinafter referred to as the "Consolidated Text")[19]. This text regulates, in the area of the competences of the State, both medicines and healthcare products as well as all the

[15] Deriving from the existence of positive externalities from the consumption of medicines and asymmetric information between prescriber and patient.

[16] The pharmaceutical manufacturers also distribute directly to hospitals (30% of the total) and, to a very limited extent, to pharmacies (4% of the total).

[17] https://www.boe.es/buscar/pdf/1986/BOE-A-1986-10499-consolidado.pdf

[18] Article 41 of Law 14/1986.

[19] Royal Legislative Decree 1/2015, of 24 July, approving the Consolidated Text of the Law on Guarantees and Rational Use of Medicines and Healthcare Products and repealing Law 29/2006, of 26 July.

activities in the medicine chain and the actions of the healthcare and economic agents involved in these activities.

According to the memorandum of the law, pharmaceutical services comprise "*medicines and healthcare products as well as all actions designed to ensure that patients receive them and use them in a manner appropriate to their clinical needs and in the correct doses according to their individual requirements, during the appropriate period, with the information necessary for their correct use and at the lowest possible cost*".

As a result of the economic crisis and the austerity measures implemented to contain expenditure on healthcare, generally, and pharmaceuticals, in particular, Law 29/2006 has been amended on various occasions. Although some amendments were of a healthcare nature, such as those relating to the guarantees of effectiveness, safety and quality of medicines and healthcare products, the most significant ones have concerned financial aspects, with the ultimate objective of containing public expenditure on pharmaceuticals.

With this aim the following laws, among others, were passed in 2010, 2011 and 2012:

- Royal Decree-Law 4/2010, of 26 March, on the rationalisation of expenditure on pharmaceuticals charged to the National Health System
- Royal Decree-Law 8/2010, of 20 May, adopting extraordinary measures to reduce the public deficit.
- Royal Decree-Law 9/2011, of 19 August, on measures to improve the quality and cohesion of the National Health System, contribute to fiscal consolidation and raise the maximum amount of State guarantees for 2011.
- Royal Decree-Law 16/2012, of 20 April, on urgent measures to ensure the sustainability of the National Health System and improve the quality and safety of its services.

Prominent among the most recent amendments to the Medicine Law are Law 10/2013, of 24 July, incorporating the transposition into the Spanish legal system of Directives 2010/84/EU of the European Parliament and of the Council, of 15 December 2010, on pharmacovigilance and 2011/62/EU of the European Parliament and of the Council, of 8 June 2011, on the prevention of the entry into the legal supply chain of falsified medicinal products, and Royal Legislative Decree 1/2015, of 24 July, approving the Consolidated Text of the Law on Guarantees and Rational Use of Medicines and Healthcare Products.

2.2.1. Medicines

2.2.1.1. Definition and types of medicines

Royal Legislative Decree 1/2015, of 24 July, approving the Consolidated Text of the Law on Guarantees and Rational Use of Medicines and Healthcare Products defines medicine for human use as "*any substance or combination of substances presented as having properties for treating or preventing disease in human beings or which may be used in, or administered to, human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.*"

Since medicines have a direct influence on people's health, they must be subject to strict regulation in order to ensure their quality, effectiveness and safety. For this reason, the sale of any medicine requires the authorisation of the Spanish Agency for Medicines and Healthcare Products and filing in the Register of Medicines, or else authorisation in accordance with the provisions of the European laws which establish the community procedures for the authorisation and control of medicines for human and veterinary use regulated by the European Medicines Agency.

In the authorisation of the medicine, the Spanish Agency for Medicines and Healthcare Products sets the conditions for prescription, classifying between:

a) Medicine subject to medical prescription.

b) Medicine not subject to medical prescription.

Medicines are subject to medical prescription when any of the following applies[20]:

1) They may present a hazard, directly or indirectly, even in normal conditions of use, if used without medical control.

2) They are used frequently and to a very considerable extent in abnormal conditions of use and this may involve, directly or indirectly, a risk to health.

3) They contain substances or preparations based on substances, the adverse actions and/or reactions of which require to be studied in further detail.

4) They are administered parenterally, except in exceptional cases, by medical prescription.

Medicines not subject to medical prescription are those "*designed for processes or conditions that do not require precise diagnosis and the toxicological, clinical or*

[20] Article 19.2 of the Consolidated Text.

usage and administration route evaluation data of which do not require medical prescription, such that these medicines can be used for self-healthcare".

Because of their characteristics, medicines and healthcare products subject to medical prescription are tightly regulated in Spain in aspects such as advertising and marketing.

For example, as regards sales, although the online sale of prescription medicines has been possible in the EU since Directive 2000/31/EC of the European Parliament and of the Council, of 8 June 2000, on certain legal aspects of information society services, in particular, electronic commerce in the Internal Market[21] ("Directive on electronic commerce"), Spanish law totally prohibits sale by correspondence or telematic means. Also, advertising of prescription medicines is forbidden[22].

These restrictions relating to advertising do not apply to OTC medicines, which may be advertised. They may also be sold retail via websites of authorised pharmacies[23].

However, these medicines can be sold via websites only by physical pharmacies open to the public, legally authorised and which have given notice of this activity in accordance with the provisions of the legislation regulating this type of sale.

In principle, the justification for this restriction in Spain is the protection of public health. According to the legislation in force, this would require as a safeguard that medicines not subject to medical prescription i) be dispensed by an authorised pharmacy ii) with the involvement of a pharmacist and iii) subject to prior personalised advice[24].

In this regard, Article 3 of the Consolidated Text establishes that the custody, conservation and dispensing of medicines for human use is reserved exclusively to pharmacies open to the public, legally authorised and to the pharmacy departments of hospitals, healthcare centres and primary care structures of the National Health System.

[21] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000L0031:En:HTML.

[22] Article 80 of the Consolidated Text establishes the requirement that for a medicine or healthcare product to be advertise to the public it must not be financed by public funds and must not require the intervention of a doctor to make the diagnosis, issue the prescription and follow up the treatment, even if it requires the involvement of a pharmacist.

[23] Royal Decree 870/2013, of 8 November, regulating remote sales to the public via websites of medicines for human use not subject to medical prescription.

[24] Direct selling, and any kind of indirect selling to the public of medicines (whether subject to medical prescription or not) are also prohibited.

Another possible classification of medicines is by reference to their financing: public or private.

Article 92 of the Consolidated Text determines the procedure for a medicine to be financed by the National Health System (NHS) and, as a prior step, establishes the necessity of the medicine being included in the reimbursement list. The general criteria for such inclusion are as follows:

a) Severity, duration and after-effects of the various conditions for which the medicine is indicated.

b) Specific needs of certain groups.

c) Therapeutic and social value of the medicine and its incremental clinical benefit taking its cost-effectiveness into account.

d) Rationalisation of public expenditure on pharmaceuticals and budgetary impact on the National Health System.

e) Existence of medicines or other therapeutic alternatives for the same conditions at a lower price or cost of treatment.

f) Degree of innovation of the medicine.

It is important to point out that only prescription drugs can be financed from public funds[25] and, furthermore, for a medicine to be included in the reimbursement list of the National Health System, its financing must be considered necessary to cover the basic healthcare needs of the Spanish population[26].

Lastly, medicines can be classified into innovative (protected by a patent) and generic.

An innovative medicine is characterised by containing a new active principle on which complete research and development has been carried out, from its chemical synthesis to its clinical use. It is therefore the first and sometimes the only one that provides data on safety and therapeutic effectiveness of the specific pharmaceutical speciality. It is generally sold in different countries by the same patent holder, even under the same name, and in some cases its trade name comes to be considered by prescribers as synonymous with the active principle.

[25] Article 92.2 of the Consolidated Text.

[26] This selective financing of medicines, according to the “basic need" criterion, is one of the measures to reduce public expenditure on pharmaceuticals and was incorporated by Royal Decree-Law 16/2012, of 20 April, on urgent measures to ensure the sustainability of the National Health System and improve the quality and safety of its services.

According to Article 2.g) of the Medicine Law, a generic drug is considered to be "*any medicine that has the same qualitative and quantitative composition in active principles and the same pharmaceutical form as the original product. Furthermore, its bio-equivalence with the original product has been demonstrated by appropriate bio-availability studies.*"

Generic drugs are medicines with the same healthcare characteristics as, and interchangeable with, the corresponding original medicines ("reference listed drugs"), and are sold once the patents for the latter have expired.

2.2.1.2. Regulation of the price of medicines

Price regulation of medicines goes hand-in-hand with their public financing by the National Health System, and the inclusion of a medicine in this financing is decided by specific resolution of the responsible unit of the Ministry of Health, Social Services and Equality[27] depending on its indications, therapeutic and social value, budgetary impact, alternative treatments and degree of innovation.

In order to sell a medicine in Spain, even in the case of medicines not financed by the NHS, it is necessary, first, to have offered it to the NHS. Holders of authorisations to sell can sell medicines on the basis of notified prices, meaning that they have to communicate the price in advance to the Ministry of Health, Social Services and Equality, which may object to it for reasons of public interest[28].

Medicines not financed by the NHS and not subject to medical prescription may be advertised to the public, and in this case the price affixed to the pack or bottle is considered as the maximum retail price. Pharmacies may apply discounts of up to 10% of this retail price, including taxes[29].

In the case of medicines financed by the NHS, it rests with the Inter-ministerial Committee on Medicine Prices, reporting to the Ministry of Health, to fix the financing prices[30]. As a general rule, the price to be financed by the NHS will be lower than the industrial price of the medicine applied when it is dispensed outside the NHS[31].

[27] The General Directorate for Pharmacy and Healthcare Products.
[28] Article 94.4 of the Consolidated Text.
[29] Article 4 of Royal Decree 823/2008, of 16 May, establishing the margins, deductions and discounts corresponding to the distribution and dispensing of medicines for human use.

[30] Article 94.5 of the Consolidated Text.

[31] Article 94.7 of the Consolidated Text.

The public financing of medicines is subject to the system of reference prices[32], the reference price being the maximum amount for which the presentations of medicines included in each of the groups decided upon will be financed, provided that their prescription and dispensation is financed by public funds. Reference prices are calculated based on the lowest cost/treatment/day of the various presentations.

The system of reference prices is based on sorting medicines into groups that include all the financed presentations of medicines that have the same active principle and administration route. In principle, these groups will include at least one presentation of generic or bio-similar medicine.

The margins corresponding to the activities of distribution and dispensing of medicines and, where appropriate, any deductions applicable to their invoicing to the NHS are fixed by the Government.

The Ministry of Health, Social Services and Equality establishes the retail price of the financed medicines and healthcare products by means of the sum of the authorised industrial price (maximum) and the margins corresponding to the activities of wholesale and retail distribution.

The criteria for the inclusion of medicines in the reimbursement list of the NHS were changed by Royal Decree-Law 16/2012, and since 2012 medicines for treating minor symptoms have been excluded from financing. Moreover, this Royal Decree-Law changed the system for setting the prices of medicines with a view to establishing selective financing of medicines based on criteria of cost-effectiveness and budgetary impact[33].

2.2.2. Pharmacies

Pharmacies in Spain are private healthcare establishments of public interest, as established in Article 1 of Law 16/1997, of 25 April, on the regulation of pharmacy services[34], subsequently confirmed by the Medicine Law[35], which incorporates the notion of Pharmaceutical Care in its text, thus acknowledging the work of the pharmacist as a healthcare agent.

[32] Article 98 of the Consolidated Text.

[33] The mechanism for determining the price of innovative medicines is still pending approval.

[34] https://www.boe.es/buscar/pdf/1997/BOE-A-1997-9022-consolidado.pdf.

[35] Article 86.6 of the Consolidated Text.

In order to carry out the activity of dispensing medicines, an indispensable requirement is to have the status of pharmacist, in accordance with Article 5 of Law 16/1997 and Article 86.2b) of the Consolidated Text, which establishes that the presence and active professional involvement of the pharmacist is an indispensable condition and requirement for dispensing medicines to the public and that the number of pharmacists necessary will depend on the pharmacy's business.

Moreover, the safekeeping, conservation and dispensing of medicines for human use, whether or not subject to medical prescription, is reserved to pharmacies and hospitals' pharmacy departments[36].

Ownership of pharmacies is regulated by Article 103.4 of Law 14/1986, of 25 April, the General Health Act, which stipulates that only pharmacists can be owners and operators of pharmacies open to the public.

We should point out that both the horizontal integration of pharmacies, which would allow pharmacy chains to be formed or at least economies of scale to be obtained, even with just two pharmacies, and the vertical integration of pharmacies with manufacturers and wholesale distributors are prohibited by law in Spain.

As regards the impossibility of horizontal integration of pharmacies in chains, the limitation of the pharmacist's ownership to a single pharmacy is not established by Law 16/1997. This limitation to economic freedom is established in some Autonomous Regions' laws on the organisation of the pharmaceutical sector[37]. The only indirect reference to this restriction in Law 16/1997 is to be found in Article 1, which defines pharmacies as private healthcare establishments of public interest, in which the pharmacist who is the *owner-operator*, supported where appropriate by assistants or auxiliary staff, must provide a number of basic services to the population.

As regards the impossibility of pharmacies' integration with pharmaceutical manufacturers and/or wholesale distributors, Article 4.6 of the Consolidated Text stipulates that the exercise of the profession of pharmacist in pharmacies, retail sales establishments, livestock entities or groupings or hospital pharmacy departments and other healthcare structures is incompatible with any kind of direct economic interests of the pharmaceutical manufacturers, intermediaries and/or distributors. However, the second transitional provision of this law allows pharmacists forming

[36] Article 3.6 of the Consolidated Text.

[37] For example, Article 6.1 of Law 11/1994, of 17 June, on the Organisation of the Pharmaceutical Sector of the Autonomous Region of the Basque Country establishes that “each pharmacist may be the owner and operator or co-owner and co-operator of only one pharmacy”.

part of cooperatives (with a minimum of 20 members) or commercial companies (with a minimum of 100 shareholders or partners) engaged in the wholesale distribution of medicines, in both cases formed exclusively by said pharmacists, and already in existence at the time the law came into force, to continue taking part in them until such time as they are dissolved[38].

The public interest of pharmacies is justified by the basic services that they provide to the population, as established in Law 16/1997:

- The acquisition, safekeeping, conservation and dispensing of medicines and healthcare products.
- The vigilance, control and custody of the prescriptions dispensed.
- The guarantee of pharmaceutical care, in their pharmaceutical zone, to population centres where there are no pharmacies.
- The preparation of magistral formulas and officinal preparations in the cases established and in accordance with established procedures and controls.
- Providing information and follow-ups of pharmacological treatment to patients.
- Collaboration on the control of the individualised use of medicines, in order to detect any adverse reactions that might arise and report them to the responsible pharmacovigilance bodies.
- Collaboration on programmes promoted by the healthcare administrations on quality assurance for pharmaceutical care and healthcare in general, the promotion and protection of health, disease prevention and healthcare education.
- Collaboration with the healthcare Administration on training and information aimed at other healthcare professionals and users on the rational use of medicines and healthcare products.
- Coordinated action with the healthcare structures of the Health Services of the Autonomous Regions.
- Collaboration on teaching students for the Diploma in Pharmacy, in accordance with the provisions of the EU Directives, State legislation and University rules establishing the corresponding curricula.

[38] Such is the case of the wholesale distribution cooperative COFARES, which with a 25% market share is the leader in the wholesale medicine distribution market in Spain.

According to Law 16/1997, in addition to the dispensing of medicines, pharmacies provide services that are fundamental for attaining the various public health objectives and ensuring the population's correct consumption and use of medicines. Despite the acknowledged importance of these services, the main function of pharmacies is the distribution of medicines.

In fact, the regulated margin received by pharmacies is, on most medicines, a percentage of the retail price of the medicines and healthcare products they dispense[39], with no specific remuneration for the services of pharmaceutical care that they provide to patients.

In this regard, Royal Decree 823/2008, of 16 May, establishing the margins, deductions and discounts corresponding to the distribution and dispensing of medicines for human use, determines the margins in force for both wholesale distributors and retailers.

The following table shows the margins obtained by pharmacies for dispensing and selling industrially manufactured medicines for human use to the public, by reference to the industrial price of the medicines.

Table 1. Pharmacies' margins on dispensing medicines

Price of Medicine (PVL* in euros)	Pharmacies' Margin (% PVP**/fixed amount in euros/package)
PVL ≤ 91,63	27,9%
91,63 < PVL ≤ 200	38,37 euros
200 < PVL ≤ 500	43,37 euros
PVP > 500	48,37 euros

*PVL: manufacturers' selling price or industrial price.
**PVP: retail price before tax.
Source: in-house based on Royal Decree 823/2008.

This Royal Decree also establishes the contribution made by pharmacies, as a function of their sales, to the financing of the National Health System. In this way, the margin obtained for dispensing medicines and healthcare products financed by the

[39] With this type of remuneration, the higher the price of the medicine and the greater the volume of sales, the higher the pharmacy's revenues.

NHS is reduced in accordance with a scale of deductions linked to the volume of sales[40].

Table 2. Deductions from pharmacies' monthly turnover for contributions to the NHS

Pharmacies' Sales (PVP IVA* in euros)	Deduction (euros)	Remainder to (euros)	Percentage applicable
0,00	0,00	37.500,00	0,00%
37.500,01	0,00	45.000,00	7,80%
45.000,01	585,00	58.345,61	9,10%
58.345,62	1.799,45	120.206,01	11,40%
120.206,02	8.851,53	208.075,90	13,60%
208.075,91	20.801,83	295.242,83	15,70%
295.242,83	34.487,04	382.409,76	17,20%
382.409,77	49.479,75	600.000,00	18,20%
600.000,01	89.081,17	En adelante	20,00%

* PVP VAT: retail price plus VAT.
Source: in-house based on Royal Decree 823/2008.

Royal Decree 9/2011 amended Royal Decree 823/2008 by introducing measures to ensure the economic viability of pharmacies, with the aim of guaranteeing the continuity of the care service that they provide. This measure was initially aimed at pharmacies located in isolated or socially deprived population centres, but Royal Decree Law 16/2012 eliminated this requirement, extending the possibility of receiving assistance to ensure their economic viability to all pharmacies.

In this way, pharmacies exempted from the aforementioned scale of deductions and complying with a number of requirements[41] benefit from a corrective index applied to the pharmacy margins for dispensed prescription medicines financed by public funds.

[40] In the case of medicines with an industrial price of more than €91.63 and for purposes of monthly invoicing, the scale of deductions excludes any monthly invoicing which, calculated in terms of retail price including VAT, exceeds the aforementioned industrial price.

[41] a) That they have not been subject to administrative sanction or disqualification from the profession and are not excluded from setting up; b) that they take part in pharmaceutical care programmes and in all such activities aimed at the rational use of medicines that the corresponding healthcare administration may establish and c) that their total annual sales, in terms of retail price plus VAT do not exceed €200,000 in the financial year corresponding to the previous calendar year.

When applying the tranche corresponding to the scale presented hereunder, the difference between €12,500 and the amount of monthly turnover for prescriptions or dispensing orders of industrially manufactured medicines for human use financed by public funds is used.

The percentage indicated in the scale is applied to the difference between the amount referred to in the previous paragraph and the lower tranche of that scale. The fixed amount specified in each tranche of the scale is added to the resulting amount. In no case may the amount deriving from the application of the margin correcting index exceed €833.33 in favour of the pharmacy in any one month.

Table 3. Corrective index for pharmacies' margins

Differencial		Percentage	Fixed
From	to		
0,01	2.750,00	7,25%	
2.750,01	5.500,00	7,75%	199,38
5.500,01	8.250,00	8,25%	412,50
8.250,01	10.466,66	8,75%	639,37
10.466,67	12.500,00		833,33

Source: in-house based on Royal Decree 823/2008.

Lastly, Royal Decree-Law 8/2010 establishes the deductions or discounts to be applied to NHS medicines dispensed by pharmacies. Pharmacies must apply a deduction of 7.5% of the retail price when invoicing industrially manufactured medicines for human use dispensed under the reimbursement list of the National Health System. However, for the purposes of applying and sharing this deduction among all the agents in the pharmaceutical chain, distributors must apply a 7.5% deduction to their selling price, and the manufacturer must also apply a 7.5% deduction to the maximum industrial price.

2.2.3. Pharmaceutical planning

The authorisation of new pharmacies is subject to planning, as established by Article 103.3 of Law 14/1986, of 25 April, the General Health Act, and Article 2.1 of Law 16/1997, and the purpose of this planning is to organise the provision of pharmaceutical care to the population.

This article also stipulates that it is for the Autonomous Regions, which are responsible for ensuring this care, to establish specific planning criteria for authorising pharmacies.

Pharmaceutical planning must be carried out in accordance with healthcare planning, and the reference demarcations for pharmaceutical planning will be the basic primary care units established by the Autonomous Regions.

Article 2.2 of Law 16/1997 stipulates that the planning of pharmacies must take into account density, dispersion and geographical characteristics of the population, so as to ensure accessibility and quality of service and sufficient supply of medicines, according to the healthcare needs in each territory.

The territorial organisation of these establishments must be carried out by population modules and distances between pharmacies, to be determined by the Autonomous Regions in accordance with the general criteria referred to previously. In any case, the rules for territorial organisation must guarantee appropriate pharmaceutical care for the whole population.

Article 2.3 establishes that the minimum population module for opening pharmacies will be, in general, 2,800 inhabitants per establishment.

The Autonomous Regions, depending on the concentration of the population, ay establish larger population modules, with a limit of 4,000 inhabitants per pharmacy. In any case, once these ratios have been exceeded, a new pharmacy may be opened for each fraction above 2,000 inhabitants.

On the other hand, the legislation also allows Autonomous Regions to establish smaller population modules for rural, tourist or mountain zones or zones in which geographical characteristics make it impossible to provide pharmaceutical care in accordance with the general criteria.

Also, for reasons of emergency and remoteness of the pharmacy or other special circumstances, in certain establishments the creation of *botiquines* or "min-pharmacies"[42] may exceptionally be authorised on such conditions as may be determined by basic regulation, without prejudice to the competences of the Autonomous Regions in this field[43].

[42] Small establishments manned by a pharmacist tied to a main pharmacy allowing accessibility to medicines in exceptional cases of inadequate pharmacy service in isolated populations. It is for the Autonomous Regions to set the requirements for their establishment and their characteristics.

[43] Article 86.4 of the Consolidated Text.

The minimum distance between pharmacies, taking into account the geographical and population dispersion criteria, is established by state legislation as 250 metres in general. Depending on demographic concentrations, the Autonomous Regions may authorise shorter distances between them; they may also set limits on the installation of pharmacies near healthcare centres.

Lastly, Article 2.5 of Law 16/1997 provides that the computation of the number of inhabitants in pharmaceutical zones and the criteria for measuring distances between pharmacies will be regulated by the Autonomous Regions.

2.3. Regulation of the Autonomous Regions

According to Article 2.1 of Law 16/1997, the Autonomous Regions, which are responsible for ensuring pharmaceutical healthcare, will establish specific planning criteria for authorising pharmacies.

The criteria for the territorial organisation of pharmacies contained in this law (for example the minimum module of 2,800 inhabitants per pharmacy) are of a subsidiary nature, meaning that they apply only in Autonomous Regions that have not legislated on the matter.

All 17 Autonomous Regions currently have their own laws on the organisation of the pharmaceutical sector[44].

As well as establishing planning criteria, the various regional laws define the functions of pharmacies, incorporating new activities and stressing Pharmaceutical Care activities, and establish the criteria for allocating new pharmacies in public competitive processes.

We now go on to describe the main aspects of the territorial organisation of pharmacies in the Autonomous Regions and at the end of this section we present a summary table of the main characteristics.

2.3.1. Andalusia

Law 22/2007, of 18 December, on pharmacy in Andalusia regulates the planning of the pharmacies, defining, as a basic planning instrument, the territorial pharmaceutical units whose references are the basic health zones.

This Law is less restrictive than Law 16/1997 because, with a view to ensuring uniform distribution and accessibility of pharmacies, it allows authorisation of the first

[44] The only exceptions are the cities of Ceuta and Melilla, where the Central State Administration manages healthcare through the National Institute for the Management of Healthcare (INGESA).

pharmacy in each territorial pharmaceutical unit, municipality, ELA[45] or EATIM[46], isolated population centre with at least 1,000 inhabitants, airport and passenger or goods traffic centre. However, the second pharmacy can be opened only if the minimum thresholds of the state Law are met (module of 2,800 inhabitants and fraction above 2,000 inhabitants).

Authorisation of the first pharmacy in any municipality and local entity or population centre had been introduced prior to this Law, in 2003, by Decree 353/2003, of 16 December, which established pharmaceutical planning and the authorisation procedures for pharmacies.

Moreover, the Andalusian Law is less restrictive in tourist areas, since the computation of the population takes into account not just registered inhabitants but also tourist accommodation and secondary residences.

It retains the state legislation's minimum distance of 250 metres between pharmacies, and the minimum distance between pharmacies and any NHS healthcare centre is 200 metres (except in municipalities with only one pharmacy, where the minimum distance is 100 metres).

2.3.2. Aragon

Law 4/1999, of 25 March, on the organisation of the pharmaceutical sector for Aragon and Decree 197/2009, of 17 November, approving the Regulations developing this Law, determine the planning criteria for pharmacies in this Autonomous Region.

Pharmaceutical planning is based on the Health Zones, which are classed as urban (where 80% or more of the population of the zone is concentrated in one municipality) and non-urban.

The population modules required for the authorisation of pharmacies in Aragon are slightly smaller than those established in the state legislation: 2,600 inhabitants and each fraction above 1,500 inhabitants in urban zones and 2,000 inhabitants and each fraction above 1,800 inhabitants in non-urban zones.

Moreover, in Health Zones with seasonal tourist populations, these populations are counted for the purpose of calculating the number of inhabitants for the authorisation of pharmacies.

[45] Autonomous local entity.
[46] Territorial entity smaller than a municipality.

The minimum distance between pharmacies is 250 metres and the distance between pharmacies and public healthcare centres is 150 metres (except in municipalities with only one pharmacy, where the distance from the health centre is not taken into account for authorisation).

2.3.3. Asturias

Law 1/2007, of 16 March, on Care and Organisation of the Pharmaceutical Sector of Asturias establishes the planning criteria for pharmacies in the Autonomous Region.

Pharmaceutical planning is carried out by pharmaceutical zones in Asturias and, as a general rule, these zones are the same as the health zones. However, depending on the density or dispersion of the population and the needs for pharmaceutical care, health zones may be grouped or disaggregated to create pharmaceutical zones.

We would highlight the authorisation of the first pharmacy in all towns, as well as in parishes and population centres below town level as long as their population is greater than 600 inhabitants and they have an all-day public healthcare centre.

The minimum distance between pharmacies is 250 metres and the distance between pharmacies and affiliated public or private hospital or non-hospital healthcare centres is 250 metres (except in pharmaceutical zones, towns, parishes or population centres below town level with only one pharmacy, in which case the minimum distance from the health centre does not apply).

2.3.4. Balearic Islands

Law 7/1998, of 12 November, on the organisation of the pharmaceutical sector in the Balearic Islands establishes the planning criteria for pharmacies in that Autonomous Region.

Pharmaceutical planning is carried out by pharmaceutical zones and, as a general rule, these zones are the same as the health zones. However, contiguous health zones may be grouped or disaggregated to create pharmaceutical zones.

The general population module required in the Balearic Islands for authorisation of a pharmacy is 2,800 inhabitants and fractions above 2,000 inhabitants (the same as the state Law) and the minimum distance between pharmacies and between these and public healthcare centres is 250 metres.

The recently approved Law 1/2015, of 19 February, altered the organisation of the pharmaceutical sector in the Balearic Islands. This new Law, while not altering the minimum general population module required for the authorisation of pharmacies, introduces the seasonal module[47], which restricts the opening of new pharmacies in pharmaceutical zones with tourist populations[48].

This law also eliminates the need for authorisation for opening a pharmacy in population centres with 750 inhabitants or more if the distance between the new pharmacy and the nearest existing one is 1,000 metres or more, which was envisaged in the previous Law 7/1998.

2.3.5. Canary Islands

Law 4/2005, of 13 July, on the organisation of the pharmaceutical sector in the Canary Islands stipulates that the territorial boundaries for the planning of pharmaceutical care are the pharmaceutical zones.

The minimum population module for authorisation of a pharmacy in the Canary Islands is the same as that established by the state Law (2,800 inhabitants and each fraction above 2,000 inhabitants), with the exception of isolated or tourist residential centres with at least 1,500 inhabitants or 2,500 beds and where the distance to the nearest pharmacy is 1,000 metres or more.

The minimum distance between pharmacies and between these and public healthcare centres is 250 metres in the Canary Islands (with the exception of population centres with only one pharmacy, in which case its installation may be authorised with a minimum distance of 125 metres from the nearest public healthcare centre).

2.3.6. Cantabria

Law 7/2001, of 19 December, on the organisation of the pharmaceutical sector in Cantabria establishes that pharmaceutical planning is carried out on the basis of pharmaceutical zones, which take as their reference either the municipalities or the basic health zones in municipalities comprising more than one basic health zone.

[47] Module of 3,500 inhabitants and fraction above 2,500 inhabitants.

[48] Prior to the approval of the Consolidated Text, the seasonal population was estimated at 40% of the number of tourist beds (hotels and holiday apartments) and 30% of secondary residences, in order to determine, together with the permanent population, the total population of each pharmaceutical zone.

As in the case of Andalusia, the opening of the first pharmacy is permitted in all municipalities of Cantabria.

The general minimum population module for authorisation of a pharmacy in Cantabria is 2,800 inhabitants and each fraction above 2,000 inhabitants, and for computing the number of inhabitants in each pharmaceutical zone, 20% of the number of tourist beds (hotels, tourist apartments and campsites) in that zone are counted.

The minimum distance between pharmacies and between these and public healthcare centres is 250 metres, although this does not apply to municipalities with only one pharmacy. Also excluded from the general rule on distance between pharmacies are population centres where the population density does not allow the distance requirement of 250 metres to be met, in which case a pharmacy may be authorised with a minimum distance of 150 metres.

2.3.7. Castile and León

Law 13/2001, of 20 December, on the organisation of the pharmaceutical sector in the Autonomous Region of Castile and León takes as its reference for pharmaceutical planning the pharmaceutical zones, which are classed as urban (included in municipalities with more than 20,000 inhabitants), semi-urban (included in municipalities with between 5,000 and 20,000 inhabitants) and rural (the remaining pharmaceutical zones).

The minimum population modules for opening a new pharmacy are 2,500 inhabitants and each fraction above 1,500 inhabitants in urban pharmaceutical zones, 2,000 inhabitants and each fraction above 1,500 inhabitants in semi-urban zones and 1,800 inhabitants and each fraction above 1,500 inhabitants in rural zones.

The minimum distance between pharmacies and between these and public healthcare centres is 250 metres in urban and semi-urban pharmaceutical zones and 150 metres in the rural zones. This requirement does not apply to local entities where healthcare centres are based and where only one pharmacy can be opened.

2.3.8. Castile-La Mancha

Castile-La Mancha is the Autonomous Region that has passed the greatest number of laws on the organisation of the pharmaceutical sector, its first law[49] predating Law 16/1997.

A characteristic feature of the organisation of the pharmaceutical sector in Castile-La Mancha is the authorisation of the first pharmacy in all population centres[50].

Moreover, the demographic criteria for pharmaceutical planning in Castile-La Mancha have always been less restrictive than those of the state law, and its first law on the organisation of the pharmaceutical sector, passed in 1996, already established the minimum population module for the opening of a pharmacy as 1,750 inhabitants and a fraction above 1,000 inhabitants.

In that law the minimum distance was set at 150 metres between pharmacies and between these and any public healthcare centre, publicly financed or affiliated, except in population centres where only one pharmacy could be authorised.

In 2000, Law 10/2000, of 26 December, was passed, amending Law 4/1996, with the aim of allowing the opening of new pharmacies in population centres with populations of more than 1,000 inhabitants at a minimum distance of 500 metres from the nearest existing pharmacy.

In 2005, with the approval of Law 5/2005, of 27 June, on the organisation of the pharmaceutical sector in Castile-La Mancha, this possibility was removed and more restrictive territorial planning criteria were established.

On the one hand, the minimum population module for authorising a pharmacy in 2005 was 1,800 inhabitants and each fraction above 1,800 inhabitants (as against 1,750 and 1,500 respectively before).

On the other hand, the minimum distance between pharmacies, which had been 150 metres, was set at 250 metres as a general rule, the same minimum distance applying to that between pharmacies and public and affiliated healthcare centres. As an exception, the minimum distance of 150 metres was retained for population centres with fewer than 5,000 inhabitants.

---

[49] Law 4/1996, of 26 December, on the Organisation of the pharmaceutical sector in Castile-La Mancha, valid until 2005.

[50] For the purposes of Law 4/1996 a population centre is understood as an independent or isolated group of at least ten buildings forming streets or squares and recognised as such on the pharmaceutical Map of Castile-La Mancha.

Finally, 2015 has seen the passing of Law 2/2015, of 19 February, amending Law 5/2005, of 27 June, on the Organisation of the Pharmaceutical Sector in Castile-La Mancha, with the aim of favouring the sustainability of pharmacies in rural areas. The planning criteria for pharmacies have not been substantially changed by this new law[51].

2.3.9. Catalonia

Law 31/1991, of 13 December, on the organisation of the pharmaceutical sector in Catalonia, which predates the state Law, establishes as the reference for the purposes of pharmaceutical planning the basic health areas of this Autonomous Region.

The basic health areas of Catalonia are classed into urban basic areas (areas with borders within a single municipality or in which 90% of the population lives in the same municipality), mountain basic areas (areas located entirely in mountain villages or zones) and semi-urban and rural basic areas (areas not falling under either of the previous definitions).

In the urban basic areas a maximum of one pharmacy for every 4,000 inhabitants and each fraction above 2,000 inhabitants is authorised; in the mountain basic areas the minimum population module is 1,500 inhabitants and in the rural and semi-urban basic areas one pharmacy for every 2,500 inhabitants is authorised.

It can be highlighted that in the calculation of the number of inhabitants, 10% of the tourist beds in the basic health area are counted, including secondary residences (four beds per dwelling), hotels and campsites.

The planning criteria of Law 31/1991 were modified in 2001 by Law 21/2001, of 28 December, on fiscal and administrative measures, which established the population module for the mountain basic areas at 2,500 inhabitants (the same as in the rural and semi-urban basic areas).

The minimum distance between pharmacies is 250 metres and the distance between these and the main primary care centres of the basic areas is set at 225 metres (except for municipalities with no pharmacy, where the minimum distance is 125 metres).

[51] As regards pharmaceutical planning: the module of 1,800 inhabitants and fraction over 1,800 inhabitants has been replaced by that of 1,900 inhabitants and each fraction over 1,600 inhabitants.

2.3.10. Extremadura

Law 6/2006, of 9 November, on pharmacy in Extremadura set the current criteria for authorisation of pharmacies and repealed the previous law[52].

One basic characteristic of the organisation of the pharmaceutical sector in Extremadura is that this Autonomous Region, like Andalusia and Castile-La Mancha, allows the opening of the first pharmacy in all municipalities or local entities below municipality level, providing they have a population of more than 500.

The total number of pharmacies in each population centre may not exceed the whole number rounded down resulting from the equation n = [(number of inhabitants-700)*0.00043)]+1.

This criterion is less restrictive than that established by the previous law, which was one pharmacy for every 1,800 inhabitants and authorisation of subsequent pharmacies in tranches of 1,801-3,600 inhabitants, 3,601-5,400 and so on.

However, Law 3/1996 authorised the first pharmacy in each municipality and entity below municipality level with a population of more than 400.

In Extremadura, new pharmacies must be at least 250 metres from the nearest existing one, and from public primary care or specialist healthcare centres. (This minimum distance does not apply to population centres where there is to be only one pharmacy).

2.3.11. Galicia

Law 5/1999, of 21 May, on the organisation of the pharmaceutical sector in Galicia establishes the planning of pharmacies in that Autonomous Region.

The bases of pharmaceutical planning in Galicia are the basic primary care units, which in turn correspond to the municipal borders of this Autonomous Region and determine the pharmaceutical zones.

The pharmaceutical zones are classed into urban (municipalities with more than 30,000 inhabitants), semi-urban (municipalities with between 10,000 and 30.000 inhabitants) and rural (municipalities with fewer than 10,000 inhabitants).

The population modules for the authorisation of new pharmacies are 2,800 inhabitants and each fraction above 1,500 inhabitants in urban zones, 2,500

[52] Law 3/1996,of 25 June, on pharmaceutical care in the Autonomous Region of Extremadura.

inhabitants and each fraction above 1,500 inhabitants in semi-urban zones and 2,000 inhabitants and each fraction above 1,500 inhabitants in rural zones.

However, as in the case of the Autonomous Region referred to previously, Galicia allows the opening of the first pharmacy in each municipality and also authorises such opening in other population centres with no pharmacy where the nearest one is more than 400 metres away, provided that they have more than 2,000 inhabitants.

In Galicia, pharmacies must be at least 250 metres apart and the same distance from the nearest public healthcare centre.

Although in 2005 Law 5/2005, of 17 March, was passed, amending Law 5/1999, of 21 May, on the organisation of the pharmaceutical sector, it did not change the planning criteria for pharmacies established in the previous law.

2.3.12. La Rioja

Law 8/1998, of 16 June, on the organisation of the pharmaceutical sector in the Autonomous Region of La Rioja establishes the planning criteria for pharmacies which, with a few subsequent changes, currently apply.

This law establishes that the reference territorial boundaries for pharmaceutical planning are the pharmaceutical zones, which are classed into urban pharmaceutical zones (those resulting from aggregating the basic health zones included in municipalities with more than 100,000 inhabitants) and non-urban pharmaceutical zones (the remaining basic health zones of La Rioja).

In urban and non-urban pharmaceutical zones that include a municipality of 5,000 inhabitants, one pharmacy is authorised for every 2,800 inhabitants and fraction above 2,000 inhabitants, while for the remaining zones, the minimum module is 2,000 inhabitants per pharmacy.

La Rioja allows the opening of the first pharmacy in each municipality with a population of more than 400, and the minimum distance between pharmacies and between these and any public healthcare centre is 250 metres. (This does not apply to municipalities with only one pharmacy).

In 2006, Law 7/2006, of 18 October, amending Law 8/1998, of 16 June, on the Organisation of the Pharmaceutical Sector in the Autonomous Region of La Rioja introduced minor changes to the planning criteria relative to the previous regulation and, as a new feature, established new geographical boundaries (tourist municipalities, urban expansion sectors and mountain or special pharmaceutical

zones) with the aim of adapting them more closely to the demographic characteristics of La Rioja.

2.3.13. Madrid

Law 19/1998, of 25 November, on pharmaceutical organisation and care in the Autonomous Region of Madrid establishes pharmaceutical planning based on pharmaceutical zones, for which the basic health zones, healthcare districts and healthcare areas of this Autonomous Region are taken as the reference.

The minimum population module for opening a new pharmacy is 2,800 inhabitants and fraction above 2,000 inhabitants in the urban zones and 2,000 inhabitants for the rural zones.

The minimum distance between pharmacies is 250 metres and new installations (due to new opening or relocation) may not be less than 150 metres from primary care or specialist centres, except in municipalities with only one pharmacy.

2.3.14. Murcia

In accordance with Law 3/1997, of 28 May, on the organisation of the pharmaceutical sector in the Region of Murcia, pharmaceutical planning is carried out on the basis of the pharmaceutical zones, for which the health zones of the Region of Murcia are taken as the reference.

The pharmaceutical zones are classed into urban (75% of the population belongs to the same municipality), tourist (the number of tourist and secondary residence beds exceeds those of habitual dwellings) and rural.

The minimum population module in the urban zones is 2,800 inhabitants per pharmacy and fraction above 2,000 inhabitants, in the tourist zones it is 2,500 inhabitants per pharmacy and fraction above 2,000 inhabitants and in the case of the rural zones, the maximum number of pharmacies corresponds to the module of 1,500 inhabitants per pharmacy.

In the tourist zones, the calculation of the number of inhabitants for the authorisation of opening of pharmacies includes 30% of the tourist beds (hotels, tourist apartments and campsites) and 40% of those of secondary residences (assuming four inhabitants per residence).

The minimum distance between pharmacies is 250 metres, although depending on the concentration of the resident population pharmacies may be authorised at distances of as little as 150 metres.

The minimum distance between new pharmacies and any public or affiliated healthcare centre is 200 metres (with the exception of municipalities or smaller population centres with no pharmacy, in which case the minimum distance is 125 metres).

2.3.15. Navarre

Regional Law 12/2000, of 16 November, on pharmaceutical care in Navarre gives a different interpretation of pharmaceutical planning from the other Autonomous Regions, defining it as the forecasting of the minimum number of pharmacies needed in each Basic Health Zone to achieve equitable access to pharmaceutical care for the whole population of the Autonomous Region.

In this regard, the law of Navarre stipulates the impossibility of authorising new pharmacies in Navarre if any Basic Health Zone does not have the minimum number of pharmacies resulting from the planning.

The planning model adopted by Navarre is different from that of the state law, and was declared constitutional by Decision of the Constitutional Court of 24 February 2004.

Instead of setting the maximum number of pharmacies per population module, as all the other regional laws do, the Navarre law sets the minimum number of pharmacies that must open in order to serve the population of the Basic Health Zones forming part of a locality and of each locality forming a Basic Health Zone.

The minimum number of pharmacies in each Basic Health Zone or locality is one pharmacy for every 2,800 inhabitants, and no additional pharmacy is allowed to open unless, and until, a minimum of one pharmacy for every 2,800 inhabitants has been reached. Once this minimum number of pharmacies has opened, any pharmacist may open a pharmacy until such time as a ratio of fewer than 700 inhabitants per pharmacy in Navarre as a whole is reached.

In any case, localities with a population of more than 700 have at least one pharmacy open to the public and the minimum distance between new pharmacies and existing ones is 150 metres. In Navarre, unlike the other Autonomous Regions, no minimum distance between pharmacies and healthcare centres is set.

Regional Law 20/2008, of 20 November, amending Regional Law 12/2000, of 16 November, on Pharmaceutical Care changes the previous law as regards the maximum number of pharmacies open to the public in each locality of Navarre.

According to this new Law, the opening of the first pharmacy in each locality is free (even if there are fewer than 700 inhabitants) but the second pharmacy is authorised only when the population of the locality is 1,400 or more, and so on for each successive 700 inhabitants.

2.3.16. The Basque Country

According to Law 11/1994, of 17 June, on the organisation of the pharmaceutical sector in the Autonomous Region of the Basque Country, pharmaceutical planning is based on the needs for pharmaceutical care of the inhabitants of a given territorial area referred to as a pharmaceutical zone and formed by one or more health zones.

This law, which predates Law 16/1997, establishes more restrictive planning criteria than those of the state law in the large municipalities (territorially bigger than the heath zone), where the maximum number of pharmacies is one for every 3,200 inhabitants and fraction above 2,500.

Where the health zone coincides with the pharmaceutical zone and with the municipality, the maximum number of pharmacies is one for every 2,800 inhabitants and fraction above 2,500 and where a health zone comprises all, or part of, more than one municipality, the pharmaceutical zone coincides with the health zone and the maximum number of pharmacies is one for every 2,500 inhabitants.

A characteristic feature of pharmaceutical planning in the Basque Country is the requirement of a minimum size of 800 inhabitants for opening a pharmacy (although exceptionally, in depressed zones with development programmes, the local Administrations may ask for a pharmacy to be opened in municipalities with fewer than 800 inhabitants).

The minimum distance between a new pharmacy and the nearest existing one, whether or not in the same health zone, is 250 metres and the minimum distance from the nearest Basque Health Service healthcare centre is 150 metres.

However, exceptionally, in pharmaceutical zones with a population density of more than 4,000 inhabitants per square kilometre, there is a provision for the establishment of a reducing scale geared to the density of each health zone, whereby the distance between pharmacies can be reduced to as little as 150 metres.

2.3.17. Autonomous Region of Valencia

Law 6/1998, of 22 June, on the organisation of the pharmaceutical sector in the Autonomous Region of Valencia provides, for purposes of pharmaceutical planning, for the creation of pharmaceutical zones based on the natural regions of the Autonomous Region of Valencia.

A characteristic feature of this Autonomous Region is that it allows the opening of the first pharmacy in each municipality and smaller population centre, with the stated objective of ensuring appropriate pharmaceutical care for these populations.

The Autonomous Region of Valencia distinguishes between general pharmaceutical zones and tourist pharmaceutical zones (those in which the annual average seasonal population exceeds the annual census population by 30% or more).

The population module for the former is 2,800 inhabitants and fraction above 2,000 inhabitants, while in the latter, once the population has been adjusted in accordance with the general module, a complementary tourist module of 3,500 seasonal inhabitants and fraction above 2,500 seasonal inhabitants is taken into account.

The minimum distance between pharmacies and between these and any Health Council healthcare centre is set at 250 metres.

Having analysed the main characteristics of the regional regulation of pharmacy planning, in Table 4 we summarise them with the aim of offering a global overview of the restrictions on the establishment of pharmacies imposed by regional regulation compared with the state regulation.

First, we list the Autonomous Regions that allow the opening of the first pharmacy in each municipality or locality, with the aim of ensuring appropriate coverage of pharmaceutical care. We should point out that some of the regions included in the table allow such opening subject to a minimum population. Such is the case of Asturias (600 inhabitants), Extremadura (500 inhabitants) and La Rioja (400 inhabitants).

Secondly, we present the Autonomous Regions with general population modules below (less restrictive criteria) and above (more restrictive criteria) the module of 2,800 inhabitants per pharmacy established by Law 16/1997 at state level.

Lastly, we summarise the Autonomous Regions that allow distances of less than 250 metres between pharmacies (except for Navarre, all the Regions appearing in the corresponding column of the table allow distances of as little as 150 metres only in municipalities with specific characteristics or density of population) and the only

Autonomous Region that does not establish a minimum distance between pharmacies and healthcare centres (Navarre).

Table 4. Summary of regional regulation of pharmacies

Autonomous Region	Authorisation of first pharmacy in any municipality	General population module < 2.800 inhabitants per pharmacy	General population module > 2.800 inhabitants per pharmacy	Distance < 250 metres between pharmacies	Mandatory minimum distance to health centre
ANDALUSIA	X				X
ARAGON		X			X
ASTURIAS	X	X			X
BALEARIC ISLANDS					X
CANARY ISLANDS					X
CANTABRIA	X			X	X
CASTILE AND LEON		X		X	X
CASTILE - LA MANCHA	X	X		X	X
CATALONIA			X		X
EXTREMADURA	X	X			X
GALICIA	X				X
LA RIOJA	X				X
MADRID					X
MURCIA				X	X
NAVARRE	X	X		X	
BASQUE COUNTRY			X		X
VALENCIA	X				X

Source: in-house based on laws on the organisation of the pharmaceutical sectors of the Autonomous Regions.

3. ECONOMIC ANALYSIS

Medicines are essential for preserving health and are considered as merit or preferential consumption goods[53] by many countries' governments. In particular, the consumption of certain products such as vaccines and medicines for treating infectious diseases not only benefits the consumer but also generates strong positive externalities for society as a whole (improving the health of society, avoiding the spread of certain diseases, generating less public healthcare expenditure, increasing productivity, etc.), which require efficient state intervention in order for them to be properly internalised. Public funding of medicines is an instrument for making sure that medicines are accessible to the whole population, regardless of their level of income or place of residence.

From an economic point of view, medicines can also be considered as experience or credential goods[54]. With these types of goods the consumer has less information on the quality of the good than the supplier does. In the case of medicines, the patient is generally unable to determine whether a medicine is safe and effective by examining it and sometimes even after consuming it.

This problem of asymmetric information (adverse selection) can create a “lemon market” in which the quality of the product would fall to inefficiently low levels. One solution for this market failure is the provision of information on the quality of the product by a trusted third party, or, in the case of medicines, through a process of approval by a regulatory agency[55].

It would also be necessary to control possible abuses of market power by manufacturers, wholesale distributors and/or health insurers[56]. The presence of this market power has traditionally justified the regulation of prices and production and distribution margins specific to this sector.

In many countries, including Spain, the activities of prescription and dispensation of medicines are separated with the aim of avoiding the occurrence of the so-called problems of agency that are specific to environments with asymmetric information.

[53] Musgrave, R. "A Multiple Theory of Budget Determination" (1957).

[54] Nelson, P., "Information and Consumer Behaviour" (1970).

[55] The regulatory agency in the case of Spain is the Spanish Agency for Medicines and Healthcare Products.

[56] Factors explaining the market power on the supply side in the pharmaceutical sector are the manufacturers' high fixed R&D costs, which entail a high cost of market entry and might explain the high levels of concentration, and the temporary monopoly power granted by patents in the case of newly created or innovative medicines.

Medicines are dispensed through establishments separate from the prescriber, namely pharmacies, in order to avoid doctors having incentives to prescribe medicines influenced by considerations other than purely medical ones (for example, prescribing medicines that are unnecessary or more expensive if these bring him financial gain).

The decision to acquire a prescription drug falls on the doctor prescribing it, not on the person or entity paying for it (patient, insurer or NHS) and that makes the demand for this type of medicines price-inelastic. Thus, doctors are generally insensitive to price, and in countries in which the patient does not pay for the total cost of medicines, patients' demand for medicines is also price-inelastic[57].

On the other hand, demand from wholesale distributors and retailers is also rigid due to the low or zero substitutability of many medicines. The low price elasticity of demand, together with the market power on the supply side explains why in many countries prices of medicines are regulated at the various levels of the medicine chain.

The regulation of the retail distribution of medicines market in Spain is nationwide for aspects such as the price of medicines. However, in aspects affecting and limiting market supply, such as the restrictions in place on the establishment of pharmacies, the regulation varies from one Autonomous Region to another.

For this reason, the characterisation of the market is carried out at national level, with information broken down by Autonomous Regions, and the analysis of competition in the market, given its local nature, is carried out at the level of municipalities in Spain[58].

[57] Demand for medicines is also inelastic in the absence of coverage, especially in the case of patients in developed countries (who would be prepared to pay a considerable price to improve their health). For example, Berndt et al. (1995) estimated the elasticity of demand for medicines indicated for the treatment of ulcers as a group, obtaining an elasticity of -0.69 and for the various molecular variants individually they obtained elasticities in a range of -0.74 to -1.03.

[58] In producing the characterisation of the market, we used various sources of information. In spite of the importance in quantitative terms of this market, the only official source of information is the Ministry of Health, Social Services and Equality, which publishes monthly statistics on “Consumption of Pharmaceuticals in the National Health System”, which provide information on the consumption of medicines and healthcare products included in the reimbursement list of the National Health System, officially prescribed under the Social Security system and dispensed by pharmacies.
The remainder of the information used in the analysis comes from the Autonomous Regions, the General Council of Official Associations of Pharmacists and the consultancy IMS Health.

3.1. Characterisation of the retail medicine distribution market in Spain

The retail distribution of medicines through pharmacies is the final link in the medicine chain, and ensures patients' access to medicines.

Although the pharmacies are the main channel of retail distribution of medicines in Spain, hospitals' pharmacy departments and primary care centres also dispense medicines.

In the past few years, hospitals' share in the retail distribution of medicines market has increased considerably, due to the fact that many drugs indicated for the treatment of outpatients with chronic diseases, which are generally high-cost and used to be acquired in pharmacies, are now dispensed in hospitals[59].

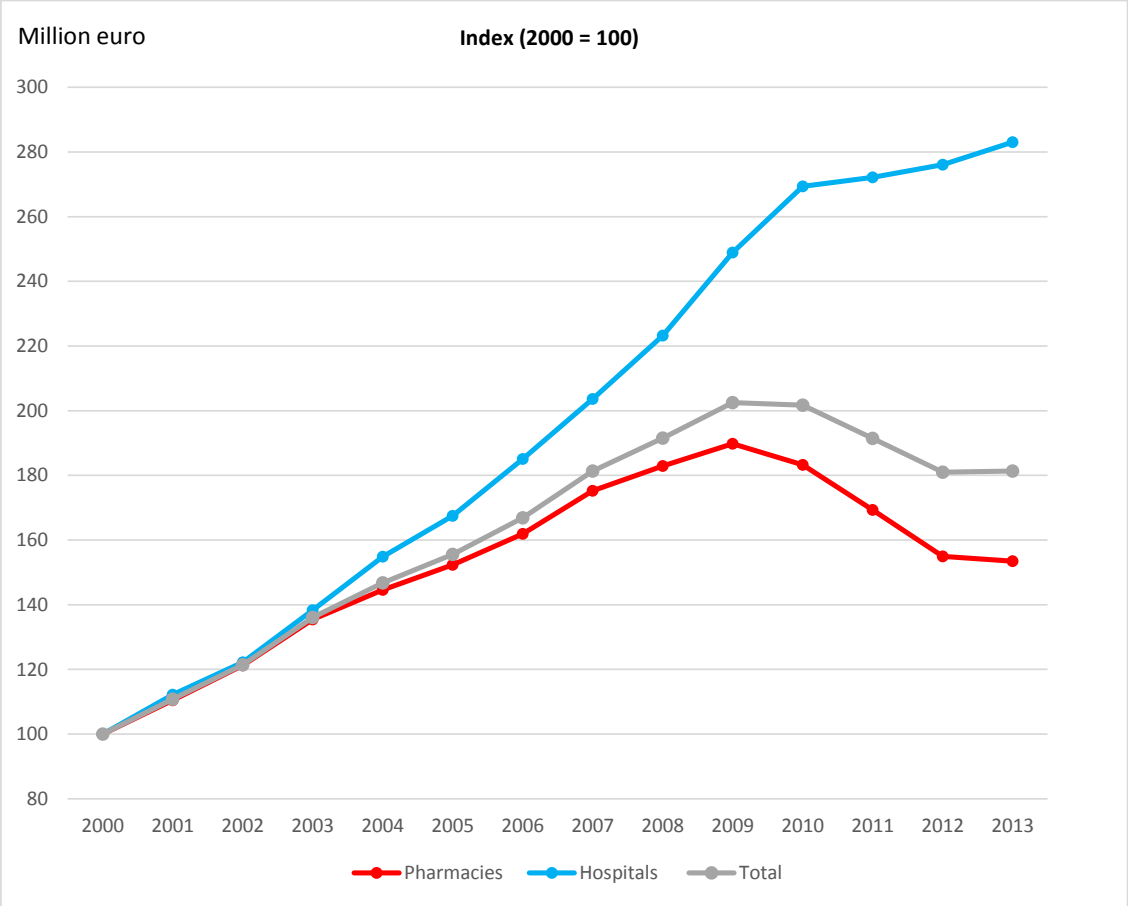
Graph 1 shows the changes in the period 2000-2013 in the amount of sales of medicines at manufacturers' selling price (PVL)[60] through pharmacies and hospitals, the base being sales of medicines in 2000.

A sustained growth in sales of medicines in hospitals throughout the period is observed, and, from 2003 on, this growth exceeds that of sales of medicines in pharmacies. It should be pointed out that the increase in hospitals' share of the retail distribution market consolidates in the period of economic crisis that began in 2008. From then on, sales of medicines in hospitals continue to grow, albeit at a slower pace than in previous years, whereas sales of medicines in pharmacies decrease significantly in the period 2008-2012, stabilising in the last two years of the period under consideration.

[59] According to data from Farmaindustria, hospitals' share in the retail medicine distribution market has gone from 21.5% in 2000 to 33.5% in 2013.

[60] The manufacturer's selling price (PVL) includes the cost of producing the medicines and the manufacture's margin. It does not include the wholesale or retail distributors' margins or VAT. It also excludes the 7.5% deduction applicable to the PVL of medicines established by Royal Decree 8/2010.

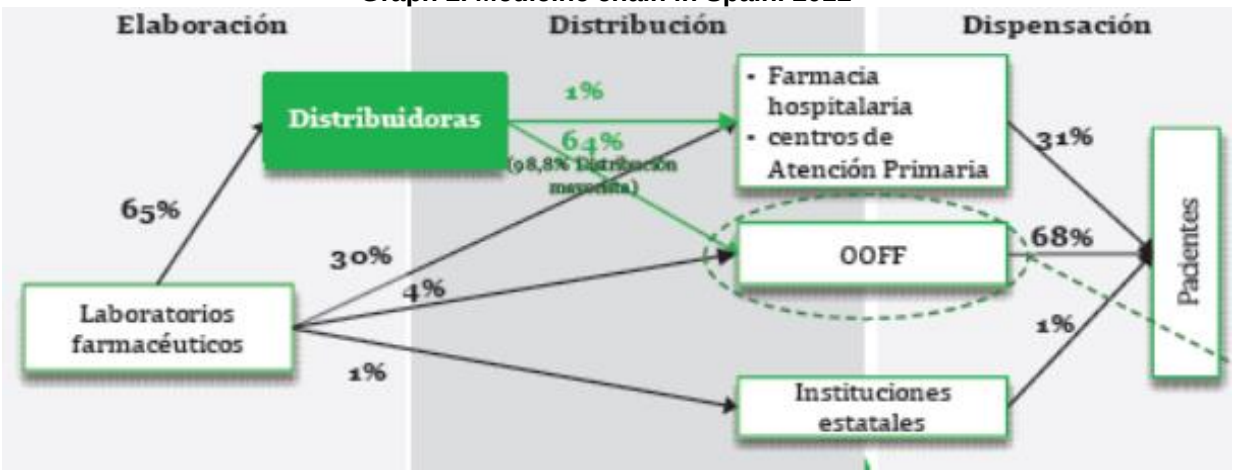
Graph 1. Changes in turnover of sales of medicines in Spain
Period 2000-2013



Source: in-house based on annual reports of Farmaindustria (Spain's national association of pharmaceutical manufacturers) (2000-2013).

Graph 2 shows the shares of the participants in the activities of the medicine chain in Spain in 2012. The pharmaceutical manufacturers produce the medicines, which are acquired mainly by wholesale distributors (65% of the total), hospitals' pharmacy departments and healthcare centres (30%) and residually by pharmacies (4%) and State institutions (1%). Wholesale distributors sell mainly to pharmacies (99% of wholesale distribution) and the remaining 1% to hospitals. Retail distribution in Spain is carried out by pharmacies (68% of retail distribution), hospitals (31%) and state institutions (1%).

Graph 2. Medicine chain in Spain. 2012



Source: FEDIFAR, Sectoral analysis of pharmaceutical distribution in Spain (2013).

3.1.1 Structure of demand

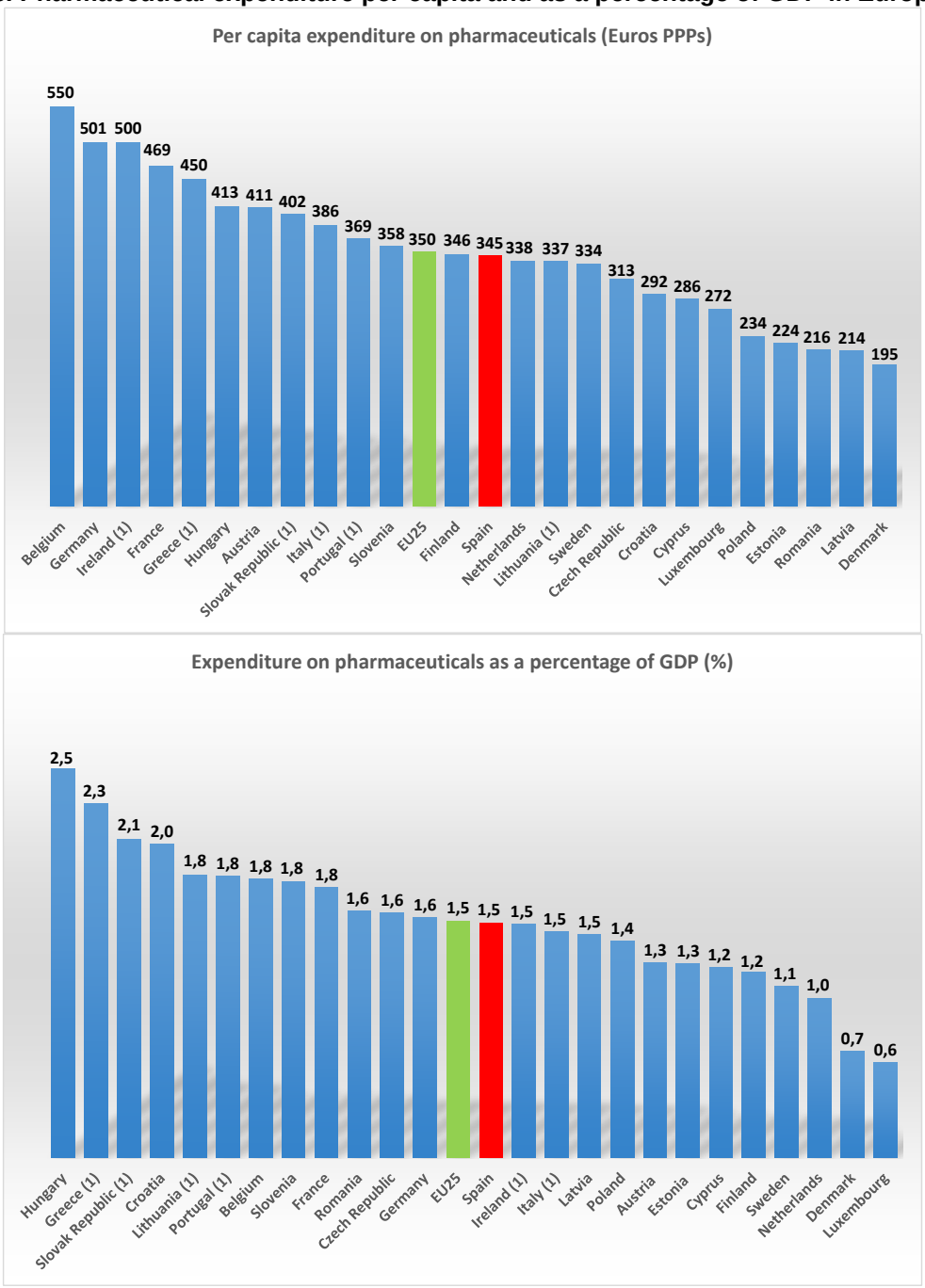
According to the OECD, expenditure on pharmaceuticals in the European Union was nearly €200 billion in 2012[61]. However, there are wide variations in pharmaceutical spending per capita among countries, reflecting differences in volume, structure of consumption and pharmaceutical prices. Per capita expenditure on pharmaceuticals in Spain (at €345 in purchasing power parity or PPP) was slightly below the European average. As a share of Gross Domestic Product (GDP), total expenditure on pharmaceuticals was equal to the European average of 1.5%.

An analysis of recent trends in per capita expenditure on pharmaceuticals shows that the economic crisis and the measures adopted have reduced this expenditure, particularly in Spain in comparison with other European countries[62]. From 2009 on, per capita expenditure on pharmaceuticals slowed on average for Europe and fell significantly in Spain (by 12% between 2009 and 2012). With regard to growth in expenditure on pharmaceuticals as a share of total healthcare costs, a convergence over the course of the period studied is observed, with Spain starting out with a larger share (22% as against 18% in 2000) and falling to 16.7% in 2012 compared with the European average of 17.2%.

[61] In the OECD's healthcare statistics, expenditure on pharmaceuticals covers the cost of medicines dispensed in pharmacies, not in hospitals, and includes both prescription and over-the-counter (OTC) medicines. Final expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax.

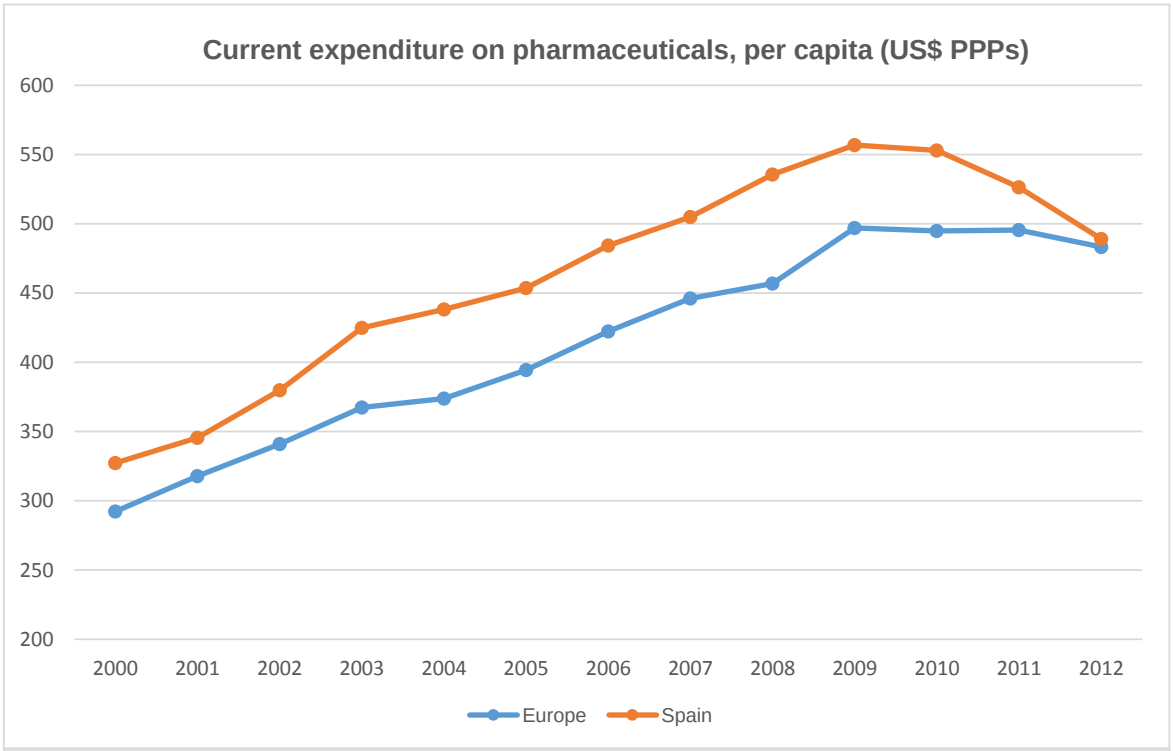
[62] Includes EU Member States belonging to the OECD.

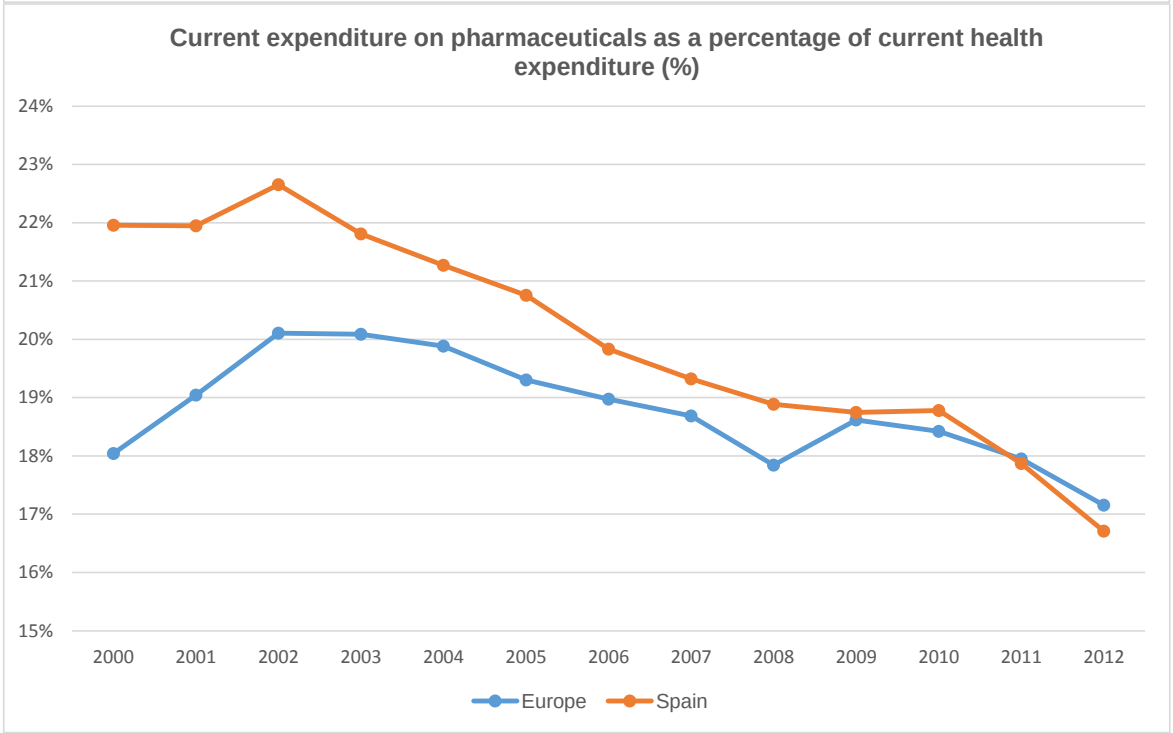
Graph 3. Pharmaceutical expenditure per capita and as a percentage of GDP in Europe. 2012



(1) Includes medical non-durables (resulting in an over-estimation of around 5-10%).
Source: in-house based on data from the OECD's "Health at a Glance: Europe 2014".

Graph 4. Pharmaceutical expenditure per capita and as a percentage of health costs in Europe. Period: 2000-2012





Pharmaceutical expenditure includes medical non-durables.
Source: in-house based on OECD Health Statistics 2015.

Total demand for medicines via pharmacies in Spain in 2013 amounted to 1,247 million units and €9,176 million at manufacturers' selling prices.

Pharmacies acquired 10% of their medicines direct from manufacturers in 2013. These direct sales by manufacturers to pharmacies account for 5% of total turnover of medicines dispensed.

The demand for medicines can be characterised in accordance with the different types of medicines described previously:

a) whether or not subject to medical prescription;

b) whether or not publicly financed by the National Health System (NHS);

c) innovative or generic.

These segmentations give rise to sub-markets with different characteristics, which we will be analysed below.

In Spain, prescription drugs account for 88% of the units sold in the market and 94% of the turnover, and 93% of these medicines are financed by the NHS or civil servants' mutual societies[63]. Medicines not subject to medical prescription[64] constitute the remaining 12% of units sold and the 6% of turnover. These medicines are excluded from the reimbursement list, and are thus not financed by the NHS.

Table 5. Total demand for medicines by type of medicine in Spain

BREAKDOWN OF TOTAL DEMAND FOR MEDICINES IN SPAIN*, 2013				
Type	**Units sold (millions)**	**number of units as % of total**	**Invoicing PVL (€ millions)**	**Invoicing PVL as % of total**
Prescription	**1.099,89**	**88,2%**	**8.605,78**	**93,8%**
Public financing	1.024,04	93,1%	8.018,57	93,2%
Free sale	75,85	6,9%	587,21	6,8%
OTC	**147,03**	**11,8%**	**570,02**	**6,2%**
TOTAL	**1.246,92**	**100,0%**	**9.175,80**	**100,0%**

[1]PVL: manufacturer's selling price. Includes direct sales by manufacturers to pharmacies.
Source: in-house based on information provided by IMS Health.

In Table 6 we present the distribution of total demand for medicines in terms of units and turnover, by Autonomous Region for the year 2013.

[63] Medicines financed by civil servants' mutual societies (Muface, Isfas and Mugeju) constitute 10% of units and 18% of turnover of medicines with public financing.

[64] Medicines not subject to medical prescription may be advertised to the public. For the sake of simplicity in the analysis these medicines will be referred to over-the-counter medicines or OTC.

We see that demand for medicines varies among Autonomous Region in line with their populations. The Autonomous Region with the greatest consumption of medicines (19.3% of the total units sold and 17.3% of total turnover) is Andalusia, which is also the Autonomous Region with the highest population, with 8.4 million inhabitants in 2013. It is followed in the ranking by Catalonia (15.8% of units sold and 14.3% of turnover), Madrid (11.6% of total units and 11.7% of turnover) and Valencia (11.1% of units and 12% of turnover) which are also, in the same order, the next most populous regions of Spain.

Table 6. Distribution of total demand for medicines by Autonomous Region

	TOTAL DEMAND FOR MEDICINES BY REGION AND NATIONAL TOTAL* 2013			
Autonomous Region	**Units sold (millions)**	**Units as % of national total**	**Invoicing PVL (€ millions)**	**PVL invoicing as % of national total**
ANDALUSIA	217,05	19,3%	1.510,89	17,3%
ARAGON	34,37	3,1%	274,91	3,2%
ASTURIAS	29,82	2,6%	232,69	2,7%
BALEARIC ISLANDS	21,33	1,9%	168,92	1,9%
CANARY ISLANDS	55,98	5,0%	417,86	4,8%
CANTABRIA	16,02	1,4%	122,26	1,4%
CASTILE AND LEON	57,27	5,1%	484,84	5,6%
CASTILE - LA MANCHA	50,82	4,5%	402,99	4,6%
CATALONIA	178,12	15,8%	1.249,06	14,3%
VALENCIA	124,56	11,1%	1.049,24	12,0%
EXTREMADURA	29,48	2,6%	243,78	2,8%
GALICIA	75,94	6,7%	632,37	7,2%
MADRID	130,02	11,6%	1.023,68	11,7%
MURCIA	34,40	3,1%	302,99	3,5%
NAVARRE	13,45	1,2%	114,05	1,3%
BASQUE COUNTRY	45,75	4,1%	402,49	4,6%
LA RIOJA	6,99	0,6%	58,50	0,7%
CEUTA	2,18	0,2%	16,35	0,2%
MELILLA	2,11	0,2%	14,53	0,2%
NATIONAL TOTAL	**1.125,66**	**100,0%**	**8.722,39**	**100,0%**

(*) Only wholesale distributors' sales to pharmacies are included, as the breakdown of manufacturers' direct sales to pharmacies by Autonomous Region is not available.
Source: in-house based on information provided by IMS Health.

If we analyse the market segment formed by prescription drugs, we see that its breakdown by Autonomous Region is very similar to that of total demand, which is explained by the high proportion of total demand accounted for by these drugs.

Table 7. Breakdown of demand for prescription drugs by Autonomous Region

	DEMAND FOR PRESCRIPTION DRUGS BY REGION AND NATIONAL TOTAL * 2013			
Autonomous Region	**Units sold (millions)**	**Units as % of national total**	**Invoicing PVL (€ millions)**	**PVL invoicing as % of national total**
ANDALUSIA	195,85	19,5%	1.430,97	17,3%
ARAGON	31,05	3,1%	261,96	3,2%
ASTURIAS	27,05	2,7%	222,29	2,7%
BALEARIC ISLANDS	18,61	1,9%	158,43	1,9%
CANARY ISLANDS	47,88	4,8%	387,28	4,7%
CANTABRIA	14,48	1,4%	116,31	1,4%
CASTILE AND LEON	51,77	5,2%	463,45	5,6%
CASTILE - LA MANCHA	45,61	4,5%	382,92	4,6%
CATALONIA	156,55	15,6%	1.165,83	14,1%
VALENCIA	110,61	11,0%	995,48	12,1%
EXTREMADURA	26,73	2,7%	233,23	2,8%
GALICIA	68,90	6,9%	605,22	7,3%
MADRID	114,63	11,4%	962,17	11,7%
MURCIA	30,96	3,1%	289,70	3,5%
NAVARRE	11,79	1,2%	107,76	1,3%
BASQUE COUNTRY	41,29	4,1%	385,23	4,7%
LA RIOJA	6,35	0,6%	56,01	0,7%
CEUTA	1,92	0,2%	15,35	0,2%
MELILLA	1,88	0,2%	13,74	0,2%
NATIONAL TOTAL	**1.003,88**	**100,0%**	**8.253,32**	**100,0%**

(*) Only wholesale distributors' sales to pharmacies are included, as the breakdown of manufacturers' direct sales to pharmacies by Autonomous Region is not available.
Source: in-house based on information provided by IMS Health.

In referring to the breakdown of the demand for generics by Autonomous Region in 2013, it should be pointed out that the Autonomous Region with the biggest share of this sub-market is Catalonia, with 17.7% of the market in both unit and turnover terms. It is followed by Andalusia, Madrid and Valencia.

Table 8. Breakdown of the demand for OTC drugs by Autonomous Region

	DEMAND FOR OTC DRUGS BY REGION AND NATIONAL TOTAL*, 2013			
Autonomous Region	**Units sold (millions)**	**Units as % of National total**	**Invoicing PVL (€ millions)**	**PVL invoicing as % of National total**
ANDALUSIA	21,20	17,4%	79,92	17,0%
ARAGON	3,32	2,7%	12,95	2,8%
ASTURIAS	2,77	2,3%	10,40	2,2%
BALEARIC ISLANDS	2,73	2,2%	10,49	2,2%
CANARY ISLANDS	8,10	6,6%	30,58	6,5%
CANTABRIA	1,54	1,3%	5,95	1,3%
CASTILE AND LEON	5,50	4,5%	21,39	4,6%
CASTILE - LA MANCHA	5,22	4,3%	20,06	4,3%
CATALONIA	21,57	17,7%	83,23	17,7%
VALENCIA	13,96	11,5%	53,76	11,5%
EXTREMADURA	2,75	2,3%	10,55	2,2%
GALICIA	7,04	5,8%	27,15	5,8%
MADRID	15,40	12,6%	61,51	13,1%
MURCIA	3,44	2,8%	13,30	2,8%
NAVARRE	1,66	1,4%	6,29	1,3%
BASQUE COUNTRY	4,46	3,7%	17,26	3,7%
LA RIOJA	0,64	0,5%	2,49	0,5%
CEUTA	0,26	0,2%	1,01	0,2%
MELILLA	0,23	0,2%	0,79	0,2%
NATIONAL TOTAL	**121,78**	**100,0%**	**469,07**	**100,0%**

(*) Only wholesale distributors' sales to pharmacies are included, as the breakdown of manufacturers' direct sales to pharmacies by Autonomous Region is not available.
Source: in-house based on information provided by IMS Health.

As regards the structure of the demand, depending on the type of financing of the medicines (public or private), Table 9 shows that 83% of units sold are publicly financed and in terms of turnover the share of these publicly financed medicines was 88% for Spain as a whole in 2013.

From the analysis of the structure of the demand in this sub-market by Autonomous Region, some differences can be identified. In terms of publicly financed units sold as a percentage of total sales, Asturias heads the list at 85%, followed by La Rioja and the Basque Country, each at 84%. Below the national average are Ceuta (78%), the Canary Islands (79%) and the Balearic Islands (80%).

Table 9. Structure of the demand for medicines by type of financing and by Autonomous Region

	DEMAND FOR MEDICINES PUBLICLY FINANCED AND SOLD FREELY BY REGION*, 2013			
	Units sold (millions)		PVL invoicing (€ millions)	
Autonomous Region	Medicines financed as % of total	Medicines sold freely as % of total	Medicines financed as % of total	Medicines sold freely as % of total
ANDALUSIA	84,3%	15,7%	88,3%	11,7%
ARAGON	83,8%	16,2%	89,3%	10,7%
ASTURIAS	85,0%	15,0%	90,1%	9,9%
BALEARIC ISLANDS	80,1%	19,9%	85,9%	14,1%
CANARY ISLANDS	79,4%	20,6%	85,6%	14,4%
CANTABRIA	83,9%	16,1%	88,9%	11,1%
CASTILE AND LEON	83,7%	16,3%	89,8%	10,2%
CASTILE - LA MANCHA	84,0%	16,0%	89,7%	10,3%
CATALONIA	81,5%	18,5%	85,9%	14,1%
VALENCIA	82,6%	17,4%	89,0%	11,0%
EXTREMADURA	85,0%	15,0%	90,9%	9,1%
GALICIA	84,4%	15,6%	90,2%	9,8%
MADRID	81,5%	18,5%	86,2%	13,8%
MURCIA	84,3%	15,7%	90,4%	9,6%
NAVARRE	81,4%	18,6%	88,5%	11,5%
BASQUE COUNTRY	84,1%	15,9%	90,1%	9,9%
LA RIOJA	84,4%	15,6%	89,7%	10,3%
CEUTA	78,3%	21,7%	85,8%	14,2%
MELILLA	83,5%	16,5%	87,5%	12,5%
NATIONAL AVERAGE	**82,9%**	**17,1%**	**88,2%**	**11,8%**

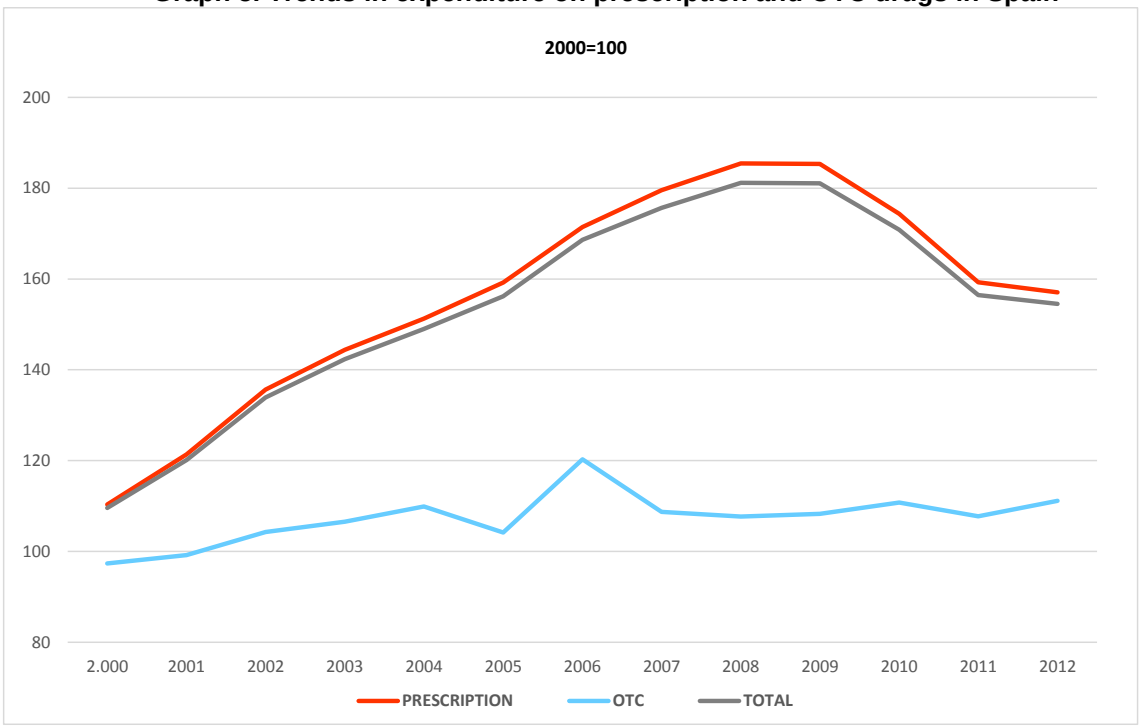
(*) Only wholesale distributors' sales to pharmacies are included, as the breakdown of manufacturers' direct sales to pharmacies by Autonomous Region is not available.
Source: in-house based on information provided by IMS Health.

As regards recent trends in the demand for medicines in Spain, growth in total demand and the demand for prescription and public financing[65] in the period 2000-2009 is observed. From 2009 on, with the onset of Spain's economic crisis, demand for these medicines stabilised before falling drastically in the period 2010-2012 and much more moderately in 2013. The demand for OTC drugs remained relatively stable over the analysed period, growing by 11% cumulatively, whereas demand for

[65] The high proportion of publicly financed prescription drugs in total demand explains the parallel trends seen in Graph 5 and Graph 6.

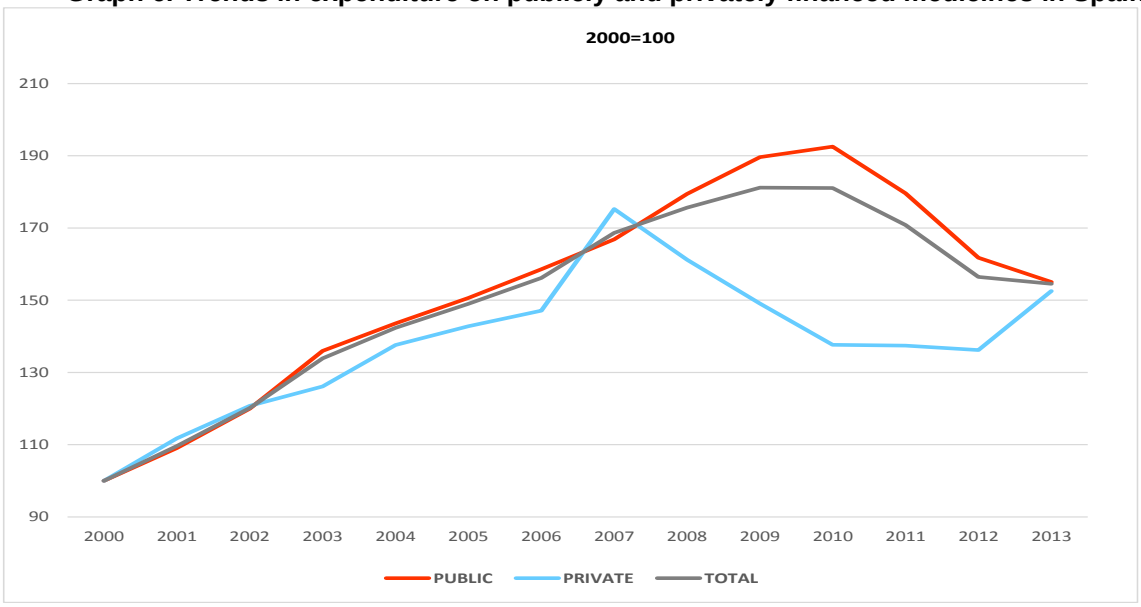
privately financed medicines shows a more erratic behaviour, with a strong growth in 2007 too and a cumulative change of 53% over the course of the period under review.

Graph 5. Trends in expenditure on prescription and OTC drugs in Spain



Source: in-house based on information from the CGCOF.

Graph 6. Trends in expenditure on publicly and privately financed medicines in Spain



Source: in-house based on information from the CGCOF.

Next it can be analysed in detail the segment of the retail distribution market formed by medicines and healthcare products financed by the National Health System (NHS), which is of great importance not only in view of its weight in the market but also in view of the impact of its financing on healthcare expenditure in Spain[66].

Table 10 shows the structure of the NHS' demand for medicines and healthcare products or consumption of pharmaceuticals. It should be noted that medicines account for 98% of prescriptions and 95% of turnover at retail price plus VAT[67] (PVP_{IVA}) of the NHS' total consumption of pharmaceuticals.

Table 10. Structure of NHS demand for medicines and healthcare products

BREAKDOWN OF NHS DEMAND FOR MEDICINES AND HEALTHCARE PRODUCTS, 2013				
Item	**Number of prescriptions (thousands)**	**Number of prescriptions as % of total**	**Invoicing PVPIVA (€ millions)**	**Invoicing PVPIVA as % of total**
Medicines	842,48	98,08%	10.669,85	95,26%
Healthcare products	15,43	1,80%	438,29	3,91%
Formulas & sundry	1,03	0,12%	92,63	0,83%
TOTAL	**858,94**	**100,00%**	**11.200,78**	**100,00%**

Source: in-house based on data from the Ministry of Health, Social Services and Equality.

It is important to study recent trends in NHS demand for medicines, especially from the onset of the Spanish economic crisis in late 2008.

As observed in

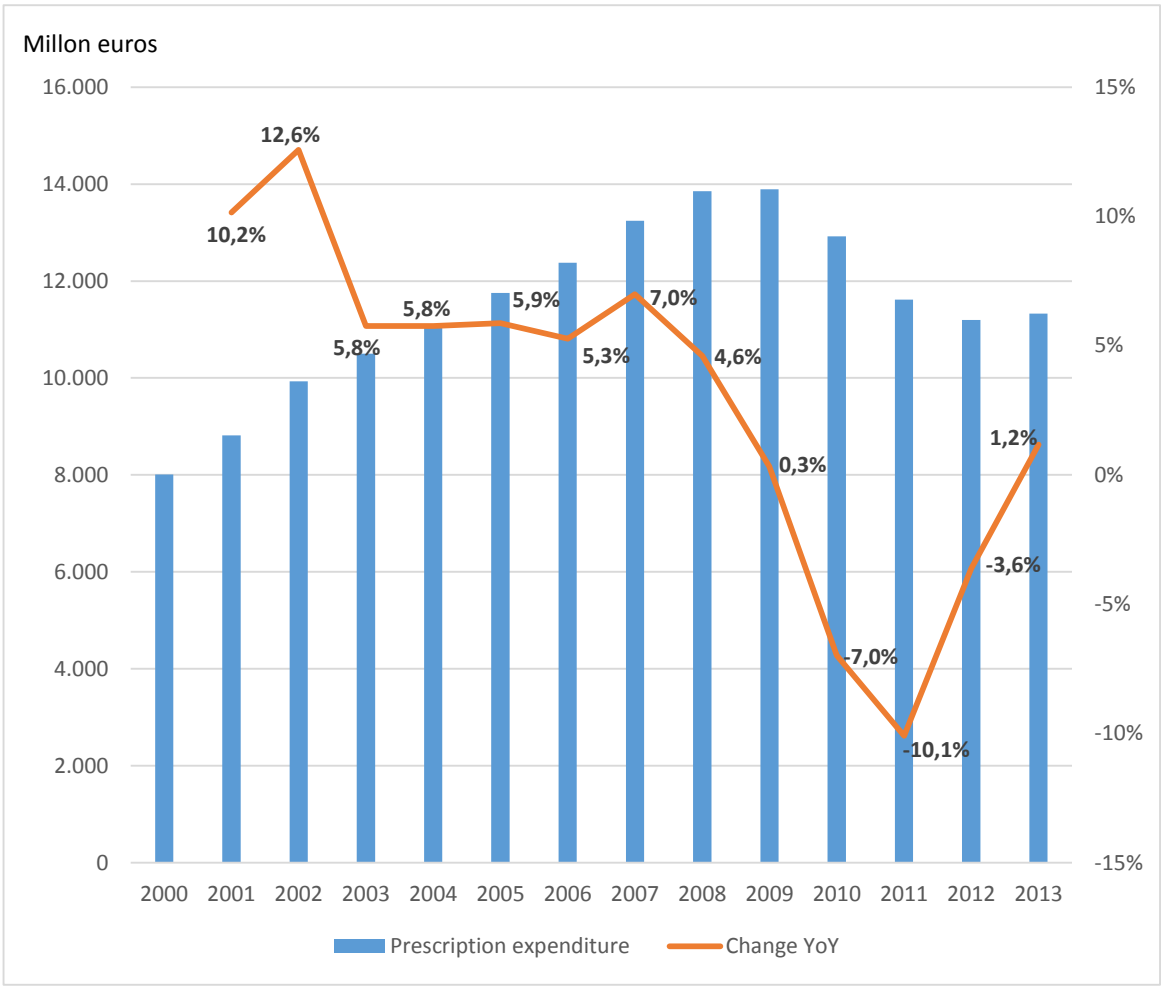
Graph 7, the economic crisis and the measures taken to contain the deficit[68] have reduced public expenditure on pharmaceuticals. From 2008 on, growth in NHS expenditure on medicines started to slow, and from 2010 on, negative rates of YoY change, as much as -10.1% in 2011, can be observed. In 2013 there was a return to positive growth, albeit modest, which points to a recovery in the demand for medicines in Spain.

[66] According to data provided by Farmaindustria, public expenditure on pharmaceuticals on NHS prescriptions in 2013 accounted for 14.5% of public healthcare expenditure.

[67] The VAT applied to medicines, healthcare products, formulas and others is the reduced rate of 4%.

[68] As already remarked previously, in the period 2010-2013 various Royal Decree-Laws and a Law were passed with the aim of containing public expenditure on pharmaceuticals in Spain.

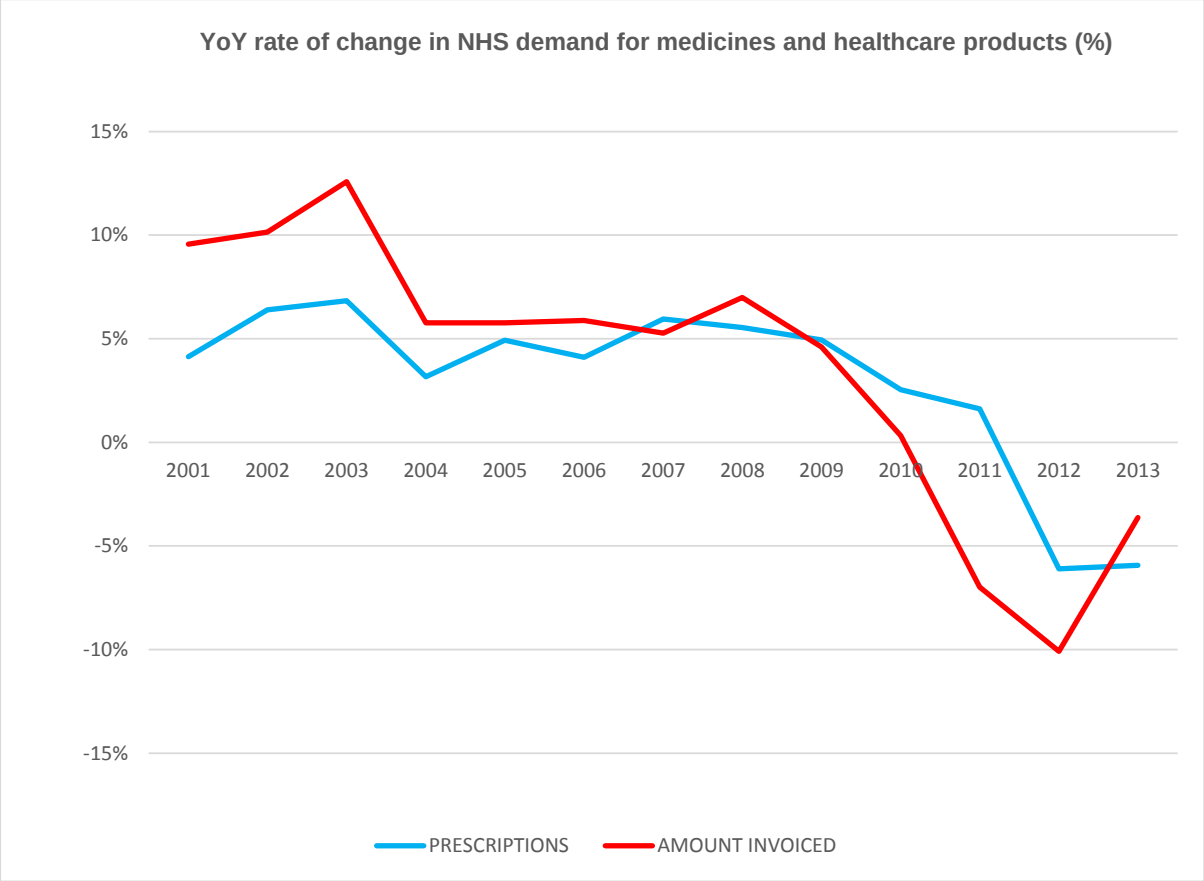
Graph 7. Changes in NHS demand for medicines and healthcare products Period 2000-2013



Source: in-house based on information from the Ministry of Health, Social Services and Equality.

When analysing the changes in the number of NHS drug prescriptions compared with the total turnover resulting from these prescription in the period 2000-2013, it can be seen that from 2009 the decline in turnover is greater than the decline in the number of prescriptions, as a result of the aforementioned steps taken to contain expenditure on pharmaceuticals. This trend changed in 2013, when public expenditure on pharmaceuticals started to recover in Spain.

Graph 8. Changes in the number of prescriptions and turnover for NHS medicines and healthcare products. Period 2000-2013



Source: in-house based on information from the Ministry of Health, Social Services and Equality.

The turnover for the NHS' consumption of pharmaceuticals can be broken down, by source of financing, into NHS expenditure on pharmaceuticals[69], users' contributions,

[69] Pharmaceutical expenditure generated by the invoicing of NHS prescriptions and charged to the public funds of the Autonomous Regions and INGESA (National Institute of Healthcare Management, formerly National Health Institute, created by Royal Decree 840/2002).

pharmacies' contributions and deductions or discounts on the price of the medicines dispensed by pharmacies under the reimbursement list of the NHS[70].

Table 11. Breakdown of the amount invoiced for the NHS' pharmaceutical consumption

	BREAKDOWN OF NHS PHARMACEUTICAL CONSUMPTION (€ millions), 2013							
Autonomous Region	NHS expenditure on pharmaceuticals (€ millions)	Users' contribution (€ millions)	Pharmacies' contribution (€ millions)	Discounts per RDL 8/2010 (€ millions)	NHS expenditure as % of NHS consumption	Users' contributions as % of NHS consumption	Pharmacies' contribution as % of NHS consumption	Discounts per RDL 8/2010 as % of NHS consumption
ANDALUSIA	1.596,55	188,19	44,79	101,07	82,7%	9,7%	2,3%	5,2%
ARAGON	287,27	43,95	8,26	18,52	80,2%	12,3%	2,3%	5,2%
ASTURIAS	246,39	33,76	9,41	16,23	80,6%	11,0%	3,1%	5,3%
BALEARIC ISLANDS	172,59	26,01	4,66	11,40	80,4%	12,1%	2,2%	5,3%
CANARY ISLANDS	407,68	47,61	16,86	26,77	81,7%	9,5%	3,4%	5,4%
CANTABRIA	119,88	17,87	4,10	7,90	80,0%	11,9%	2,7%	5,3%
CASTILE AND LEON	527,08	73,68	10,06	33,80	81,8%	11,4%	1,6%	5,2%
CASTILE - LA MANCHA	444,43	62,75	7,00	27,45	82,1%	11,6%	1,3%	5,1%
CATALONIA	1.315,13	153,23	37,15	71,17	83,4%	9,7%	2,4%	4,5%
VALENCIA	1.105,95	146,79	38,54	71,65	81,1%	10,8%	2,8%	5,3%
EXTREMADURA	278,04	38,58	6,52	17,81	81,5%	11,3%	1,9%	5,2%
GALICIA	692,76	80,46	24,48	45,88	82,1%	9,5%	2,9%	5,4%
MADRID	1.003,32	134,28	26,09	61,26	81,9%	11,0%	2,1%	5,0%
MURCIA	313,52	46,27	14,91	20,93	79,2%	11,7%	3,8%	5,3%
NAVARRE	118,85	18,49	-0,20	7,56	82,1%	12,8%	-0,1%	5,2%
BASQUE COUNTRY	467,16	41,29	16,98	30,78	84,0%	7,4%	3,1%	5,5%
LA RIOJA	63,51	10,07	1,74	4,12	80,0%	12,7%	2,2%	5,2%
CEUTA	12,44	1,89	0,50	0,87	79,3%	12,1%	3,2%	5,5%
MELILLA	10,71	1,42	0,34	0,76	80,9%	10,8%	2,6%	5,7%
NATIONAL TOTAL	**9.183,25**	**1.166,62**	**272,17**	**575,92**	**82,0%**	**10,4%**	**2,4%**	**5,1%**

Source: in-house based on data from the Ministry of Health, Social Services and Equality.

In 2013, at a national level, the NHS financed 82% of the cost of medicines and healthcare products in the reimbursement list (€ 9,183,250,000), users contributed 10.4%, pharmacies 2.4% and the remaining 5.1% corresponded to deductions or discounts on the price of these medicines.

However, at an Autonomous Region level, we observe significant differences in agents' relative contributions to the financing of the NHS' pharmaceutical consumption. The Basque Country is the region in which the relative weight of the NHS is the greatest (84%) and in which users' contribution is the lowest (7.4%). Users have a greater relative weight in Navarre (12.8%), which offsets the

[70] Article 8 of Royal Decree-Law 8/2010 establishes, from 2010, a deduction of 7.5% of the retail price of these medicines and the same deduction is applied to the distributor's selling price and to the maximum industrial (manufacturer's) price, with aim of achieving an “equitable sharing among all agents in the medicine chain”.

pharmacies' contributions, which in 2013 were negative in this Autonomous Region[71].

As regard trends in the agents' contributions to the financing of the NHS' consumption of pharmaceuticals, it should be pointed out that the amount of expenditure on pharmaceuticals financed by the NHS increased in the period 2000-2009, with the contribution remaining steady (90.6% on average) and from 2010 on, coinciding with the implementation of various measures aimed at reducing public expenditure on pharmaceuticals, the NHS' expenditure on pharmaceuticals shrank to 82% of total expenditure in 2013.

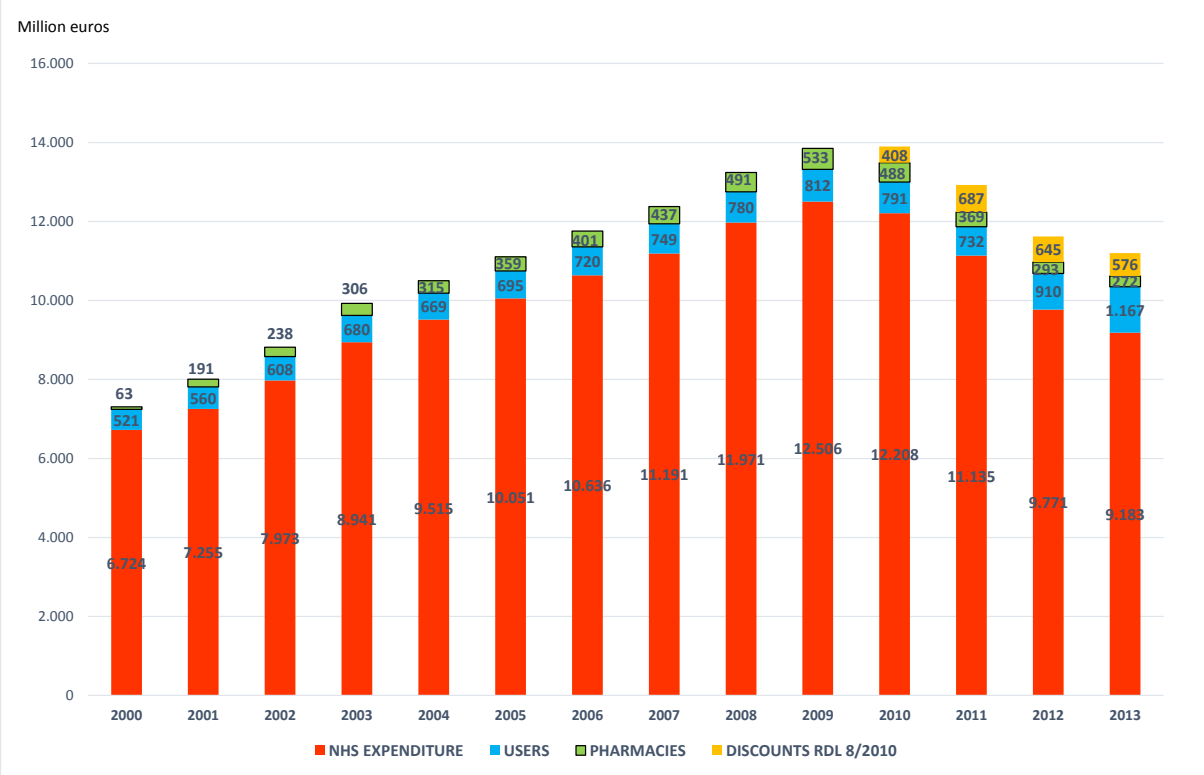
Users' contributions have increased notably in the past two years (7.8% in 2012 and 10.4% in 2013), compared with an average contribution of 6.3% in the period 2000-2011. This is due to the recent implementation of pharmaceutical co-payment[72]. Pharmacies' contributions, on the other hand, have declined since 2010 because of the reduction in sales of NHS medicines deriving from the economic crisis and the removal of certain medicines from the reimbursement list[73].

Graph 9. Changes in the breakdown of the NHS' consumption of pharmaceuticals

[71] As previously explained, the pharmacies' contributions to the financing of the NHS' consumption of pharmaceuticals are linked to their sales by applying a scale of deductions. However, the margins of pharmacies with total annual sales (retail price plus VAT) of not more than €200,000 are corrected by an index, giving rise to public assistance to ensure their economic viability.

[72] Article 94 b) of Royal Decree-Law 16/2012 stipulates that outpatient pharmaceutical care (dispensing prescription drugs in pharmacies) is subject to user contribution in proportion to the user's income.

[73] Article 85 c) of Royal Decree-Law 16/2012.



Source: in-house based on data from the Ministry of Health, Social Services and Equality.

It is relevant to analyse the breakdown of the NHS' expenditure on pharmaceuticals (total and per capita) by Autonomous Region.

Table 12. Total and per capita NHS expenditure on pharmaceuticals by Autonomous Region

	NHS EXPENDITURE ON PHARMACEUTICALS AND NHS PER CAPITA EXPENDITURE ON PHARMACEUTICALS, 2013			
Autonomous Region	NHS expenditure on pharmaceuticals (€ millions)	NHS expenditure on pharmaceuticals as % of total	NHS per capita expenditure on pharmaceuticals (euros)	NHS per capita expenditure as % of national average
ANDALUSIA	1.596,55	17,4%	189,16	97,1%
ARAGON	287,27	3,1%	213,24	109,4%
ASTURIAS	246,39	2,7%	230,66	118,4%
BALEARIC ISLANDS	172,59	1,9%	155,25	79,7%
CANARY ISLANDS	407,68	4,4%	192,42	98,8%
CANTABRIA	119,88	1,3%	202,53	103,9%
CASTILE AND LEON	527,08	5,7%	209,17	107,3%
CASTILE - LA MANCHA	444,43	4,8%	211,53	108,6%
CATALONIA	1.315,13	14,3%	174,11	89,4%
VALENCIA	1.105,95	12,0%	216,27	111,0%
EXTREMADURA	278,04	3,0%	251,85	129,3%
GALICIA	692,76	7,5%	250,46	128,5%
MADRID	1.003,32	10,9%	154,46	79,3%
MURCIA	313,52	3,4%	212,98	109,3%
NAVARRE	118,85	1,3%	184,42	94,6%
BASQUE COUNTRY	467,16	5,1%	213,15	109,4%
LA RIOJA	63,51	0,7%	197,23	101,2%
CEUTA	12,44	0,1%	147,75	75,8%
MELILLA	10,71	0,1%	127,99	65,7%
NATIONAL TOTAL/AVERAGE	**9.183,25**	**100,0%**	**194,85**	**100,0%**

Source: in-house based on information from the Ministry of Health, Social Services and Equality and the National Statistics Institute.

NHS per capita expenditure on pharmaceuticals amounted to €194.90 in 2013. The lowest rates of per capita expenditure on pharmaceuticals are those of Melilla and Ceuta (65.7% and 75.8% of the national average respectively) and the highest is that of Extremadura (129.3% of the national average), followed by Galicia (128.5%). Per capita expenditure on pharmaceuticals is below the national average in the most populous Autonomous Regions (Andalusia, Catalonia, Madrid and Valencia).

Lastly, NHS demand for medicines can be classified into generic and non-generic. It is also important to analyse recent trends, since the policies promoting the use of generics adopted by the government in the past few years, such as prescription by

active principle and substitution by pharmacists[74], have increased very considerably the share of generic drugs in this market.

In 2013, demand for generic drugs included in the NHS reimbursement list amounted to 394 million units and €2,244 million in billings. Andalusia heads the list of Autonomous Regions by consumption of generic drugs, followed by Catalonia and Madrid.

Table 13. Demand for generic drugs by Autonomous Region

	NHS DEMAND FOR GENERIC DRUGS, 2013			
Autonomous Region	**Number of packages (millions)**	**Number of packages as % of National total**	**Invoicing (€ millions)**	**Invoicing as % of National total**
ANDALUSIA	84,36	21,4%	462,70	20,6%
ARAGON	11,10	2,8%	68,39	3,0%
ASTURIAS	8,00	2,0%	45,28	2,0%
BALEARIC ISLANDS	7,30	1,9%	39,12	1,7%
CANARY ISLANDS	15,49	3,9%	89,55	4,0%
CANTABRIA	4,76	1,2%	25,12	1,1%
CASTILE AND LEON	25,81	6,6%	160,80	7,2%
CASTILE - LA MANCHA	18,93	4,8%	108,01	4,8%
CATALONIA	65,59	16,7%	334,02	14,9%
VALENCIA	34,57	8,8%	219,67	9,8%
EXTREMADURA	9,01	2,3%	50,44	2,2%
GALICIA	23,39	5,9%	151,94	6,8%
MADRID	48,50	12,3%	257,67	11,5%
MURCIA	9,00	2,3%	55,89	2,5%
NAVARRE	4,73	1,2%	29,64	1,3%
BASQUE COUNTRY	20,45	5,2%	129,01	5,7%
LA RIOJA	2,08	0,5%	11,80	0,5%
CEUTA	0,49	0,1%	2,95	0,1%
MELILLA	0,37	0,1%	1,73	0,1%
NATIONAL TOTAL	**393,92**	**100,0%**	**2.243,71**	**100,0%**

Source: in-house based on information from the Ministry of Health, Social Services and Equality.

As regards the share of generics in the NHS market, it should be pointed out that in 2013 demand for these drugs amounted to 46.5% of the market in unit terms and

[74] Prescription by active principle was introduced by Law 29/2006 on Medicine and was made general, by making it mandatory for the prescriber, by Royal Decree-Law 9/2011. Pharmacist substitution means that the pharmacist replaces the medicine with another equivalent, cheaper medicine.

21% in terms of turnover. The lower share in turnover terms is due to the lower price of generics compared with non-generic or branded drugs.

There are significant differences among Autonomous Regions as regards the share of generics, with Castile and León having the biggest share, followed by Andalusia and Catalonia. At the other extreme are Murcia and Valencia.

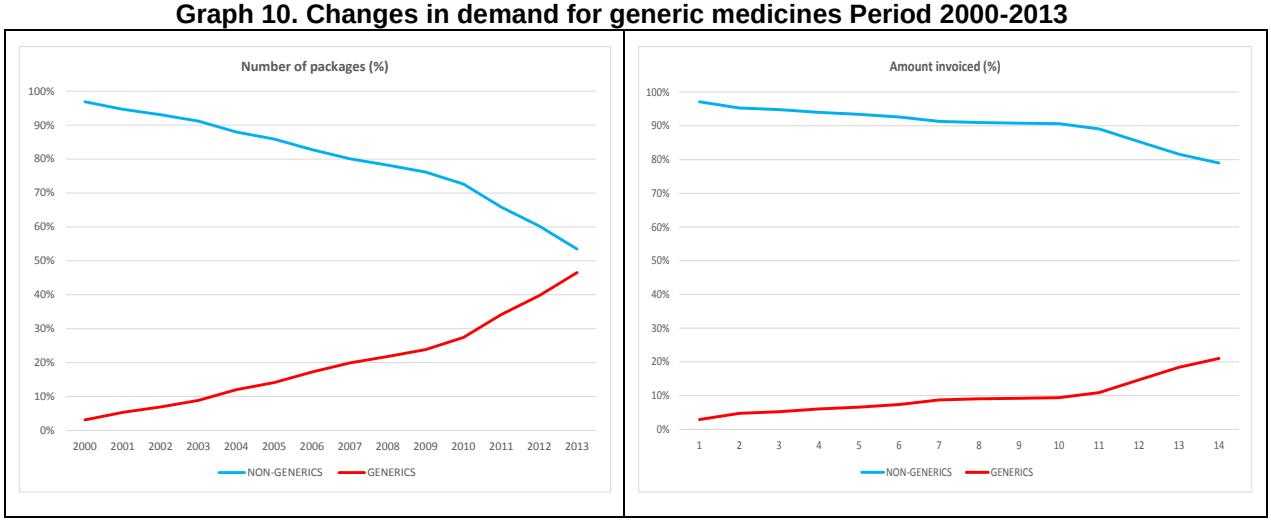
Table 14. Structure of the demand for generic and non-generic medicines by Autonomous Region

	NHS DEMAND FOR GENERIC AND NON-GENERIC MEDICINES, 2013			
	Number of packages		Amount invoiced	
Autonomous Region	Non-generic medicines as % of total	Generic medicines as % of total	Non-generic medicines as % of total	Generic medicines as % of total
ANDALUSIA	46,1%	53,9%	74,1%	25,9%
ARAGON	56,7%	43,3%	80,0%	20,0%
ASTURIAS	64,3%	35,7%	84,6%	15,4%
BALEARIC ISLANDS	54,1%	45,9%	80,9%	19,1%
CANARY ISLANDS	59,1%	40,9%	81,9%	18,1%
CANTABRIA	58,4%	41,6%	82,5%	17,5%
CASTILE AND LEON	45,6%	54,4%	74,1%	25,9%
CASTILE - LA MANCHA	53,6%	46,4%	79,0%	21,0%
CATALONIA	48,7%	51,3%	77,0%	23,0%
VALENCIA	63,3%	36,7%	83,2%	16,8%
EXTREMADURA	63,2%	36,8%	84,5%	15,5%
GALICIA	60,8%	39,2%	81,7%	18,3%
MADRID	49,8%	50,2%	78,1%	21,9%
MURCIA	67,6%	32,4%	85,7%	14,3%
NAVARRE	56,2%	43,8%	79,0%	21,0%
BASQUE COUNTRY	48,4%	51,6%	76,4%	23,6%
LA RIOJA	63,2%	36,8%	84,5%	15,5%
CEUTA	54,2%	45,8%	80,6%	19,4%
MELILLA	60,2%	39,8%	86,6%	13,4%
NATIONAL TOTAL	**53,5%**	**46,5%**	**79,0%**	**21,0%**

Source: in-house based on information from the Ministry of Health, Social Services and Equality.

Lastly, we analyse the changes in the share of generics in the NHS medicine market in the period 2000-2013. A spectacular growth in this share can be observed, especially in terms of the number of bottles or packages, from a minimal market presence in 2000 to almost 50% in 2013. In terms of billings, growth has been slower, due to the lower price of generics.

Graph 10. Changes in demand for generic medicines Period 2000-2013



Source: in-house based on information from the Ministry of Health, Social Services and Equality.

3.1.2 Structure of supply

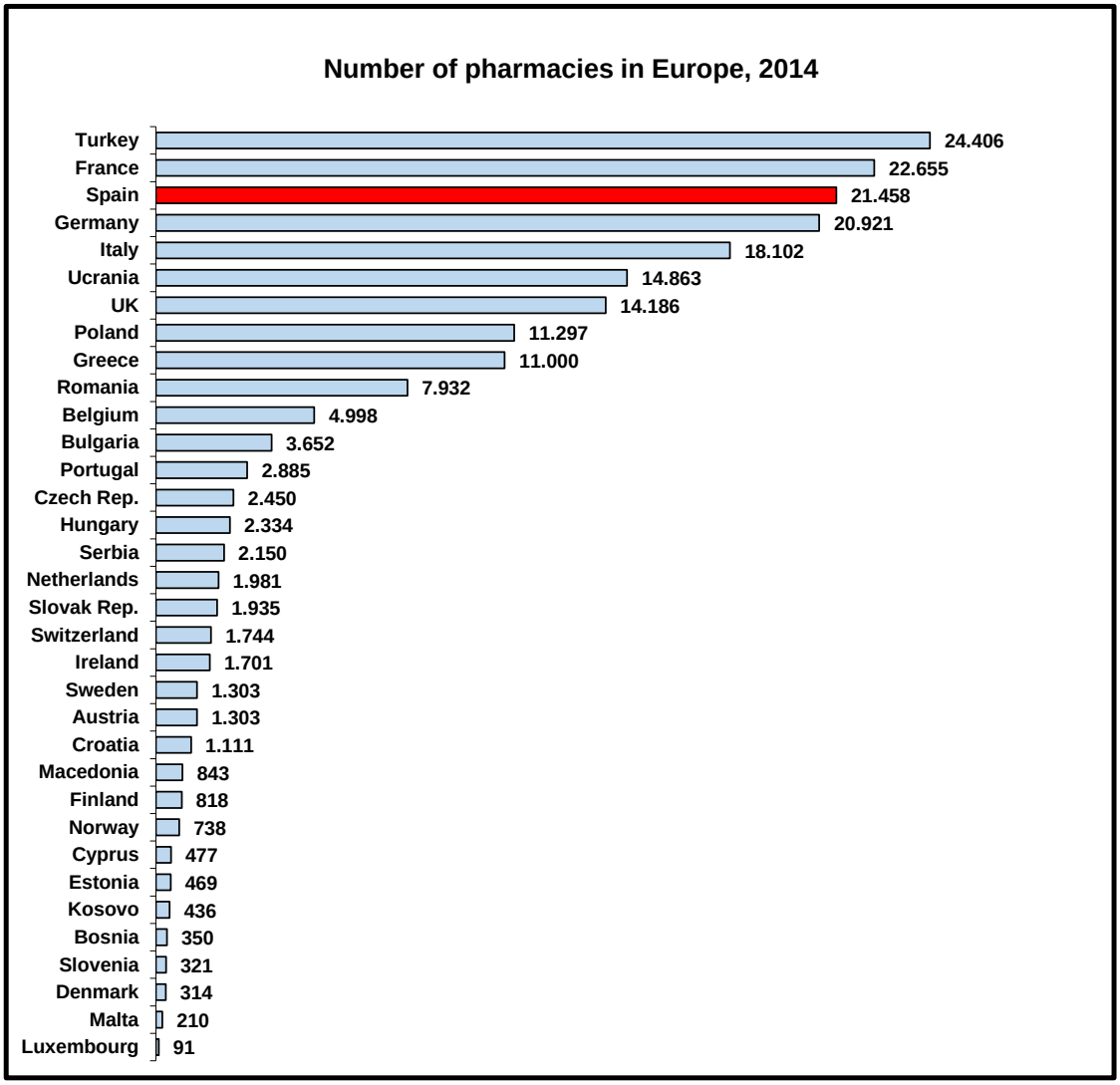
Spain has a large number of physical pharmacies compared with most other European countries. In

Graph 11 we see that Spain, with approximately 21,500 pharmacies in 2014, is the country with the third largest number of pharmacies, only behind Turkey and France and ahead of more populous countries such as Germany, the U.K. and Italy. It must be borne in mind that these differences are largely due to the different relative weights of pharmacies and hospitals in the dispensing of medicines, and also, to a lesser extent, due to the fact that in various European countries doctors are legally entitled to dispense medicines to patients for their greater convenience.

Another significant factor to be taken into account in this comparison is that in Spain, unlike countries such as Germany, the U.K. and the Netherlands, the sale of non-prescription medicines is restricted to pharmacies. Consequently, pharmacies are

the only distribution channel for medicines and are therefore over-represented relative to other countries[75].

Graph 11. Number of pharmacies in Europe



Source: in-house based on information from the Pharmaceutical Group of the European Union (PGEU, 2014).

[75] In the Netherlands, approximately 80% of non-prescription medicines are sold in establishments other than pharmacies (drugstores and supermarkets), compared with 40% in the U.K. and 20% in Germany (IMS Health (2010), "The Rising Tide of OTC in Europe").

In many European countries supermarkets and other establishments such as drugstores are not the only alternative distribution channels to pharmacies; the Internet is another channel of distribution for medicines, but its penetration and functioning presents important differences. As shown in Table 15, the sale of medicines online is allowed in the 18 European countries for which there is information, with the exception of Austria[76]. However, this type of sale is very recent in countries such as Spain and France,[77] whereas in others such as the Netherlands and Sweden, OTC medicines have been sold online for years[78].

Moreover, in eight of these 18 countries (Germany, Denmark, Finland, the Netherlands, Norway, the U.K., Sweden and Switzerland) the online sale of prescription drugs is also permitted.

Table 15. Online sale of medicines in Europe by type of medicine

[76] Although the online distribution of generics drugs is forbidden to Austrian pharmacies, Austrian consumers can acquire them from websites of other EU Member States, providing the medicines are not subject to medical prescription in either Austria or the corresponding Member State.

[77] In these countries, the online sale of OTC drugs has been allowed since 2013 following the approval of various Decrees incorporating the provisions of Directive 2011/62/EU.

[78] For example in Sweden, OTC drugs have been sold online since 2002, and in Ireland since 2006.

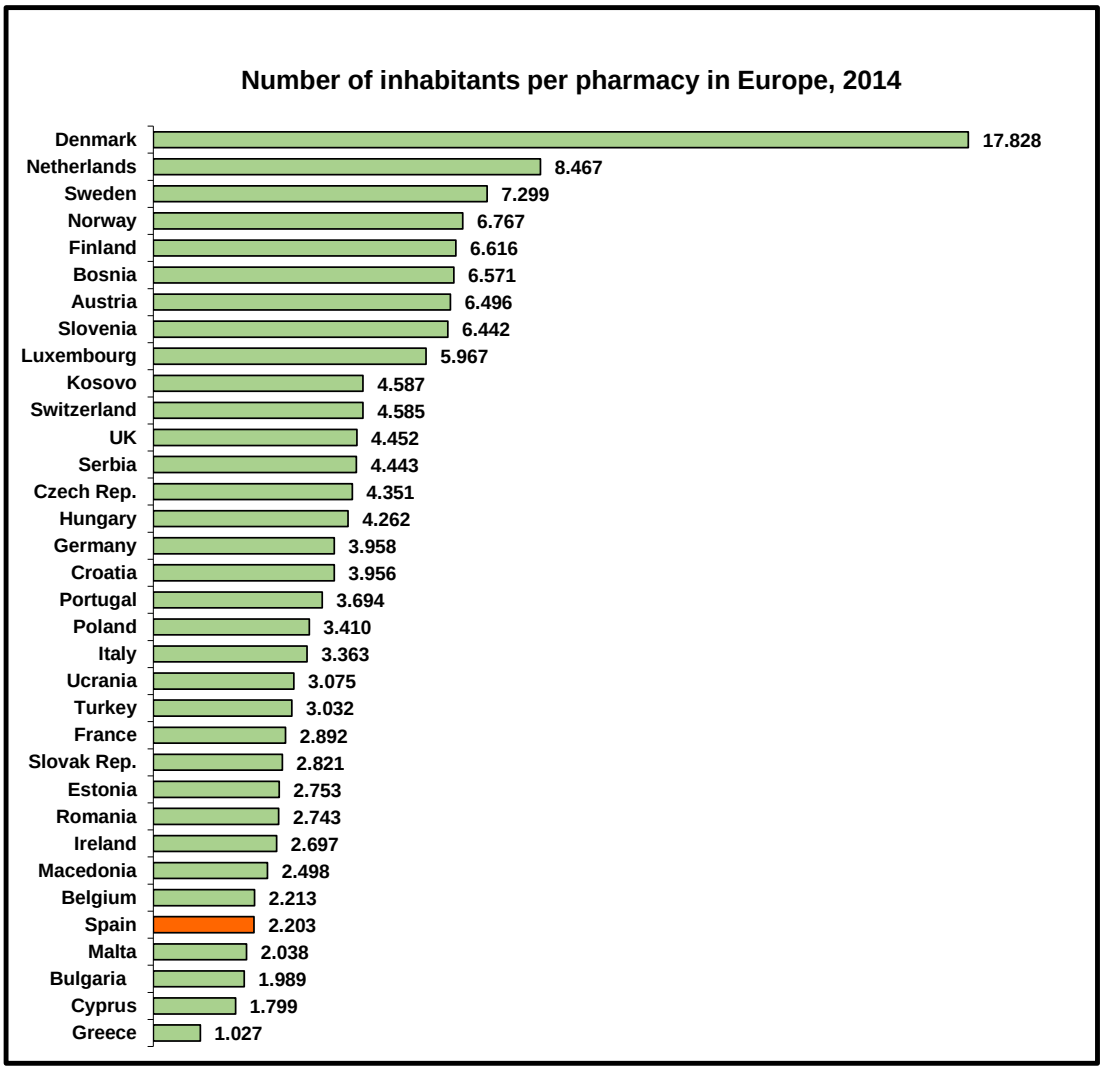
	ONLINE SALES OF MEDICINES IN EUROPE, 2013	
COUNTRY	OTC drugs	Prescription drugs
Germany	YES	YES
Austria	NO	NO
Belgium	YES	NO
Denmark	YES	YES
Slovak Republic	YES	NO
Spain	YES	NO
Finland	YES	YES
France	YES	NO
Netherlands	YES	YES
Italy	YES	NO
Norway	YES	YES
Poland	YES	NO
Portugal	YES	NO
United Kingdom	YES	YES
Czech Republic	YES	NO
Sweden	YES	YES
Switzerland	YES	YES

Source: in-house based on ECORYS (2007) and Dudley J.W. (2012).

When comparing the number of inhabitants per pharmacy in Spain with the rest of Europe, it can be seen that Spain, with 2,203 inhabitants per pharmacy in 2014, is in fifth place in the list of countries with the smallest numbers of inhabitants per pharmacy, behind Greece, Cyprus, Bulgaria and Malta. At the other extreme is Denmark which, with 7,828 inhabitants per pharmacy in 2014, is by far the country with the highest number of inhabitants per pharmacy[79].

Graph 12. Number of inhabitants per pharmacy in Europe

[79] The number of inhabitants per pharmacy is more than double that of the other Nordic countries, which could be explained by the bigger average size of pharmacies in Denmark, enabling them to serve a larger number of patients in comparison with other countries (GÖG FP (2012)) and also by the possibility of acquiring prescription drugs online.



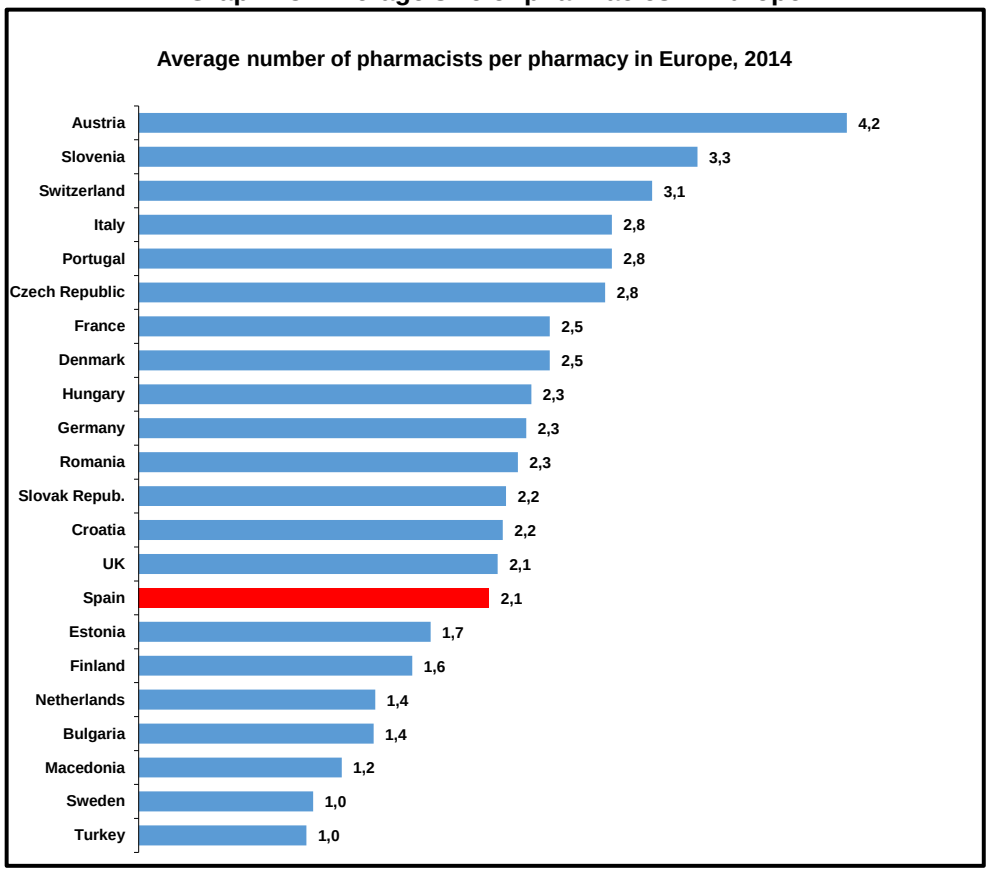
Source: in-house based on information from PGEU (2014).

Finally, there are seven European countries which, unlike Spain, allow doctors to dispense medicines: Switzerland, the U.K., Austria, the Netherlands, Ireland, France and Norway.

As for the average size of pharmacies in Spain compared with other European countries, Spain is in the lower-mid range of the ranking, with 2.1 pharmacists per pharmacy in 2014, slightly less than the average size in the 22 countries considered (2.2 pharmacists per pharmacy). The country with the highest average size of pharmacy is Austria (4.5 pharmacists per pharmacy) and the country with the

smallest average size is Turkey, which is also the European country with the largest number of pharmacies in 2014[80].

Graph 13. Average size of pharmacies in Europe



Source: in-house based on information from PGEU (2014).

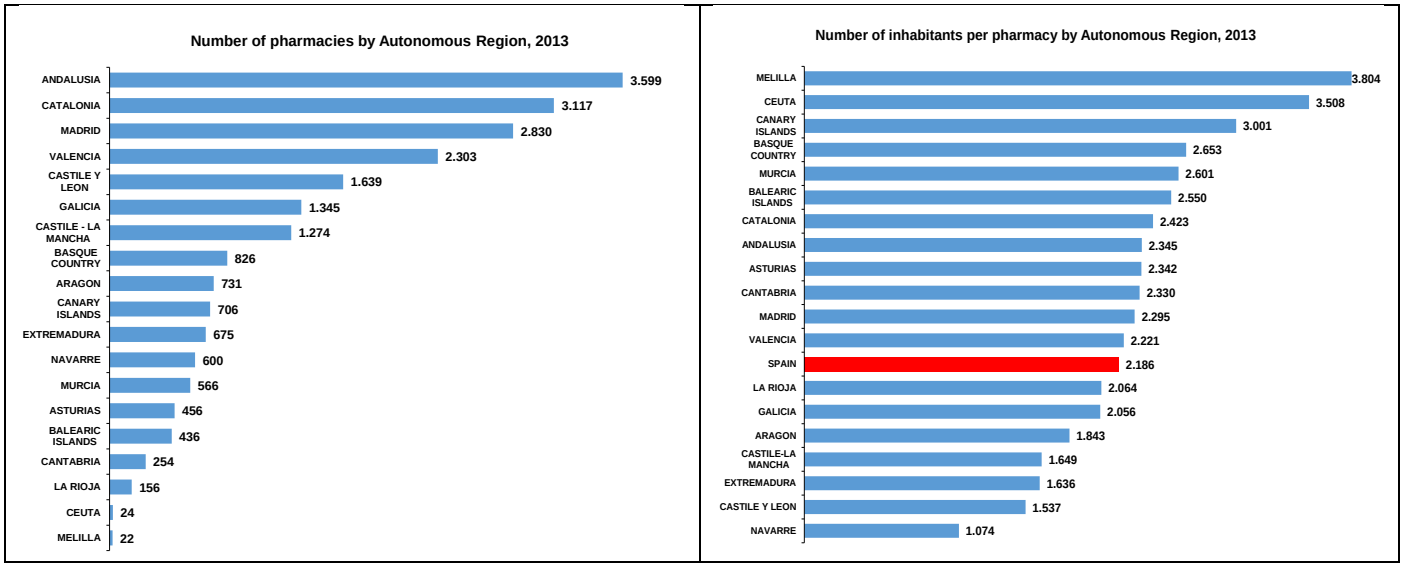
In the analysis of the supply structure of the retail medicine distribution market in Spain, the breakdown by Autonomous Region is of particular significance. As it has already been observed, the geographical planning of pharmacies is a regional competence, and the differences in regulation among Autonomous Regions have an effect on the structure of supply in each region.

[80] Spain's low population density (92.9 inhabitants/km^2) in comparison with the average density of the EU 28 (116.4 inhabitants/km^2) could explain the small size of pharmacies in Spain compared with other more densely populated countries such as Italy (199.4 inhabitants/km^2) or Portugal (113.4 inhabitants/km^2).

The number of pharmacies in Spain was 21,559 in 2013[81], Andalusia, the largest region by area, having the highest number of pharmacies (17% of the total), followed by Catalonia, Madrid and Valencia.

The average number of inhabitants per pharmacy in Spain was 2,186 in that year, with very significant differences among Autonomous Regions. Navarre stands out, with the lowest number of inhabitants per pharmacy (1,074), followed by Castile and León, Extremadura and Castile-La Mancha. At the other extreme are the autonomous cities of Melilla and Ceuta, with 3,804 and 3,508 inhabitants per pharmacy respectively.

Graph 14. Classification of Autonomous Regions by number of pharmacies and inhabitants per pharmacy in 2013

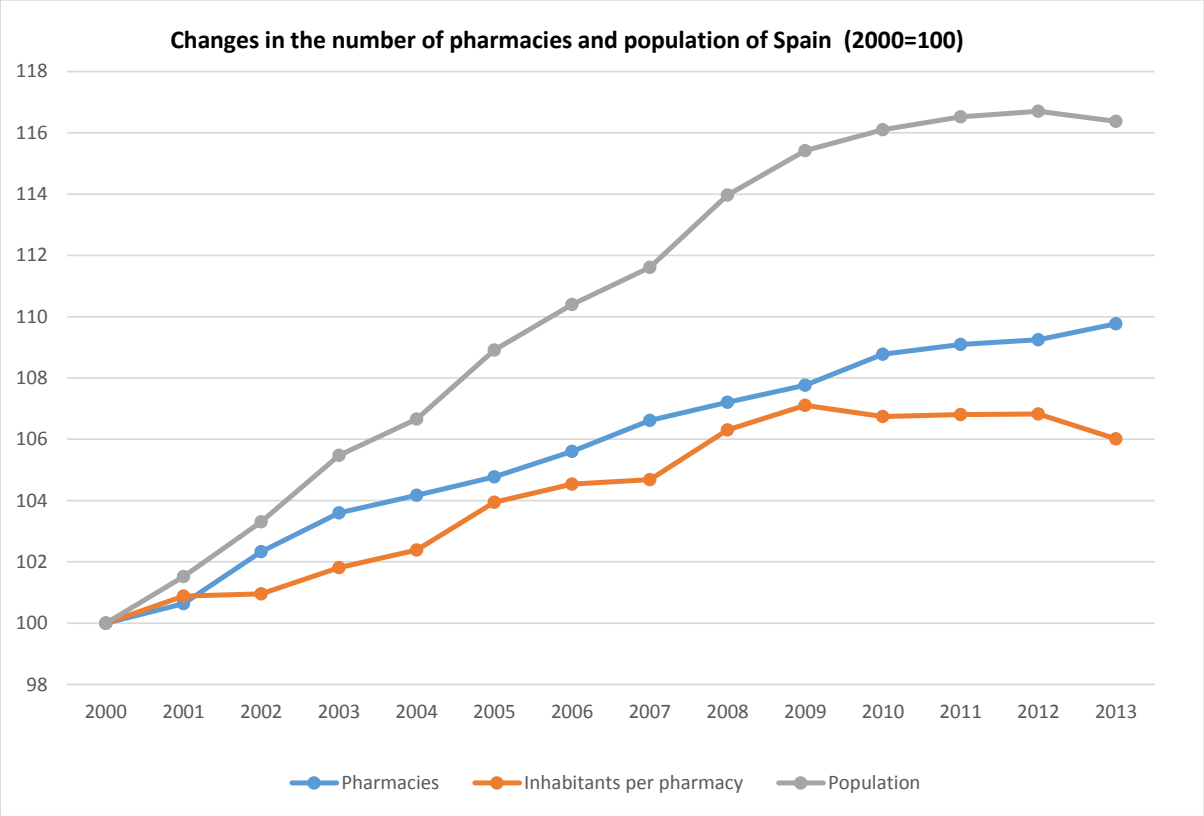


Source: in-house based on information from the CGCOF and the National Statistics Institute.

As regards recent trends in the number of pharmacies in Spain, we would point out that in the period 2000-2013, the total number of pharmacies increased by 9.8%. As shown in Graph 15, this increase was substantially less than the increase in Spain's population over the period (16.4%). As a result of the greater growth in population relative to the growth in the number of pharmacies, the number of inhabitants per pharmacy increased by 6%.

[81] Information on pharmacies by Autonomous Region, December 2013.

Graph 15. Changes in pharmacies and population in Spain. Period: 2000-2013

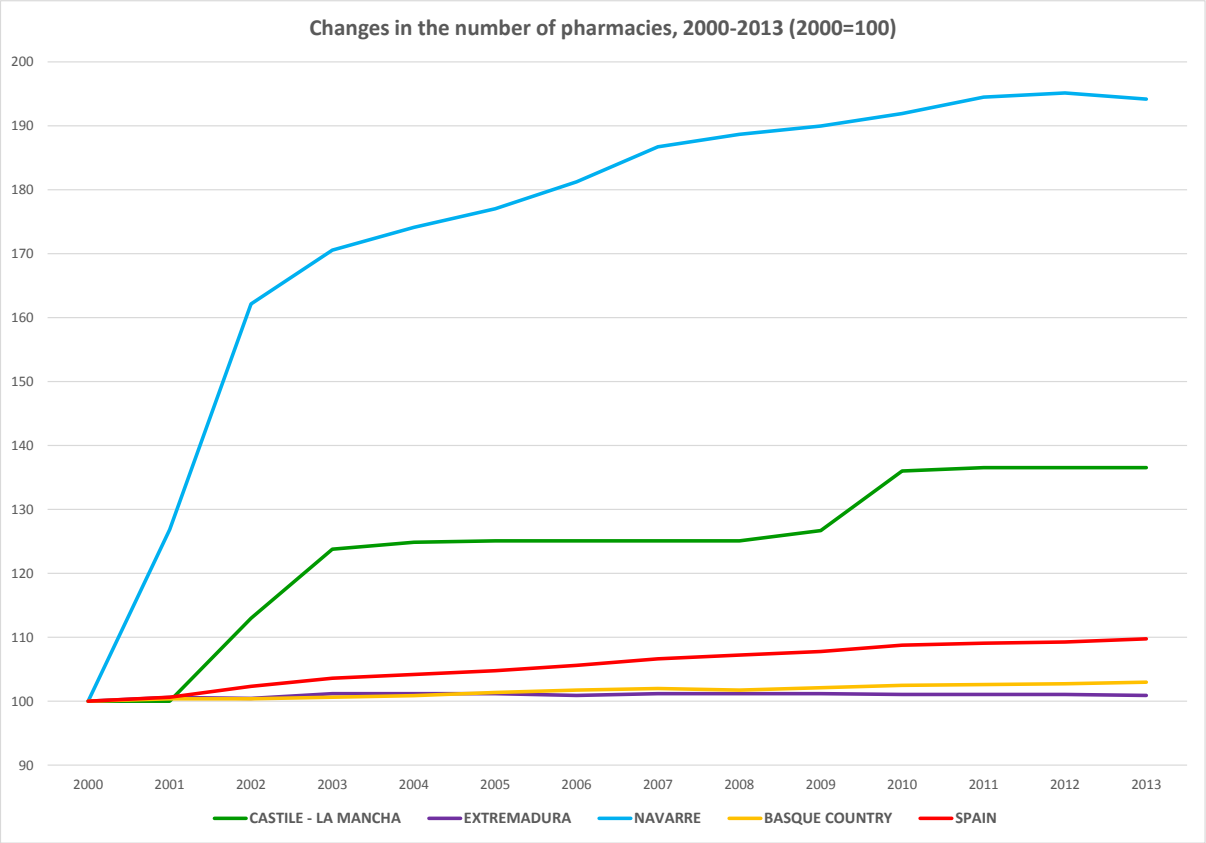


Source: in-house based on information from the CGCOF and the National Statistics Institute.

If we analyse the changes in the number of pharmacies by Autonomous Region, very significant differences among regions are observed, as shown in Graph 16 .

It should be pointed out that Navarre is the Autonomous Region with the highest increase in the number of pharmacies (94.2%) in this period, from 309 in 2000 to 600 in 2013. The increase in the number of pharmacies in Castile-La Mancha (36.5%) is also significant, although much smaller than in the case of Navarre. The remaining Autonomous Regions show modest increases (especially taking into account the length of the period considered), with the Balearic Islands and Valencia showing increases of 14.4% and 13.2% respectively, above the national average of 9.8%, and the remainder below that average, being the increases in Extremadura (0.9%), the Basque Country (3%) and Asturias (3.2%) particularly modest.

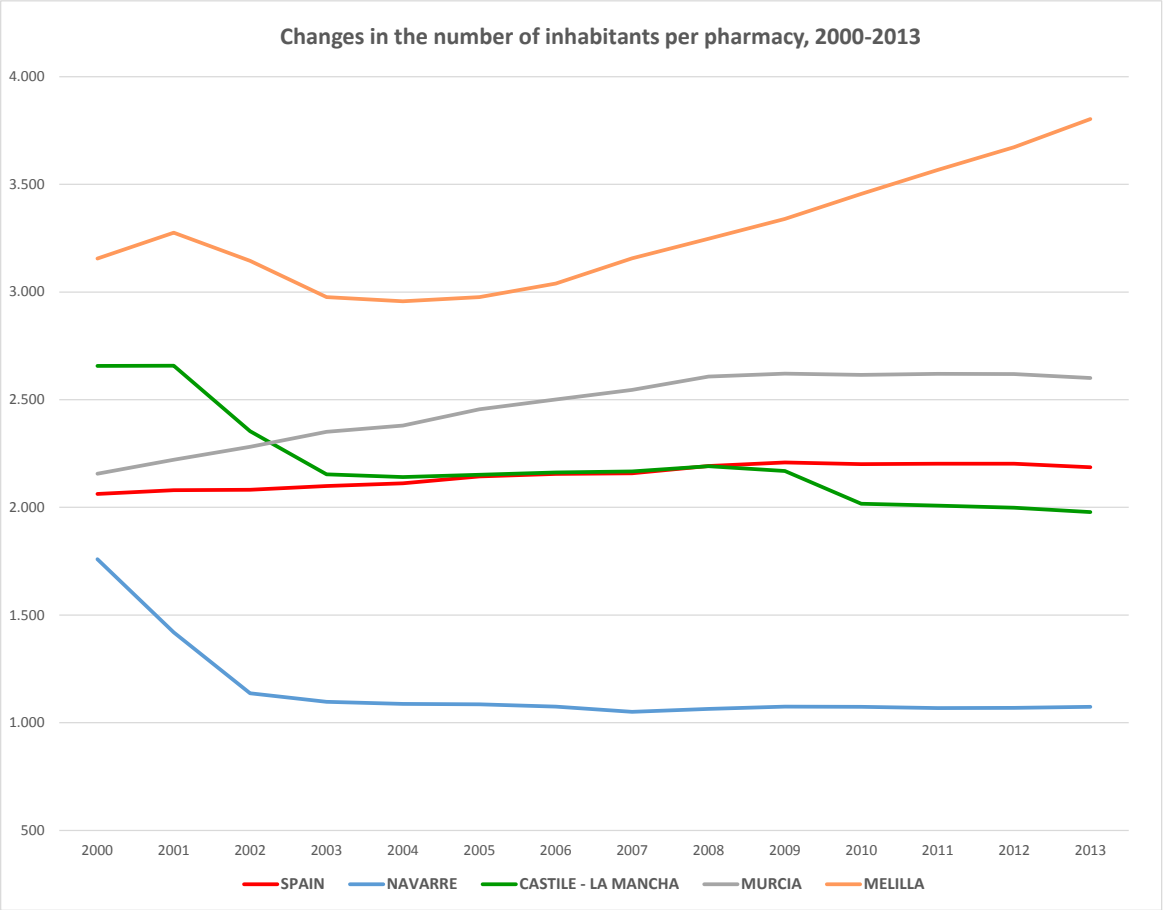
Graph 16. Changes in the number of pharmacies by Autonomous Region Period: 2000-2013



Source: in-house based on information from the CGCOF.

The two Autonomous Regions with the most growth in the number of pharmacies, Navarre and Castile-La Mancha, are also two of the three regions in which the number of inhabitants per pharmacy has decreased over the period under review. The growth in the number of pharmacies has more than matched the growth in the population (18.5% and 21.1% respectively) in both regions. Consequently, the number of inhabitants per pharmacy has declined substantially, by 39% in Navarre and 25.6% in Castile-La Mancha. In contrast, the number of inhabitants per pharmacy increased considerably in Murcia (20.6%) and Melilla (20.5%), among others.

Graph 17. Changes in the number of inhabitants per pharmacy and by Autonomous Region Period: 2000-2013



Source: in-house based on information from the CGCOF and the National Statistics Institute.

In this market, supply is tightly regulated and the establishment of new pharmacies requires authorisation by the competent bodies of the Autonomous Regions. This authorisation depends, in turn, on the compliance with certain geographical planning criteria. Consequently, changes in the number of pharmacies are not significantly dependent on demand variables such as the average age or income of the population.

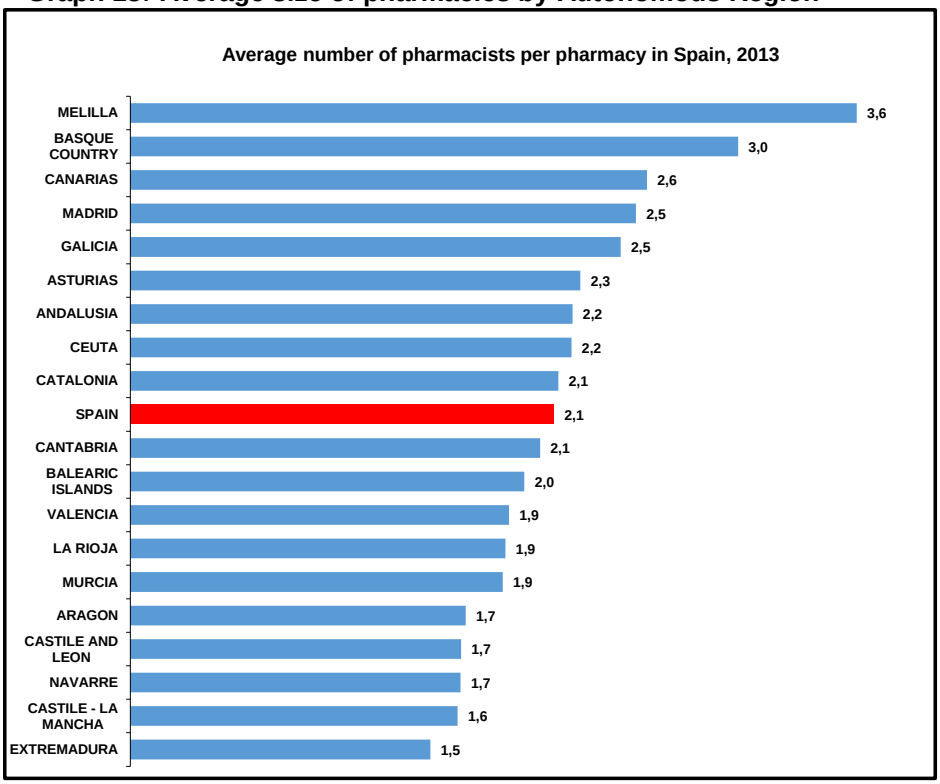
As will be analysed in section 4.2 of this study, the considerable increase in the number of pharmacies in Navarre from 2000 on is the result of a change in the regulation of pharmaceutical planning in that region with the passing of its law on the organisation of the pharmaceutical sector in the latter part of that year. Navarre

adopted a model of pharmaceutical planning different from that established for Spain as a whole by Law 16/1997 and different from the other Autonomous Regions[82].

In Castile-La Mancha, Law 10/2000 was passed, allowing the opening of pharmacies in population centres with populations of more than 1,000 inhabitants at a minimum distance of 500 metres from the nearest existing pharmacy. This Law had a considerable impact in terms of the opening of new pharmacies in the period 2001-2003.

As regards the structure of the supply by average size of pharmacies, measured by the number of pharmacists, it should be pointed out that the average number of pharmacists per pharmacy in Spain was 2.1 in 2013, the pharmacies with the largest average number of pharmacists being those of Melilla (3.6) and the Basque Country (3) and those with the smallest being the ones in Extremadura (1.5), Castile-La Mancha (1.6) and Navarre (1.7).

Graph 18. Average size of pharmacies by Autonomous Region



Source: in-house based on information from the CGCOF.

[82] Regional Law 12/2000 determines the *minimum* number of pharmacies needed to ensure appropriate geographical coverage of pharmaceutical care, whereas the other Autonomous Regions all establish the maximum number of pharmacies for a given number of inhabitants.

Lastly, the effects of the restrictions on the establishment of pharmacies on the labour market of pharmaceutical association members in Spain should be analysed. As shown in Table 16, the number of pharmacy association members in Spain was 66,657 in 2013 compared with 24,367 pharmacy owner-operators, which implies that only 36.6% of affiliated pharmacists in Spain are owner-operators of a pharmacy.

The percentage of members holding a pharmacy is highest in Castile-La Mancha and Extremadura (50.4% and 47.5% respectively) and lowest in Madrid, where only 28.3% of members are owner-operators of a pharmacy.

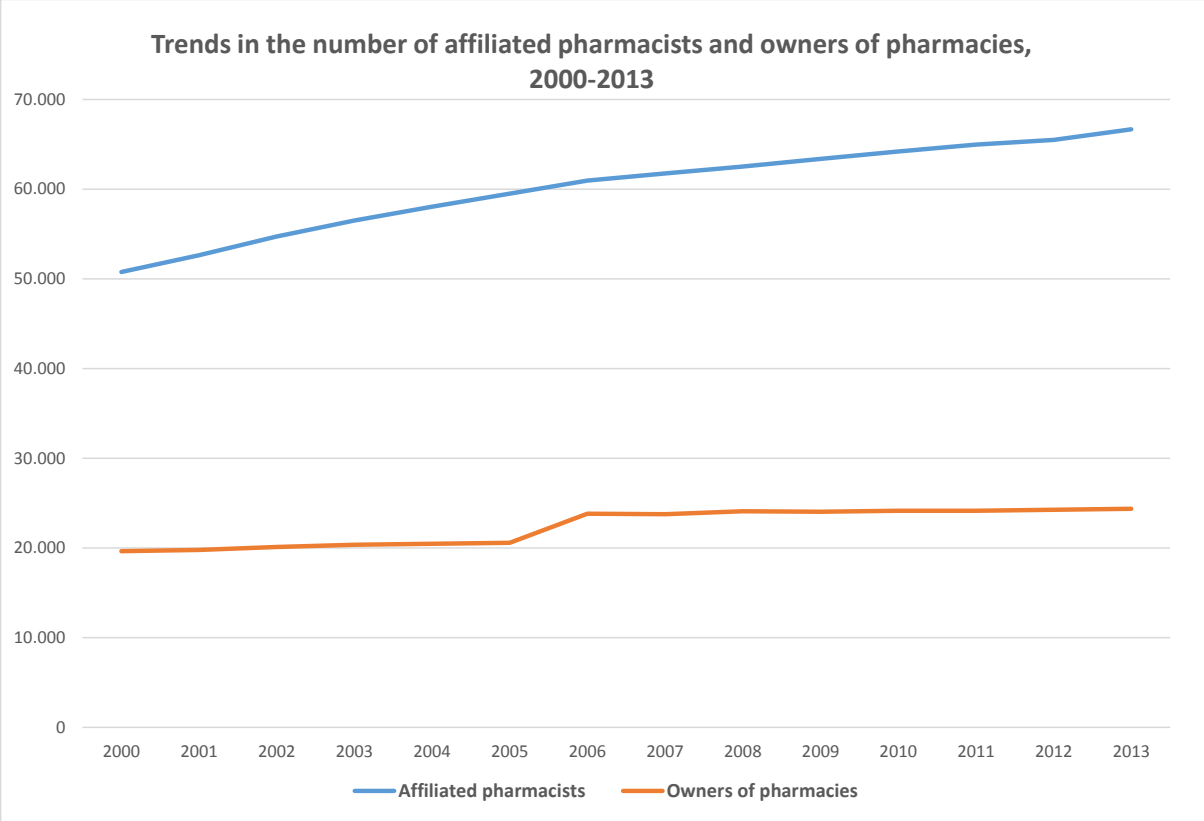
As regards the changes in both groups in the period 2000-2013, we see that the mismatch between the number of registered pharmacists and those holding a pharmacy, far from declining, actually increased over the period. While the number of members grew continuously throughout the period, the number of owner-operators has stabilised following a small increase in 2006.

Table 16. Number of registered pharmacists and owners by Autonomous Region. 2013

Autonomous Region	Number of affiliated pharmacists	Number of owners of pharmacies	% Members who are owners of pharmacies
ANDALUSIA	11.151	4.379	39,3%
ARAGON	1.715	795	46,4%
ASTURIAS	1.331	496	37,3%
BALEARIC ISLANDS	1.225	529	43,2%
CANARY ISLANDS	2.474	794	32,1%
CANTABRIA	690	280	40,6%
CASTILE AND LEON	3.899	1.744	44,7%
CASTILE - LA MANCHA	2.684	1.352	50,4%
CATALONIA	10.451	3.508	33,6%
VALENCIA	6.738	2.770	41,1%
EXTREMADURA	1.547	735	47,5%
GALICIA	4.723	1.456	30,8%
MADRID	11.269	3.190	28,3%
MURCIA	1.647	600	36,4%
NAVARRE	1.398	602	43,1%
BASQUE COUNTRY	3.131	919	29,4%
LA RIOJA	430	168	39,1%
CEUTA	74	26	35,1%
MELILLA	80	24	30,0%
NATIONAL TOTAL	**66.657**	**24.367**	**36,6%**

Source: in-house based on information from the CGCOF.

Graph 19. Changes in the number of registered pharmacists and owner-operators of pharmacies in Spain. Period: 2000-2013



Source: in-house based on information from the CGCOF.

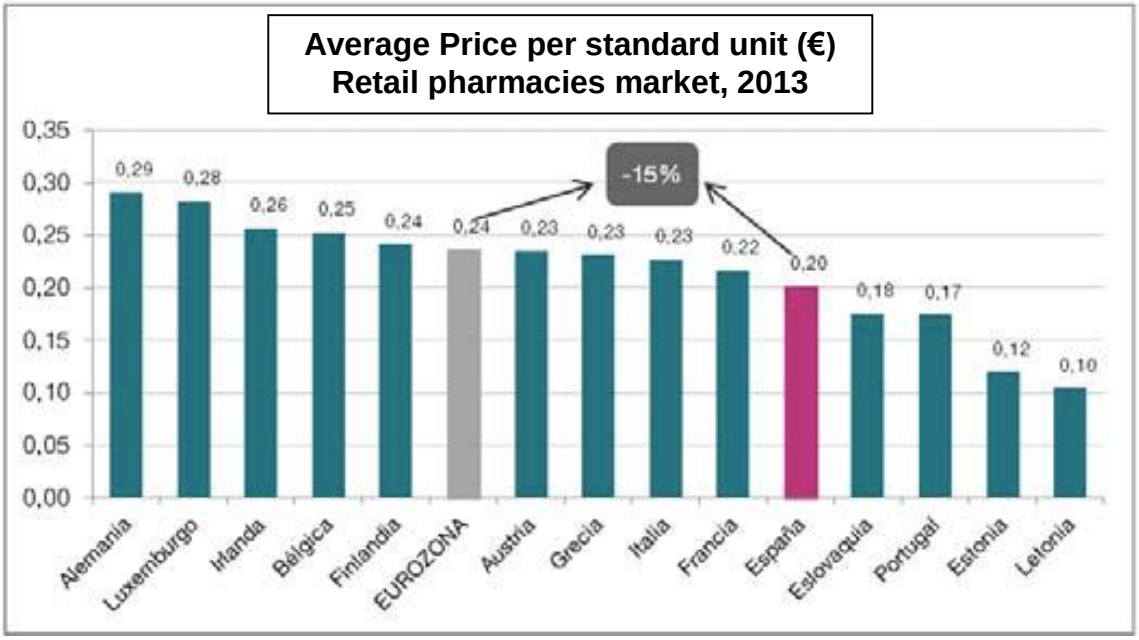
3.1.3 Price of medicines and breakdown of the components of the distribution chain

There are no official sources of information that enable the comparison between the price of medicines in Spain with other European countries. The OECD's healthcare expenditure statistics do not provide a breakdown of expenditure on pharmaceuticals in units and price of medicines. However, the OECD data does show a greater reduction in expenditure on pharmaceuticals in Spain than in other European countries, Spain being one of the most affected countries by the economic crisis. As can be seen from the analysis of the structure of demand, the fall in public

expenditure on pharmaceuticals in Spain, from 2009, is due to a decline in both the number of units sold and in their average price[83].

According to Farmaindustria, the average standard unit price[84] of medicines in Spain compared with other European countries is 15% below the average for euro zone countries[85].

Graph 20. Average price of medicines in Europe



Source: Farmaindustria (2014).

As regards the price structure of medicines, according to the relative weight of the activities in the medicine distribution chain in the final price, several differences between Spain and the average for European countries can be observed[86].

Graph 21 shows that 65.2% of the retail price including VAT of all medicines dispensed in pharmacies in Spain in 2013 corresponded to the manufacturers' selling

[83] In Graph 8 we see a more pronounced fall in the amount invoiced for NHS medicine and healthcare product prescriptions than in the number of prescriptions, which indicates a reduction in the average price per prescription. This trend seems to correct itself in 2013.

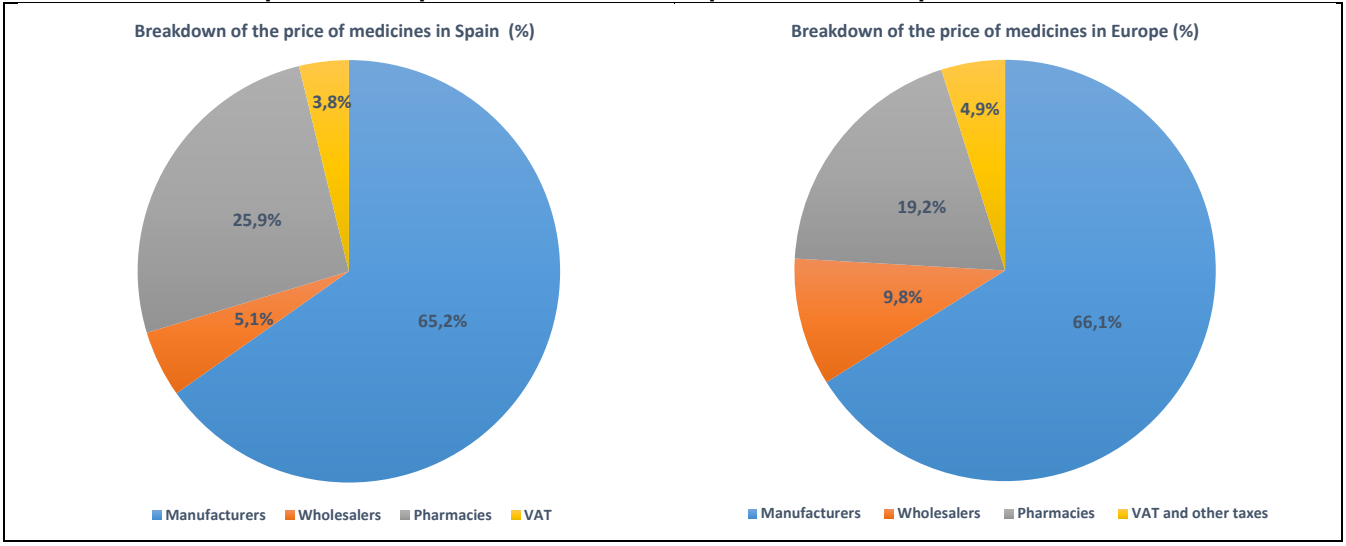
[84] The standard unit according to Farmaindustria eliminates the possible distortion in average price comparison caused by differences among countries in relative consumption of different drugs or different doses of the same drug.

[85] Except Cyprus, Slovenia, the Netherlands and Malta, for which data are not available.

[86] Non-weighted average price of medicines in 23 European countries.

price, 5.1% to the wholesale distributors' margin, 25.9% to the pharmacies' margin and 3.8% to VAT. In Europe, the weight of the pharmacies' margin in the retail price including tax is substantially lower than in Spain (19.2%) while the wholesale distributors' margin is nearly double (9.8%)[87].

Graph 21. Final price of medicines in Spain and in Europe. 2013



Source: in-house based on data from the CGCOF and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The price of medicines in Spain is regulated in the case of medicines financed by the NHS and, in the case of medicines excluded from the reimbursement list, mainly non-prescription, the price is free, although it must be reported to the Ministry of Health, Social Services and Equality.

Based on the information on units sold or prescriptions (in the case of NHS medicines and healthcare products) and the turnover for the various types of medicines, the average price can be calculated by dividing the total turnover by the number of units sold.

In Table 17 we show the average price of all medicines dispensed by pharmacies[88] in 2013 and the different medicines, classified according to whether or not they are subject to medical prescription and whether the source of financing is public or

[87] Wholesale and retail distributor margins for medicines are regulated in all EU countries. According to the ÖBIG (2006), 18 of the 25 Member States regulate fixed margins (maximums and minimums) and the other seven set maximum commercial margins below which discounts are freely permitted, allowing greater possibilities of competition.

[88] Since we do not have disaggregated information by Autonomous Region, medicines acquired by pharmacies direct from manufacturers are not taken into account.

private. The average manufacturers' selling price in this market amounted to €7.75 per unit. In the prescription drug segment the average price was €8.22 per unit, while for generics it was just €3.85 per unit. Since 93% of prescription drugs are publicly financed, the price of the market segment formed by publicly financed medicines is practically the same as for the prescription drugs segment. However, the average price of privately financed medicines (€5.35) is higher than that of generics, since it includes prescription drugs either excluded from the reimbursement list or prescribed by a private doctor, which are more expensive than generics.

Among Autonomous Regions, Andalusia and Catalonia stand out as those with the lowest average prices for all medicines (except for the autonomous city of Melilla) and the Basque Country and Navarre as those with the highest.

As regards the medicines and healthcare products included in the NHS reimbursement list, the average retail price plus VAT amounted to €13.03 per prescription for Spain as a whole in 2013. The high average price of prescription medicines (€18.60 per bottle or package) compared with generic drugs (€5.70) should be highlighted. It is due to the fact that the former are innovative medicines protected by patent.

Table 17. Average price of medicines by Autonomous Region

	AVERAGE PRICE OF MEDICINES BY REGION AND NATIONAL TOTAL*, 2013				
Autonomous Region	**Total Medicines (euros/uniT)**	**Prescription medicines (euros/unit)**	**OTC (euros/unit)**	**Public financing (euros/unit)**	**Private financing (euros/unit)**
ANDALUSIA	6,96	7,31	3,77	7,29	5,17
ARAGON	8,00	8,44	3,90	8,52	5,31
ASTURIAS	7,80	8,22	3,75	8,27	5,15
BALEARIC ISLANDS	7,92	8,52	3,85	8,48	5,64
CANARY ISLANDS	7,46	8,09	3,78	8,05	5,22
CANTABRIA	7,63	8,03	3,85	8,08	5,26
CASTILE AND LEON	8,47	8,95	3,89	9,09	5,29
CASTILE - LA MANCHA	7,93	8,40	3,85	8,47	5,11
CATALONIA	7,01	7,45	3,86	7,39	5,34
VALENCIA	8,42	9,00	3,85	9,07	5,34
EXTREMADURA	8,27	8,73	3,84	8,84	5,02
GALICIA	8,33	8,78	3,86	8,90	5,21
MADRID	7,87	8,39	3,99	8,33	5,86
MURCIA	8,81	9,36	3,87	9,44	5,42
NAVARRE	8,48	9,14	3,79	9,22	5,24
BASQUE COUNTRY	8,80	9,33	3,87	9,42	5,49
LA RIOJA	8,37	8,82	3,87	8,89	5,52
CEUTA	7,49	7,99	3,81	8,21	4,89
MELILLA	6,88	7,29	3,49	7,21	5,24
NATIONAL TOTAL	**7,75**	**8,22**	**3,85**	**8,24**	**5,35**

(*) Manufacturer's selling price. Source: in-house based on information from IMS Health.

Table 18. Average price of NHS medicines by Autonomous Region

	AVERAGE PRICE OF NHS MEDICINES BY REGION AND NATIONAL TOTAL*, 2013		
Autonomous Region	**NHS medicines (euros/unit)**	**Non-generic (euros/unit)**	**Generic (euros/unit)**
ANDALUSIA	11,96	18,31	5,48
ARAGON	13,76	18,90	6,16
ASTURIAS	13,52	17,29	5,66
BALEARIC ISLANDS	13,19	19,25	5,36
CANARY ISLANDS	12,94	18,14	5,78
CANTABRIA	14,35	17,73	5,28
CASTILE AND LEON	13,42	21,20	6,23
CASTILE - LA MANCHA	13,06	18,57	5,71
CATALONIA	11,96	17,93	5,09
VALENCIA	14,26	18,22	6,35
EXTREMADURA	13,73	17,75	5,60
GALICIA	14,06	18,71	6,50
MADRID	12,62	19,03	5,31
MURCIA	14,28	17,86	6,21
NAVARRE	13,29	18,35	6,27
BASQUE COUNTRY	14,21	21,72	6,31
LA RIOJA	13,91	18,09	5,68
CEUTA	14,38	21,14	6,00
MELILLA	14,19	20,12	4,69
NATIONAL TOTAL	**13,03**	**18,60**	**5,70**

(*) Retail price incl. VAT.
Source: in-house based on information from the Ministry of Health, Social Services and Equality.

3.2. Analysis of competition in the market

The retail distribution market of medicines is a highly regulated market. Both the price of medicines and the margin obtained by pharmacies for retail dispensing of medicines are determined by the Government[89]. Therefore, the pharmacies compete basically on variables other than price, which is set, such as quality of service (home

[89] As mentioned, prices of OTC drugs are not regulated, although they must be reported to the Ministry of Health, Social Security and Equality. Although discounts of up to 10% are permitted on these medicines, because of the lack of incentives for pharmacies to compete, such discounts are infrequent.

delivery, travelling time to the establishment, speed of dispensing, personalised dosage systems, etc.) or opening hours.

In order for competition, however limited, to be effective, pharmacies must have incentives to compete. The barriers to entry for the establishment of new pharmacies significantly limit these incentives. The establishment of population modules and minimum distances between pharmacies limits the opening of new establishments, ensuring the profitability of established pharmacies and impeding the development of competitive dynamics with beneficial effects for patients in terms of quality of service or in the form of discounts on prices of OTC drugs.

Competition among pharmacies in dispensing medicines is of a local nature and competitive interaction among pharmacies takes place mainly in the limited area surrounding the patients' homes and the healthcare centres where the medicines are prescribed.

The study by the Office of Fair Trading (OFT, 2003)[90] on the retail medicine distribution market through pharmacies in the U.K. provides empirical evidence on the local nature of the relevant geographic market in which pharmacies compete. This study included a survey of purchasing patterns in the U.K. which shows that most patients go to pharmacies close to either the medical centre (48%) or to their homes (29%), while only 6% use pharmacies close to their place of work.

In this regard, Schaumans and Verboven (2008), considering previous studies, define the relevant geographic market at a municipal level. In each municipality, pharmacies are usually concentrated around a town centre, except for densely populated urban zones, which are excluded from the analysis because of overlapping markets. Local markets are defined as municipalities with populations of 15,000 or less and population densities of not more than 800 inhabitants per square kilometre.

Once the geographic market has been defined as the local market around the home and the healthcare centres, the concentration indicator for analysing competition in the market is the number of pharmacies in the various geographical markets defined at municipality level, as in Borrell and Padrós (2007).

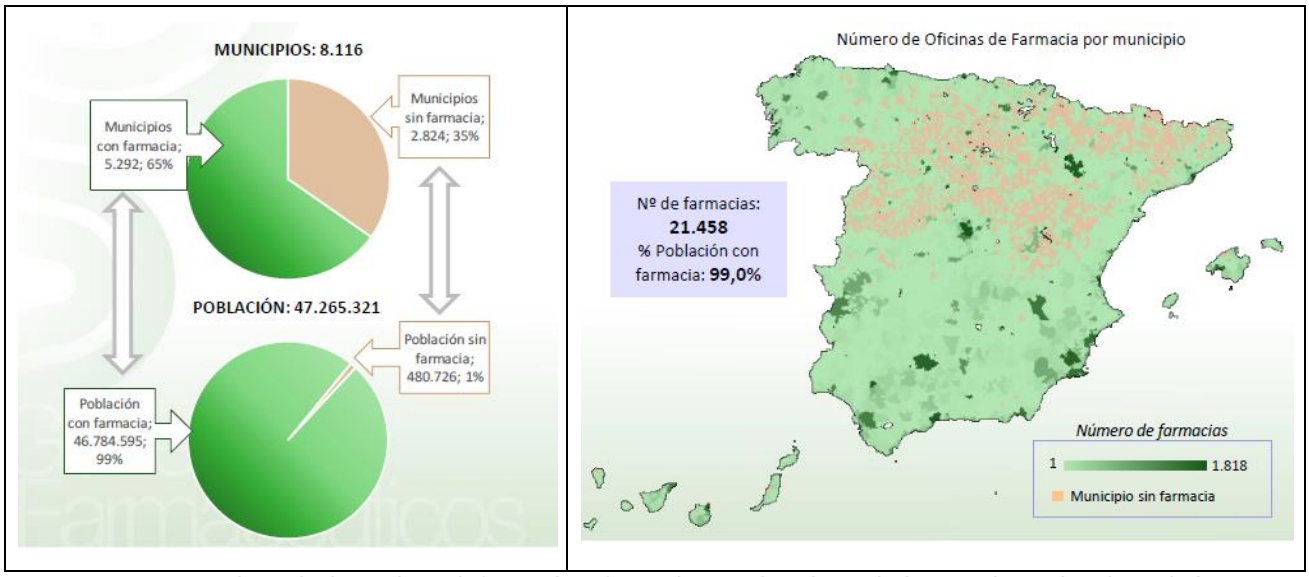
In Spain, the number of municipalities with no pharmacy stood at 2,824 in 2012 (35% of the country's municipalities, 1% of the population). A glance at a map of Spain

[90] http://webarchive.nationalarchives.gov.uk/20140402142426/http:/www.oft.gov.uk/OFTwork/markets-work/pharmacies.

shows that these municipalities are located in the northern half of Spain and the vast majority of them have fewer than 500 inhabitants in total and fewer than ten per square kilometre.

However, as it will be shown below, the geographical planning of pharmacies established by the Autonomous Regions determines the non-existence of a straight link between population and the number of pharmacies due to minimum distance requirements and population modules that vary from one region to another.

Graph 22. Number of pharmacies per municipality in Spain. 2012



Source: CGCOF (2013), based on information from the National Statistics Institute (INE) and the National Geographical Institute.

The relevant markets analysed, since competition in the retail distribution market is of a local nature, are municipalities with fewer than 15,000 inhabitants and with a population density of less than 800 inhabitants per square kilometre.

The following table shows all municipalities of these characteristics and their relative size in the national market. In 2013, a total of 7,469 municipalities (92% of the total) had the characteristics of mutually exclusive local markets, representing 24.7% of the Spanish population, with a total of 6,621 pharmacies, approximately 31% of the total number of pharmacies in Spain.

Table 19. Characterisation of relevant markets in the national market. 2013[91]

Population segments	Number of municipalities	Municipalities as % of total	Population	Population as % of total	Number of pharmacies	Pharmacies as % of total
≤ 500	3.861	47,6%	738.143	1,6%	1.149	5,4%
501-1.000	1.030	12,7%	738.167	1,6%	949	4,4%
1.001-2.000	909	11,2%	1.291.421	2,7%	933	4,3%
2.001-5.000	966	11,9%	3.028.224	6,4%	1.360	6,3%
5.001-10.000	518	6,4%	3.594.560	7,6%	1.363	6,4%
10.001-15.000	185	2,3%	2.258.908	4,8%	867	4,0%
> 15.000*	648	8,0%	35.480.360	75,3%	14.837	69,1%
TOTAL	**8.117**	**100,0%**	**47.129.783**	**100,0%**	**21.458**	**100,0%**

* Municipalities with more than 15,000 inhabitants and/or more than 800 inhabitants per square kilometre.
Source: in-house based on data from the CGCOF and INE.

Table 20 shows the breakdown of municipalities subject to analysis by population segments. It is important to point out that the most populous and the most densely populated municipalities are not included, since in these urban areas there are overlapping markets. More than half of the municipalities in this sub-group have 500 inhabitants or fewer, although these represent only 6.3% of the population, and they have 17.4% of the pharmacies of the local market group. At the other extreme, municipalities with more than 5,000 inhabitants are only 9.4% of the total, yet they represent half the population and 34% of the total number of pharmacies.

Table 20. Number of municipalities and pharmacies by size of municipality in Spain*. 2013

Population segments	Number of municipalities	Municipalities as % of total	Population	Population as % of total	Number of pharmacies	Pharmacies as % of total
≤ 500	3.861	51,7%	738.143	6,3%	1.149	17,4%
501-1.000	1.030	13,8%	738.167	6,3%	949	14,3%
1.001-2000	909	12,2%	1.291.421	11,1%	933	14,1%
2.001-5000	966	12,9%	3.028.224	26,0%	1.360	20,5%
5.001-10.000	518	6,9%	3.594.560	30,9%	1.363	20,6%
10.001-15.000	185	2,5%	2.258.908	19,4%	867	13,1%
TOTAL	**7.469**	**100,0%**	**11.649.423**	**100,0%**	**6.621**	**100,0%**

(*) Municipalities with populations of 15,000 or less and density of 800 or fewer per square kilometre.
Source: in-house based on data from the CGCOF and INE.

As for the number of pharmacies in each municipality, we see that 70.3% of municipalities with 500 inhabitants or fewer have no pharmacy. The predominant structure in municipalities with populations of between 500 and 2,000 is the

[91] Information on pharmacies at municipality level, March 2013.

monopoly (92% of these municipalities have only one pharmacy). 34.2% of municipalities with populations between 2,000 and 5,000 have two or more pharmacies, most of them (28.2% of the total) having two. In municipalities with 5,000 inhabitants or more, the number of pharmacies per municipality increases, and therefore so do the possibilities of competitive interaction in the relevant market. These municipalities (9.4% of the total) account for 50.3% of the population and 33.7% of the total number of pharmacies.

Table 21. Number of pharmacies per municipality in Spain*. 2013

	Municipalities ≤ 500 inhabitants		500 < Municipalities ≤ 1.000		1.000 < Municipalities ≤ 2.000		2000 < Municipalities ≤ 5.000		5.000 < Municipalities ≤ 10.000		10.000 < Municipalities ≤ 15.000	
Number of pharmacies	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total
0	2.713	70,3%	90	8,7%	17	1,9%	3	0,3%	0	0,0%	0	0,0%
1	1.147	29,7%	931	90,4%	852	93,7%	633	65,5%	64	12,4%	1	0,5%
2	1	0,0%	9	0,9%	39	4,3%	272	28,2%	204	39,4%	6	3,2%
3	0	0,0%	0	0,0%	1	0,1%	52	5,4%	153	29,5%	27	14,6%
4	0	0,0%	0	0,0%	0	0,0%	3	0,3%	71	13,7%	54	29,2%
5	0	0,0%	0	0,0%	0	0,0%	3	0,3%	13	2,5%	48	25,9%
6+	0	0,0%	0	0,0%	0	0,0%	0	0,0%	13	2,5%	49	26,5%
TOTAL	**3.861**	**100,0%**	**1.030**	**100,0%**	**909**	**100,0%**	**966**	**100,0%**	**518**	**100,0%**	**185**	**100,0%**

(*) Municipalities with populations of 15,000 or less and density of 800 or fewer per square kilometre.
Source: in-house based on data from the CGCOF and INE.

At a national level, for municipalities constituting relevant markets, municipalities with no pharmacy account for 38% of the total, the biggest percentage (48.6%) corresponding to those with a single pharmacy. It should be pointed out that the average municipality or local market in Spain has 1,560 inhabitants and a population density of 46.52 inhabitants per square kilometre.

In accordance with the characteristics of the regional regulation of pharmacies, summarised in Table 4, the breakdown of municipalities by pharmacy in Spain as a whole and in four Autonomous Regions, Navarre, La Rioja, the Basque Country and Andalusia is presented hereunder.

Firstly, Navarre, because it is the only Spanish region in which the opening of new pharmacies is not restricted (provided they do not exceed one for every 700 inhabitants in any one municipality). Secondly, La Rioja, because it has demographic characteristics similar to those of Navarre but regulation similar to that established by Law 16/1997 at State level. Thirdly, the Basque Country in view of its regulation, which is more restrictive than that established by the aforementioned law, and lastly Andalusia, because it is one of the Autonomous Regions that allows the establishment of the first pharmacy in all municipalities.

The average size of municipalities in Navarre is 1,106 inhabitants, below the national average and the average for the other Autonomous Regions represented in the

table. At the other extreme is Andalusia, with an average size of 3,228 inhabitants, followed by the Basque Country and La Rioja with 2,379 and 1,678 inhabitants respectively.

Despite having municipalities of a smaller average size than the other regions, Navarre has a higher percentage of municipalities with two or more pharmacies (23% of the total), compared to La Rioja (6%), the Basque Country (15.5%) and the national average (13.6%). Andalusia has a higher percentage (28.7%), but the average size of its municipalities is almost three times that of those of Navarre. Andalusia stands out because of its very small number of municipalities with no pharmacy (0.9% of the total), which is a consequence not only of the size of its municipalities but also of regional regulation that authorises the opening of the first pharmacy in each municipality. As regards La Rioja, it is noticed that the majority of its municipalities lack a pharmacy, due basically to the fact that most of them have 500 or fewer inhabitants (78% of the total). Lastly, the Basque Country is characterised by a high percentage of municipalities with no pharmacy in relation to the average size of its municipalities and by a monopolistic structure in nearly half of them.

Table 22. Number of pharmacies per municipality in Spain and its Autonomous Regions*. 2013

	Spain		Navarre		La Rioja		Basque Country		Andalusia	
Number of pharmacies	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total
0	2.823	37,8%	123	47,1%	99	57,6%	83	39,0%	6	0,9%
1	3.628	48,6%	78	29,9%	63	36,6%	97	45,5%	455	70,3%
2	531	7,1%	25	9,6%	5	2,9%	16	7,5%	97	15,0%
3	233	3,1%	19	7,3%	2	1,2%	6	2,8%	45	7,0%
4	128	1,7%	2	0,8%	2	1,2%	8	3,8%	23	3,6%
5	64	0,9%	7	2,7%	1	0,6%	2	0,9%	11	1,7%
6+	62	0,8%	7	2,7%	0	0,0%	1	0,5%	10	1,5%
TOTAL	7.469	100,0%	261	100,0%	172	100,0%	213	100,0%	647	100,0%

(*) Municipalities with populations of 15,000 or less and density of 800 or fewer per square kilometre.
Source: in-house based on data from the CGCOF and INE.

Table 23 contains the number of pharmacies per municipality in the municipalities with fewer than 1,000 inhabitants and in those with between 1,000 and 5,000 inhabitants. In the first group of municipalities the effects of allowing or not allowing the opening of the first pharmacy in each municipality are analysed and in the second group the analysis focuses on the effects of the various regulations of the Autonomous Regions on competition in the relevant market (the probability of a municipality's having two or more pharmacies).

As regards municipalities with fewer than 1,000 inhabitants, it should be pointed out that the average size for Spain as a whole is 302 inhabitants, 296 in Navarre, 202 in La Rioja, 463 in the Basque Country and 525 in Andalusia. Both in Spain as a whole and in the remaining regions studied, with the exception of Andalusia, the majority of these municipalities have no pharmacy. The small average size of the municipalities in Navarre and La Rioja might explain this high percentage in the two regions.

However, when comparing the Basque Country and Andalusia it can be observed that in spite of their municipalities' being of similar average size (slightly bigger in Andalusia), 81% of those in the Basque Country have no pharmacy, as against just 3% in Andalusia. As already pointed out, these differences reflect the different regulation of pharmacies. In the case of the Basque Country, the opening of pharmacies in municipalities with fewer than 800 inhabitants is not authorised, whereas in Andalusia the opening of the first pharmacy in each municipality is permitted.

Table 23. Municipalities with populations of 1,000 or less. 2013

	Spain		Navarre		La Rioja		Basque Country		Andalusia	
Number of pharmacies	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total
0	2.803	57,3%	122	65,2%	99	68,8%	81	81,0%	6	3,1%
1	2.078	42,5%	60	32,1%	45	31,3%	19	19,0%	190	96,9%
2	10	0,2%	5	2,7%	0	0,0%	0	0,0%	0	0,0%
3+	0	0,0%	0	0,0%	0	0,0%	0	0,0%	0	0,0%
TOTAL	**4.891**	**100,0%**	**187**	**100,0%**	**144**	**100,0%**	**100**	**100,0%**	**196**	**100,0%**

Source: in-house based on data from the CGCOF and INE.

In the case of municipalities with between 1,000 and 5,000 inhabitants, significant differences between Navarre and the remaining Autonomous Regions analysed are observed, as well as between Navarre and Spain as a whole. As can be seen in Table 24, the commonest structure in these municipalities, both in Spain as a whole and in the other Autonomous Regions studied, is the monopoly (79% in Spain, 86% in La Rioja, 95% in the Basque Country and 80% in Andalusia have only one pharmacy).

The exception is Navarre, the only Autonomous Region whose regulation practically liberalised the establishment of pharmacies in its territory and in which 70% of municipalities of this size have two or more pharmacies. Therefore, competitive interaction among pharmacies in these local markets is possible.

It is important to stress that the average size of these municipalities is very similar in the Autonomous Regions studied and in Spain as a whole, at 2,392 inhabitants in

Navarre, 2,278 in La Rioja, 2,238 in the Basque Country, 2,541 in Andalusia and 2,304 in Spain as a whole.

As will be shown in section 4.2, the population is the most significant variable for explaining the number of pharmacies per municipality[92]. For this reason, the differences observed as regards the number of municipalities with two or more pharmacies in Navarre compared with the other regions, being municipalities of similar size, can be explained by the pro-competitive reform that this region implemented by passing Regional Law 12/2000.

Table 24. Municipalities with between 1,000 and 5,000 inhabitants. 2013

	Spain		Navarre		La Rioja		Basque Country		Andalusia	
Number of pharmacies	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total	Number of municipalities	Municipalities as % of total
0	20	1,1%	1	1,6%	0	0,0%	2	2,5%	0	0,0%
1	1.485	79,2%	18	28,6%	18	85,7%	76	95,0%	247	80,2%
2	311	16,6%	20	31,7%	3	14,3%	2	2,5%	52	16,9%
3+	59	3,1%	24	38,1%	0	0,0%	0	0,0%	9	2,9%
TOTAL	**1.875**	**100,0%**	**63**	**100,0%**	**21**	**100,0%**	**80**	**100,0%**	**308**	**100,0%**

Source: in-house based on data from the CGCOF and INE.

From the foregoing analysis significant differences are observed among Autonomous Regions which are explained not by differences in their demographic characteristics but by the different pharmaceutical planning criteria applied in each of them. Regulation based on a criterion of maximums as applied in the remaining Autonomous Regions, following the basic principles of Law 16/1997 at state level, is limiting the number of pharmacies and impeding the existence of competition in the local markets analysed. This and other restrictions on access and on the exercise of the pharmaceutical activity in the retail segment are analysed hereunder.

[92] Both Schaumans and Verboven (2008) and Borrell and Villadangos (2009) conclude that population is the most significant variable for explaining the number of pharmacies.

4. ANALYSIS OF THE PHARMACEUTICAL ORGANISATION MODEL FROM THE POINT OF VIEW OF COMPETITION AND EFFICIENT ECONOMIC REGULATION

The special characteristics of the retail medicine distribution market, due to the nature of the medicines, public health protection and the existence of market failures, justify public intervention in the market by means of regulation. However, if the public intervention is not in accordance with the principles of efficient economic regulation, it could prove damaging, and the same public health objectives could be achieved by means of other mechanisms which are less detrimental to the general interest.

Although the main objective of the regulation is the protection del public interest regarding safety and access to medicines, this regulation affects the protection of private interests (financial viability of pharmacies and wholesale distributors), which in turn frequently conflicts with the main objective of ensuring the quality of pharmaceutical care and reducing costs of distribution.

In the first section we analyse the current regulation from the point of view of competition and efficient economic regulation, i.e. in accordance with the principles of necessity, appropriateness and proportionality. The analysis takes account of the extent to which the restrictions imposed by the regulation inhibit or encourage competition in the retail medicine distribution market, and whether these restrictions benefit consumers or on the contrary impose additional costs on them.

In the second section we present an assessment of the impact of Navarre's reform, with the passing of Regional Law 12/2000, on the entry of new pharmacies to the market. The analysis is carried out at country, Autonomous Region and municipality level in order to determine the impact of this reform on the geographical coverage of pharmaceutical care in small municipalities.

4.1. Restrictions on competition

4.1.1 Restrictions on market access

The restrictions on market access identified are the requirements based on population modules and minimum distances between pharmacies necessary to permit the entry of new pharmacies to the market. These restrictions are based on the grounds of equity and public health, and seek to ensure an equitable access to medicines and pharmaceutical services in population centres.

The argument for the need of geographical restrictions combined with pharmacies' high margins seeks to ensure an adequate supply of medicines in less profitable

population centres (rural areas) and avoiding excess supply in the other population centres (urban areas).

However, this regulation favours the private interests of pharmacists who are owner-operators of pharmacies which, thanks to these restrictions, do not face competition from other pharmacies, and on the other hand is detrimental to patients, who could benefit from better quality of service, less distance to cover to obtain medicines or lower prices of medicines not subject to medical prescription if there were competition among different establishments.

This conflict between public and private interest derives from the nature of pharmacies in Spain as private healthcare establishments of public interest[93]. The public interest aspect derives from the supply of medicines included in the pharmaceutical provision of the NHS and the services of pharmaceutical care, which are important from the point of view of public health.

For this reason, the planning of pharmacies faces opposing interests. A greater number of pharmacies improves the population's access to medicines, but reduces the volume of sales per pharmacy and therefore the return obtained by each pharmacy on its human and physical assets invested in the provision of the service is lower.

Apart from this, the relationship between the number de pharmacies and the degree of geographical coverage of the service is not unequivocal: a greater number of pharmacies might not improve geographical service coverage if there is "skimming": in other words new pharmacies tend to be concentrated geographically in urban zones, leaving small villages without service.

As was analysed under the previous heading, the restrictions on market access established by Autonomous Regions' pharmaceutical planning have an impact on competition in the market. The model adopted in Navarre favours competition among pharmacies, since the percentage of small local markets[94] with more than one pharmacy is higher in Navarre than in the other Autonomous Regions, which impose more restrictive criteria for the opening of pharmacies.

In the second section, we show the effect of Navarre's reform in 2000 on the entry of pharmacies to the market, and in particular we analyse the entry to small municipalities. We obtain positive results in these municipalities, which shows that

[93] Article 86.6 of the Consolidated Text.

[94] Municipalities with between 1,000 and 5,000 inhabitants.

the reform has not had a negative impact on the geographical coverage of pharmaceutical care.

This evidence calls into question the arguments in favour of geographical restrictions based on population modules and minimum distances to ensure appropriate geographical coverage of pharmaceutical care, and shows that the model of Law 16/1997, applied in all Autonomous Regions except Navarre, which establishes the maximum number of pharmacies per population module, is not necessary to ensure appropriate pharmaceutical care for the population. In fact, similar or even better coverage is achieved by regulation less restrictive to competition, such as that in force in Navarre.

We should point out that Navarre's greater pharmaceutical coverage, with Spain's lowest ratio of inhabitants per pharmacy, does not translate into greater per capita expenditure on pharmaceuticals for the National Health System. As was analysed in section 3.1.1, per capita expenditure on pharmaceuticals in Navarre, at €184.42, is less than the national average of €194.85.

As detailed in the Appendix to the study, experiments in liberalisation of pharmacies in some European countries have led to a substantial increase in the number of pharmacies, with a tendency to concentration in urban areas. There is evidence of scant opening of new pharmacies in small municipalities that already have one pharmacy in countries such as the U.K. or Denmark, but there have been no shortages in rural or less populated areas.

In these countries, policies have been put in place to avoid the closure of pharmacies in rural areas by establishing financial incentives. In the case of the U.K., rural pharmacies receive subsidies through the “Essential Small Pharmacies/ Local Pharmaceutical Services (ESP LPS)” scheme, and Denmark has implemented a mechanism called “Tax Equalization Scheme” to finance rural pharmacies.

There are other mechanisms for either encouraging pharmacies to remain in rural areas or ensuring the supply of medicines. In Norway, there is an arrangement between the State and the pharmacy chains whereby if a pharmacy in a rural area closes, the pharmacy chain takes control of the establishment and a new pharmacy is opened in the same area, while in the U.K., doctors are allowed to dispense medicines in rural areas, so that in these areas there is less need for a large number of possibly unprofitable pharmacies and yet care of patients and their access to medicines in proper conditions of safety and quality is assured.

These countries' practices demonstrate that there are alternative mechanisms for increasing competition in the market and at the same time ensuring appropriate

geographical coverage of pharmaceutical care without restricting the entry of pharmacies to all parts of the market.

Apart from this, restricting the opening of a first pharmacy in each municipality is irreconcilable with the objective of ensuring pharmaceutical care in rural areas. For this reason, current restrictions in many Autonomous Regions, which do not allow the opening of a first pharmacy in each municipality, is inappropriate: it is the smallest municipalities that are most harmed by this regulation: were it not for this restriction, at least some, and possibly many of them might have a pharmacy.

It is for this reason that some Autonomous Regions, such as Andalusia and Valencia, allow the opening of the first pharmacy in each municipality irrespective of minimum population thresholds. Others, such as the Basque Country, do not allow the opening of pharmacies in municipalities with fewer than 800 inhabitants, and as we have already pointed out, because of this restriction the percentage of small municipalities[95] with no pharmacy in the Basque Country is far higher than in Andalusia.

As it is also shown by the analysis of competition in the market, the restriction on the opening of the second and subsequent pharmacies in a municipality is unnecessary and disproportionate: in comparing Navarre with the other Autonomous Regions, we see that the percentage of municipalities[96] with two or more pharmacies is much higher in Navarre than in other Autonomous Regions, even though the average size of these municipalities is similar from one Autonomous Region to another. The legal requirement for a minimum population module of 2,800 inhabitants (or more, in the case of the Basque Country) for opening a pharmacy is limiting competition in the market and harming consumers, other professionals that might be owner-operators of pharmacies and, in short, the general interest.

This restriction impedes the possibility of competition among pharmacies in many municipalities and favours incumbent pharmacies[97] with regulatory rents. Moreover,

[95] Municipalities with populations of 1,000 or less.

[96] Municipalities with populations of more than 1,000 and 5,000 or fewer.

[97] One proof of the substantial regulatory rents provided to incumbent pharmacies by restrictions on market access is the high price of transfers of pharmacies in cities such as Madrid. See link: www.comprar-pharmacies-urbagesa.es/buscar-pharmacies.php?region=4&facturacion=0&facturacion1=15000000&Precio=0&Precio1=15000000.
We should point out that in this Autonomous Region, the number of pharmacies increased by only 7% between 2000 and 2013, compared with an increase of 25% in its population in the same period. Moreover, Madrid is the Autonomous Region in which the smallest percentage of affiliated pharmacists are owner-operators of a pharmacy (just 28.3% of members, as against 36.6% for Spain as a whole).

it limits greater proximity of pharmacies to homes, leading to increased costs of travel and a loss of patients' welfare.

Apart from this, every Autonomous Region, with the exception of Navarre, establishes a minimum distance between pharmacies and healthcare centres[98]. This restriction is supposedly aimed at avoiding excessive concentrations of pharmacies around health centres and a consequent shortage of pharmacies in other areas. Pharmacies may have an interest in locating closer to healthcare centres due to the concentration of prescriptions in these centres. The absence of minimum distances between pharmacies and healthcare centres might lead to the phenomenon of leap frogging, with pharmacies relocating to be as close as possible to the health centre[99].

This restriction favours the existence of a small number of pharmacies (or even a single pharmacy located close to the health centre for historical reasons and not subject to subsequent legislation) since it prohibits competition with other pharmacies, and is basically detrimental to patients, who are forced to travel the minimum distance established by the law in order to access the pharmacy, instead of being able to obtain the prescribed medicines in an establishment closer to, or actually in, the health centre.

Moreover, the introduction and spread of electronic prescription means that more and more patients will replace the pharmacy closest to the health centre with the pharmacy closest to home, facilitating patients' purchases at any pharmacy, not necessarily those closest to healthcare centres.

4.1.2 Restrictions on the exercise of the activity

As well as the restrictions on opening pharmacies, state and regional legislation also pose a number of obstacles to competition for the pursuit of the pharmaceutical activity, which are assessed in the following sections.

[98] Some Autonomous Regions, such as Andalusia and the Balearic Islands, establish a minimum distance between pharmacies and public healthcare centres, with no such restriction in the case of private centres. From the economic point of view, this differentiation is unfounded. Pharmacies would have similar incentives to concentrate close to private healthcare centres as they would to public ones, since both constitute sources of demand for medicines.

[99] Borrell and Fernández-Villadangos (2011) show that in the case of Navarre such concentration does not occur in generalised form, and that in any case it would only affect the location of one or two pharmacies, the remainder locating so as to be close to homes.

4.1.2.1 Requirement to have the status of pharmacist in order to dispense medicines

Article 86.2 b) of the Consolidated Text establishes the presence and professional involvement of a pharmacist as an indispensable requirement for the dispensing of medicines to the public, taking account that the number of pharmacists needed depends on the level of activity of the pharmacy.

The obligation to be a competent technician, qualified to exercise the activity of distribution of medicines, is supposedly justified from the point of view of economic efficiency, based on the need to regulate a minimum level of quality of services provided in pharmacies[100], in the presence of several market failures. On the one hand, the information asymmetry between the professional dispensing the medicine and patients (moral hazard and adverse selection), where i) the professional might have an incentive to prescribe a more profitable product even if it does not provide sufficient healthcare benefits to the patient and ii) the average consumer has less information on the efficacy and properties of the medicine than the dispenser does. Both problems may lead to inappropriate dispensing and a deterioration in the quality of service. Apart from this, in the absence of regulation of this quality, negative externalities would appear in the form of a greater probability of the spread of diseases in the case of inappropriate dispensing and a less healthy population, leading to reduced quality of life and increased healthcare costs.

Therefore, the presence of a competent technician would be justified in accordance with the principle of necessity to meet the aforementioned objectives of public health and economic efficiency, especially if the dispenser has some influence on the medicine supplied to the patient.

Consequently, the attention or advice of a professional is considered necessary to ensure appropriate dispensing of prescription drugs. However, this competent technician should not necessarily have to be an affiliated pharmacy graduate, since there might be other healthcare professions, qualified diploma holders of which, with

[100] These services include, among others, information and follow-up on treatments dispensed to patients and pharmacies' collaboration with healthcare authorities on the promotion and protection of health, the prevention of diseases and healthcare education.

equivalent training[101], would also be qualified to carry on this activity, in principle, with equivalent safeguards in terms of quality and safety of patients' health[102].

Likewise, in the interests of economic efficiency, it might sometimes be appropriate in certain areas with low population densities to allow these services to be offered by other healthcare professionals in addition to pharmacists, typically doctors, as analysed in point 4.1.1. In these cases, empirical evidence shows the desirability of designing mechanisms to avoid financial incentives which may contribute to unjustified increases in expenditure on healthcare.

4.1.2.2 Reservation of activity to pharmacies for the distribution of medicines

Article 3 of the Consolidated Text establishes that the custody, conservation and dispensing of medicines for human use is reserved exclusively to legally authorised pharmacies open to the public, and to the pharmacy departments of hospitals, healthcare centres and primary care centres of the National Health System.

This reservation of activity of the safekeeping, conservation and retail dispensing of medicines to pharmacies constitutes a restriction to competition, since, except for hospitals, it limits the channels of distribution of medicines to pharmacies.

Be that as it may, bearing in mind the objective of safeguarding public health, in the case of prescription drugs, which may require special protection because of their characteristics, this restriction should be limited to specialised establishments (pharmacies, hospitals and health centres) that have the necessary facilities for keeping medicines in perfect condition for dispensing and consumption. In the case of OTC medicines, the lesser need for protection would imply that they could be sold

[101] Article 44 of and Appendix V to Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications refer to the training needed for dispensing medicines and providing pharmaceutical care services.

[102] The dispensing of medicines by other healthcare professionals, for example doctors, is carried out in Europe in various circumstances such as rural zones or absence of pharmaceutical care. Never as a general rule. Additionally there is empirical evidence, for example in the case of Switzerland, that dispensing by doctors might increase expenditure on medicines in cases where there is a financial incentive to prescribe more expensive medicines. *See* Kaiser, B., and Schmid, C. (2013), "Does physician dispensing increase drug expenditures?" Discussion Paper No. dp1303, Department of Economics, University of Berne. http://www.vwl.unibe.ch/papers/dp/dp1303.pdf

in a greater number of establishments, facilitating access by patients in similar conditions of information, quality and safety.

The main advantage of liberalising sale channels for OTC medicines, apart from better access for patients, is the greater competitive tension, with the consequent reduction *ceteris paribus* in the price of these medicines[103]. This liberalisation would also facilitate competition on quality, location and innovation.

In Spain, the legislation allows discounts only up to 10% of the maximum authorised price of OTC medicines. However, such discounts are hardly ever granted because of pharmacies' lack of incentive to compete and the non-existence of alternative retail channels. Moreover, it would facilitate consumers' access to these types of medicines, which could be acquired in a greater number of physical points of sale.

A more efficient regulation in the variety of distribution channels for OTC medicines includes the possibility of their being sold not only by pharmacies but also through other kinds of establishments assuring the protection of the reasons of imperative general interest that exist in the distribution of medicines (commercial distribution, grocery stores that are also subject to heath requirements assuring conservation and hygiene, sale by mail and online for medicines technically suited to this type of distribution, etc.)[104].

In fact, in Spain, the online sale of OTC medicines has been allowed since the approval of Royal Decree 870/2013[105]. However, at present such sales can be made only by pharmacies open to the public, legally authorised and which have given notice of this activity in accordance with the provisions of the legislation regulating this type of sale. In other words, the online sale of OTC drugs by graduate pharmacists or other competent technicians who are not owners of a physical pharmacy is not allowed.

The justification for this restriction is based on the protection of public health, which supposedly requires OTC medicines to be dispensed by an authorised pharmacy,

[103] The report of the OFT (2003) shows that pharmacy chains integrated within supermarkets in the U.K. offer discounts of up to 30% of the price of OTC medicines.

[104] In various European countries such as the U.K., the Netherlands, Norway and Denmark, OTC medicines may be acquired in establishments other than pharmacies, such as supermarkets for example.

[105] Directive 2011/62/EU establishes an EU code on medicines for human use as regard the prevention of the entry into the legal supply chain of falsified medicines, and permits solutions more favourable to competition than that adopted in Spain, with the possibility of allowing online sale of prescription drugs.

with the involvement and ownership of a pharmacist, subject to prior personalised advice[106].

The reservation of activity to pharmacies as regards the online sale of prescription and OTC medicines is unnecessary and disproportionate for ensuring the protection of public health.

In the case of prescription drugs, the involvement of a competent technician is sufficient to ensure this protection, and the technician need not necessarily be the owner-operator of a pharmacy. Therefore, this online sale could be carried out by other establishments, as well as physical sale, with the requirement that there is advice or consultation prior to the sale by a competent technician (who might not necessarily be the owner or operator of a physical pharmacy).

4.1.3 Restrictions on ownership of pharmacies

Article 103.4 of Law 14/1986, of 25 April, the General Health Act, establishes that only pharmacists can be owners and owner-operators of pharmacies open to the public.

The restriction whereby the owner of a pharmacy must be a pharmacist might have an economic justification if there is a problem of asymmetric information (moral hazard or principal-agent problem). If the pharmacist providing her/his services in the pharmacy is not its owner, (she or he might have less incentive to provide quality services, since not all the pharmacy's operating profit accrues to her/him, to the consequent detriment of the owner of the pharmacy (principal) in terms of reduced income, and also of patients[107], in terms of lesser quality in the provision of the service.

[106] Direct selling, and any kind of indirect selling to the public of medicines (whether subject to medical prescription or not) are also prohibited.

[107] The problem of agency described is not resolved by granting ownership of the pharmacy to a pharmacist, since in many circumstances it will not be the owner-operator who dispenses the medicines but a contracted pharmacist. Additionally, this problem of agency is very similar to that of dispensing in any other retail distribution business, and van be mitigated by means of various economic instruments such as supervision of employees, aligning their incentives by means of commissions, variable remuneration linked to the effort observed or to results, etc. As we have seen previously, the presence of the pharmacist is an indispensable condition and requirement for dispensing medicines to the public, although the state law does not specify that the pharmacist must be the owner of the pharmacy. Some Autonomous Regions, such as Andalusia, require the presence of the pharmacist owner during the mandatory minimum opening hours of the pharmacy, while others, such as Madrid, only require the presence of a pharmacist (not necessarily the owner-operator) throughout the time the pharmacy is open.

It is questionable, however, that this agency problem exists in the case of pharmacies and not in private hospitals, where the object of safeguard is the same, namely public health, and there is no requirement for investors to be affiliated doctors in order for the opening of hospitals to be authorised[108].

From the points of view of healthcare and efficient economic regulation, this restriction to competition is unnecessary, since the presence of a pharmacist in dispensing medicines would in itself provide sufficient assurance of appropriate public health protection.

Moreover, this restriction represents a barrier to market entry, since it prevents agents who are not pharmacists but who have capital to invest from becoming owners of pharmacies. Again, this restriction to competition seems to be imposed for safeguarding the interests of established pharmacists, whom it provides, via reduced competitive tension, with economic rents stemming from the ownership of the incumbent pharmacies.

In Spain, the holding and ownership of pharmacies is limited by law to a single pharmacy, which prevents even minimal horizontal integration and the formation of pharmacy chains.

The voluntary formation of pharmaceutical chains[109] under the freedom of enterprise would allow optimisation of resources and the free assumption of shared risk which would otherwise be impracticable. From the point of view of economic efficiency, the economies of scale deriving from the greater size of pharmacies allow reductions in the costs of procurement, distribution of medicines, storage and administration.

If the purpose of this restriction is to avoid a possible abuse of market power owing to excessive concentration, since a single chain would have the majority of pharmacies in the market and be able to engage in anti-competitive practices, then there are alternative policy instruments for the defence of competition in order to mitigate such abuse, and which are likely to lead to fewer distortions in terms of

[108] One of the arguments put forward in favour of the unity of ownership and authorised operator by various associations of pharmacists is that it ensures the pharmacist's independence on economic interests.

[109] Pharmacy chains exist in various European countries. According to Vogler et al. (2014), in the UK 61.4% of pharmacies formed part of pharmacy chains in 2013, and the three biggest chains had a combined market share of 35%. In Norway, the percentage of pharmacies belonging to chains was 96.5% in 2011 and the three biggest chains had a combined market share of 81% in that year. Pharmacy chains also compete in the market in countries such as Ireland, the Netherlands and Sweden.

efficiency. Hence, even if this restriction were to be accepted as necessary, it would be disproportionate relative to the end pursued[110].

The prohibition on pharmacies' integrating with pharmaceutical manufacturers and/or wholesale distributors (vertical integration) established in Article 4 of the Consolidated Text supposedly aims to ensure that pharmacists are independent of the direct economic interests of the pharmaceutical manufacturers and/or wholesale distributors.

However, vertical integration of the various activities in the medicine chain could generate gains in efficiency deriving from economies of scale and scope among these activities[111]. Among the advantages stemming from vertical integration are reductions in procurement, marketing and transaction costs and more information on final consumers, enabling their needs to be fully met[112].

This legal restriction prevents the materialisation of these efficiencies. As in the case of horizontal integration, the regulators, the market itself and competition authorities all have alternative instruments with which to mitigate the market power and any abuses of such power coming from the vertical integration of pharmacies, so this restriction has no justification whatever. Eliminating this prohibition while applying the competition authority's existing control mechanisms would allow greater efficiency in the pharmaceutical sector, which could result in lower costs and therefore lower public expenditure for the state and lower costs for patients and taxpayers.

4.1.4 Pharmacies' remuneration for dispensing medicines

The margin obtained by pharmacies for dispensing medicines, as described in section 2.2.2, is a percentage of the retail price before tax if the price is below a certain amount. Once that price is reached, the margin is a fixed amount which increases in bands as the price of the medicine increases.

[110] In Norway, the number of pharmacies belonging to a chain may not exceed 40% of the total. The Norwegian Competition Authority set this limit after as single group acquired more than 80% of the total number of pharmacies.

[111] The OMC medical association, in a recent report on the pharmaceutical sector in Spain, proposes that the activities and functions of the pharmaceutical value chain be vertically integrated.

[112] Sutton (1980); Stuckey, J. and White, D (1983).

With this type of remuneration, pharmacies' revenues increase with the price of the medicines, thus giving pharmacists an incentive to dispense higher-priced medicines[113] so as to produce more profit for the pharmacy.

If the purpose of pharmacies' margins is to remunerate the provision of pharmaceutical care services, it is questionable whether the remuneration should increase with the price of the medicines, since the quality of service is unrelated to this price.

Even assuming all the other restrictions identified are kept in place, an efficient system of financing pharmacies should link revenue from dispensing medicines to the healthcare benefits provided (patient-oriented system) as opposed to the current product-oriented system in Spain in which pharmacies' revenues are linked to volumes and prices of medicines dispensed.

An alternative system of remuneration to the current Spanish one is, according to Meneu (2006), a mixed system combining a fixed tariff for dispensing[114] with the partial or total reimbursement of the price of the medicine by the NHS[115] and remuneration of certain specific services by the NHS.

4.1.5 Other restrictions

4.1.5.1 Opening hours of pharmacies

Article 6 of Law 16/1997 establishes that pharmacies will provide their services freely and flexibly, without prejudice to compliance with official opening hours and rules on duty rosters, holidays, emergencies and other circumstances deriving from the nature of their service established by the Autonomous Regions with the purpose of ensuring continuity of care.

[113] Measures implemented recently, such as the pharmacist's replacing prescribed medicines with cheaper equivalents, would correct these incentives if the doctor prescribed the medicine by active principle and not by brand.

[114] The fixed tariff for dispensing is used in countries such as the U.K. and Ireland. This advantage of this system is that it remunerates the act of dispensing (irrespective of the price of the medicine) but on the other hand it does not provide incentives to improve the quality of service. For this reason, in the U.K., the National Health System remunerates pharmacies for the provision of so-called "advanced services", which include flu vaccines among other things.

[115] The partial refund of the (maximum) price of the medicine is referred to as a "claw-back" and is applied in countries such as the U.K.. The NHS refunds to pharmacies the price paid by them to the manufacturers and wholesale distributors, such that the discounts obtained by the pharmacies are passed on to the NHS and to patients.

The provisions established by the Autonomous Regions in this area must adopt the form of minimums, so consequently these establishments are allowed to operate for more hours than the official minimums.

Establishments opening for longer than the established minimums must report this in advance to the Autonomous Region and must maintain the same timetable continuously on such terms as the health authority dictates.

The Autonomous Regions have approved their respective laws which establish the minimum hours for serving the public, increases in timetables relative to the minimum and other emergency services.

Even today there are certain aspects in the rules on pharmacies' opening hours that are incompatible with the principles of freedom and flexibility in pharmacies' provision of services established in Law 16/1997, to the consequent detriment of patients.

In particular, the possibilities of extending the hours beyond the minimum are restricted so that they have to conform to a number of fixed modules, during a minimum period of one year, which limit pharmacies' freedom of organisation and which may be a factor restricting competition[116].

Compliance having been assured with the minimum opening hours and emergency duty rosters established to ensure the appropriate pharmaceutical care of the population, any regulatory or administrative obstacle to pharmacies' extending their opening hours should be eliminated.

4.1.5.2 Advertising by pharmacies

The express prohibition of advertising by pharmacies has been incorporated either into the laws on the organisation of the pharmaceutical sector or into the specific legislation of the Autonomous Regions[117], despite the lack of state law explicitly permitting or prohibiting advertising by pharmacies.

[116] Article 9 of Decree 116/1997 of 15 April, regulating the days and hours of pharmacies in Andalusia, Article 4 of Decree 259/2001 of 15 November, establishing hours of service to the public, emergency duty services and holidays in the Autonomous Region of Madrid and Order SAN/744/2015 of 7 September determining the continuous pharmaceutical care of the pharmacies of the Autonomous Region of Castile and León.

[117] For example, Article 9 of Law 4/2005 of 13 July on the Pharmaceutical Organisation of the Canary Islands expressly prohibits advertising of pharmacies, and in the case of Galicia, Article 4 of Decree 107/2008 of 15 May regulating the signage, information and advertising of pharmacies prohibits such advertising. It is also prohibited by Article 43 of Decree 44/1998 of 16 July regulating service to the public and advertising by pharmacies in the Autonomous Region of Murcia; Article 30 of Law 19/1998

Pharmacies are private healthcare establishments of public interest, in view of the importance of the services they provide for the health of the population. As healthcare establishments, they are subject to inspection and control by the competent health authorities, and in particular, their promotion and advertising activities[118].

In this regard, Article 44 of Law 44/2003, of 21 November, on the organisation of the healthcare professions, allows the advertising of services and benefits offered to the public by healthcare professionals providing it complies rigorously with the scientific basis of the activities and prescriptions, and is objective, prudent and truthful, so as not to raise false hopes or spread unfounded ideas.

In particular, healthcare professionals may provide the media with information on their professional activities, or express such information directly in the media, providing the information provided is truthful, discreet and prudent and expressed in a manner readily understandable to the social group at which it is directed.

As regards the activities of advertising and promotion of pharmacies, we should distinguish between advertising of the services they provide and advertising of the medicines and healthcare products they dispense.

The advertising of medicines and healthcare products is regulated by the Consolidated Text[119] and is subject to a series of requirements to ensure the protection of patients' health. Moreover, it is permitted only for OTC medicines not financed by public funds.

If the objective of prohibiting advertising by pharmacies were to protect patients' health from possible untruthful information about the properties of the medicines, this restriction would lack economic foundation, since the advertising of medicines is already tightly regulated.

For this reason, the restriction on advertising by pharmacies should be lifted, since it prevents pharmacies from being able to use advertising to differentiate their services and constitutes an additional obstacle to competition.

---

of 25 November on Pharmaceutical Organisation and Care of the Autonomous Region of Madrid; Article 19.2 of Law 6/2006 of 9 November on Pharmacy of Extremadura, and Article 6 of Law 1/2007 of 16 March on pharmaceutical care and organisation in the Principality of Asturias.

[118] Article 30.1 of Law 14/1986 of 25 April, the General Healthcare Act.

[119] Article 80 of the Consolidated Text.

4.1.5.3 Criteria for granting administrative authorisation for the opening of pharmacies

Article 3 of Law 16/1997 determines that it is for the Autonomous Regions to process and resolve applications for authorisation to open new pharmacies which will be processed in accordance with the principles of openness and transparency, subject to prior specific procedures to be established by the Autonomous Regions.

We have identified restrictions stemming from some criteria included in competitive examinations for the granting of the administrative authorisation necessary for opening new pharmacies, which not only constitute barriers to market entry for recent pharmacy graduates but also in some cases introduce criteria that are not in accordance with the aim of ensuring appropriate pharmaceutical care[120].

A significant barrier to market access for young pharmacy graduates is the accumulation of professional experience points obtained in previous competitive processes. Some Autonomous Regions, such as Castile-La Mancha, have eliminated this barrier, specifying that the obtention of an authorisation to set up a pharmacy uses up all such points for professional experience and post-graduate training relating to the profession as the applicant may have held prior to the process in which (s)he obtained the authorisation[121].

Other Autonomous Regions, such as Madrid and Cantabria, consider professional experience in pharmacy in the past ten years as a major plus-point, which puts recently qualified pharmacists at a disadvantage. It also favour older pharmacists and those that are already own a pharmacy over those that do not[122].

[120] For example, in the Canary Islands, practising in the Official Associations of Pharmacists is considered a plus point in the competitive processes for awarding new pharmacies (Resolution of 23 July 2014 of the Director of the Canary Islands Health Department calling for applications to a competitive process for the award of pharmacies).

[121] Article 22.6 of Law 2/2015 of 19 February amending Law 5/2005 of 27 June on the Organisation of Pharmaceutical Services for Castile-La Mancha.

[122] Article 6.1. of Decree 115/1997 of 18 September, establishing pharmaceutical planning, the criteria for assessing academic knowledge and professional experience, the opening hours and emergency duty rosters and the procedure for authorisations of pharmacies in the Autonomous Region of Madrid and Appendix II to Order SAN/20/2015 of 9 March calling candidates for a competitive examination la for the authorisation of new pharmacies in Cantabria.

4.1.5.4 Supply of medicines to social health centres

The supply of medicines to healthcare centres via pharmacies was studied by the former CNC, which declared a practice previously followed by the Castile-La Mancha Health Service (SESCAM) by means of a collaboration agreement with the Council of the Official Associations of Pharmacists of Castile-La Mancha to be restrictive of competition, by means of Resolution of 14 April 2009[123].

We should point out that this resolution was confirmed by both the National Court (SAN of 5 June 2012 RJ 283/2009) and on appeal by the Supreme Court (STS of 9 March 2015 RJ 294/2013).

The practice sanctioned consisted in an agreement between SESCAM and the Association of Pharmacists of Castile-La Mancha of 29 June 2006 establishing rotating turns among pharmacies for the supply of medicines to healthcare centres, thus sharing markets.

Subsequently, the state law regulating pharmaceutical care in hospitals, social care centres and psychiatric centres was passed,[124] establishing that *"hospitals and social care centres that provide specific healthcare and psychiatric centres without their own hospital pharmacy service and not obliged to have one shall have a stock linked to the pharmacy service of the healthcare area under the responsibility of the head of the service in the case of public sector hospitals, and a pharmacy established in the same pharmaceutical zone or a hospital pharmacy service in the case of a private sector hospital*".

The CNMC has pronounced against systems tying social healthcare centres to pharmacies in the same pharmaceutical zone, since it considers that, as well as restricting competition among pharmacies for the provision of pharmaceutical services to these social healthcare centres, they also establish reservations of activity by reason of the territory or geographical zone of the operator assigned, which are contrary to the principles of necessity and proportionality set forth in Law 20/2013, of 9 December, guaranteeing the single market[125].

Recently, Castile-La Mancha passed Law 2/2015, of 19 February, amending Law 5/2005 of 27 June on the Organisation of the Pharmaceutical Service of Castile-La

[123] Case 639/08 Association of Pharmacists, Castile-La Mancha.

[124] Article 6 of Royal Decree-Law 6/2012 of 20 April.

[125] Case SAMUR 01/14, PHARMACIES.

Mancha, which envisages the requirements for stocks of medicines of private social healthcare centres to be supplied by local pharmacies[126].

The CNMC, in its letter to the Ombudsman of May de 2015, already considered that this law "*introduces restrictions to competition in a sector (the pharmaceutical), which in accordance with the doctrine of the CNMC is so regulated as to leave very little space for real or potential competition among pharmacies".*

4.1.5.5 Mandatory affiliation of owner-operators and contracted pharmacists in pharmacies

Although there is no explicit reference in the Medicine Law to mandatory affiliation in order to practise as a pharmacist in a pharmacy or to own a pharmacy, this requirement is included expressly in the laws on the organisation of the pharmaceutical sector or regulations developing them of some Autonomous Regions[127].

The CNMC, in IPN 110/13 on the Draft Bill on Professional Services and Associations, came out against mandatory membership of associations as a requirement for operating a pharmacy as determined by Law 44/2003 of 21 November on the organisation of the healthcare professions. In that report we indicated that "*[mandatory membership] should not extend to ownership or operating of pharmacies, since it does not comply with the principles of necessity, proportionality and non-discrimination*". We also pointed out that "*[for] the elimination of this reservation of the activity to produce the desirable pro-competitive effects, it should be accompanied by an in-depth review of the organisation of the activity of the pharmacies, which is mainly contained in Law 16/1997, of 25 April, on the regulation of pharmacies' services*".

As regards mandatory membership of an association for practising the profession of pharmacist in a pharmacy, we consider it unnecessary for the performance of the functions of the pharmacist, and it imposes an unnecessary cost which translates into a barrier to market entry. The knowledge deriving from the pharmacist's training would be enough to ensure that patients are cared for to appropriate standards of safety and quality.

[126] Articles 53.1 and 62.3 of Law 5/2005 on the Organisation of the Pharmaceutical Service of Castile-La Mancha, after amendment by Law 2/2015.

[127] For example, Catalonia (Article 4 of Law 3/1991), Murcia (Article 9 of Law 3/1997) and Madrid (Article 27 of Law 19/1998).

4.1.5.6 Reservation of activity of the Official Associations of Pharmacists for certain services

Article 94.7 of the Consolidated Text stipulates that pharmaceutical manufacturers, distributors and pharmacies, through the Organisation of Pharmaceutical Associations, must provide such information as may be determined in order to effect reimbursement due by pharmacies to pharmaceutical manufacturers and distributors for such medicines as may be established and as have been dispensed outside the National Health System. The Official Associations of Pharmacists are also intermediaries between the pharmacies and the NHS for invoicing and collecting amounts relating to medicines included on the reimbursement list of the National Health System, through agreements signed with the Health Departments of the Autonomous Regions[128].

The gradual introduction of electronic prescriptions and pharmacies' necessary adaptation by adopting information technologies represent a potential saving on transaction costs deriving from the improved handling and collection of prescriptions in individualised form.

For this reason, we consider that, in terms of economic efficiency, the exclusive right of the Official Associations of Pharmacists to invoice and collect prescriptions might not be justified.

4.2. Evaluation of the impact of the 2000 Navarre reform on the entry of new pharmacies

Under this heading we carry out a quantitative analysis of the impact of the reform introduced by Regional Law 12/2000, of 16 November, on pharmaceutical care on the number of pharmacies in the Autonomous Region of Navarre.

The analysis[129] is a dual one. On the one hand, we quantify the increase in the number of pharmacies at aggregate level years after the passing of the reform. On

[128] See, by way of example, Appendix 4 to the Agreement between the Healthcare Department of the Autonomous Region of Madrid and the Official Association of Pharmacists of Madrid: www.cofm.es/Buscador-general/recursos/doc/Utilidades/Concierto/8111_747420111375.pdf and point 10 of the Agreement setting the conditions for the performance of pharmacy services through the Pharmacies of Andalusia: www.formulistasdeandalucia.es/ficheros/concierto.pdf.

[129] The analysis contributes to the literature on the impact of Navarre's reform of 2000, outstanding among which are the articles of Borrell and Fernández-Villadangos (2009) and Borrell and Cassó (2011). It also extends the application of the synthetic control method proposed in the seminal article by Abadie and Gardeazabal (2003) to the field of evaluating the effects of pro-competitive reforms.

the other hand, we analyse the effect of the reform in relatively small municipalities, excluding the larger ones. In both cases, the analysis shows clearly that the reform had a considerable positive effect in terms of market entry.

In the first section, we carry out a descriptive analysis of Navarre's 2000 reform and of the changes seen in the number of pharmacies in the region. In the second section, we construct a synthetic control group using the method proposed by Abadie and Gardeazabal (2003), so as to have a counter-factual Navarre and be able to quantify the effect of the reform at aggregate level in terms of entry. In the third section we carry out various quantitative exercises to study the impact of the reform on relatively small municipalities.

4.2.1. Descriptive analysis of the reform and of the change in the number of pharmacies

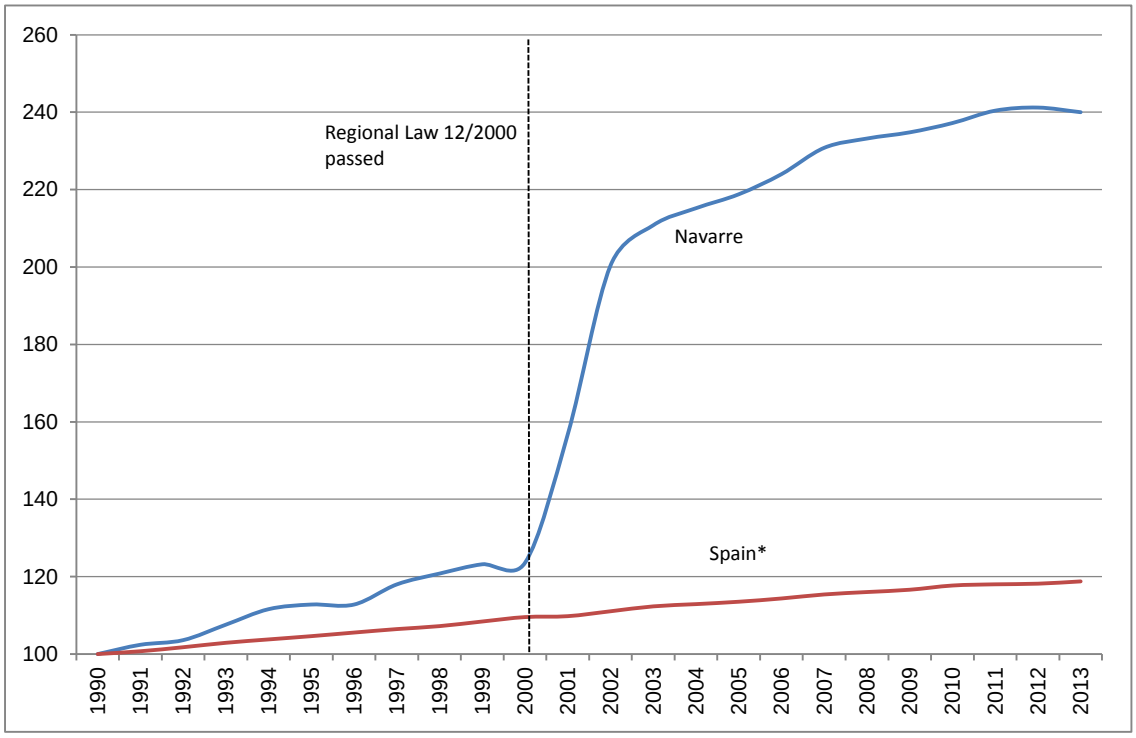
Until the end of 2000, Navarra's rules on the opening of pharmacies incorporated geographical restrictions to entry similar to those established in Law 16/1997, of 25 April, on the regulation of services of pharmacies, applicable nationwide. In particular, the rules on entry were characterised by a fixed ratio of one pharmacy for every 2.800 inhabitants in a health zone and a minimum distance of 250 metres between pharmacies.

Towards the end of 2000, the parliament of Navarre approved Regional Law 12/2000, of 16 November, on Pharmaceutical Care, which opted for a regulation based on minimums, establishing (i) a minimum number of pharmacies in each basic health zone, (ii) an indirect maximum number of pharmacies for the Autonomous Region as a whole - the density of pharmacies at aggregate level could not be less than 700 pharmacies per inhabitant – and (iii) the reduction of the minimum distance between pharmacies to 150 metres. Once the minimums per zone have been met, the entry of pharmacies would basically be restricted by the regional maximum and the minimum distances. Therefore, the reform constituted a considerable liberalisation of entry to the pharmacies sector of Navarre. As argued by Borrell and Fernández-Villadangos (2009), this regulatory change can be considered a natural experiment, since it was unexpected and not desired by the sector subjected to the legislative change.

Following the approval of Regional Law 12/2000 of 16 November on Pharmaceutical Care, the number of pharmacies in Navarre increased considerably (Graph 23). In

2000, before the passing of the reform, the total number of pharmacies in Navarre was 309. Five years later, in 2005, the total number stood at 547. The change in trend compared with the creation of new pharmacies in the rest of Spain suggests a considerable impact stemming from the reform, and indicates that the legislative framework in force prior to the reform was generating a notable degree of shortage in terms of pharmaceutical supply.

Graph 23. Changes in the number of pharmacies, Navarre and Spain (1990=100) 1990 - 2013

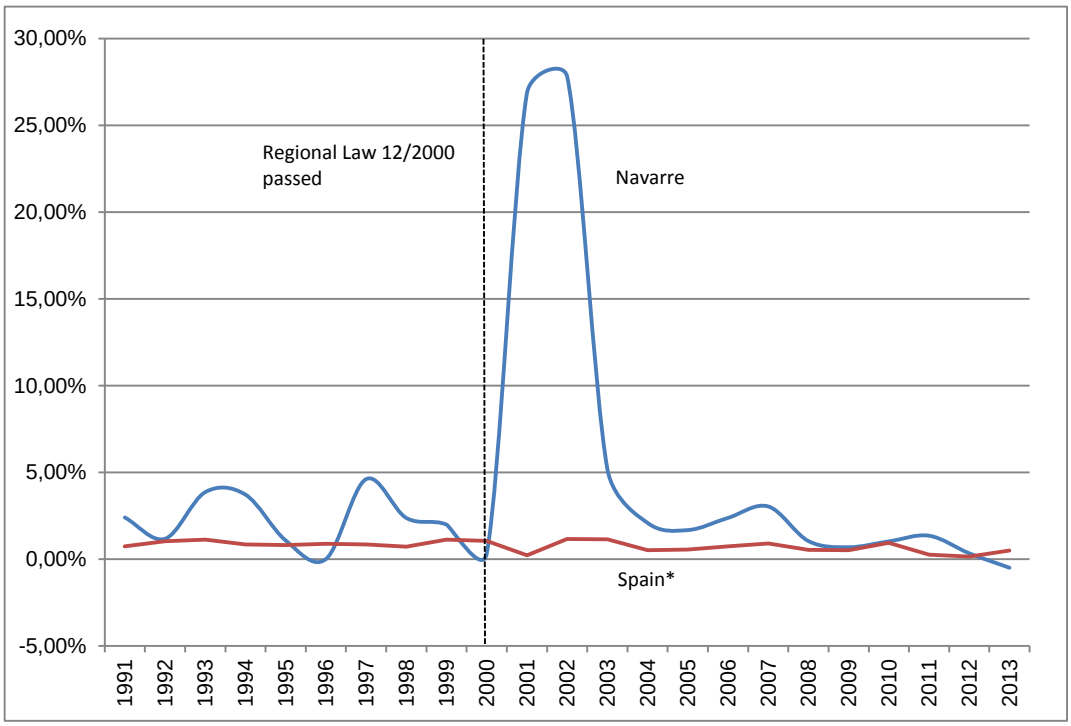


Note: Spain not including Navarre.*

Source: prepared by the CNMC from data of the General Council of Official Associations of Pharmacists (CGCOF).

The rates of change in the number of pharmacies in Navarre and in Spain (Graph 24) illustrate the effects of Navarre's pro-competitive reform and the intensity and duration of its main impact. Following the shock generated by the regulatory change in late 2000, the rates diverged considerably from the historical ones during the three years following the reform. After 2003, the rate of change in the number of pharmacies begins to revert to its stationary (long-term) state, growing at similar rates to those recorded in the period prior to the reform.

Graph 24. Changes in the number of pharmacies in Navarre, annual growth rate 1991 - 2013



Note: Spain not including Navarre.*

Source: prepared by the CNMC from data of the General Council of Official Associations of Pharmacists (CGCOF).

The increase in the number of pharmacies following the reform was not accompanied by changes in other factors relevant to changes in this variable, which suggests that the reform is the crucial factor explaining the increase seen.

In Table 25 we present data on the change in the number of pharmacies and some of the determinants, such as the total population, the elderly population or the youth population for both Navarre and Spain as a whole in the periods 1997-2000 and 2000-2003. The development of the determinants is similar in both periods, with no fundamental changes being observed. However, the change recorded in the growth of the number of pharmacies in Navarre between the two periods is substantial. Moreover, both the total population and the proportion of old people increased more at national level than in Navarre, and yet the national growth rate in the number of pharmacies remained fairly constant, in contrast with that of Navarre.

In view of the natural experiment nature of the legislative change and the change seen in the number of pharmacies, the case of Navarre constitutes an appropriate

candidate for studying the impact of reform by means of different methods for evaluating the causal effects of policies and programmes.

Table 25. Changes in the number of pharmacies and in certain of its determinants in Navarre and Spain*. 1997-2000 and 2000-2003

	Navarre		Spain*	
	1997-2000	2000-2003	1997-2000	2000-2003
Number of pharmacies	4,7%	70,6%	2,9%	2,5%
Total population	1,9%	4,4%	1,3%	4,6%
Population ages 14 or younger	13,7	13,9	15,0	14,5
Population ages 75 or older	8,0	8,5	6,9	7,4

Notes: (a) in the "number of pharmacies" and "total population" variables, the data express percentage rates of change in absolute terms in each period; (b) in the variables "young population" (age 14 or less) and "elderly population" (age 75 or more), the data express percentages of the total population averaged over the period; (c) Spain does not include Navarre.*

Source: prepared by the CNMC from data of the General Council of Official Associations of Pharmacists (CGCOF) and the National Statistics Institute (INE).

4.2.2. Impact of the reform at aggregated level

The descriptive analysis highlighted the fact that following the reform introduced by Regional Law 12/2000, the number of pharmacies in Navarre increased considerably. In this section we carry out a quantitative exercise to determine the effect of the reform in terms of entry of new pharmacies. Specifically, we quantify the increase in the number of pharmacies generated by the legislative change, compared with the counterfactual situation that would have been observed in Navarre if Regional Law 12/2000 had not been passed.

In order to assess to what extent the increase observed in the number of pharmacies is due to the reform passed, it is necessary to identify one or more control Autonomous Regions that have followed the trajectory that a counterfactual Navarre – i.e. with no reform – would have followed[130].

There are various different strategies for forming this control group. One strategy might consist in choosing one or more Autonomous Regions that have similarities

[130] We use the terminology used for evaluating programmes or policies. The control group or unit is the group or unit not subjected to the treatment (policy, reform, shock), and the treatment group or unit is the group or unit that is subjected to the treatment (policy, reform, shock). The control group or unit serves to estimate how the treatment group or unit would have developed in the absence of treatment. In other words it provides us with a *counter-factual* for the treatment unit.

with Navarre as regards the changes in the number of pharmacies. This strategy may prove appropriate, and in many cases it is the only one that can be used. However, it is not without its problems. On the one hand, these control regions may not exist, since any Autonomous Region is systematically different, in terms of changes, from the Autonomous Region in which the reform has been applied. On the other hand, choosing one or more control Autonomous Regions may prove subjective and to some extent arbitrary, which would call into question their ability to effectively approximate the counterfactual scenario of the Autonomous Region that has applied the reform.

A second strategy would consist in constructing a synthetic control Autonomous Region based on a combination of several control Autonomous Regions in which no reform had been implemented. This method can be applied in cases when there is a set of aggregated units such as regions or countries and only one or a small group of these units has been exposed to the treatment. The synthetic control is obtained as a weighted average of the units not subject to the treatment which best approximate the characteristics and development of the treatment unit.

We now go on to apply the synthetic control method in order to quantify the effect of Navarre's reform on the number of pharmacies at aggregate level some years after the reform.

4.2.2.1. Synthetic control method: formal aspects

Abadie and Gardeazábal (2003) and Abadie, Diamond and Hainmueller (2010) define a synthetic control unit as a weighted average of available control units that approximates the characteristics and development of the treatment unit (in this case, Navarre) during the periods prior to the treatment (in this case, the treatment in the reform introduced by Regional Law 12/2000). The weights for obtaining this weighted average are selected so as to effectively achieve this approximation in the periods prior to the treatment. Once it has been constructed, the synthetic control is used to estimate the changes that the treatment unit would have undergone in the counter-factual scenario of absence of treatment.

Abadie et al. (2010) develop a formal discussion of the theoretical properties of the synthetic control method, justifying this method on the basis of a model that generalises the traditional difference-in-differences method and allows the effect of the non-observable characteristics of a unit to vary over time. Next, following Abadie, Diamond and Hainmueller (2011), we briefly describe the basic formal aspects of this method.

Suppose that the following units exist $j = 1,\ldots, J+1$ for the periods $t = 1,\ldots,T$. We assume that only one unit is subjected to the treatment, leaving J units available to contribute to the synthetic control. The literature refers to this group of potential control regions as the donor pool. In studies using the synthetic control method, the units are usually entities of an aggregated kind, mainly countries or regions. The treatments tend to refer to legislative changes or economic or other kinds of shocks. The intervention takes place at a given point in time T_0+1, so the periods 1, 2, ..., T_0 constitute the periods prior to the treatment and T_0+1, T_0+2, ..., T those subsequent to it.

The possible results in relation to the variable "result of interest" are two: (i) Y_{it}^N is the result that would be observed for unit i at point of time t if unit i were not subjected to the treatment; (ii) Y_{it}^I is the result that would be observed for unit i at point of time t if unit i were subjected to the treatment. Formally, the effect of the treatment on the unit treated is the difference between the two possible results $\alpha_{1t} = Y_{1t}^I - Y_{1t}^N$ for periods T_0+1, T_0+2, ..., T. For the unit treated, Y_{it}^N it cannot be observed in periods subsequent to the treatment. Therefore, the basic objective of the synthetic control method is to construct a synthetic control unit to provide a reasonable counter-factual of the unit treated.

It is best to have a synthetic control unit that resembles the treatment unit in its relevant characteristics during the periods prior to the treatment. To this end we define U_ia vector $(rx1)$ of co-variables observed for each unit. These variables are normally those that contribute to predicting the result of interest[131]. In turn, the order (T_0x1) vector $K = (k_1, \ldots, k_{T_0})'$ refers to a particular linear combination of the result in the period prior to the intervention: $\bar{Y}_i^K = \sum_{s=1}^{T_0} k_s Y_{is}$. The linear combinations of the result in the periods prior to the treatment can be used to control for non-observable factors that vary over time. Up to $M < T_0$ linear combinations can be incorporated.

To construct the synthetic control unit, we define a vector $(Jx1)$ of weights $W = (w_2, \ldots, w_{J+1})'$ such that $w_j \geq 0$ for $j=2, \ldots, J+1$ and $w_2 + \ldots + w_{J+1} = 1$. Each W gives rise to a specific weighted average of the possible control units and therefore allows us to obtain a potential synthetic control. The optimal weights W* are chosen to ensure that the synthetic control unit is that which best approximates the treatment unit during the periods prior to the treatment as regards the predictors U_i of the result

[131] The result variable is a variable affected by the treatment and on which the impact analysis centres.

variable and the M linear combinations of the result variable in the prior to the intervention: $\bar{Y}_i^{K_1}$, …, $\bar{Y}_i^{K_M}$.

Implementing the synthetic control method and obtaining the weights requires a distance between the synthetic control unit and the treated unit to be defined. To do so, we combine the characteristics of the unit treated in a $(\mathrm{kx1})$ order matrix $X_1 = (U_1', \bar{Y}_1^{K_1}, \ldots, \bar{Y}_1^{K_M})'$ and the values of the same characteristics of the control units in an order (kxJ) $\mathrm{X_0}$ matrix with the j[th] row $(U_j', \bar{Y}_j^{K_1}, \ldots, \bar{Y}_j^{K_M})'$. To obtain a synthetic control as similar as possible to the treatment unit, we seek a W* that minimises the following expression:

$$\|X_1 - X_0 W\|_V = \sqrt{(X_1 - X_0 W)' V (X_1 - X_0 W)}$$

V is a symmetrical positive-semidefinite matrix (kxk) . The matrix V allows different weights to exist for the variables in $\mathrm{X_0}$ and $\mathrm{X_1}$. V is chosen in such a way that its weights minimise the mean squared error of the synthetic control estimator, i.e. the expectation of $(Y_1 - Y_0 W^*)'(Y_1 - Y_0 W^*)$.

Once we have the weights W*, the synthetic control is constructed for the treatment period: $\hat{Y}_{1t}^N = w_2 Y_{2t} + \cdots + w_J Y_{Jt}$

The synthetic control method has been used to study the effect of legislative and institutional changes or economic shocks of other kinds. Abadie and Gardeazabal (2003) develop this method in seminal form to analyse the effect of the activity of the terrorist organisation ETA on changes in the per capita GDP of the Basque Country. For their part, Abadie et al. (2010) study the impact on the consumption of tobacco of California's tobacco control programme in the late 1990s.

With time, the literature using this method has grown considerably: Abdallah and Lastrapes (2012) analyse the effect of a change in Texas state mortgage lending legislation, estimating the importance of credit constraints for households' behaviour; Acemoglu, Johnson, Kermani, Kwak and Mitton (2013) study the value that firms derive from their political connections, using the announcement of the appointment of a United States Secretary of the Treasury, Timothy Geithner, at the end of 2008 as the shock; Billmeier and Nanncini (2013) construct synthetic controls to study the impact of international trade liberalisation processes on a number of countries; Abadie, Diamond and Hainmueller (2014) quantify the impact of German reunification in 1990 on the GDP per capita of West Germany during the period following reunification; Bohn, Lofstrom and Raphael (2014) study the impact of a change in Arizona labour law on employment in the Hispanic immigrant population.

4.2.2.2. Construction of the synthetic control for Navarre and quantification of the impact of the reform of 2000

The synthetic control method requires that the case to be studied meets a number of conditions, which are met in the case of the Navarre reform:

In the first place, the intervention must take place in only one unit or in a very small group of units. Otherwise, there would not be a pool of potential donors and it would not be possible to construct a synthetic control. In the case of Navarre, no similar reform was applied in any other Autonomous Region, and the majority of them underwent no significant legislative changes relating to pharmacies in 2000 et seq.

In the second place, there must be no interference among units as regards the effects of the policy. In other words, in the periods following the treatment, changes in the units not treated must not be affected by the treatment in the treated unit. In the case of Navarre, it is reasonable to suppose that there are no such effects. The liberalisation of entry affects only Navarre, since in most of the other Autonomous Regions restrictions to entry remain in force.

Thirdly, the treatment or shock must be exogenous. If there were endogeneity of the treatment in the result variable, it would not be possible to capture the effect of the treatment, since the result would in turn be affecting the treatment. In the case of Navarre, the policy change was unwished for and unexpected, and unrelated to the result of interest. Therefore it is reasonable to regard it as exogenous.

Fourthly, the values of the result variable for the treated unit before the intervention must not be extreme. There must be units which, when combined in weighted form, are able to replicate them approximately. In the case of Navarre, as can be seen from the results obtained, there are some Autonomous Regions that can closely replicate the trends in pharmacies in Navarre in pre-treatment periods.

To construct the synthetic control we use regional data for the period 1990-2005. Although data are available beyond 2005, the analysis stops at 2005 for several reasons. On the one hand, the aim is to calculate the impact of the reform at aggregated level for the years immediately following the reform. On the other hand, as time goes by both in the treatment Autonomous Region and in the control Autonomous Regions there may be legislative changes in the pharmaceutical field, or other kinds of shocks, that would affect the result of interest. In fact, from 2005 on, in some control Autonomous Regions included in the donor pool significant legislative changes were made as regards the opening of pharmacies, which would disqualify them as control regions if the analysis were extended beyond 2005. By

stopping the analysis in 2005, we avoid the possibility of these effects influencing the results.

The synthetic control, which we shall refer to henceforth as "synthetic Navarre", is constructed with a weighted average of potential control Autonomous Regions, selecting the weights so that synthetic Navarre approximates the values of the number of pharmacies in real Navarre in the periods prior to the treatment. Since synthetic Navarre is designed to show how Navarre would have evolved in the absence of the regulatory change of 2000, Autonomous Regions that applied significant legislative changes albeit of a different degree relating to the opening of pharmacies around 2000 and in subsequent periods to 2005 are excluded from the donor pool used. Such is the case of Castile-La Mancha, Andalusia, Madrid and the Canary Islands[132]. Ceuta and Melilla are also excluded from the analysis in view of possible atypical developments in these two Autonomous Cities that might affect the results. Once these Autonomous Regions and Cities have been excluded, the number of potential controls in the donor pool is 12 Autonomous Regions.

The result variable of interest is the aggregate number of pharmacies at regional level. The predictors used to construct the synthetic indicator are the values of number of pharmacies in 1990, 1995 and 2000, the average population in the period 1990-2000 and the average percentages of the elderly and youth populations. Several of the predictors were obtained from the literature that has studied the determinants of the number of pharmacies (see for example Borrell and Fernández-Villadangos (2009) and Schaumans and Verboven (2008)). We carried out tests with other predictors such as the structure of the population by size of municipality and population density, and the fit in the period of treatment was not as good as with the selection made. Including lagged values of the result variable of interest – in this

[132] The legislative changes are the following. Castile-La Mancha approved Law 10/2000 of 26 December amending Law 4/1996 of 26 December on the Organisation of the Pharmaceutical Service of Castile-la Mancha, allowing the opening of pharmacies in population centres with populations of more than 1,000 inhabitants at a minimum distance of 500 metres from the nearest existing pharmacy. This Law had a considerable impact in terms of the opening of new pharmacies. In 2003 Andalusia passed Decree 353/2003 of 16 December establishing the pharmaceutical planning and procedures for authorisation of pharmacies. This Decree, later incorporated into Law 22/2007 of 18 December on Pharmacy in Andalusia, relaxed the restrictions on opening the first pharmacy in any municipality. In 1998 Madrid passed Law 19/1998 of 25 November on the Pharmaceutical Organisation and Care in the Autonomous Region of Madrid, which had persistent effects in subsequent years. In 2002 the Canary Islands, as part of the development of the Pharmaceutical Map, approved the Order of 5 June amending the Order of 19 June 1998 delimiting the pharmaceutical zones of the Canary Islands, which led to a considerable increase in the number of pharmacies in the region in 2003.

case, the number of pharmacies - is standard practice in the literature using the synthetic control method (see Abadie et al. (2010)).

4.2.2.3. Results

Using this method, we constructed a synthetic Navarre as a convex combination of control regions, ensuring that the synthetic region constructed approximated Navarre in terms of the number of pharmacies in the period 1990-2000. The year 2000 is considered as prior to the treatment, since the reform was passed in November 2000 and its effects started to be seen in 2001 - the first year of the treatment in the quantitative construction of the synthetic control.

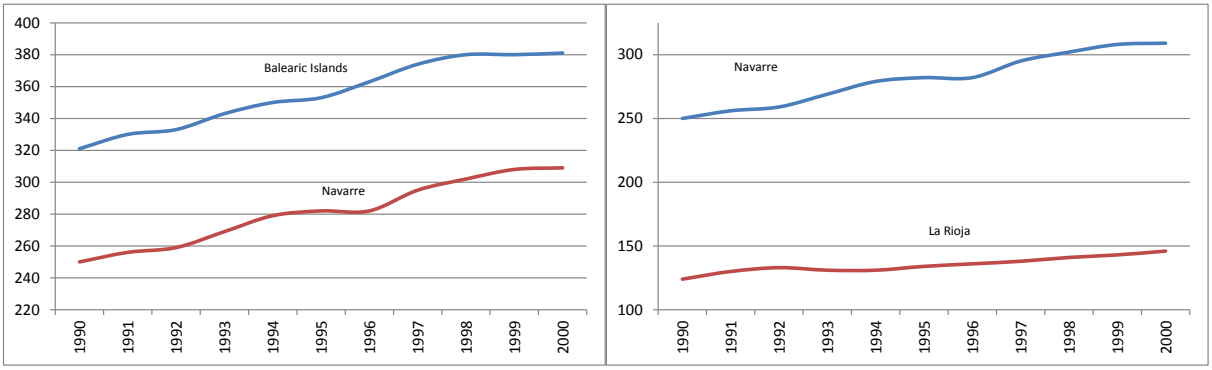
In Table 26 we present the computationally calculated weights used to construct synthetic Navarre. The weights indicate that the combination which best replicates the trend in the number of pharmacies in Navarre in the years prior to the reform - the period 1990-2000 - is that formed by the Balearic Islands (with a weight of 0.664) and La Rioja (with a weight of 0.336). The remaining Autonomous Regions obtain a weighting of 0. The choice of a small group of units to form the synthetic control is consistent with other results in the literature (see for example Abadie and Gardeazabal (2003), Abadie et al. (2010) and Bohn et al. (2014)). The synthetic control method shows that the Autonomous Regions most similar to Navarre as regards changes in the number of pharmacies at aggregate level are the Balearic Islands, followed by La Rioja. In fact, a simple descriptive analysis confirms similarities in terms of the changes (Graph 25).

Table 26. Weights of each Autonomous Region in the synthetic control for Navarre

Autonomous Region	Weight	Autonomous Region	Weight
Aragon	0.000	Extremadura	0.000
Asturias	0.000	Galicia	0.000
Balearic Islands	0.664	Murcia	0.000
Cantabria	0.000	Basque Country	0.000
Catalonia	0.000	La Rioja	0.336
Castile and Leon	0.000	Valencia	0.000

Source: prepared by the CNMC.

Graph 25. Changes in the number of pharmacies, Navarre, the Balearic Islands and La Rioja. 1990 - 2000

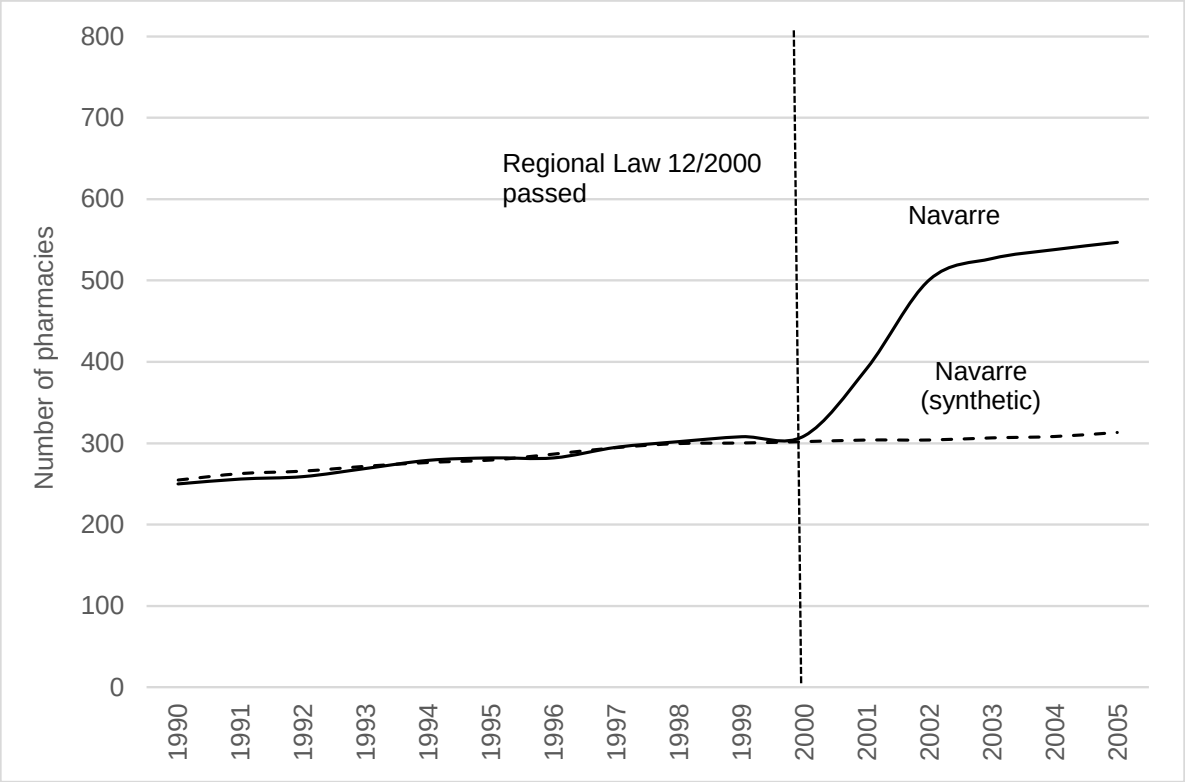


Source: prepared by the CNMC from data of the General Council of Official Associations of Pharmacists (CGCOF).

In Graph 26 we show the trends in real Navarre and synthetic Navarre for the period 1990-2005. In period prior to the reform, synthetic Navarre closely approximates the trend in real Navarre, which suggests that it may constitute a good counter-factual for real Navarre in the period following the reform. The estimated effect of the reform is the difference between real Navarre and synthetic Navarre. Starting in 2000, we see a wide divergence in trends, especially in the period to 2003. From 2003, the two trends start to be more similar, in spite of the difference in levels. The effect of the reform was considerable. In the period 2001-2005, the number of pharmacies in Navarre increased on average by 63% compared with a scenario with no reform. In 2005, the number of pharmacies was 75% higher than that which would have been seen without the reform.

Therefore, the quantitative evidence shows how the previous legislation was considerably limiting entry to the pharmaceutical care markets of Navarre, and how the elimination of the geographical restrictions to entry notably intensified entry to these markets.

Graph 26. Changes in the number of pharmacies, Navarre actual and Navarre synthetic 1990-2005



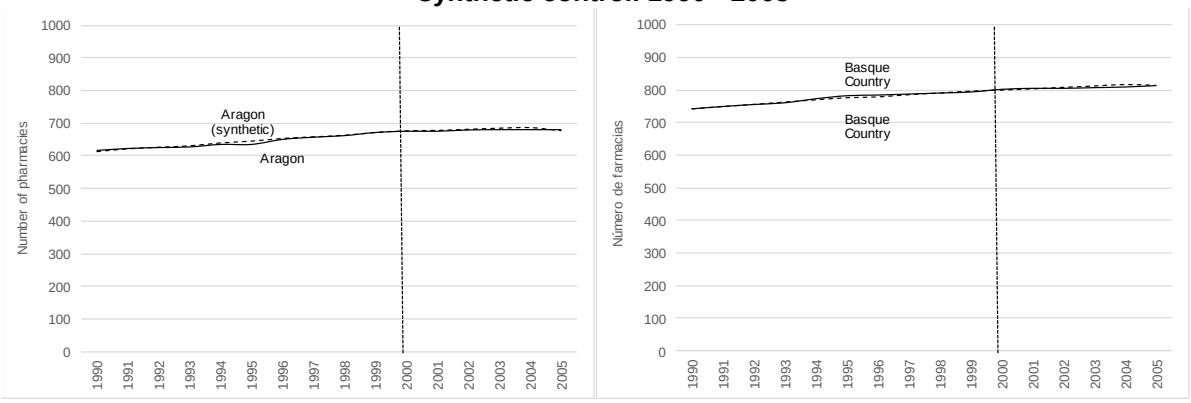
Source: prepared by the CNMC.

4.2.2.4. Placebo tests

One interesting aspect of the synthetic control method is that it allows placebo studies to be carried out, in line with Abadie and Gardeazabal (2003) and Bertrand, Duflo and Mullainathan (2004). Placebo studies - or falsifiability tests, a notion that goes back to Popper (1959) - consist in applying the synthetic control method to the control Autonomous Regions which did not undergo any reform. In essence, they constitute the way of making statistical inferences in the non-parametric synthetic control methodology. Examples of these tests can be found in other articles in the literature, albeit under different names (see for example Angrist and Krueger, 1999). If the synthetic control method is applied to the control Autonomous Regions and no difference is detected between their actual trends and those of their synthetic controls, this constitutes evidence that the result obtained for the treatment Autonomous Region is significant, and that the synthetic control has appropriately captured the counterfactual situation that would have existed in this Autonomous Region in the absence of treatment.

Using the same variables as for the case of Navarre, we apply the synthetic control method to other Autonomous Regions, excluding Navarre from the pool of donors. The Graph 27 shows the results obtained for Aragon and the Basque Country. In both cases we see a close fit in the period prior to the placebo reform. It is also very close in the period following the reform, which indicates a high degree of predictive precision, especially bearing in mind that this is a five-year prediction: the average percentage prediction error in the period 2001-2005 is 0.1% in the case of Aragon and -0.6% in the case of the Basque Country. For the other Autonomous Regions (8)[133], this figure is between 0.5% and 1% in three cases, between -0.9% and el -1.7% in another three, and between 1.6% and 1.9% in the remaining two cases.

Graph 27. Change in the number of pharmacies in Aragon and the Basque Country, actual and synthetic control. 1990 - 2005



Note: the dotted line is in all cases the synthetic control.
Source: prepared by the CNMC.

Additionally, after applying the synthetic control method to all the control Autonomous Regions – excluding Navarre from the donor pool – we calculated the root mean squared error (RMSE) for each of them in (i) the periods prior to the reform and (ii) the periods following the reform. We now proceed to obtain the ratio of the RMSE for the period following the reform to that of the period prior to the reform[134]. The results obtained for Navarre are considered significant if the ratio in

[133] The method was not applied to La Rioja or Catalonia, since these two Autonomous Regions have extreme values in the distribution (they are the Autonomous Regions with fewest and most pharmacies, respectively) and therefore they have no place in a synthetic control appropriate for the number of pharmacies of these two Regions.

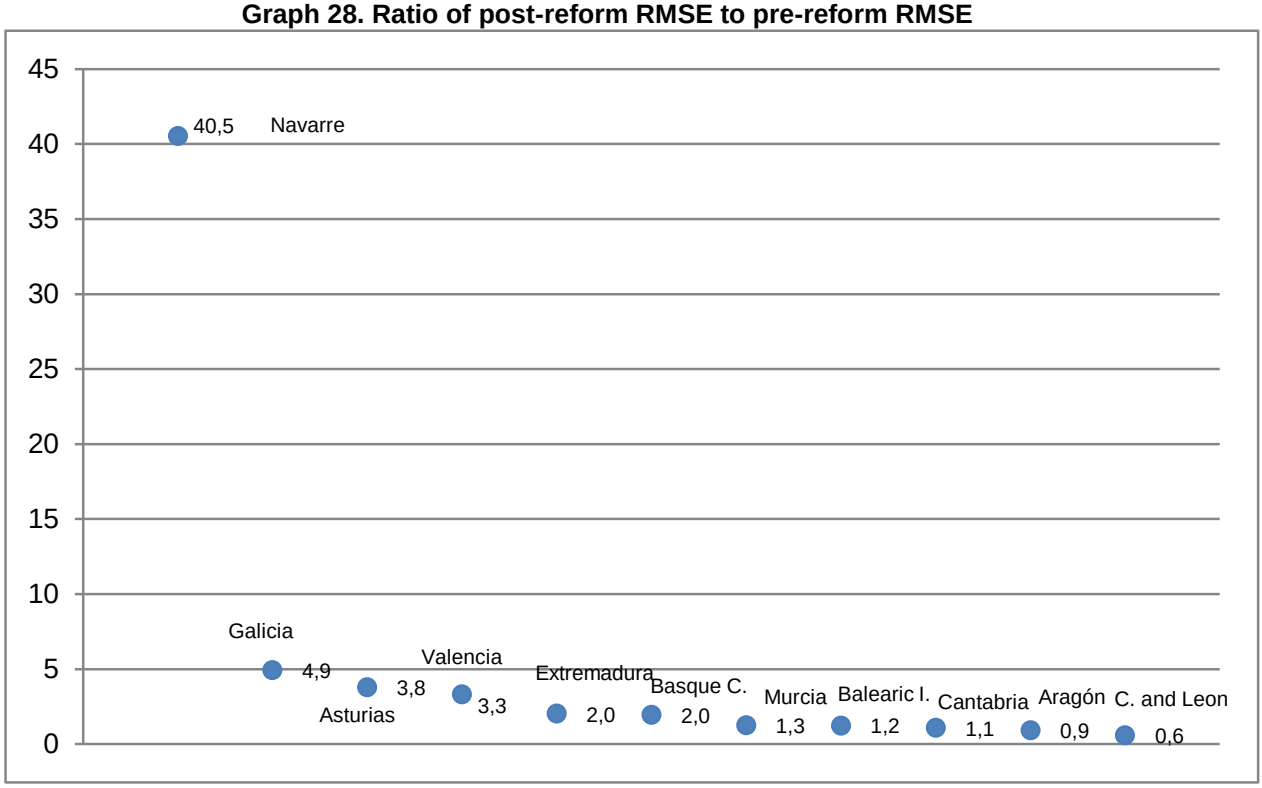
[134] For any region *r*, the root-mean-square error (RMSE) in the pre-reform period – eleven years – is:

$$\left(\frac{1}{11}\sum_{t=1}^{11}\left(Y_{rt}^{I}-\hat{Y}_{1rt}^{N}\right)^{2}\right)^{1/2},$$

whereas in the post-reform period – five years – it is:

this region is unusually different from the ratios calculated for the rest of the control units. As can be seen from Graph 28, Navarre's ratio is considerably higher than those of the other regions. If we were to choose a region at random from among the thirteen regions included in Table 2, the probability of finding a divergence like that of Navarre would be 1/11 ≅ 0.09.

Graph 28. Ratio of post-reform RMSE to pre-reform RMSE



Source: prepared by the CNMC.

4.2.3. Impact of the reform on small municipalities

Having quantified the aggregate impact of the reform, in this section we study the impact of the reform on relatively small municipalities.

It has sometimes been argued that eliminating the geographical restrictions to entry would lead to an increase in the number of pharmacies in relatively large municipalities and a reduction in the number of pharmacies in relatively small

$\left(\frac{1}{5}\sum_{t=1}^{5}\left(Y_{rt}^{I}-\hat{Y}_{1rt}^{N}\right)^{2}\right)^{1/2}$.

The root-mean-square error measures the magnitude of the difference in the result of interest variable between each real Autonomous Region and its synthetic control. The ratio divides the post-reform RSME by the pre-reform RSME. A ratio of 1 indicates that the RSME is the same for both periods. The ratio can be more than 1 even if the error of prediction is very small.

municipalities, i.e. a kind of skimming of pharmacies in relatively unattractive areas and intense entry to relatively attractive areas. The reasoning being that with high regulated margins in a context of free entry, pharmacies would tend to be concentrated in the more attractive areas, possibly leaving less attractive areas unattended. Schaumans and Verboven (2008) point out that this has been the reason traditionally given to justify the imposition of geographical restrictions to entry to the pharmaceutical sector.

In this section we carry out various quantitative exercises to study the impact of the reform on relatively small municipalities. First, we give a descriptive analysis of trends in the number of pharmacies by various types of municipalities, pre- and post-reform. Secondly, we make an estimate of a traditional difference-in-differences model to provide more robust evidence of the impact of the reform on relatively small municipalities.

The quantitative analysis concludes that the reform in Navarre increased the number of pharmacies in relatively small municipalities in comparison with what would have happened in a scenario with no reform. Thanks to the reform of 2000, the relatively small municipalities of Navarre are better supplied as regards the provision of pharmaceutical services. In fact, the data illustrate how the restrictive legislation in force before the reform condemned these municipalities to a considerable shortage in the supply of pharmacies. Therefore, the reform generated gains in welfare for Navarre consumers living in these municipalities in comparison with the situation that would have prevailed in a scenario of no reform.

4.2.3.1. Descriptive analysis

Following the approval of Regional Law 12/2000, of 16 November, on Pharmaceutical Care, the number of pharmacies in Navarre increased considerably at aggregate level. In this section we analyse descriptively the dynamic observed following the reform by types of municipalities according to size.

In Table 27 we show the annual growth rates in the number of pharmacies in Navarre in different types of municipalities by size for the period 1998-2000 (prior to the reform) and 2000-2003 (the period in which the reform had its main effect). Following the reform, the number of pharmacies increased considerably in practically all types of municipalities, the rate of growth being slightly higher in municipalities with populations of less than 15,000 than in those with populations of more than 15,000. As a result of this greater dynamism, the share of municipalities with fewer than 15,000 inhabitants in the total number of pharmacies in Navarre increased slightly between 2000 and 2003, from 56.4% to 56.6%. Therefore, following the

reform the pace of entry was very high in small municipalities and slightly more intense than in the larger municipalities.

In turn, the difference between the rates recorded in the two periods provides preliminary confirmation of the positive effect of the reform in terms of the entry of new pharmacies. During the period 1998-2000, the annual rate of growth in most categories of municipalities with fewer than 15,000 inhabitants was 0.0%, and in no case was it more than 1.5%. Between 2000 and 2003, after the reform, the rates were 28.6%, 39.6% and 30.4% respectively in municipalities with 10,000 to 15,000 inhabitants, 5,000 to 10,000 inhabitants and 1,000 to 5.000 inhabitants[135]. These data highlight how the pre-reform legislative framework was limiting entry and leading to a considerable shortage of pharmaceutical services in small municipalities, and how following the establishment of a free entry system, entry was intense and vigorous, benefiting residents of these municipalities, who after the reform had access to pharmaceutical services in an environment of greater contestability and competition. The large difference between (i) the change observed in the annual rate of growth of the number of pharmacies and (ii) the change observed in the annual rate of growth of the population confirms that the increase in the number of pharmacies was due to the reform and not to population growth.

Table 27. Annual growth rate of the number of pharmacies in Navarre, by different types of municipalities by size. 1998-2000 and 2000-2003

	Δ % Pharmacies 1998-2000	Δ % Population 1998-2000	Δ % Pharmacies 2000-2003	Δ % Population 2000-2003
≥ 15,000 inhabitants	1,6%	2,9%	19,8%	1,8%
< 15,000 inhabitants	0,3%	-0,2%	20,1%	2,3%
< 15,000 inhabitants, ≥ 10,000 inhabitants	0,0%	2,4%	28,6%	3,0%
< 10,000 inhabitants, ≥ 5,000 inhabitants	0,0%	2,2%	39,6%	3,8%
< 5,000 inhabitants, ≥ 1,000 inhabitants	0,0%	-1,6%	30,4%	2,3%
< 1,000 inhabitants, ≥ 500 inhabitants	0,0%	0,0%	3,0%	0,6%
< 500 inhabitants	1,2%	-0,3%	-4,2%	0,0%

Note: (i) the rate is a compound annual rate, starting from the level datum in 1998 and 2000 for the first period (1998-2000) and from the level datum of 2000 and 2003 for the second period (2000-2003) (ii) the municipalities are allocated to each type by their population in 2000.
Source: prepared by the CNMC from data of the Government of Navarre (Department of Health).

[135] The rates are compound annual rates in each period. The rates for the period following the reform are not *long-term* rates, since they correspond to the time of the shock. However, they prove very useful for illustrating the effect of the reform in terms of stimulating entry in the analytical framework of a before-and-after shock analysis.

Following the reform, some reductions were observed in the number of pharmacies in very specific municipalities, which partly explains why there is a type of municipality in which the number of pharmacies fell: those with fewer than 500 inhabitants, where the number of pharmacies was 40, 41 and 36 in 1998, 2000 and 2003 respectively.

A more detailed analysis of all municipalities in Navarre indicates that between 2000 and 2003 the number of pharmacies went from one to zero in six municipalities with fewer than 500 inhabitants, these municipalities being the only ones in the whole of Navarre showing reductions in the number of pharmacies between 2000 and 2003. In any case, account should also be taken of the fact that the number of pharmacies increased from zero to one in one municipality with fewer than 500 inhabitants, from zero to one in one municipality with between 500 and 1,000 inhabitants, and from zero to two in one municipality with between 2,000 and 2,500 inhabitants, these being the only municipalities with no pharmacies in 2000 where at least one pharmacy opened between 2000 and 2003. Therefore, in net terms, the number of municipalities without a pharmacy increased by only three between 2000 and 2003. The reason is not necessarily to be found in the reform, since pharmacies do sometimes close. For example, in the Basque Country in 2000 and in La Rioja in 2006 the sole pharmacy in a municipality of fewer than 500 inhabitants closed. The losses seen in Navarre may also be explained by various real factors stemming not from the reform but from various dynamics at municipal level.

In any case, supposing that the reform were the cause of the closures and openings aforementioned, we should analyse the extent to which the allocation generated by the reform increased or reduced the population resident in Navarre municipalities with no pharmacy. In 2000, the percentage of the total population of Navarre living in municipalities with no pharmacy was 4.4%. By 2003, the percentage had fallen to 3.8%. Therefore, the proportion of the population living in municipalities with no pharmacy was smaller after the reform than before it.

However, this trend was already being seen before the reform, and although the reform did not lead to a change in trend, a composition effect deriving from the demographic dynamic at municipal level in Navarre might explain part of the reduction in the percentage. A comparative static analysis allows another quantitative exercise to be carried out. The exercise consists in transferring to 2000 the allocation of pharmacies for 2003 in the case of municipalities with no pharmacies, leaving the 2000 population constant. In other words, in 2000 (i) six pharmacies are eliminated in the municipalities that had one pharmacy in 2000 and where closures were seen between 2000 and 2003, and (ii) four pharmacies are

added to municipalities with no pharmacies in 2000 and in which opening s were seen between 2000 and 2003. From carrying out this reallocation exercise statically we conclude that there would also have been an improvement in terms of pharmaceutical coverage, since the effective 4.4% of 2000 would go to 4.0% in the hypothetical event of reallocation. Therefore, if one of the objectives of the pre-reform legislative framework was to reduce or minimise the percentage of the population living in municipalities with no pharmacy, the available evidence suggests that the reform contributed more to that objective than did the previous restrictive legislation.

In short, following the reform, we see a generalised increase in pharmacies in the majority of types of municipality by population size. Municipalities with fewer than 15,000 inhabitants have seen considerable increases in the number of pharmacies, slightly more than in municipalities with more than 15,000 inhabitants, which translates into an increase in the weight of the former category of municipalities in the aggregate number of pharmacies in Navarre. Therefore the idea that there was any skimming off of pharmacies in relatively small municipalities following the reform can be dismissed. In fact, compared with the pre-reform period we see a more pronounced change and more vigorous and intense growth in municipalities with fewer than 15,000 inhabitants than in the larger ones. Additionally, we see that following the reform, the proportion of the population living in municipalities with no pharmacy fell relative to the level seen before the reform.

4.2.3.2. Traditional difference-in-differences analysis

In this section we construct a simple model of difference-in-differences to provide additional evidence of the positive effect of the reform on the smaller municipalities[136]. The difference-in-differences method has been widely used in economics and other social sciences. Classic articles in this field are those of Card (1992) and Card and Krueger (1994), which analyse the impact of changes in the minimum wage on the level of employment at state level in the U.S., by means of

[136] The synthetic control cannot be applied directly in this second dimension of the analysis, because we do not have municipal data for all regions of Spain, only the aggregate datum. Irrespective of this, the results of the synthetic control also show intense creation of pharmacies in municipalities with fewer than 15,000 inhabitants, simply because even if all the new pharmacies in municipalities with 15,000 inhabitants or more were due to the reform, the difference between the synthetic control and the actual Navarre situation would be much less than that estimated. Therefore many of the pharmacies that entered the market thanks to the reform must necessarily have been in municipalities with fewer than 15,000 inhabitants, as is also very clearly indicated by the descriptive analysis.

different approximations. We now go on to describe the basic aspects of this method in accordance with Wooldridge (2002).

In its simplest form, there are two periods, pre- and post-treatment. There are two groups, a control group and a treatment group. Summarising what has been said in previous sections, members of the treatment group - which may be a group of people, workers, firms, municipalities, etc. - are in that group by chance, i.e. they have not chosen to be treated. The control group is a similar group that is not treated.

More formally, let A be the control group and B the treatment group. Let dB be a dummy variable equal to 1 for units in the treatment group and 0 for all other cases. Let d2 be a dummy variable for the second period, when the reform has taken effect. The simplest equation for analysing the impact of a treatment or policy in this analytical framework is:

$$y = \beta_0 + \delta_0 d2 + \beta_1 dB + \delta_1 d2dB + u$$

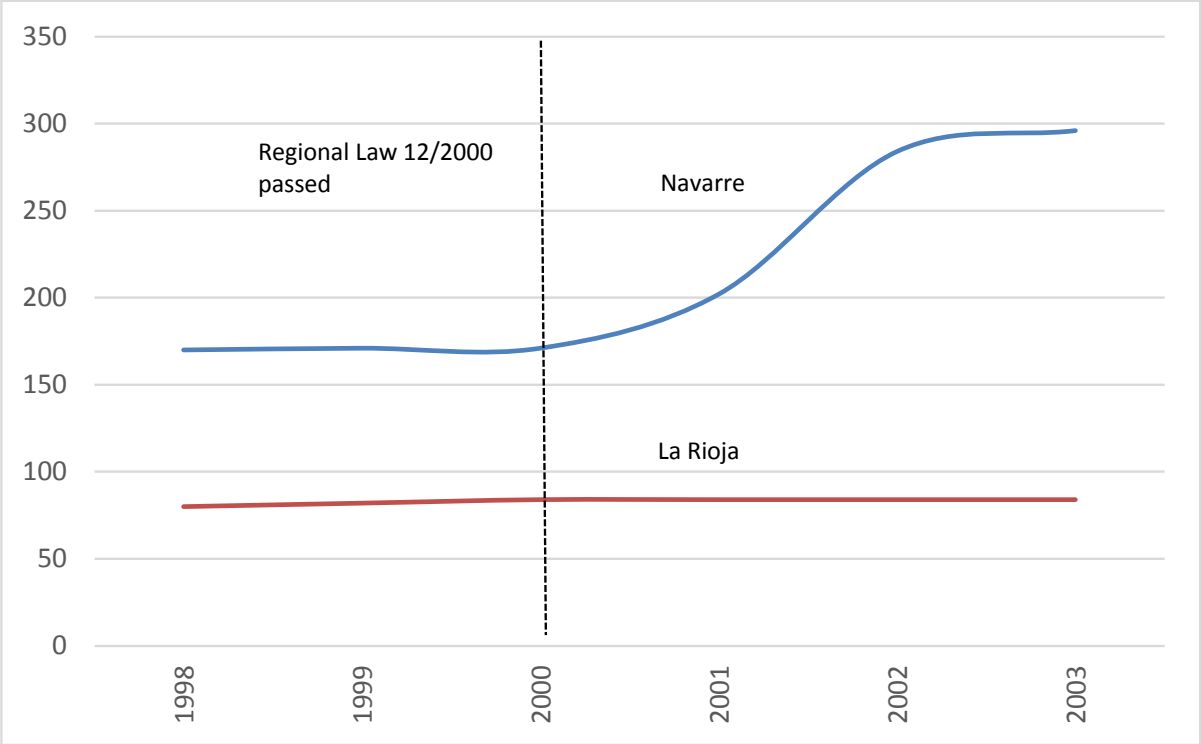
y is the variable result of interest. The d2 dummy variable reflects factors affecting the variable over time similarly for both groups. The dummy variable dB captures possible differences between the treatment and control groups prior to the policy change. The coefficient of interest is the coefficient of the effect of the treatment, δ_1, which multiplies a dummy obtained by multiplying d2 by dB, which is the same as a dummy variable equal to one for those observations in the treatment group in the second period.

In the foregoing specification, the ordinary least squares estimate of δ_1 can be interpreted from the averages of the control and treatment groups in each period. Let $\bar{Y}_{A,1}$ ($\bar{Y}_{B,1}$) be the average of the sample for the control (treatment) group in the first year and $\bar{Y}_{A,2}$ ($\bar{Y}_{B,2}$) the average for the control (treatment) group in the second period. Therefore $\delta_1 = \left(\bar{Y}_{B,2} - \bar{Y}_{B,1}\right) - \left(\bar{Y}_{A,2} - \bar{Y}_{A,1}\right)$. This estimator is referred to as the difference-in-differences estimator and serves to estimate the effects of the treatment. The interesting and useful thing about this estimator is that it allows one to control for specific group and time effects, unlike a simple before-and-after comparison for the treated group or a comparison between the control group and the treated group for the period following the treatment. In many empirical applications covariables are added to the difference-in-differences equation in order to control for individual characteristics in both periods. The interpretation of the difference-in-differences estimator is the same, although its representation is not as simple as the difference shown between differences in the averages.

The use of the traditional difference-in-differences methods relies on relevant hypothesis. In the first place, the treatment must be exogenous. In the case of Navarre, because of the characteristics of the change in legislation commented upon earlier, it is reasonable to suppose that the condition of exogenous treatment is met.

In the second place, there must be a common trend between the control group and the treatment group. In other words the method assumes that in the absence of treatment, the control group and the treatment group would evolve in exactly the same way. One accepted way of having a degree of certainty about the second condition's being met is to see whether in the past, before the reform, both groups followed a common trajectory. In this case we use as control group the municipalities of La Rioja, for sampling reasons and because of the trend followed by the municipalities of La Rioja during the years for which data by municipality are available. For municipalities with fewer than 15,000 inhabitants, La Rioja and Navarra follow a similar trend, basically flat for the period 1998-2000. In Graph 29 we show the changes in the number of pharmacies in the municipalities of La Rioja and of Navarre with fewer than 15,000 inhabitants between 1998 and 2003. Until 2000, the trend can be described as common. Although the period is a short one, the data could be indicating that in terms of small municipalities La Rioja can be an appropriate control for Navarre, irrespective of the fact that at aggregate level the parallels are not so intense, as has been indicated previously.

Graph 29. Changes in the number of pharmacies in Navarre and La Rioja, municipalities with fewer than 15,000 inhabitants. 1998-2003



Source: prepared by the CNMC from data of the Government of Navarre (Department of Health) and the Government of Rioja (General Directorate of Care, Benefits and Pharmacy).

4.2.3.3. Econometric estimation

We have data at municipal level for Navarre and la Rioja for the period 1998-2003 for the variables (i) number of pharmacies by municipality and (ii) population by municipality. The data on the number of pharmacies come from the Government of Navarre (Department of Health) and the Government of Rioja (General Directorate of Care, Benefits and Pharmacy). Population data of the National Statistics Institute (INE). The number of municipalities with fewer than 15,000 inhabitants for which we have information is 171 in La Rioja and 268 in Navarre.

The data on the number de pharmacies and population are collapsed in time dimension, into averages by municipality for two periods: pre-reform (average of 1998-2000) and post-reform (average of 2001-2003). On the one hand this helps avoid section effects of any one particular year. On the other, it helps mitigate possible problems of serial correlation in the estimates with each year of the time series. Based on the available data, we estimate several models in the spirit of the model presented in the previous section, which also incorporate as a variable the

population of each municipality. The specific equation to be estimated is the following:

$$nfarm_{it} = \beta_0 + \delta_0 post + \beta_1 Navarra + \delta_1 post * Navarra + \beta_2 población_{it} + u_{it}$$

where:

t may correspond to the pre-reform or to the post-reform period.

$nfarm_{it}$: is the average number of pharmacies in municipality i in period t.

$post$: is a dummy variable that takes the value 0 for the pre-reform period and the value 1 for the post-reform period.

$Navarra$: is a dummy variable that takes the value 0 for a municipality of La Rioja and 1 for a municipality of Navarre.

$post * Navarra$: is an interactive dummy that takes the value 1 for a municipality of Navarre in the second period.

$población_{it}$: is the average population in thousands in municipality i in period t.

u_{it} is the error term.

Table 28 shows the main statistical data for the variables number of pharmacies and population in the sample of municipalities with fewer than 15,000 inhabitants. The econometric strategy used centres on making different estimates of the foregoing equation taking as the sample the municipalities with fewer than 15,000 inhabitants, those with fewer than 10,000 inhabitants and those with fewer than 5,000 inhabitants, with and without incorporation of the population. The estimates are made by ordinary least squares. Assuming that if the reform had not been passed the municipalities of Navarre would have behaved like the La Rioja control group, the estimate by ordinary least squares of δ_1 would serve to measure the effect of the Navarre reform of 2000. A positive and significant ratio indicates a positive and significant effect of the reform.

Table 28. Main statistics for the variables number of pharmacies and population, sample of municipalities with fewer than 15,000 inhabitants

	Mean	Standard deviation	Minimum	Maximum
Variable				
Number of pharmacies	0.68	1.05	0.00	14.00
Population (in thousands)	0.96	1.79	0.01	13.40

Source: prepared by the CNMC.

Table 29 shows the models estimated for the various samples by size of municipality. For the case of municipalities with fewer than 15,000 inhabitants, in specification (i) - without controlling for the population - the ratio of interest seems to indicate that the effect of the reform was to increase the average number of pharmacies in Navarre municipalities of fewer than 15,000 inhabitants by 0.32[137].

Controlling for population, the ratio remains practically unaltered - 0.31 - which indicates that the difference in averages after the reform is not associated with changes in the demographic characteristics of the municipalities.

As was to be expected, the model's explanatory capability increases considerably when the population is included, since this variable constitutes the main determinant of the number of pharmacies in a municipality.

As regards the parameters of the variables Navarre and post, in the specification without population they prove significant, and serve to provide information on the difference between the averages of the control group and the treatment group, as well as on the difference between the averages of each period. However, when controlling for population, these ratios become less significant, given the high explanatory capability of the population variable for the number of pharmacies in a municipality.

Based on the average number of pharmacies in Navarre municipalities with fewer than 15,000 inhabitants before the reform, the ratio of interest in the estimate with population - 0.31 - indicates an average increase of 50% in the period 2001-2003 compared with a scenario of no reform.

[137] We stress that the result is in average terms for all the municipalities.

Table 29. Results of the econometric estimation

	Municipalities < 15,000		Municipalities < 10,000		Municipalities < 5,000	
	(i)	(ii)	(i)	(ii)	(i)	(ii)
Constant	0,48 ***	0,15 ***	0,45 ***	0,18 ***	0,40 ***	0,17 ***
	(0,06)	(0,04)	(0,05)	(0,03)	(0,04)	(0,03)
Post	0,01 *	- 0,00	0,01 *	0,00	0,01 *	0,00
	(0,01)	(0,01)	(0,01)	(0,01)	(0,01)	(0,01)
Navarre	0,16 **	- 0,04	0,13 **	- 0,03	0,14 ***	- 0,04
	(0,07)	(0,05)	(0,06)	(0,04)	(0,05)	(0,04)
Post*Navarre	0,32 ***	0,31 ***	0,28 ***	0,27 ***	0,21 ***	0,20 ***
	(0,05)	(0,05)	(0,04)	(0,04)	(0,04)	(0,04)
Population		0,48 ***		0,43 ***		0,52 ***
		(0,04)		(0,02)		(0,03)
Number of obs.	878	878	870	870	844	844
R^2	0,04	0,71	0,05	0,64	0,05	0,55

Notes: (i) in all estimates, the dependent variable is the average number of pharmacies in the municipality; (ii) standard errors robust to heteroscedasticity in parentheses; (iii) * indicate that the ratio is significant to 10%, ** that the ratio is significant to 5% and *** that the ratio is significant to 1%.

Source: prepared by the CNMC.

The estimates for municipalities with fewer than 10,000 and fewer than 5,000 inhabitants show similar results. Controlling for population, the ratio of interest is 0.27 and 0.20 respectively. As in the previous case, when controlling for population, the results of the ratio in the difference-in-differences remain practically unchanged. In both cases the ratios of interest are significant.

In short, the difference-in-differences models estimated indicate a positive and significant effect of the reform on Navarre municipalities with fewer than 15,000, 10,000 and 5,000 inhabitants, confirming the preliminary conclusions of the descriptive analysis carried out in the previous section.

5. CONCLUSIONS

The special characteristics of the retail medicine distribution market, due to the nature of medicines, public health protection and the existence of market failures such as asymmetric information, explain public intervention in the market by means of regulation.

The CNMC is fully aware of the imperative need to protect the public interest as it relates to the safety of, and access to, medicines, which is inherent in the regulation of the retail distribution of medicines.

Therefore, regulation must be aimed at this objective based on the principles of necessity and proportionality, avoiding the introduction of unwarranted restrictions to competition that hinder or prevent the attainment of greater efficiency in the functioning of the market.

If public intervention conforms to the principles of efficient economic regulation, the same public health and efficiency objectives can be achieved at less social and economic cost.

Although the protection of public health is the main argument for regulating the pharmaceutical sector, regulation imposes a number of restrictions, both on market access and on the exercise of pharmacies' activity, which limit competition in the market and in many cases neither protect public health nor are justified from the point of view of efficiency.

In Spain, Law 16/1997 established some basic precepts for the organisation of the pharmaceutical sector, leaving it to the Autonomous Regions to establish the specific planning criteria, which must take into account the density, dispersion and geographical characteristics of the population, with a view to ensuring accessibility, quality of service and sufficient supply of medicines according to the healthcare needs of each territory. Having different models of pharmaceutical planning in the Autonomous Regions has allowed us to analyse the effect of the restrictions imposed by each model both on competition in the market and on the degree of attainment of the objective of ensuring the population's access to medicines.

We have seen that the model of access to the market adopted in all the Autonomous Regions with the exception of Navarre, which establishes the maximum number of authorised pharmacies per population module, is limiting the opening of pharmacies and impeding the existence of competition in many municipalities.

Moreover, this model is not necessary in order to ensure appropriate pharmaceutical care of the population, as demonstrated by the fact that in Navarre not only did

pharmaceutical coverage in small municipalities not diminish with the reform of 2000 but the reform had a positive effect on small municipalities, as shown by the quantitative analysis of the impact of the reform in section 4.2 of the study.

There are other elements restrictive of competition in the national and regional legislation which unnecessarily and/or disproportionately affect the exercise of the activity, ownership and organisation of pharmacies. These restrictive elements have been systematically analysed in this study, and to correct or mitigate them we now go on to propose a series of recommendations directed at the competent national and regional administrations.

6. RECOMMENDATIONS

The analysis of the retail medicine distribution sector in Spain carried out in this study has identified a number of restrictions to access and to the exercise of the activity which are inefficient and harmful to competition and to the general interest. Therefore, the following recommendations directed at the competent administrations at national and regional level are made.

FIRST. Greater freedom of access to the market

Law 16/1997 establishes some requirements for the authorisation of the opening of new pharmacies, based on population modules and distances between pharmacies, which have been adopted, with minor variations, by all the Autonomous Regions except Navarre.

The model adopted in Navarre in 2000, based on minimums, not only favours competition in small municipalities but also ensures pharmaceutical coverage that is similar to, or greater than, that existing in other Autonomous Regions with regulations that are much more restrictive to competition.

The analysis of competition in the market and of the impact of the reform in Navarre shows that **pharmaceutical planning should determine the minimum number of pharmacies required in each pharmaceutical zone to ensure appropriate pharmaceutical care** (Navarre) instead of the maximum number of pharmacies depending on the population of each zone (all other Autonomous Regions).

Moreover, the experience of liberalisation in some European countries shows that **the protection of public health and appropriate geographical coverage of pharmaceutical services are compatible with competition in this market**.

For these reasons, **it is recommended to eliminate the restrictions on access to the market: population modules and mandatory minimum distances, whether between pharmacies or between pharmacies and healthcare centres.**

In order to ensure appropriate pharmaceutical coverage in rural and isolated zones, it is recommended to the adopt similar mechanisms to those adopted in other European countries, in the form of subsidies or tax incentives for rural pharmacies, or assessing the possibility of doctors dispensing medicines in certain rural zones where the opening of a pharmacy is not economically viable, establishing appropriate mechanisms to eliminate economic incentives that might lead to an increase in healthcare expenditure.

SECOND. Greater freedom in the exercise of the activity

Article 3 of the Consolidated Text establishes that the custody, conservation and dispensing of medicines for human use is reserved exclusively to pharmacies open to the public, legally authorised, and to the pharmacy departments of hospitals, healthcare centres and primary care structures of the National Health System.

The reservation of activity concerning the safekeeping, conservation and dispensing of medicines to pharmacies constitutes a restriction to competition, since it limits the channels of distribution of medicines to pharmacies.

Having analysed this restriction from the point of view of the principles of necessity and proportionality, for OTC medicines it is recommended to eliminate the reservation of activity to pharmacies as regards dispensing. It is also recommended to allow the sale of these medicines in other establishments, provided that they comply with a number of mandatory minimum health requirements of conservation and hygiene; the desirability of the involvement of a competent technician might also be considered.

Royal Decree 870/2013 regulates the sale of medicines not subject to medical prescription via websites of pharmacies open to the public and legally authorised.

As with the sale of medicines in physical establishments, the reservation of activity to pharmacies as regards the sale of OTC medicines online is an unnecessary and disproportionate mean of ensuring the protection of public health.

Concerning prescription drugs, it is recommended to extend the cases in which they can be dispensed to specialised establishments (hospitals and healthcare centres), provided that they meet the necessary technical conditions for conserving the medicines in optimal state for consumption and they can count on the advice of a

competent technician who meets the training requirements set forth in Directive 2005/36/EC.

Furthermore, it is recommended to propose the extension of the relevant diplomas to other competent technicians who, in light of the professions authorised in other EU countries[138], have the necessary training for dispensing medicines in Spain, fully respecting the protected reasons of imperative general interest.

Moreover, allowing the online sale of prescription drugs is recommended, with the essential requirement that the medicines are dispensed by a competent technician who ensures the public interests affected, without necessarily being the owner of the website or of a physical pharmacy.

In line with the foregoing recommendations, it is proposed to remove entirely the limit (currently 10%) on discounts of prices of OTC medicines advertised to the public.

This limit on discounts restricts the potential benefits to patients deriving from price competition and from liberalising the sales channels for OTC medicines.

Also, in line with the reduction in administrative burdens, the elimination of the requirement to report the price of OTC medicines to the Ministry of Health, Social Services and Equality is recommended, to avoid the maximum price established by the Ministry acting as a reference price and hindering price competition in this segment of the market; appropriate statistical techniques can be used to obtain such price information as may be considered of interest to the administration.

THIRD. Greater freedom of ownership of pharmacies

Article 103.4 of Law 14/1986, of 25 April, the General Health Act, establishes that only pharmacists can be owners and owner-operators of pharmacies open to the public.

This restriction is not justified by healthcare reasons, since the presence of a pharmacist in dispensing medicines already provides appropriate protection of public health. This restriction constitutes a barrier to market entry for agents with resources and knowledge to invest but lacking the status of pharmacist.

[138] In the U.K. and the Netherlands “pharmacy technicians” are allowed to dispense prescription drugs. In the case of the U.K., the qualification required is National Vocational Qualification level 3 (post-secondary), and in the Netherlands the requirement is for three years of experience in dispensing medicines under the direct supervision of a pharmacist (Göeg FP (2012)).

Therefore, it is proposed to eliminate the rules establishing the requirement for owners and operators of pharmacies to be pharmacy graduates exclusively, so as to allow freedom of ownership of pharmacies at least similar to that allowed by current legislation on the ownership of private hospitals.

Also, in Spain, the ownership and operation of pharmacies is limited to a single pharmacy, which impedes horizontal integration (the ownership of two or more pharmacies) and the forming of pharmacy chains, with the consequent harm to the efficiency of the system.

The free formation of pharmaceutical chains allows optimisation of resources and the assumption of shared risk which would otherwise be impracticable. From the point of view of efficiency, the economies of scale deriving from the greater size of pharmacies allow reductions in the distribution, storage and administration costs of medicines.

Current legislation also prohibits vertical integration of pharmacies with pharmaceutical manufacturers and/or wholesale distributors, in accordance with Article 4 of the Consolidated Text.

Vertical integration of the various activities in the medicine chain could generate gains in efficiency deriving from economies of scale and scope among these activities.

The elimination of this prohibition, together with the functioning of the free market and the competition authority's existing control mechanisms would allow greater efficiency in the pharmaceutical sector, which could result in better quality, more innovation, lower costs and, therefore, lower public expenditure for the State and lower costs for patients and consumers.

Freedom to own more than one pharmacy and eliminating the restriction on vertical integration of pharmacies, by amending the corresponding legislation, are recommended.

FOURTH. Increased efficiency in the remuneration of pharmacies for dispensing medicines

The margin obtained by pharmacies for dispensing medicines is proportional to the retail price before tax if the price is below a certain amount. Once that price is reached, the margin is a fixed amount which increases in bands as the price of the medicine increases.

If the purpose of pharmacies' margin is to remunerate the provision of pharmaceutical care services, it is questionable that it is proportional to the price of the medicine, the quality of service being, therefore, independent of this price.

Alternative financing systems to that in force should be studied - systems in which there is an effective correspondence between the services provided by the pharmacies and the remuneration received by them, and in particular systems that provide incentives to improve the quality of the services offered or that remunerate additional services that might be of particular benefit to patients.

FIFTH. Greater freedom as regards pharmacies' opening hours

Article 6 of Law 16/1997 establishes that pharmacies will provide their services freely and flexibly, without prejudice to compliance with official opening hours and rules on on-call duties, holidays, emergencies and other circumstances deriving from the nature of their service established by the Autonomous Regions with the purpose of ensuring continuity of care.

There are certain aspects in the rules on pharmacies' opening hours that are incompatible with the principles of freedom and flexibility in pharmacies' provision of services, which is detrimental to competition and consequently to patients and to the sector itself.

In particular, the possibilities of extending the hours beyond the minimum are unjustifiably restricted in that they have to conform to a number of fixed modules, during a minimum period of one year. This limits pharmacies' freedom of organisation and constitutes a factor restrictive of competition.

Having ensured the appropriate pharmaceutical care of the population with minimum opening hours and the on-call duty, it is proposed to eliminate the regulatory and administrative obstacles that prevent pharmacies from voluntarily extending their opening hours should they wish to do so.

SIXTH. Greater freedom of advertising for pharmacies

The specific prohibition on advertising of pharmacies has been incorporated either in the laws on the organisation of the pharmaceutical sector or in the specific legislation of the Autonomous Regions.

The advertising of medicines and healthcare products is regulated in the Consolidated Text and is subject to a number of requirements that ensure the

protection of patients' health, so the prohibition of pharmacies' advertising is not justified by reasons of public health. The prohibition prevents pharmacies from being able to use advertising to differentiate their services and constitutes an additional obstacle to competition.

It is proposed to remove the prohibition on advertising by pharmacies, provided that such advertising conforms to the provisions of Article 44 of Law 44/2003, of 21 November, on the organisation of the healthcare professions.

SEVENTH. Pro-competitive revision of the criteria for granting administrative authorisations for the opening of pharmacies

Article 3 of Law 16/1997 determines that it is for the Autonomous Regions to process and resolve applications for authorisation to open pharmacies which will be processed in accordance with the principles of openness and transparency, subject to prior specific procedures to be established by the Autonomous Regions.

Restrictions deriving from some criteria included in competitive examinations for the granting of the administrative authorisation necessary for opening new pharmacies have been identified. They not only constitute barriers to market entry for recent pharmacy graduates but also, in some cases, introduce criteria that are not in accordance with the aim of ensuring appropriate pharmaceutical care.

It is recommended that the Autonomous Regions dispense those requirements contained in the competitive examinations that unnecessarily restrict competition and do not strictly relate to healthcare criteria.

EIGHTH. Maintaining and promoting competition in the supply of medicines to social healthcare centres

The supply of medicines to social healthcare centres via pharmacies was studied by the former CNC, which declared that a practice previously followed by the Castile-La Mancha Health Service (SESCAM) in collaboration with the Council of the Official Associations of Pharmacists of Castile-La Mancha was restrictive of competition. The practice consisted in the establishment of rotating turns among pharmacies for the supply of medicines to healthcare centres, thus establishing market sharing.

Recently, the CNMC has expressed its opposition to the amendment to the Law on the Organisation of the Pharmaceutical Service of Castile-La Mancha, which

envisages the requirement for stocks of medicines of private social healthcare centres to be supplied by local pharmacies.

It is recommended that the Autonomous Regions eliminate such restrictions to competition in the supply of social healthcare medicines as they do not strictly relate to healthcare criteria.

NINTH. Elimination of the mandatory affiliation of owner-operators and contracted pharmacists in pharmacies

The requirement for mandatory affiliation in order to practise as a pharmacist in a pharmacy or to own a pharmacy is included explicitly in the laws on the organisation of the pharmaceutical sector or some regional regulations developing them.

This provision is considered unnecessary for the performance of the functions of the pharmacist and it imposes an unnecessary cost which translates into a barrier to market entry.

It is proposed to eliminate the requirements for membership of an association for holders and pharmacists in pharmacies by means of the corresponding legislative amendments.

TENTH. Elimination of the reservation of activity to the Official Associations of Pharmacists in certain economic services in the retail dispensing of medicines

At present, the Official Associations of Pharmacists act as intermediaries between the pharmacies and the NHS for invoicing and collecting amounts relating to medicines included on the reimbursement list of the National Health System, through agreements signed with the Health Departments of the Autonomous Regions.

The gradual introduction of electronic prescriptions and pharmacies' necessary adaptation by adopting information technologies represent a potential saving on transaction costs deriving from the improved handling and collection of prescriptions in individualised form.

For this reason, it is recommended to eliminate the exclusive right of the Official Associations of Pharmacists to invoice and collect prescriptions.

APPENDIX: EUROPEAN COMPARISON

The majority of European countries establish restrictions on the location and number of pharmacies, and in some countries there are also restrictions on the ownership of pharmacies, while in others pharmacies have a monopoly on the dispensing of OTC medicines.

Of the 27 European countries for which information is available, only 13 (Bulgaria, Cyprus, the Czech Republic, Germany, Ireland, Lithuania, Malta, the Netherlands, Norway, Poland, Romania, Sweden and the U.K.[139]) do not impose restrictions on the location of new pharmacies. In the remaining countries, there are restrictions either of a demographic nature (minimum population required for the opening of a new pharmacy) or of a geographical nature (minimum distance between pharmacies) or both.

	RESTRICTIONS ON THE OPENING OF PHARMACIES IN EUROPE, 2013	
COUNTRY	Demographic restrictions	Geographic restrictions
Germany		
Austria	X	X
Belgium	X	
Bulgaria		
Cyprus		
Denmark	X	
Slovak Republic	X	X
Spain	X	X
Estonia	X	X
Finland	X	
France	X	
Greece	X	X
Netherlands		
Hungary	X	X
Ireland		
Italy	X	X
Latvia	X	
Lithuania		
Luxembourg	X	
Malta		
Norway		
Poland		
Portugal	X	X
United Kingdom		
Czech Republic		
Romania		
Sweden		

[139] Although the U.K. has never applied legal requirements to the opening of new pharmacies, controls on entry for pharmacies that dispense medicines financed by the NHS have been in place since 2005 (following the report of the OFT in 2003) when four categories of pharmacies exempt from these controls were established. In September 2012, the controls on entry were partly introduced with the elimination of three of the four categories of exempt pharmacies.

As regards restrictions on the ownership of pharmacies, only pharmacists can be owners of pharmacies in ten countries (among them Spain) out of the 25 considered in the analysis. In 21 European countries, a pharmacist is allowed to own more than one pharmacy. In Spain, Greece, Italy and Luxembourg this is not allowed. Vertical integration of pharmacies with manufacturers and/or wholesale distributors is allowed in ten of the 25 European countries for which information is available, as shown in the following table.

	RESTRICTIONS ON OWNERSHIP OF PHARMACIES IN EUROPE		
COUNTRY	Only pharmacists	Ownership of more than one pharmacy allowed	Vertical integration allowed
Germany	X	X	
Austria		X	X
Belgium		X	X
Cyprus	X	X	
Denmark	X	X	
Slovak Republic		X	
Spain	X		
Estonia		X	
Finland	X	X	
France	X	X	
Greece	X		
Netherlands		X	X
Hungary		X	
Ireland		X	X
Italy	X		
Latvia	X	X	X
Lithuania		X	
Luxembourg	X		
Malta		X	X
Norway		X	X
Poland		X	X
Portugal		X	
United Kingdom		X	X
Czech Republic		X	
Sweden		X	X

Source: Ecorys (2007), CGCOF (2007) and Vogler et al. (2014).

As regards the reservation of activity to pharmacies for the dispensing of OTC drugs, it exists in 11 of the 27 countries considered in the analysis, while in the remaining 16 countries OTC medicines may be acquired either in specific dispensaries, as is the case of Austria, Portugal and Finland, or in other establishments such as supermarkets, grocery stores, drugstores and filling stations (Germany, U.K., Ireland and the Netherlands, among others).

	PHYSICAL SALE OF OTC MEDICINES IN EUROPE, 2013	
COUNTRY	Monopoly of pharmacies	Sale in other establishments
Germany		X
Austria		X
Belgium	X	
Bulgaria		X
Cyprus	X	
Denmark		X
Slovak Republic	X	
Spain	X	
Estonia	X	
Finland		X
France	X	
Greece	X	
Netherlands		X
Hungary		X
Ireland		X
Italy		X
Latvia	X	
Lithuania	X	
Luxembourg	X	
Malta	X	
Norway		X
Poland		X
Portugal		X
United Kingdom		X
Czech Republic		X
Romania		X
Sweden		X
Switzerland		X

Source: Vogler (2014).

In the past few years there have been significant changes in the regulation of pharmacies in several European countries, by means of processes of deregulation or liberalisation, which have affected, inter alia, the restrictions on access to the market, on ownership and on the exercise of the pharmacies' activity of dispensing medicines as previously described.

In countries with a regulated sector, as is the case of Spain, Greece and Luxembourg, there are restrictions on the establishment of new pharmacies based on demographic and/or geographical criteria, ownership is reserved to pharmacists and the forming of pharmacy chains is not permitted.

Liberalisation in the pharmacies sector is characterised generally by one or more of the following components[140]:

- Liberalisation of establishment of new pharmacies (no requirements for the establishment of new pharmacies in Germany, Ireland, the Netherlands, Norway, Sweden or the U.K., among others).
- Liberalisation of ownership of pharmacies (removal of requirement for mandatory affiliation of the owner/operator of the pharmacy, possibility of vertical integration with wholesalers or manufacturers and possibility of multi-ownership):
  - The requirement for mandatory affiliation for owners of pharmacies exists in countries with a regulated sector such as Austria and Spain.
  - Although any individual or legal entity can own a pharmacy in countries with a liberalised sector, some of these countries exclude specific agents from the ownership of pharmacies:
    - Iceland, Ireland, Norway and Sweden do not allow doctors to own pharmacies, due to possible conflicts of interest between the activities of prescription and dispensing of medicines.
    - In Iceland, Norway and Sweden, pharmaceutical manufacturers are not allowed to have pharmacies.
  - Multi-ownership is a characteristic of countries that have liberalised the pharmaceutical sector, and is not permitted in countries with a regulated sector:
    - The establishment of pharmacy chains is a phenomenon seen following liberalisation, and the number of pharmacies belonging to a single chain

[140] See Vogler (2014).

varies among countries with a liberalised sector (in the U.K. the biggest pharmacy comprises 2,000 pharmacies (18% of the total), the second biggest has approximately 1,400 pharmacies (13% of the total) and the nine next biggest chains have between 100 and 500 pharmacies each).

  - Limits on the number of pharmacies in a single chain are possible although rare (in Norway, the number of pharmacies in a chain may not exceed 40% of the total, following the intervention of the Competition Authority after a single group acquired more than 80% of the total number of pharmacies after liberalisation).

- Liberalisation of the sale of OTC medicines in establishments other than pharmacies.
  - A trend seen in the past few decades, even in some countries with a regulated pharmaceutical sector.
  - In 11 of the 27 European countries considered in the analysis the pharmacies have a monopoly on the sale of OTC medicines.
  - Although 16 European countries allow the sale of OTC medicines other than in pharmacies, the number of OTC medicines allowed varies among these countries.

In some countries such as the U.K., Ireland and the Netherlands deregulation processes have recently been carried out in this already fairly liberalised sector, while others such as Norway and Sweden have seen a rapid transition from a regulated to a liberalised system.

The main characteristics of the processes of deregulation or liberalisation of pharmacies in these countries are described hereunder:

- U.K.: the system known as “control of entry test”, which restricts entry to the market to pharmacies that provide pharmaceutical services financed by the State and, in particular, pharmacies that dispense medicines financed by the NHS (National Health System), was completely overhauled in 2005 and four exemptions to this control of entry were introduced. In that year a new contractual framework was introduced between the NHS and the pharmacies, distinguishing the different services provided by the latter (essential, advanced and local).
- Ireland: this country introduced restrictions on market entry based on demographic and geographical criteria in 1996, and these were abolished in

2002, following a recommendation in a report by the OECD[141]. Online sale of medicines not subject to medical prescription has been allowed since 2006.

- The Netherlands: horizontal integration of pharmacies allowing the formation of pharmacy chains is permitted since 1987. Although there have never been any legal requirements for the establishment of new pharmacies, the association of pharmacists applied certain restrictions which were prohibited by the Competition Law of 1998.
- Norway: restrictions on access and ownership of pharmacies were abolished in 2001 and since then horizontal and vertical integration of pharmacies have been allowed. Since 2003 the sale of a limited number of OTC medicines in establishments other than pharmacies has been permitted.
- Sweden: in 2009 Sweden abolished the monopoly of the state-owned enterprise *Apoteket AB* which had owned all the country's pharmacies. Since then private legal or natural persons as well as *Apoteket AB* have been allowed to own pharmacies and the forming of pharmacy chains has been allowed. Sweden also allows the sale of OTC medicines in establishments other than pharmacies.

One of the objectives of liberalising the establishment of pharmacies is to improve the population's access to medicines, which is achieved with the increase in the number of pharmacies after the liberalisation and has been observed in countries such as Norway and Sweden. Moreover, the liberalisation process also leads to the opening of establishments for the sale of OTC medicines. (It is estimated that there are 8,000 establishments selling OTC medicines in the Netherlands and 6,000 in Norway).

However, we see that the new pharmacies are concentrated in urban zones and none or very few set up in rural municipalities that already have one pharmacy (this phenomenon has been observed in Sweden and the U.K., for example).

The concentration in urban zones is also seen in establishments for the sale of OTC medicines (in Sweden, only 4% of new establishments for the sale of OTC medicines opened in localities with fewer than 200 inhabitants).

To ensure appropriate pharmaceutical coverage in rural zones, these countries have implemented policies to avoid the closure of pharmacies by putting financial incentives in place.

[141] OECD (2001), "Regulatory Reform in Ireland. Regulatory Reform in Electricity, Gas, Pharmacies, and Legal Services", Organisation for Economic Co-operation and Development, 2001.

In the U.K., rural pharmacies receive subsidies through the "Essential Small Pharmacy Local Pharmaceutical Services Scheme (ESP LPS)", while in Denmark the "Tax Equalisation Scheme" exists to finance rural pharmacies and in Norway there is an agreement between the State and the pharmacy chains that if a pharmacy in a rural area closes, the pharmacy chain has to take control of the establishment and open a new pharmacy there.

Eliminating restrictions on the establishment of pharmacies also has positive effects on the quality of services provided by them, since these restrictions limit the entry of pharmacies to the market and create local monopolies. In this regard, the study of the Office of Fair Trading (OFT (2003)) showed that, in the case of U.K., the pharmacies with the most extensive hours were those nearest to the healthcare centres and those faced with a larger number of competitors per health centre in their locality; the probability of having a consulting space in the pharmacy increased with the number of pharmacies in supermarkets within the locality; and when a pharmacy had no other pharmacy within five kilometres, it was less likely that it would offer a home delivery service.

BIBLIOGRAPHY

Abadie, A. y J. Gardeazabal (2003): "The Economic Costs of Conflict: A Case Study of the Basque Country", *American Economic Review*, 93(1): 113-132.

Abadie, A., A. Diamond y J. Hainmueller (2010): "Synthetic Control Methods for Comparative Case Studies: Estimating the Effect of California's Tobacco Control Program", *Journal of the American Statistical Association*, V.105, Issue 490, 2010.

Abadie, A., A. Diamond y J. Hainmueller (2012): "Synth: An R Package for Synthetic Control Methods in Comparative Case Studies", *Journal of Statistical Software*, June 2011, V. 42, Issue 13.

Abadie, A., A. Diamond y J. Hainmueller (2014): "Comparative Politics and the Synthetic Control Method", *American Journal of Political Science*, 59 (2), pp. 495-510.

Abdallah, C. S. y W. D. Lastrapes (2012), "Home Equity Lending and Retail Spending: Evidence from a Natural Experiment in Texas" *American Economic Journal: Macroeconomics*, 4(4): pp. 94-125.

Acemoglu D., S. Johnson, A. Kermani, J. Kwak y T. Mitton (2013), "The Value of Connections in Turbulent Times: Evidence from the United States", NBER Working Paper No. 19701.

Angrist, J. D., y A. B. Krueger (1999), "Empirical Strategies in Labor Economics," *Handbook of Labor Economics*, Vol.3, (eds.) A. Ashenfelterand y D. Card.

Berndt, E. R., L. Bui, D. R. Reiley, G. L. Urban (1995), Information, Marketing, and Pricing in the U.S. Antiulcer Drug Market. *American Economic Review* 85 (2), pp.100–105.

Bertrand, M., E. Duflo y S. Mullainathan (2004), "How Much Should We Trust Differences-in-Differences Estimates?", *Quarterly Journal of Economics*, 119 (1), 249–275.

Billmeier A. y T. Nanncini (2013), "Assessing Economic Liberalization Episodes: A Synthetic Control Approach", *Review of Economics and Statistics*, July 2013, Vol. 95, No. 3, pp. 983-1001.

Bohn S., M. Lofstrom y S. Raphael (2014), "Did the 2007 Legal Arizona Workers Act Reduce the State's Unauthorized Immigrant Population?" *Review of Economics and Statistics*, Vol. 96, No. 2, pp. 258-269.

Borrell, J.R. y C. Cassó (2011), "Welfare and geographic entry policies", mimeo.

Borrell J. R. y L. Fernández-Villadangos (2009), "Assessing excess profits from different entry regulations", Document de Treball 2009-3, Xarxa de Referència en Economía Aplicada.

Borrell J. R. y L. Fernández-Villadangos (2011), "Clustering or scattering: the underlying reason for regulating distance among retail outlets", Document de Treball XREAP 2010-12, Xarxa de Referencia en Economia Aplicada.

Borrell, J.R. y C. Padrós (2007), "Competencia, regulación y oficinas de farmacia en la Comunidad Autónoma de Euskadi", Informe jurídico-económico y de competencia, Gobierno Vasco.

Bresnahan T. F. y P.C. Reiss (1990), "Entry in Monopoly Markets", *The Review of Economic Studies*, 57(4), 531-53.

Card, D (1992), "Using regional variation in wages to measure the effects of the federal minimum wage," *Industrial and Labor Relations Review*, ILR Review, Cornell University, ILR School, vol. 46(1), pp 22-37, October.

Card, D. (1990), "The Impact of the Mariel Boatlift on the Miami Labor Market", *Industrial and Labor Relations Review*, Vol. 43, No. 2. (Jan., 1990), pp. 245-257.

Card, D. y A. B. Krueger (1994), "Minimum Wages and Employment: A Case Study of the Fast-Food Industry in New Jersey and Pennsylvania", American Economic Review, 84, pp. 772–793.

Dudley, J.W. (2012), "Can e-commerce in Healthcare Succeed? Developments in Mail Order and Internet Pharmacy in Europe".

CGCOF (2013), "La distribución de la Farmacia en España", Consejo General de Colegios Oficiales de Farmacéuticos.

CGCOF (2007), "Modelos de Farmacia en la Unión Europea", Consejo General de Colegios Oficiales de Farmacéuticos.

ECORYS (2007), "Study of regulatory restrictions in the field of pharmacies", Comisión Europea, Internal Market and Services DG.

Farmaindustria (2014), "El mercado del medicamento en España", Boletín de Coyuntura Nº 115, noviembre 2014.

FEDIFAR (2013), "Análisis sectorial de la distribución farmacéutica en España", Federación de Distribuidores Farmacéuticos, Madrid, octubre 2013.

García-Fontes, W. y M. Motta **(**1997), "Regulación de las oficinas de farmacia: precios y libertad de entrada", en López Casanovas, G., Rodríguez Palenzuela, D. coordinadores: *La regulación de los servicios sanitarios en España,* Ed. Cívitas, Madrid. Cap. IX, pp. 325-347.

GÖG FP (2012), “Impact of pharmacy deregulation and regulation in European countries”, Commissioned by Danmarks Apotekerforening (Association of Danish Pharmacies).

Imbens, G. W. y J. M Wooldridge (2009), "Recent Developments in the Econometrics of Program Evaluation." *Journal of Economic Literature*, 47(1): pp.5-86.

Jansson, E. (1999), “Libre competencia frente a regulación en la distribución minorista de medicamentos”, *Revista de Economía Aplicada*, 19, 85-112.

Kaiser, B., y C. Schmid (2013), “Does physician dispensing increase drug expenditures?”, Discussion Papers No. 13-03, Department of Economics, Universität Bern.

Lobo, F. (2015), “Políticas actuales de precios de medicamentos en Europa: panorama general”, Springer Healthcare, Madrid 2015.

Lobo, F. (2014), “La intervención de precios de los medicamentos en España: panorama de la regulación y los estudios empíricos”, Springer Healthcare, Madrid 2014.

Lluch M. y P. Kanavos (2010), “Impact of regulation of Community Pharmacies on efficiency, access and equity. Evidence from the UK and Spain”, *Health Policy* 95 (2010), pp. 245–254.

Meneu, R. (2006), “La distribución y dispensación de medicamentos”, *Gaceta Sanitaria* Vol. 20, pp. 154-159.

Meyer, B. D (1995), “Natural and Quasi-Experiments in Economics”, *Journal of Business & Economic Statistics* Vol. 13, No. 2, JBES Symposium on Program and Policy Evaluation (Apr., 1995), pp. 151-161.

ÖBIG (2006), “Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States”, Comisión Europea, DG-Competition.

OECD (2001), “Regulatory Reform in Ireland: The Role of Competition Policy in Regulatory Reform”.

OCDE (2002), “Competition and Regulation Issues in the Pharmaceutical Industry”, OECD Journal of Competition Law and Policy Vol.4, No. 3.

OFT (2003), “The Control of Entry Regulations and Retail Pharmacy Services in the UK”, Office of Fair Trading.

OFT (2010), “Evaluating the impact of the 2003 OFT study on the Control of Entry regulations in the retail pharmacies market”, Office of Fair Trading.

OMC (2014), “Informe sobre el sector farmacéutico”, Organización Médica Colegial, Madrid, octubre de 2014.

Padrós, C., J.R. Borrell y L. Fernández-Villadangos (2008), "Restricciones al libre establecimiento de farmacias: lecciones de las recientes sentencias del TJCE y de la experimentación autonómica", *Anuario de la Competencia* Nº 1, pp. 173-206.

PGEU (2014), Annual Report, Pharmaceutical Group of the European Union.

Popper, K. R. (1959): *The Logic of Scientific Discovery*, Hutchinson & Co, London.

Scott Morton, F. y M. Kyle (2012), "Markets for Pharmaceutical Products", *Handbook of Health Economics*, Volume 2, 2012 Elsevier B.V.

Schaumans, C. y Verboven F. (2008), "Entry and regulation: evidence from health care professions" *The RAND Journal of Economics*, Volume 39, Issue 4, pp. 949–972.

Scherer, F.M. (2000), "The Pharmaceutical Industry", *Handbook of Health Economics*, Volume 1B, 2000 Elsevier B.V.

Vogler S. (2014), "Liberalization in the Pharmacy Sector", Competition Issues in the Distribution of Pharmaceuticals, OECD contribution (2014).

Vogler S., Habimana K. y Arts D. (2014), "Does deregulation in community pharmacy impact accessibility of medicines, quality of pharmacy services and costs? Evidence from nine European countries", *Health Policy* 117 (2014), pp. 311–327.

Wooldridge, J. M. (2002), *Econometric Analysis of Cross Section and Panel Data*, Massachusetts Institute of Technology.

CNMC

COMISIÓN NACIONAL DE LOS MERCADOS Y LA COMPETENCIA

www.cnmc.es