

Pricing

Table 8 Price control

What price?	What regulation?	Who regulates?
Price of prescription drugs	Maximum prices (1) (+) (+) To be changed according to the draft law, introducing fixed prices.	Government (Pricing Bill)
Price of OTC drugs	Maximum prices (1)	Government (Pricing Bill)
Profit margin	Maximum margins (1) (+) (+) To be changed according to the draft law, introducing fixed profit margins.	Government (Health Bill)

Source: (1) ECORYS questionnaire (2006)

Other

Recent reforms:

2000 - Ownership of community pharmacies no more limited to pharmacists only

2001 - Deregulation of the monopoly

2004 - Limiting the number of pharmacists to support economic performance of individually-owned pharmacies; chain companies can own up to 1% of community pharmacies, chain companies are reluctant to cooperate with the Chambers

References

- Pharmaceutical Law of 06/09/2001 and Law on Pharmaceutical Chambers of 19/04/1991;
- Law of 27/07/2002 on amendment of the Law on Pharmaceutical Chambers and Pharmaceutical Law;
- Data from the European Commission;
- ECORYS questionnaire.

http://ec.europa.eu/internal_market/services/docs/pharmacy/appendices_en.pdf

6.20 Portugal

6.20.1 Narrative description

Portugal is somewhat restrictive in its regulatory framework, both on conduct as well as on entry regulation. The regulatory framework consists of an extensive collection of Acts and Decrees.

Educational requirements are laid down in the Pharmaceutical Act (Decree-Law 288/2001). Also requirements to register, to obtain a licence and to become member of the professional association are laid down in this Act.

The scope of the professional monopoly is determined by a set of laws:

- Decree-Law 48547 of 27th August 1968, Articles 29 and 97;
- Decree-Law 134/2005, 16th August;
- Governmental Decree 827/2005, 14th September;
- Governmental Decree 367/72, 3rd July, as amended;
- Decree-Law 320/99, 11th August.

Ownership and changes in ownership are subject to Law 2125 (1965) and Decree-Law 48547 (1968). The establishment of pharmacies is legally organised through criteria set by Governmental Decree 936-A/99.

Cooperation of pharmacies with other professions, the design of the practice, the presence of a pharmacist, the required stock and requirements with respect to product/service differentiation are all subject to Decree-Law 48547 (1968) with some additional Decrees and amendments (see Overview, below).

Opening hours are restricted by Governmental-Decree 256/81, amended by Governmental Decrees 91/82, 361/82, 792/91 and 146/96.

Prices of prescription drugs and profit margins are set by decision of the Ministry of Health.

Entry regulation

In Portugal the duration of education is 5.5 years, of which 6 months consist of compulsory practice. The annual number of students who begin a course of academic study to become pharmacists is limited to about 900. Community pharmacists are required to register, obtain a licence and become members of the professional association.

Only community pharmacists are allowed to dispense prescription drugs to the public. Druggists may also dispense OTC drugs to the public. The number of pharmacy outlets is restricted by a minimum number of customers (4000), geographical requirements (500 metres - distance between pharmacies) and by a minimum distance of 100 metres between a pharmacy and healthcare centre or hospital.

Ownership of a pharmacy is restricted to pharmacists only, and there is a limited number of branches or a limited number of branches in which the owner may hold a majority stake. Only after a number of years may the ownership of a specific pharmacy change. The possible business form of a pharmacy is not restricted.

Barriers for pharmacists from other EU countries exist in the form of language requirements.

Conduct regulation

A pharmacist may form a not partnership or merge with other pharmacists, druggists, wholesalers, insurance companies or general practitioners.

Opening hours are subjected to a maximum level. Issues such as floor space, advertising, outdoor and indoor signs and storage space are subjected to regulation. The presence of a pharmacist is required at all times.

The sale of non-pharmaceutical products is allowed to a limited extent. Pharmacists are allowed to provide diagnostic services, such as measuring blood sugar or blood pressure, etc. Internet pharmacies are not allowed.

Price regulation

Prices of prescription drugs are subjected to a maximum level. Prices of OTC drugs are unregulated. Profit margins are fixed per medicine by an absolute margin.

6.20.2 Data

Table 1 National data on the Pharmacy market

	Value	Additional remarks
Total number of community pharmacy outlets (i.e. number of locations)	2,671 2,684	Date: June 2006 2004
Number of inhabitants per community pharmacy	2,806	Date: Population size as per 1/1/2005 10,529,300 (Eurostat)
Total number of community pharmacists	5,752	Date: June 2006
Total number of employees	13,318	2004
Total number of hospital pharmacists	790	Date: June 2006
Total number of hospital pharmacists that are allowed to dispense prescription drugs to the public	0	Hospital pharmacies do not dispense medicines to the general public. Hospital pharmacies dispense medicines to out-patients, who have specific illnesses (e.g. cancer, HIV) that are treated in those hospitals. Therefore, hospital pharmacists of those hospitals are
		only allowed to dispense these medicines to those specific patients.
Total number of other pharmacists (e.g. those in industry, research, education, etc.)	3,793	Date: June 2006
Total number of other pharmacists that are allowed to dispense prescription drugs to the public	0	Dispensary to the general public is prohibited to community pharmacists.

	Value	Additional remarks
Total number of non-pharmacists that are allowed to dispense prescription drugs to the public (e.g. general practitioners, veterinarians, etc.)	0	Dispensary to the general public is by community pharmacists is prohibited.
Total number of registered community pharmacists	5,752	Date: June 2006
Total number of community pharmacists with membership of a professional association	5,752	Date: June 2006
Percentage share of community pharmacist that are members of the professional association(s)	100%	Membership of the Ordem dos Farmacêuticos is compulsory.
Annual total number of people who begin a course of academic study to become pharmacists (on average between 2000 and 2005)	750	
Annual total number of people who successfully finished the course of academic study to become pharmacists (on average between 2000 and 2005)	478* or 516	Depending on the source used * Average between 2000 and 2004
Average turnover per community pharmacy outlet	964,344	
Average operating result per community pharmacy outlet	113,227	

Source: ECORYS questionnaire (2006), Eurostat

6.20.3 Overview

Education

Table 2 Educational requirements

	Scope	What law/regulation?
Degree and duration	<p>Bachelor's degree + Master's degree: 5.5 years Compulsory practice: 6 months</p> <p>Compulsory practice included in Bachelor's degree + Master's degree.</p> <p>Location requirements: community pharmacy (4 months) and hospital pharmacy (2 months).</p>	
Limitation on the number of students	<p>Yes</p> <p>Phase: Master's degree</p> <p>Number: 889 (in 2006), 580 (in 2005)¹³⁴</p> <p>Limitation: <i>numerus fixus</i> and <i>numerus clausus</i>.</p>	
Continuous training	<p>Obligatory</p> <p>Enforced (+)</p> <p>Approximately 24 hours/year average (*)</p> <p>Continuous training is conducted by the Pharmaceutical Society (<i>Ordem dos Farmacêuticos</i>).</p> <p>(+)The educational activities undertaken are converted into Professional Development Credits (<i>Créditos de Desenvolvimento Profissional, CPD</i>). The earning of training credits is mandatory for the renewal of the registration/membership.</p>	<p>Qualification of <i>Ordem dos Farmacêuticos</i> (internal regulation)</p>

¹³⁴ The difference between 2005 and 2006 is also due to the lower number of universities that offered the curriculum. The amounts of universities were, respectively, 5 public- and 4 private universities in 2006, against only 3 public universities in 2005.

	Scope	What law/regulation?
	(*) For renewal, one should at least earn 15 CDP points (<i>Créditos de Desenvolvimento Profissional, CPD</i>) during registration, i.e. within 5 years. There is no direct relation between the number of training hours completed and CDPs. (1)	

Source: (1) ECORYS questionnaire (2006), (2) website FIP, (3) Ministry for Technology, Science and Higher Education (www.acessoensinosuperior.pt)

Registration, licensing and membership of professional organisation(s)

Table 3 Registration, licensing and membership of a professional body

	Type	Scope	What law/regulation?
Registration, licensing or membership of a regulatory body	Is it required?	Yes, - registration with the Ordem dos Farmacêuticos - registration with the National Institute of Medicines and Pharmacy (Infarmed) (*) - licence from the National Institute of Medicines and Pharmacy (Infarmed) (x) - membership of the Ordem dos Farmacêuticos (+) (*) There are 2 registers that are administered independently for different purposes. (x) registration of Infarmed constitutes a licence (+) registration to Ordem dos Farmacêuticos comes with membership.	
Requirements	Diploma/educational requirements	Yes	Decree-Law 288/2001, 10th November
	Practice (duration in months)	No	
	Examination	No, except as substitute(s) for the educational requirements	

	Type	Scope	What law/regulation?
	Declaration of good conduct	No	
	Language requirement/other	No	
	Nationality limitations/obligatory residency	No	
General information	Number	5,752 (= 100%)	Date: June 2006
	Restrictions on numbers?	No	
	Cost structure	Annual fee: € 217,8 One-off fee: € 165	
	Who administers the register, list of licences of list of members?	The registers are administered independently by the Ordem dos Farmacêuticos and Infarmed	
	Does the registration, licence or membership expire?	Yes, both registrations expire every 5 years (if the renewal conditions are not met)	
	Revocation possible? When?	Yes, as a disciplinary action or in cases of misconduct	

Source: ECORYS questionnaire (2006)

Table 4 Professional bodies

Name	Scope	Membership
Associação Nacional das Farmácias (National Association of Pharmacies)	It is its remit, the National Association of Pharmacies undertakes the following duties, amongst others: i) to create better conditions for pharmacists and pharmacies; ii) to improve the quality of pharmacies and of the services provided by these establishments; iii) to cooperate with the State in the implementation of projects or campaigns. (1)	Membership is voluntary. Coverage: almost 100%, the latest data from the Associação reports 2,700 members*. * Note that this amount exceeds the number of pharmacy outlets in Table 1.1. This is because of the inclusion of the number of outlets located in the autonomous regions: Madeira and The Azores.
Ordem dos Farmacêuticos (Pharmaceutical Society)	Administers one of the registers and provides legal and professional assistance to its members. Furthermore, the Society is active in the provision and / or accreditation of continuous training programmes. (1)	Membership is compulsory for all professionals who perform actions prescribed in the Pharmaceutical Act <i>(Acto Farmacêutico) (3)</i>
Infarmed		

Source: ECORYS questionnaire (2006), (2) Website ANP, (3) Website PS

Rules on the profession

Table 5 Scope of the monopoly

		Scope	What law/regulation?
Professional monopoly	Who is allowed to dispense prescription drugs?	Pharmacists only	Decree-Law 48547 of 27th August 1968, Articles 29 ^o and 97 ^o
	Who is allowed to dispense OTC drugs?	Pharmacists and other outlets. Other outlets: places allowed to sell non-reimbursed OTC drugs (*) (* Presence of a pharmacist or pharmacist technician required. The pharmacist's technician needs to possess the professional recognition / certificate of the General Secretariat of the Ministry of Health	- Decree-Law 48547 of 27th August 1968, Articles 29 ^o and 97 ^o - Decree-Law 134/2005, 16th August - Governmental Decree 827/2005, 14 th September - Governmental Decree 367/72, 3 rd July, as amended
	Are there additional requirements for non-pharmacists to dispense drugs (both OTC drugs and prescription drugs)?	Other outlets: - Education / know-how	Same as above and - Decree-Law 320/99, 11 th August

Source: ECORYS questionnaire (2006)

Rules and other obligations on establishing a pharmacy

Table 6 Ownership and diversification requirements

	Scope/conditions	Comments	What law/regulation?
Ownership restrictions on pharmacies	Pharmacists only	Government regulation	- Law 2125, 20 th March 1965 - Decree-Law 48547, 27th August 1968
Is ownership of more than one pharmacy allowed?		Government regulation A pharmacy licence can only be awarded to a pharmacist or to a society - in a collective partnership (sociedade em nome colectivo)	Same as above

	Scope/conditions	Comments	What law/regulation?
	No	- or in a share (quota) arrangement if every partner is a pharmacist (sociedade por quotas). A pharmacist cannot own more than one pharmacy, even if integrating into a society.	
Are there restrictions on the business forms of pharmacies?	No	Business forms that are allowed are: - Sole practitioner - Association - Legal person / private company - Legal person / private company with limited liability	
How can one take over a pharmacy?	- by private agreement	There is no regulation with respect to taking over a pharmacy. The transmission of the pharmacy may be motivated by the change of ownership of the property, namely, when there is a change in the proprietor; by constitution of a society, alteration of social part or quota of a society. Equally, the property can be transmitted in the event of the death of the proprietor.	- Law 2125, 20 th March 1965 - Decree-Law 48547, 27 th August 1968
What is the allocation mechanism for changes in ownership of pharmacies?	Public tender with specific selection criteria of candidates. These criteria favour the professional value-added of the candidates and they are objective and transparent.	For individual candidates, the criteria are weighted as follows: i) Professional activity in a community or hospital pharmacy; 1 point per year, with a maximum of 10 points.	

	Scope/conditions	Comments	What law/regulation?
		<p>ii) Residence in the district (<i>concelho</i>) where the pharmacy is being opened; 1 point per year with a maximum of 5.</p> <p>In the case of a society, the arithmetic average of all partners is taken.</p> <p>In cases where point scores are equal, preference is given to the younger candidate.</p> <p>When there is no age difference, the candidate who obtained the best course average at university will be preferred.</p>	
What requirements exist with respect to the location of pharmacies?	<ul style="list-style-type: none"> - Minimum number of inhabitants: 4000 - Geographical distance: 500 metres between pharmacies (in a straight line) - Other: Minimum distance of 100 metres between pharmacy and healthcare centre or hospital 	Government regulation	The establishment of pharmacies is legally organised through criteria set by Governmental Decree n° 936-A/99, 22nd October.
What barriers exist to pharmacists from other EU countries?	- language requirement	The required competence of speaking Portuguese.	
Are Internet pharmacies allowed to operate?	Prescription drugs: no OTC drugs: no		
Is co-operation of pharmacies with other professionals allowed?		The regulation in force prohibits the association of pharmacists with other healthcare professionals, such as doctors, in the management of a pharmacy. It is also forbidden for these healthcare professionals to be partners in a contract with a pharmacist	Government Regulation: (Decree-law n° 48 547, 27th August 1968, Article 33)

	Scope/conditions	Comments	What law/regulation?
	No	in order to receive a share of the profits by the dispensing of medicines	
Horizontal partnerships/mergers allowed?	Other pharmacies: no Druggists: no	Ownership of pharmacy cannot be associated with other entities (including pharmacies) for commercial reasons.	Government
Vertical partnerships/mergers allowed?	Wholesalers: no Drug producers: no Insurance companies: no General Practitioners: no	Exception for cooperative system within the wholesalers.	Government

Source: ECORYS questionnaire (2006)

Table 7 Operating requirements on pharmacies

	Scope	Comments	What law/regulation
Opening hours	- Minimum hours/24-hour service	As a pharmaceutical practice is considered by law to be a service of public interest, pharmacies are subject to a mandatory system whereby access to medicinal products and pharmaceutical advice must be available 24 hours a day, seven days a week anywhere in the country. Therefore, in addition to the normal opening hours, there is regulation that establishes the functioning of pharmacies on duty in order to ensure the dispensing of medicines in cases of urgency.	Governmental-Decree 256/81, 10th March amended by Governmental Decrees 91/82, 361/82, 792/91 and 146/96.
Design of the practice	Floor space/design: yes Promotion: yes Outdoor signs: yes Indoor signs: yes Shelf space: no Storage space: yes (+)	All restrictions regulated by Government. The regulation aims to achieve a functional environment with	Several, including: Decreto-Lei n.º 48547, de 27 de Agosto de 1968 Despacho de 4 de Março de 1970

	Scope	Comments	What law/regulation
	(+) Control of storage conditions such as temperature and humidity	conditions for a better service to the public. It ensures the same standardised minimum quality of the pharmacy facilities all over the country. As far as promotion is concerned, the regulation in force has the rational use of medicines as its final goal.	Despacho do Ministério da Saúde n.º 18/90, de 27 de Dezembro Despacho do Ministério da Saúde n.º 8/91, de 19 de Novembro Deliberação n.º 1500/2004, 7 de Dezembro
Is the presence of a pharmacist required?	Yes		Decree-Law 214/90 of 28 th June and Decree-Law 48 547 of 27 th of August 1968
Is it required to stock all prescription drugs?	- Delivery within a set time: 24 hours (or 12 hours, in some cases)	Article 63 of Decree-Law 48547 of 27 th August 1968, establishes that when the pharmacist does not have the prescribed medicine prescribed in stock, he should be able to provide it as soon as possible, if the patient wishes; the pharmacist is not allowed to charge any fee for this service. Note that in certain cases, legislation obliges the pharmacist to supply the medicinal product within 12 hours if it is not available in the pharmacy.	Article 63 of Decree-Law 48547 of 27 th August 1968 Decree-Law 270/2002, 2 nd December
Product/service differentiation - Sale of non-pharmaceutical products allowed? - Provision of diagnostic services?	Yes, limited (products must be health-related) Yes (limited)	There are limitations on the kind of products allowed to be sold. Only health-related products are authorised. The regulation in this field aims to protect consumers.	Article 63 of Decree-Law 48547 of 27 th August 1968
Consumer registration required?	OTC drugs: no Prescription drugs: no		

	Scope	Comments	What law/regulation
Can one operate a pharmacy without a contract with a health insurer?	Legally: yes Economically: yes	In fact, pharmacies are not allowed to have contracts with health insurers.	

Source: ECORYS questionnaire (2006)

Pricing

Table 8 Price control

What price?	What regulation?	Who regulates?
Price of prescription drugs	Maximum prices	Government, via the decision of the Ministry of Health
Price of OTC	Not regulated	
Profit margin	POM: Medicine related – fixed fee (“fixed profit margins”)	Government, via the decision of the Ministry of Health

Source: ECORYS questionnaire (2006)

NPM free pricing

Since 16 September 2005, legislation is in force to allow the selling of Non-Prescription Medicines (NPM) outside pharmacies, through Decree-Law 134/2005 of 16th August, and Governmental-Decree 827/2005 of 14th September. Through this regulation, the prices of NPM have been free since 16 September.

The profit margins for reimbursed medicines changed in 2005: from 20% to 19.15% for pharmacists; and from 8% to 7.45% for wholesalers. The calculations for this margin are based on pharmacy prices (public price) excluding VAT (5%) (Portaria n° 618-A/2005, 27th July).

Other

The Portuguese Government has recently announced that there will be changes to the law governing national pharmacies in the near future, namely in respect of the property of pharmacies, number of inhabitants per pharmacy and the distance between pharmacies.

References

- Portuguese Pharmaceutical Society, 2005 (used for sector information);
- Pharmacy Faculties and Superior Institutes (used for sector information);
- Website Association Nationale des Pharmacies, <http://www.anf.pt/>;
- Website Pharmaceutical Society, <http://www.ordemfarmaceuticos.pt/>;
- Website International Pharmaceutical Federation, <https://213.206.88.26/www2/>;
- ECORYS questionnaire.