

Pricing

Table 8 Price control

What price?	What regulation?	Who regulates?
Price of prescription drugs	Maximum prices	Government, (1) Règlement grand-ducal du 4 juillet 2002 fixant le tarif des préparations galéniques for medication prepared by the pharmacist, (2) Règlement grand-ducal du 29 juillet 2004 concernant les prix des spécialités pharmaceutiques et des médicaments préfabriqués for prefabricated medication. [Translations: (1) Grand-ducal ruling of 4 July 2002 fixing the tariff for medication prepared by the pharmacist, (2)) Grand-ducal ruling of 29 July 2004 concerning the prices of pharmaceutical specialities and prefabricated medications.]
Price of OTC drugs	Maximum prices	Same regulations
Profit margin	Regulated profit margin	Same regulations

Source: ECORYS questionnaire (2006)

Other

References

- ECORYS questionnaire;
- Eurostat.

6.17 Malta

6.17.1 Narrative description

The regulatory structure in Malta is among the least restrictive in Europe. The regulatory framework is mainly formed by the Medicines Act 2003.

Educational requirements are set by the University of Malta and by the Health Care Professions Act. The Health Care Professions Act also sets the requirement to register as a community pharmacist. The scope of the professional monopoly is subject to the Medicines Act 2003, which also determines the conditions for establishing a pharmacy (obtaining a licence) and changes of ownership (transfer of the licence).

The formation of partnerships and the ability to merge, are also subject to the Medicines Act 2003. Furthermore the Act regulates the appearance of a pharmacy and the required presence of a pharmacist. Opening hours, however, are regulated by the Legal Notice 364 (2002).

Prices and profit margins are unregulated.

Entry regulation

In Malta the duration of education is 5 years, of which 6 months consist of compulsory practice. The number of students who annually begin a course of academic study to become pharmacists is unlimited. Community pharmacists are required to register.

Only community pharmacists are allowed to dispense prescription drugs and OTC medicines to the public. The number of pharmacy outlets and ownership of a pharmacy is unrestricted. Nevertheless, establishing a pharmacy is dependent on obtaining a licence, which may involve an economics needs test. However, pending new regulation, the applicability of such test is unclear.¹¹⁸ Changes of ownership are not subjected to any regulation, but the transfer of licence must be approved. The possible business form of a pharmacy is also not restricted.

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

Conduct regulation

A pharmacist may form a partnership or merge with other pharmacists, druggists, wholesalers, producers and insurance companies.

Opening hours are not subjected to regulation. Issues such as advertising, outdoor signs and storage space are subjected to regulation.¹¹⁹ The presence of a pharmacist is required at all times.

The sale of non-pharmaceutical products is only allowed to a limited extent. However, 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 and OTC drugs are unregulated by law but practices of retail price maintenance by wholesalers are rather common. Profit margins are unregulated.

¹¹⁸ Requirements for pharmacists wanting to obtain an operating license:

i) Geo-demographic criteria *

ii) EU citizen

iii) Good conduct

iv) Registration with the Pharmacy Council. The exact conditions are currently under discussion with the relevant stakeholders. * Until new criteria have been formulated, the legal requirements are not relevant. Accordingly, no new licences have been issued since 1995.

¹¹⁹ Some forms of advertisement are forbidden (for the pharmacist-only drugs and prescription drugs), for OTC drugs the ban is self-regulated. Also, there are rules of the professional body governing outdoor signs, and public laws on storage space.

6.17.2 Data

Table 1 National data on the Pharmacy market

	Value (default 2006)	Additional remarks
Total number of community pharmacy outlets (i.e. number of locations)	207 2002: 200	The last ten years have seen a small increase in the number of outlets (no exact numbers)
Number of inhabitants per community pharmacy	1,945	Population: 402,700 (Eurostat 2005)
Total number of community pharmacists	445	The last ten years have seen a small increase in the number of pharmacists (No exact numbers)
Total number of employees	639	2004
Total number of hospital pharmacists	65	
Total number of hospital pharmacists that are allowed to dispense prescription drugs to the public	65	
Total number of other pharmacists (e.g. those in industry, research, education, etc.)	210	
Total number of other pharmacists that are allowed to dispense prescription drugs to the public	884	Every pharmacist registered with the Pharmacy Council can dispense prescriptions
Total number of non-pharmacists that are allowed to dispense prescription drugs to the public (e.g. general practitioners, veterinarians, etc.)	0	Only pharmacists are allowed to dispense prescriptions (Medicines Act 2003)
Total number of registered community pharmacists	445	End of 2005
Total number of community pharmacists with membership of a professional association	200	Estimate by the European Commission
Percentage share of community pharmacist that are members of the professional association(s)	45%	
Annual total number of people who begin an academic course of study to become pharmacists (on average between 2000 and 2005)	40	
Annual total number of people who finished an academic course of study to become pharmacists (on average between 2000 and 2005)	40	The number of students who drop out during their course of study is almost zero

	Value (default 2006)	Additional remarks
Average turnover per community pharmacy outlet	295,000	Year: 2002
Average operating result per community pharmacy outlet	35,500	Year: 2002

Source: ECORYS questionnaire (2006), Eurostat

6.17.3 Overview

Education

Table 2 Educational requirements

	Scope	What law/regulation?
Degree and duration	Total duration: 5 years Bachelor + Master's degrees: 5 years Compulsory practice: 6 months (+) (+) Conducted in a community pharmacy.	University of Malta
Limitation on the number of students	No	University of Malta
Continuous training	Not obligatory Continuous training is followed on a voluntary basis and is facilitated by the Malta College of Pharmacy Practice. In practice, most pharmacists do follow these training courses.	

Source: ECORYS questionnaire (2006)

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	Health Care Professions Act
Requirements	Diploma/educational requirements	Educational requirements	Health Care Professions Act (Chapter 464 of the laws of Malta) Article 17
	Practice (duration in months)		
	Examination		

	Type	Scope	What law/regulation?
	Declaration of good conduct		
	Language requirement/other		
	Nationality limitations/obligatory residency	EU citizen	Health Care Professions Act (Chapter 464 of the laws of Malta) Article 17
General information	Number	445 (coverage 100%)	
	Restrictions on numbers?	None	
	Cost structure	Annual fee: € 11.65 (MTL 5)	
	Who administers the register, list of licences of list of members?	Pharmacy Council	Health Care Professions Act (Chapter 464 of the laws of Malta) Article. 16(1)(c)
	Does the registration, licence or membership expire?	Yes, an annual renewal of the registration is required.	Health Care Professions Act (Cap 464 of the laws of Malta) Article 16(1)(i)
	Revocation possible? When?	Yes In cases of misconduct	Health Care Professions Act (Chapter 464 of the laws of Malta) Part VII Disciplinary Action, Offences and Erasure of Names Pharmacy Council (Erasure of Names Procedure) Rules

Source: ECORYS questionnaire (2006)

Table 4 Professional bodies

Name	Scope	Membership
Pharmacy Council	Registers all pharmacists.	884 of which 445 are community pharmacists (=100% coverage) 60 hospital pharmacists
Malta Chamber of Pharmacists (http://www.synapse.net.mt/mcp)	Representation, advisory service and international cooperation.	

Source: ECORYS questionnaire (2006)

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	Medicines Act 2003
	Who is allowed to dispense OTC drugs?	Pharmacists only	Medicines Act 2003
	Are there additional requirements for non-pharmacists to dispense drugs (both OTC drugs and prescription drugs)?	Not applicable	

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 to pharmacies	- No restrictions	In cases of a full takeover of a licensed pharmacy (i.e. including existing management) there are no restrictions.	
Is ownership of more than one pharmacy allowed?	- Yes, unlimited		
Are there restrictions to the business form?	No	Business forms which are allowed are: - Sole practitioner - Association - Legal person / private company	
		- Legal person / private company with limited liability	

	Scope/conditions	Comments	What law/regulation?
How can one take over a pharmacy?	<p>- by private agreement to transfer the operating licence (+)</p> <p>(+) An operating licence, granted by the President of Malta, is required. Note that the Pharmacy Council advises the President of its decision.</p> <p>Requirements for pharmacists wanting to obtain an operating licence:</p> <p>i) Geo-demographic criteria *</p> <p>ii) EU citizen</p> <p>iii) Good conduct</p> <p>iv) Registration with the Pharmacy Council</p> <p>Furthermore, the new owner will have to pay a fee for the licence transfer (cf. changes in ownership).</p>	<p>* The exact conditions are currently under discussion with the relevant stakeholders.</p> <p>Until new criteria have been formulated, the legal requirements are not relevant. Accordingly, no new licenses have been issued since 1995.</p> <p>The transfer cost is: € 46.60 (MTL 20), i.e. equal to the costs of a new licence.</p>	Medicines Act 2003
What is the allocation mechanism for changes in ownership of pharmacies?	Not relevant		Medicines Act 2003
What requirements exist with respect to the location of pharmacies?			<p>Medicines Act 2003</p> <p>Health Care Professions Act (Chapter 464 of the laws of Malta) Part VII Disciplinary Action, Offences and Erasure of Names</p> <p>Pharmacy Council (Erasure of Names Procedure) Rules</p>
What barriers exist to pharmacists from other EU countries?	- language requirement		Health Care Professions Act

	Scope/conditions	Comments	What law/regulation?
Are Internet pharmacies allowed to operate?	Prescription drugs: no OTC drugs: no		
Is co-operation of pharmacies with other professions allowed?	No		
Horizontal partnerships/mergers allowed?	Other pharmacies: yes Druggists: yes		Medicines Act 2003
Vertical partnerships/mergers allowed?	Wholesalers: yes* Drug producers: yes General Practitioners: no Note that there are no insurers on Malta.	Pharmacies can work with partners, but are not allowed to have partnerships with General Practitioners. (* cf. pricing)	Medicines Act 2003

Source: ECORYS questionnaire (2006)

Table 7 Operating requirements on pharmacies

	Scope	Comments	What law/regulation
Opening hours	- Fixed opening hours	Mon-Sat. 9am-12pm AM and 4pm-7pm Sunday 9am-12pm (<i>rota</i>)	Legal notice 364 (2002)
Design of the practice	Floor space/design: no Promotion: yes Outdoor signs: yes Indoor signs: no Shelf space: no Storage space: yes	Some forms of advertisement are forbidden (for the pharmacists and for prescription drugs) Adds for OTC are self-regulated. There are rules by the professional body for outdoor signs. There are laws on storage space.	Medicines Act 2003
Is the presence of a pharmacist required?	Yes, the presence of a pharmacist is required at all times.		Medicines Act 2003
Stock	- No requirements	There has been a regulation on minimum stock levels for some medicines but this regulation is no longer in force.	

	Scope	Comments	What law/regulation
Product/service differentiation			Medicines Act 2003
- Sale of non-pharmaceutical products allowed?	Yes, limited (products must be health-related)*	* Medical appliances and devices, toiletries, perfumes, optical goods, cosmetics, baby foods and goods, and photographic equipment.	
- Provision of diagnostic services?	Yes		
Consumer registration required?	OTC drugs: no Prescription drugs: no		
Can one operate a pharmacy without a contract with a health insurer?	Legally: yes Economically: yes	No insurance system exists, people are not reimbursed.	

Source: ECORYS questionnaire (2006)

Pricing

Table 8 Price control

What price?	What regulation?	Who regulates?
Price of prescription drugs	Not regulated The wholesaler determines the retail price of the product and the pharmacist has to sell the product at that price.	Wholesaler
Price of OTC drugs	Not regulated	Wholesaler
Profit margin	Not regulated. Used to be around 20% of the retail prices, unknown now.	Wholesaler

Source: ECORYS questionnaire (2006)

Other

Unlike in most other countries, no insurance system exists. People pay for their medicines themselves.

References

- The Malta Chamber of Pharmacists (<http://www.synapse.net.mt/mcp>);
- The Medicines Authority (<http://www.medicinesauthority.gov.mt>);
- ECORYS questionnaire.