

- http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV (Act CLIV, 1997, on health care in Hungary);
- Ministerial decrees:
 - 44/2004 (IV.28) on ordering and distribution of human medicines
 - 52/2005 (XI.18) on reporting unexpected side effects of medicines to the Hungarian health authority;
- ECORYS questionnaire.

6.12 Ireland

6.12.1 Narrative description

Ireland is among the least regulated countries. It scores very low on both conduct as well as entry regulation. The regulatory framework consists of multiple Acts.¹⁰²

Educational requirements are determined by the Pharmacy Acts 1875-1977, complemented with regulations of the Pharmaceutical Society of Ireland 1971-2002. Membership of the professional association is required by the Pharmacy Acts 1875-1977, as well.

The scope of the professional monopoly is determined by the Pharmacy Acts 1875-1977 and Medicinal Products (Prescription and Control of Supply) Regulations 2003-2005. Regulation on ownership and ownership changes are laid down in the Pharmacy Act 1962, as well as the required presence of a pharmacist. Until recently, this Act also imposed the so-called 3-year clause on pharmacists from other EU Member States.¹⁰³

Opening hours are subject to the Health Service Executive - Community Pharmacy Contractor Agreement.

Pricing of pharmaceuticals supplied to the health service is outlined in an agreement between the industry association (Irish Pharmaceutical Healthcare Association, IPHA) and the Department of Health and Children. Profit margins are subject to the General Medical Services Scheme (GMS), to the Drugs Payment Scheme (DP) and the Long Term Illness scheme (LTI).

Entry regulation

In Ireland, the duration of education is 6 years, of which 12 months consist of compulsory practice. The annual number of students that begin a course of study to become pharmacists is limited to about 100. Community pharmacists are only required to be registered. Community pharmacists and other medical professionals (such as GPs) may dispense prescription drugs and OTC drugs to the public.¹⁰⁴ Also, druggists and corner shops, petrol stations and supermarkets may dispense OTC drugs to the public. The number of pharmacy outlets is unrestricted.

¹⁰² As of 2007, a new Pharmacy Bill is in place. See also <http://www.dohc.ie/press/releases/2007/20070309a.html>.

¹⁰³ The 3-year clause has been removed by the new Pharmacy Bill 2007.

¹⁰⁴ Only in cases where the nearest pharmacy is more than 3 miles (5 kilometres) away.

Ownership of a pharmacy is unrestricted, changes of ownership are not subjected to any regulation; and the possible business form of a pharmacy is also unrestricted.

Barriers for pharmacists from other EU countries exist in the form of the so-called 3 year clause.

Conduct regulation

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

Opening hours are subjected to a minimum requirement. The appearance of a pharmacy is not subjected to regulation, but the presence of a pharmacist is required at all times.

The sale of non-pharmaceutical products is allowed. Pharmacists are allowed to provide diagnostic services, such as measuring blood sugar or blood pressure, etc. Internet pharmacies are only allowed to sell OTC drugs.

Price regulation

Prices of prescription drugs are fixed. Prices of OTC drugs are unregulated. Profit margins are regulated by a variable scheme:

Prescription drugs via the General Medical Services Scheme (GMS) come with a dispensing fee of € 2.98.

Prescription drugs via the Drugs Payment Scheme (DP) or Long Term Illness scheme (LTI) come with a medicine-related variable fee in terms of a 50% mark-up on the wholesale price. In addition, the pharmacist gets a dispensing fee of € 2.59

Profit margins on OTC drugs are not regulated but pharmacies typically apply a margin of between 25 percent and 33 percent.

6.12.2 Data

Table 1 National data on the Pharmacy market

	Value	Additional remarks
Total number of community pharmacy outlets (i.e. number of locations)	2005: 1,457	
Number of inhabitants per community pharmacy	2005: 2,755	
Total number of community pharmacists	2005: 3,028	Estimation (1)
Total number of employees	N.A.	
Total number of hospital pharmacists	2005: 378	Estimation (1)

	Value	Additional remarks
Total number of hospital pharmacists that are allowed to dispense prescription drugs to the public	N.A.	
Total number of other pharmacists (e.g. those in industry, research, education, etc.)	2005: 110	Estimation
Total number of other pharmacists that are allowed to dispense prescription drugs to the public	N.A.	
Total number of non-pharmacists (e.g. general practitioners, veterinarians, etc.) that are allowed to dispense prescription drugs to the public	N.A.	
Total number of registered community pharmacists	2005: 3,028	Registration is compulsory.
Total number of community pharmacists with membership of a professional association	1,600	Estimation, member of the Irish Pharmaceutical Union
Percentage share of community pharmacists that are members of the professional association(s)	100%	
Annual total number of people who begin a course of academic study to become pharmacists (on average between 2000 and 2005)	70	Varies from 50-120. Note that 2 new universities began offering pharmacy courses recently. Last year only 1 university offered the programme.
Annual total number of people per year who successfully finish the course of academic study to become pharmacists (on average between 2000 and 2005)	50	Because of the recent increase in capacity, the number will increase in the coming years up to 120.
Average turnover per community pharmacy outlet	N.A.	Pharmaceutical expenditure in Ireland according to OECD data amounted to € 1,180 million in 2003.
Average operating result per community pharmacy outlet	N.A.	

Source: ECORYS questionnaire (2006), Eurostat

6.12.3 Overview

Education

Table 2 Educational requirements

	Scope	What law/regulation?
Degree and duration	Total duration: 6 years Bachelor + Master's degree: 5 years Compulsory practice: 12 months	- Pharmacy Acts 1875-1977 - Regulations of the Pharmaceutical Society of Ireland 1971-2002 The Government sets down the law. The Pharmaceutical Society of Ireland - under this law - accredits university training courses and also operates the one year of compulsory practical training.
Limitation on the number of students	Yes Phase: Master's degree Number: varies from 50 to 120 Limitation: <i>numerus fixus</i> .	
Continuous training	Not obligatory (*) (*) With the exception of tutors (pharmacists who supervise graduates during their one-year practice training), who must spend at least 30 hours per year on training; there is no compulsory continuous education for pharmacists or any of the other staff groups. (1) However, the Pharmaceutical Society of Ireland, the Irish centre for Continuing Pharmaceutical Education and the IPU encourage pharmacists to undertake continuous education. (1)	

Source: (1) 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 with the Pharmaceutical Society of Ireland (PSI)	
Requirements	Diploma/educational requirements	Yes, an accredited pharmacy degree	
	Practice (duration in months)	Yes, one year of practical training, of which at least 6 months have to be spent in a hospital or community pharmacy	
	Examination	No	
	Declaration of good conduct	No	
	Language requirement/other	No	
	Nationality limitations/obligatory residency	No	
General information	Number	3,785 (1)(2)	
	Restrictions on numbers?	None	
	Cost structure	Annual fee: € 404	
	Who administers the register, list of licences of list of members?	Pharmaceutical Society of Ireland	
	Does the registration, licence or membership expire?	An annual fee must be paid in order to retain it	
	Revocation possible? When?	Yes, where the retention fee not paid, or where there is a failure to respond to defined correspondence from the Pharmaceutical Society of Ireland	

Source: (1) ECORYS questionnaire (2006), (2) ÖBIG

Table 4 Professional bodies

Name	Scope	Membership
Pharmaceutical Society of Ireland	The Pharmaceutical Society of Ireland (PSI) is the statutory body for pharmacists and pharmacies in Ireland. It acts in the public interest to regulate the profession. Annual registration fee of € 404 (2006)	All pharmacists [all 3,028 community pharmacists] (= 100% coverage)
Irish Pharmaceutical Union	Lobbying professional defence. Annual fee: € 230 to € 447. [Membership expires annually]	1,600 (= 100% of the community pharmacies), also has hospital pharmacists and industry pharmacists as members

Source: ECORYS questionnaire (2006), websites of the organisations

Rules on the profession

Table 5 Scope of the monopoly

		Scope	What law/regulation?
Professional monopoly	Who is allowed to dispense prescription drugs?	Community pharmacists Other medical professionals: Self-dispensing doctors (+) (+) only in cases where the nearest pharmacy is more than 3 miles (5 kilometres) away (2)	Pharmacy Acts 1875-1977 Medicinal Products (Prescription and Control of Supply) Regulations 2003-2005
	Who is allowed to dispense OTC drugs?	Community pharmacists Other medical professionals: Self-dispensing doctors (+) Druggists (*) Other outlets, e.g. corner shops, petrol stations, supermarkets (*) (+) only in cases where the nearest pharmacy is more than 3 miles (5 kilometres) away (2)	Pharmacy Acts 1875-1977 Medicinal Products (Prescription and Control of Supply) Regulations 2003-2005

		Scope	What law/regulation?
		(*) may dispense only a very limited number of OTC drugs	
	Are there additional requirements for non-pharmacists to dispense drugs (both OTC and prescription drugs)?		

Source: (1) ECORYS questionnaire (2006), (2) ÖBIG

Rules and other obligations on establishing a pharmacy

Table 6 Ownership and diversification requirements

Since January 2002 there have been no rules governing the establishment of pharmacies in Ireland. According to the policy-makers interviewed by ÖBIG, there are currently no plans to introduce such rules in the future.

	Scope/conditions	Comments	What law/regulation?
Ownership restrictions on pharmacies	- No restrictions	The only rules concerning the ownership of pharmacies, which date back to 1962, state that four separate entities are entitled to own a pharmacy: i) A pharmacist or partnership of pharmacists; ii) A person who was a legal representative of a deceased pharmacist at the time of his/her death; iii) A trustee of a pharmacist in practice who is declared bankrupt or becomes of unsound mind iv) A corporate body. In this case, there should be a legal representative i.e. a certified pharmacist present during opening hours.	Pharmacy Act 1962
Is ownership of more than one pharmacy allowed?	- Yes, unlimited (1)		Pharmacy Act 1962

	Scope/conditions	Comments	What law/regulation?
Are there restrictions on the business form of pharmacies?	No	Business forms that are allowed are: - Sole practitioner - Association - Legal person / private company - Legal person / private company with limited liability	Pharmacy Act 1962
How can one take-over a pharmacy?	- by private agreement		Pharmacy Act 1962
What is the allocation mechanism for changes in ownership of pharmacies?	Simple notification to the Pharmaceutical Society of Ireland		Pharmacy Act 1962
What requirements exist with respect to the location of pharmacies?	None		
What barriers exist to pharmacists from other EU countries?	None	The 3-year clause has been removed by the new Pharmacy Bill 2007	
Are internet pharmacies allowed to operate?	Prescription drugs: No OTC drugs: Yes	OTC medicines have only recently been allowed to be supplied via the Internet (2)	Medicinal Products (prescription and Control of Supply) Regulations 2003-2005
Is co-operation of pharmacies with other professions allowed?	Yes		
Horizontal partnerships/mergers allowed?	Other pharmacies: yes Druggists: yes		
Vertical partnerships/mergers allowed?	Wholesalers: yes Drug producers: yes Insurance companies: yes General Practitioners: yes* * conditionally Condition: not in the area of their practice	Physicians, dentists and vets may not hold a contract for a pharmacy if they have their practice in the same area. (1) Concerning vertical (wholesale-retail) integration, United Drugs is the only one of the three wholesalers who does not own pharmacies. (2)	

Source: (1) ECORYS questionnaire (2006), (2) ÖBIG

Table 7 Operating requirements on pharmacies

	Scope	Comments	What law/regulation
Opening hours	<p>- Minimum hours up to 24-hour service (OBIG)</p> <p>There are minimum opening hours stated by the government for pharmacies which have a GMS contract. This is to ensure patient access to pharmacy services. (E-Q)</p>	<p>Opening hours are subject to the contract between the pharmacy and the HSE.</p> <p>The opening hours indicated must be “reasonable”, a typical contract would state the following hours:</p> <ul style="list-style-type: none"> • On weekdays (Monday to Friday): from 9am to 6 pm • On Saturday: from 9am to 6pm 	Health Service Executive - Community Pharmacy Contractor Agreement
Design of the practice	<p>Floor space/design: no</p> <p>Promotion: no</p> <p>Outdoor signs: no</p> <p>Indoor signs: no</p> <p>Shelf space: no</p> <p>Storage space: no</p>	<p>In Ireland, there is no tradition of the manufacture of pharmaceuticals in a pharmacy, and therefore most pharmacies do not have a laboratory. Nonetheless, both the PSI guidelines and the contract with the HSE do say that a pharmacy is obliged to have the equipment needed to prepare pharmaceuticals - such as scales. (2)</p>	
Is the presence of a pharmacist required?	Yes	<p>For quality assurance in each pharmacy, a fully-qualified pharmacist has to be in charge as supervising pharmacist. (2)</p>	Pharmacy Act 1962
Stock	- No requirements		

	Scope	Comments	What law/regulation
Product/service differentiation - Sale of non-pharmaceutical products allowed? - Provision of diagnostic services?	Yes, unlimited Yes	Yes, pharmacists are allowed to sell non-pharmaceutical products. The following categories of products are sold in pharmacies: • Prescription-only medicines (POM) • OTC medicines • Non-pharmaceutical products, including diagnostic services (2)	
Consumer registration required?	OTC: no POM: no		
Can one operate a pharmacy without a contract with a health insurer?	Legally: yes Economically: no	The state is the health insurer. Legally it is possible to work without a contract with the state but it is economically not possible. It is only possible for pharmacies within private hospitals, and pharmacies of drug companies selling drugs to their employees (1).	

Source: (1) ECORYS questionnaire (2006), (2) ÖBIG

Pricing

Table 8 Price control

What price?	What regulation?	Who regulates?
Price of prescription drugs	Fixed prices	Pricing of pharmaceuticals supplied to the Health Service is outlined in an agreement between the industry association (Irish Pharmaceutical Healthcare Association, IPHA) and the Department of Health and Children. The Department of Health is currently in negotiations with the pharmaceutical manufacturers and wholesalers to agree prices for prescription medicines for the next 5 years.

What price?	What regulation?	Who regulates?
Price of OTC	Not regulated	-
Profit margin	POM – GMS (+) Dispensing fee: € 2.98 POM – DP/LTI (++) Medicine related – variable fee: 50% mark-up on wholesale price Dispensing fee: € 2.59 OTC Not regulated Pharmacies typically apply a margin of between 25 percent and 33 percent. (2) (+) GMS stands for General Medical Services Scheme (++) DP stands for Drugs Payment Scheme; LTI stands for Long Term Illness scheme	Government

Source: (1) ECORYS questionnaire (2006), (2) ÖBIG

Other

The first years of the new millennium have seen a review of the regulatory framework for pharmacies in Ireland. In 2001, the OECD published a study in which critical views on any existing restrictions were expressed (OECD 2001). In response to that report, the Minister for Health and Children established a high-level group, the so-called Pharmacy Review Group, to examine pharmacy issues. The Pharmacy Review Group submitted its report in 2003.

There were several recommendations, which require implementation in the drafting of two new Pharmacy Acts:

1. Priority legislation will include:
 - the removal of the prohibition - the 'derogation' - on non-Irish graduates being supervising pharmacists in pharmacies less than 3 years old;
 - fitness to practice provisions, to ensure the highest standards from pharmacists, and to safeguard the safe and effective delivery of pharmaceutical services to all citizens of the state;
 - a stronger statutory basis for the Pharmaceutical Society of Ireland, to include;
 - governance of the PSI, including wider non-pharmacist representation on its Council;
 - updating regulations for the registration of pharmacists, including non-EU and EEA graduates;