

**ÖSTERREICHISCHES BUNDESINSTITUT FÜR GESUNDHEITSWESEN
AUSTRIAN HEALTH INSTITUTE**

**BENCHMARKING
PHARMACEUTICAL EXPENDITURE**

**Cost-Containment Strategies
in the European Union**

**COMMISSIONED BY
THE FEDERAL MINISTRY OF SOCIAL SECURITY AND GENERATIONS**

Österreichisches Bundesinstitut für Gesundheitswesen
Austrian Health Institute



ÖBIG

BENCHMARKING PHARMACEUTICAL EXPENDITURE

Cost-Containment Strategies in the European Union

Ingrid Rosian

Katja Antony
Claudia Habl
Sabine Vogler
Marion Weigl

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Summary

Tight public budgets and a tough economic situation as well as changed basic conditions (increased life expectancy, medical-technological progress) created a need for health reforms in the Europe of the 1990s. Alterations to the systems were implemented which were primarily aimed at cost-containment.

Pharmaceutical expenditure, which accounts for between eight per cent (Denmark) and 26 per cent (Portugal) of health expenditure in the European Union, is in most countries the third-largest health budget item. In the 1990s pharmaceutical expenditure rose drastically in Europe, in most countries more sharply than the gross domestic product and health expenditure.

ÖBIG study covering all European Member States

As a consequence, nearly all fifteen EU Member States initiated reforms: Between 1990 and 1999 an average of more than ten radical measures for the containment of pharmaceutical expenditure were taken per Member State. Belgium, Germany, Spain, Italy, Denmark and the Netherlands adopted most cost-containment measures. Only Luxembourg did not follow the general trend towards cost-containment.

This is one of the results of the study “Benchmarking Pharmaceutical Expenditure. Cost-Containment Strategies in the European Union” of the Austrian Health Institute (ÖBIG), which offers a detailed investigation of the health and pharmaceutical systems in the EU Member States and an analysis of cost-containment measures for pharmaceuticals.

Cost-containment strategies in the European Union

Reform efforts were not only characterised by numerous measures, but also by a variety of strategies which were aimed at price and volume control (pharmaceutical prescriptions).

Price strategies involved statutory pricing as well as implementing price freezes and reductions. Since the mid 90s there has also been pressure on pharmaceutical wholesalers and pharmacies, via repeated reductions in margins in many EU countries. An EU-wide tendency which intensified especially during the late 1990s is to promote generics (pharmaceuticals with patent-expired active substances).

A further cost-containment measure has been to fix pharmaceutical budgets on a national level and/or for physicians. Additionally, increased control of the prescription patterns of physicians was established in all EU Member States.

In order to reduce public budgets a considerable number of pharmaceuticals were de-listed in the 1990s. Another frequent measure was switching prescription-only-medicines to OTC which shifted expenditure from public sector to private households. A standard cost-containment strategy was to increase co-payment: In Belgium co-payments were raised considerably, five times during the 90s, and in Germany, Italy and Sweden four times.

The influence of the European Union on the control of the national pharmaceutical markets became more evident in the past decade. The registration of pharmaceuticals within the EU has already been harmonised to a great extent. The influence of the European Union also became apparent in recent years in the introduction and form of certain measures as regards pricing and reimbursement, which fall within the competence of the Member States, as the EU Transparency Directive asks for certain requirements to be fulfilled for the listing of pharmaceuticals and for transparent criteria as prerequisite of the decisions by the responsible authorities.

Benchmarking of pharmaceutical expenditure

Belgium, Germany, France and Austria have the highest pharmaceutical expenditure per inhabitant: Belgium did not succeed in containing expenditure despite massive interventions in the pharmaceutical sector, but in the other three countries the growth rate for pharmaceutical expenditure could at least be contained. An additional problem is the high pharmaceutical consumption in France and the decrease in contribution revenues of the health insurance funds in Austria and Germany.

The ÖBIG study concluded that – with the exception of Belgium – countries which adopted cost-containment measures to a greater extent succeeded in stemming the increase in public pharmaceutical expenditure – at least for a while. Simultaneous volume control and price control measures enhanced the effects. Countries with minor growth rates within the European Union are Denmark, Germany, Italy and the Netherlands.

The analyses proved that the development of pharmaceutical expenditure and of prescriptions differed. Prescriptions could be contained much more drastically: Between 1990 and 1999 the number of prescriptions decreased by 40 per cent in Italy, and by at least 25 per cent in Germany. In the remaining EU countries the number of prescriptions covered by the health insurance funds or the national health services only increased moderately, in any case considerably less than public pharmaceutical expenditure.

Average costs per prescription rose drastically in the 90s in Europe. This can be seen in the light of the increasing number of new, expensive pharmaceuticals on the market. Some EU countries are adopting measures to oppose this trend (e.g. the foundation of institutions for the evaluation of the therapeutic and economic benefit of new pharmaceuticals, e.g. NICE in Great Britain).

Successful savings?

The price for the “success” of savings measures, which aimed at cost-containment in public pharmaceutical expenditure, had to be borne by the patients: Pharmaceutical expenditure was shifted to the private households via higher co-payments and/or increased self-medication.

Basically, the “pendulum” which is characteristic of many fields of policy can be observed: Dissatisfaction with the original condition leads to reforms (pendulum swings in one direction), which are reversed after some time because of problems and/or altered circumstances (e.g. new government). Instead, new, contrary strategies are implemented (pendulum swings back in the other direction). Examples can be found both in predominantly liberal countries, which fell back on state intervention if necessary (e.g. Denmark, Great Britain, the Netherlands), and in more strictly regulated countries which had switched to market instruments (e.g. introduction of a reference price system in Spain and Italy).

The success of reforms is limited in time: As every control strategy has a loophole, no bundle of measures can last forever. Due to the tight budgets cost-containment efforts have to be continued in the following years, which is also evident from recent developments. An end of the savings policy is not in sight.

ÖBIG: Pharmaceutical expenditure. Cost-containment strategies

November / December 2001, Vienna

Arzneimittelausgaben. Strategien zur Kostendämpfung in der Europäischen Union

474 p., 115 tables, 85 figures
ISBN 3-85159-024-4, ATS 4,816.10 / € 350.-

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<http://www.oebig.at>
by selecting "publications"

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Belgium

Association Générale de l'Industrie du Médicament (AGIM)

Association Pharmaceutique Belgique (APB)

Institut National d'Assurance Maladie – Invalidité (INAMI)

Denmark

Sundhedsministeriet (SUM), 4 Kontor

Danmarks Apotekerforeningen

Lægemiddelindustriforeningen (LIF)

Germany

Bundesministerium für Gesundheit (BMG)

Bundesvereinigung Deutscher Apothekerverbände (ABDA)

Finland

Kansaneläkelaitos (KELA)

Lääkelaitos

Lääkeiden hintalautakunta

Suomen Apteekkariliitto / Tiedotus

France

Caisse Nationale d'Assurance Maladie des Travailleurs Salariés (CNAMTS)

Syndicat National de l'Industrie Pharmaceutique (SNIP)

Greece

National Drug Organisation (EOF)

Pharmetrica S.A.

Hellenic Association of Pharmaceutical Companies (SFEE)

Social Insurance Institute (IKA)

Great Britain

Association of British Pharmaceutical Industry (ABPI)
British Association of Pharmaceutical Wholesalers (BAPW)
Department of Health (DoH), Medicines Pharmacy and Industry Branch
Medicines Control Agency (MCA)
Pharma Pricing & Reimbursement (PPR)
Royal Pharmaceutical Society of Great Britain (RPSGB)

Ireland

Department of Health and Children, General Medical Services (GMS) Division
General Medical Services (Payments) Board
Irish Medicines Board (IMB)
Irish Pharmaceutical Healthcare Association (IPHA)
Irish Pharmaceutical Union (IPU)

Italy

Federfarma

Luxembourg

Groupement des Grossistes
Ministère de l'Economie, Office des Prix
Union des Caisses de Maladie

The Netherlands

Ministerie van Volksgezondheit, Welzijn en Sport (VWS)

Austria

Bundesministerium für Soziale Sicherheit und Generationen (BMSG)
Hauptverband der österreichischen Sozialversicherungsträger
Österreichische Apothekerkammer (ÖAK)
Statistik Austria

Portugal

Instituto Nacional da Farmácia e do Medicamento (INFARMED)

Sweden

Kronans Droghandel
Läkemedelsverket
Landstingsförbundet
Riksförsäkringsverket (RFV)
Apoteket

Spain

Ministerio de Sanidad y Consumo

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List of abbreviations

ABDA	Bundesvereinigung Deutscher Apothekerverbände (Germany)
ABPI	Association of British Pharmaceutical Industry (Great Britain)
AESGP	Association Européene des Spécialités Pharmaceutiques Grand Public (EU)
AGIM	Association Générale de l'Industrie du Médicament (Belgium)
APB	Association Pharmaceutique Belgique (Belgium)
approx.	approximately
AT	Austria
BAPW	British Association of Pharmaceutical Wholesalers (Great Britain)
BASYS	Beratungsgesellschaft für angewandte Systemforschung mbH (Germany)
BE	Belgium
BMAGS	Bundesministerium für Arbeit, Gesundheit und Soziales (Austria)
BMG	Bundesministerium für Gesundheit (Germany)
BMSG	Bundesministerium für soziale Sicherheit und Generationen (Austria)
CENSIS	Centro Studi Investimenti Sociali (Italy)
cf.	compare
cit.	cited
CNAMTS	Caisse Nationale d'Assurance Maladie des Travailleurs Salariés (France)
DE	Germany
DK	Denmark
DoH	Department of Health (Great Britain)
€	Euro
EC	European Community
EEC	European Economic Community
EFP	Especialidades Farmacéuticas Publicitarias (Spain)
EFPIA	European Federation of Pharmaceutical Industries Associations (EU)
e.g.	for example
EMA	European Medicines' Evaluation Agency (EU)
EOF	National Drug Organisation (Greece)
ES	Spain
EU	European Union
FI	Finland
FR	France

GB	Great Britain
GDP	gross domestic product
GMS	General Medical Services (Ireland)
GR	Greece
HE	health expenditure
HTA	Health Technology Assessment
IE	Ireland
IKA	Social Insurance Institute (Greece)
IMB	Irish Medicines Board (Ireland)
IN	inhabitant
INAMI	Institut National d'Assurance Maladie – Invalidité (Belgium)
INFARMED	Instituto Nacional da Farmácia e do Medicamento (Portugal)
IPHA	Irish Pharmaceutical Health Association (Ireland)
IPU	Irish Pharmaceutical Society (Ireland)
IT	Italy
IWI	Industriewissenschaftliches Institut (Austria)
KELA	Kansaneläkelaitos (Finland)
LIF	Lægemiddelindustriforeningen (Denmark), Läkemedelsindustrieföreningen (Sweden)
LU	Luxembourg
MCA	Medicines Control Agency (Great Britain)
MRFG	Mutual Recognition Facilitation Group (EU)
n.a.	not available
NHS	National Health Service (Great Britain)
NICE	National Institute for Clinical Excellence (Great Britain)
NL	the Netherlands
no.	number
ÖAK	Österreichische Apothekerkammer (Austria)
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen (Austria)
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-Counter

p.	page
PE	pharmaceutical expenditure
pharm.	pharmaceutical
pkg.	package
POM	prescription-only medicines
PPP	pharmacy purchase price
PPR	Pharma Pricing Review, since May 1999: Pharma Pricing & Reimbursement
PPRS	Pharmaceutical Price Regulation Scheme (Great Britain)
PR	prescription
priv.	private
PRP	pharmacy retail price
PT	Portugal
pub.	public
reimb.	reimbursable
RFV	Riksförsäkringsverket (Sweden)
RPSGB	Royal Pharmaceutical Society of Great Britain (Great Britain)
SE	Sweden
SFEE	Hellenic Association of Pharmaceutical Companies (Greece)
SNIP	Syndicat National de l'Industrie Pharmaceutique (France)
SNS	Sistema Nacional de Salud (Spain)
SUM	Sundhedsministeriet (Denmark)
VAT	value-added tax
VMRFG	Veterinary Mutual Recognition Facilitation Group (EU)
vol.	volume
VWS	Ministerie voor Volksgezondheid, Welzijn en Sport (the Netherlands)
WS	wholesale

1 Introduction

The Austrian Health Institute ÖBIG (Österreichisches Bundesinstitut für Gesundheitswesen) has been commissioned by the Federal Ministry of Labour, Health and Social Affairs (BMAGS), which is now called the Federal Ministry of Social Security and Generations (BMSG), to prepare a study on the regulation of pharmaceutical markets in the European Member States. The German version of this study was published in November 2001 under the title “Arzneimittelausgaben. Strategien zur Kostendämpfung in der Europäischen Union“ (ÖBIG 2001a). This comprehensive study of approx. 500 pages (long version) describes and analyses the current health and pharmaceutical systems and cost-containment measures in the pharmaceutical sector in all 15 individual Member States, and presents a comparison of results on the EU level.

With the publication at hand “Benchmarking Pharmaceutical Expenditure. Cost-Containment Strategies in the European Union“ ÖBIG is taking a further step and meeting the demand for a compact summary of results: The compact version “Benchmarking Pharmaceutical Expenditure. Cost-Containment Strategies in the European Union“ offers a systematic description of the health care systems of the EU member countries, a comparative study of the pharmaceutical systems, a chronological survey of central cost-containment measures for pharmaceuticals and an analysis of the effects of these cost-containment measures.

The study, published in December 2001, is available in German as “Benchmarking Arzneimittelausgaben. Strategien zur Kostendämpfung in der Europäischen Union“ and in English as “Benchmarking Pharmaceutical Expenditure. Cost-Containment Strategies in the European Union“.

Furthermore, country portraits of all EU Member States are available at ÖBIG (cf. list of publications).

1.1 Background

Low economic growth, high unemployment and restricted public spending characterised the economic situation of European countries during the 90s. The aggravated economic situation in connection with changed basic conditions in the health sector (aging population, increasing life expectancy, medical-technological progress) have created need for reforms, to which all Member States of the European Union (EU) have reacted with cost-containment measures.

In most countries pharmaceutical spending represents the third-largest amount in the health budget after the in-patient and out-patient sectors. The average spending of EU countries on the pharmaceutical sector amounts to 15 per cent of the health budget (1999).

During the 90s public interest in the pharmaceutical sector increased steadily. In the last decade a series of measures have been taken in the EU countries, among them various drastic alterations to the system. In the ÖBIG studies published in 1998 “Pharmaceuticals. Market Control in nine European Countries” (ÖBIG 1998a) and “Arzneimittel. Vertrieb in Europa” [German version only] (ÖBIG 1998b) control measures of the European pharmaceutical markets during the first half of the 1990s were documented and analysed. However, the reform process has been continued in all EU countries and has by no means been finished yet.

1.2 Objectives

The main objective of the study at hand is to analyse cost-containment measures in the pharmaceutical sector in the fifteen Member States of the European Union and the success of reforms in containing – public – pharmaceutical expenditure.

The study

- describes and compares health and pharmaceutical systems as regards common features and differences;
- comprehensively documents and analyses trends in the pharmaceutical sector during the 90s;
- analyses cost-containment strategies of pharmaceutical expenditure by ranking key indicators (benchmarking) and
- evaluates them according to their effectiveness.

1.3 Methodology

The collection of information and data has essentially been based on three methodological tools:

- literature and Internet research (up to late June 2001),
- collection of key data from international publications and databases (e.g. OECD Health Data 2000) and
- surveys made by ÖBIG (written inquiries such as questionnaires and lists of questions, telephone and other personal interviews).

When collecting and processing data major importance has been attached to comparability and continuity.

During the empirical inquiries between June 2000 and April 2001 the project team contacted a total of 49 institutions in the fifteen EU countries (cf. Table 1.1). Primarily, we contacted health ministries, medicines agencies and health insurance funds, complemented by interest

groups of the participants in the pharmaceutical market. All bodies which supported the project team by providing information are listed in our acknowledgements.

Table 1.1: Introduction – Institutions contacted

Institution	BE	DK	DE	FI	FR	GR	GB	IE	IT	LU	NL	AT	PT	SE	ES
State															
Health Ministry		✓	✓				✓	✓	✓		✓	✓			✓
Health Authority							✓ ¹	✓ ¹	✓ ¹					✓ ²	
Medicines Agency ³				✓			✓	✓					✓	✓	
Reimbursement Body				✓ ⁴		✓ ⁵									
Social Insurance															
Head Organisation				✓										✓	
Health Insurance	✓				✓	✓				✓					
Interest Group															
Industry	✓	✓			✓		✓	✓							
Wholesalers							✓	✓		✓		✓		✓ ⁶	
Pharmacies	✓	✓	✓	✓			✓	✓	✓	✓		✓		✓	
Others															
Other Authorities										✓ ⁷				✓ ⁸	
Monitoring Institution						✓ ⁹									
Special Interest Media							✓								

¹ authority within the National Health Service

² regional health authority

³ registration body

⁴ national authority for pharmaceutical pricing and reimbursement

⁵ expert committee for reimbursement at the medicines agency

⁶ wholesale company

⁷ Ministry of Economic Affairs

⁸ interregional Scandinavian authority

⁹ independent institute for pharmaceutical monitoring

Source: ÖBIG

1.4 Structure

The study “Benchmarking Pharmaceutical Expenditure. Cost-Containment Strategies in the European Union” is divided into eight chapters, which deal with the following topics:

- **Pharmaceutical Expenditure (Chapter 2)**

Determinants of pharmaceutical expenditure and fundamental control measures are discussed against the backdrop of the current level of pharmaceutical expenditure in the European Union.

- **European Union (Chapter 3)**

This chapter provides a summary of all current regulations at the EU level which are relevant for the pharmaceutical sector.

- **Health Care Systems (Chapter 4)**

In this chapter the health care systems of the fifteen Member States are compared as regards the institutional framework and their organisation (social insurance systems versus national health service) as well as their financing. The services offered in the out-patient and in-patient sectors and access to those services (keyword: gatekeeper) are described for each Member State. The chapter concludes with a survey of the reforms in the health care sector.

- **Pharmaceutical Systems (Chapter 5)**

This chapter gives a comparative presentation of the pharmaceutical systems of the fifteen EU countries including registration, reimbursement, pricing and co-payment regulations. One sub-chapter is dedicated to regulations as regards margins for pharmaceuticals as well as to a comparison of average wholesale and pharmacy margins and VAT in the pharmaceutical sector.

- **Cost-containment Strategies (Chapter 6)**

A comprehensive table gives a chronological overview of cost-containment measures in the pharmaceutical sector. Control measures are analysed taking into consideration the objectives of the activities (price control versus volume control), the frequency, the countries concerned and the actors.

- **Benchmarking (Chapter 7)**

Key indicators of the pharmaceutical sector (pharmaceutical expenditure, public and private financing, regulations, etc.) of the fifteen countries are ranked in a table. A connection between the development of public pharmaceutical expenditure between 1990 and 1999 and cost-containment measures is established and evaluated.

- **Conclusion (Chapter 8)**

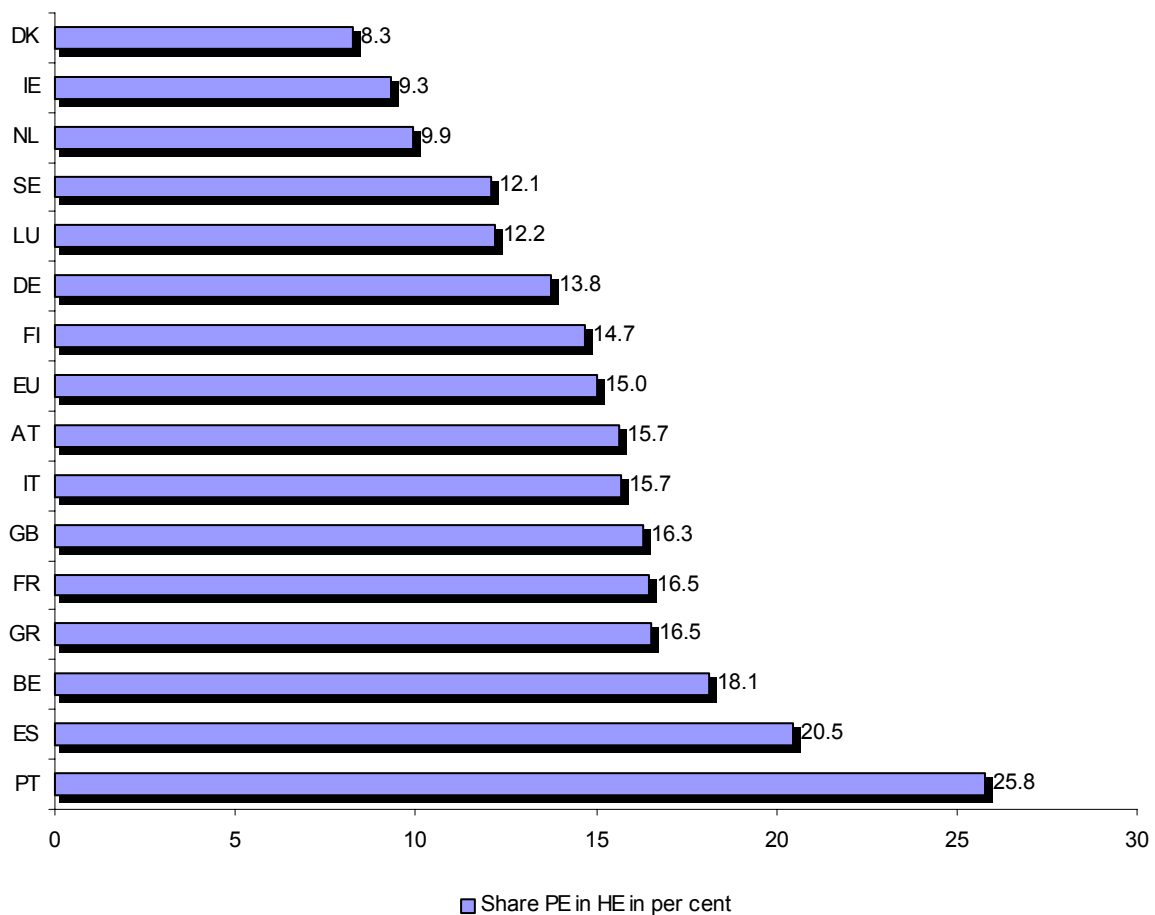
In a final conclusion the effectiveness of the control measures in the EU Member States is assessed as regards cost-containment of pharmaceutical expenditure.

2 Pharmaceutical expenditure

2.1 Importance

Expenditure on pharmaceuticals is the third-largest item in health budgets, after expenditure on in-patient and out-patient health care. Figure 2.1 shows the significance of pharmaceutical expenditure in relation to health expenditure in the Member States of the European Union.

Figure 2.1: Pharmaceutical expenditure – Share of pharmaceutical expenditure¹ in total health expenditure 1997 / 1998 / 1999



PE = pharmaceutical expenditure, HE = health expenditure

1997: IE; 1998: PT, ES, BE, GR, GB, FI, LU, SE, NL; 1999: FR, IT, AT, DE, DK

¹without hospital market

Source: OECD 2000; information gathering by ÖBIG

2.2 Determinants

The level of pharmaceutical expenditure is determined by several factors:

- General level of income:
The higher the per capita gross domestic product, the higher the expenditure on health care and/or pharmaceuticals.
- Remuneration system for practising physicians:
Flat-rate capitation fees for practising physicians lead to lower pharmaceutical expenditure if access to specialist health care is restricted, whereas fees for services in a system with a free choice of physicians generally lead to increased pharmaceutical expenditure (BASYS 1995, Wieninger 1998).
- Age structure of the population:
The older the population, the higher the need for pharmaceuticals, and the higher the expenditure.
- Regulatory framework:
Intervention by the state and measures taken to control the pharmaceutical market also have an impact on pharmaceutical expenditure.

In addition, political and economic conditions, such as the significance of the pharmaceutical industry in a country, can play an important role.

The level and development of pharmaceutical expenditure is affected by several factors which may often be interrelated. Without any doubt, the decisive factor is the structure of the regulation and control systems.

2.3 Control measures

In its broadest sense, the term 'control' includes any kind of state intervention in the behaviour of economic subjects. Depending on the degree of influence exerted, one distinguishes between orders and prohibitions (direct control), and monetary and non-monetary incentives or deterrents (indirect control). In its narrow sense, the term "control" only refers to direct interventions (cf. Ewers 1989, Weizäcker 1982, cited in: Schöffski 1995). Control measures aim at replacing missing market impacts or correcting undesired market impacts.

In the health care sector in general and also in the pharmaceuticals system, there is broad consensus that control measures are required because of the peculiarities of the market such as

- the three-tier demand system
(physician = demander, patient = consumer, health care system = payer),
- limited competition on the supply side
(partly restricted competition among the suppliers) and
- positive and negative external effects
(e.g. treatment or non-treatment of infectious illnesses has an impact on society as a whole)

This is to say that the health care and the pharmaceutical market cannot be left to the free market forces.

Table 2.1: Pharmaceutical expenditure – Control measures for cost-containment

Control measures	Level of primary impact		Control effect	
	price	volume	direct	indirect
determination of prices by the state	✓		✓	
price freezes and reductions by the state	✓		✓	✓
reference price system ¹	✓			
pharmaceutical budgets		✓		✓
positive and negative lists ²	✓			✓
exclusion from positive list ³		✓		✓
re-classification ³		✓		✓
co-payments ⁴		✓		✓
promotion of generics	✓			✓

¹ In the reference price system, similar groups of pharmaceuticals are combined and a (maximum) price for reimbursement is determined. If this price is exceeded, the patient has to pay the difference to the reference price.

² Lists in which pharmaceuticals which may be prescribed at the expense of the social insurance institutions and/or the National Health Service (positive list) or must not be prescribed at the expense of such bodies (negative list).

³ The exemption of previously prescription-only pharmaceuticals from prescription and the de-listing of pharmaceuticals mainly has a restricting impact on the volume of pharmaceuticals prescribed at the expense of the health care system. In most cases, the costs are shifted towards the patients.

⁴ Co-payments usually have a minor impact only on the limitation of quantity. In order to have a controlling impact, co-payments have to be relatively high, as has been proved in surveys. This would be at the expense of sick and socially disadvantaged persons (distribution conflict).

Source: ÖBIG 1998a, Scheil-Adlung 1998

Initially, the national and Community regulations on the pharmaceutical market focused on safeguarding the safety of pharmaceuticals (e.g. provisions on the marketing of pharmaceuticals). Since the beginning of the 1990s, an increasing number of control measures have been taken in the individual countries in order to limit – in particular public – pharmaceutical

expenditure. However, various different ways have been chosen in order to achieve one and the same goal.

In general, control measures for the limitation of expenditure may be aimed at effecting price and/or volume. Furthermore, direct or indirect strategies can be applied:

- direct strategies include statutory provisions having a direct impact on the actors involved (suppliers of pharmaceuticals, patients) (control in the narrow sense of the term).
- indirect strategies are behaviour incentives, usually entailing financial consequences for the actors.

Table 2.1 shows typical control instruments for the limitation of expenditure on the pharmaceutical market according to the distinction described above.

In most countries, a combination of market-economic and state control elements is used to control pharmaceutical expenditure.

3 European Union

3.1 Current provisions

The European market for pharmaceuticals is regulated both by Community and national legislation. As the aim of the control measures taken by the European Union (EU) is to achieve a single market for pharmaceuticals (ensuring the free movement of goods), the provisions predominantly refer to the registration and distribution of pharmaceuticals. An overview of the most important provisions laid down by law, directive, regulation or administrative action of the EU is given in Table 3.1.

Table 3.1: European Union – Overview of the most important statutory provisions regarding pharmaceuticals

Area	Provisions
Patents	<ul style="list-style-type: none"> • Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products
Registration	<ul style="list-style-type: none"> • Council Directive 65/65/EEC of 3 May 1989 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products • Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products • Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology • Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products • Council Regulation (EEC) No. 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products
Classification	<ul style="list-style-type: none"> • Council Directive 92/26/EEC of 31 March 1992 concerning the classification for the supply of medicinal products for human use
Prices of medicinal products	<ul style="list-style-type: none"> • Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems
Distribution	<ul style="list-style-type: none"> • Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use • Guidelines on good distribution practice regarding medicinal products for human use 94/C 63/03 • Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts

☞ table to be continued

Table 3.1 (continued): European Union – Overview of the most important statutory provisions regarding pharmaceuticals

Area	Provisions
Advertising	<ul style="list-style-type: none"> • Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use • Council Directive 89/552/EEC of 3 October 1989 on the co-ordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities • Directive 97/36/EC of the European Parliament and of the Council of 30 June 1997 amending Council Directive 89/552/EEC on the co-ordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities • Directive 97/55/EC of the European Parliament and of the Council of 6 October 1997 concerning comparative advertising

Source: ÖBIG 1998a, 1998b and 2000b

Since 1 January 1995 there exist three different registration procedures:

- the centralised procedure for pharmaceuticals derived from biotechnology (compulsory) and innovative pharmaceuticals (optional) which is carried out at the European Medicines' Evaluation Agency (EMA) in London and is automatically valid for all Member States of the EU,
- the decentralised procedure in which national registrations are mutually recognised, and
- the national authorisation procedure in cases where pharmaceuticals are brought on the market in one country only.

From the beginning of 1995 to January 2001, 155 pharmaceuticals were registered in centralised procedures and 444 pharmaceuticals were authorised according to the decentralised procedure. Among the products registered in decentralised procedures 182 were pharmaceuticals with a new active substance, 16 were OTC-products and 246 were generics. During the same period, 309 procedures resulted in the withdrawal of a pharmaceutical product from the market in at least one Member State in order to prevent arbitration proceedings at Community level. If no mutual recognition can be achieved a Member State is theoretically entitled to institute arbitration proceedings. However, this is avoided in practice by withdrawing the application for registration in at least one Member State.

In December 1999 a regulation on orphan medicinal products (Regulation (EC) No. 141/2000) was adopted which introduced a Community procedure for the classification of orphan drugs. A separate committee (Orphan Drug Committee of the EMA) was set up for the examination of the relevant applications. This regulation contains provisions on the application for a Community registration for bringing a pharmaceutical on the market, on market exclusivity rights for ten years and the criteria for support. At the end of 2000, the first pharmaceutical was granted orphan status in accordance with this regulation.

The control measures, e.g. pricing and reimbursement regulations, are still predominantly within the sphere of responsibility of national regulation. Only one Community directive

(89/105/EC – Transparency Directive) has been adopted which aims at safeguarding transparency of national pricing and limiting the duration of pricing procedures.

3.2 The future

As the legal framework of the EU in the area of pharmaceuticals is composed of a multitude of directives, a proposal for the preparation of a Community code for medicinal products for human use was submitted in 1999. This Community code is to create a harmonised source of law without substantially changing existing legislation.

In order to optimise registration procedures, the EU has made numerous recommendations in recent years, e.g. to the Member States regarding the increase of acceptance of bio-equivalence studies from other countries, or to the applicants regarding the reduction of formal problems.

A revision of the registration procedure on the basis of an evaluation was already provided for in Article 71 of Regulation 2309/93/EC. The evaluation was carried out in the year 2000. On 22 January 2001, a first working document of the European Commission was published as a basis for a revision of the legal provisions (European Commission 2001). On 18 July 2001, the Commission adopted a proposal for a comprehensive renewal of EU pharmaceutical legislation. This proposal contains a draft regulation on the marketing authorisation and the functioning of the EMEA, a draft directive on medicinal products for veterinary use and a draft directive for medicinal products for human use. Some of these proposals are listed in Table 3.2.

Table 3.2: European Union – Proposals for the revision of Community procedures for pharmaceuticals for human use

Area	Proposals
Duration of registration procedure	Shortening of the time periods so that all procedures take less than one year.
Renewal procedure	Renewal after five years is cancelled, all authorisations are to be valid for an unlimited period of time.
Centralised procedure	As the centralised procedure was rated very positively upon evaluation, the scope of application of this procedure is to be extended to all new active substances, and the option to choose between registration procedures is to be extended (to all medicinal products not derived from biotechnology) or general freedom of choice between options may be introduced.
Generics	For generics of brands which have been registered in a centralised procedure, registration according to the centralised procedure is to be made possible.
“Fast-track procedure”	For pharmaceuticals which have a significant therapeutic effect and are urgently required by patients, a “fast-track procedure” could be introduced.

☞ table to be continued

Table 3.2 (continued): European Union – Proposals for the revision of Community procedures for medicinal products for human use

Area	Proposals
"Compassionate use"	The use of pharmaceuticals not yet registered could be tolerated under certain conditions by creating a European system of "compassionate use".
Decentralised procedure	Different modalities for pharmaceuticals already registered and those not yet registered are to be introduced. The informal groups for mutual recognition (MRFG and VMRFG) are to be given formal and legal status. Arbitration proceedings have to be improved and the time periods for evaluation shortened.
EMA	As regards the EMA, organisational changes are proposed in order to increase its independence, quality and efficiency.
Procedures for the adoption of resolutions	In order to shorten the decision making process at the Commission, authorisations have been extended and signing powers granted.

Source: European Commission 2001a and 2001b

Furthermore, in discussions on the different price levels of pharmaceuticals within the EU, the Council and the Commission found that fixing of prices at Community level was not desirable as regards safeguarding health and economic interests. However, the single market could be promoted by a process differentiating between certain groups of pharmaceuticals (OTC/prescription-only products, pharmaceuticals with/without patent protection).

Given the significance of innovations in the pharmaceutical sector for health policy and the economy, research is to be promoted at Community level. Such promotion is to focus on co-operation between the Member States (e.g. strategies against antibiotic resistance) on the one hand and concrete programmes facilitating innovations at the EU level on the other hand.

4 Health care systems

This chapter contains an overview of the health care systems of the 15 EU Member States. The main characteristics of the health care systems are described briefly, for example the institutional framework, financing, organisation and particularities of out-patient and in-patient health care as well as the reform measures adopted in the past decade. The core subject of this study – pharmaceuticals – is dealt with and analysed in detail in Chapters 5 to 8.

4.1 Institutional framework

All EU countries offer primary health care financed on the principle of solidarity. Yet both the organisational type and the range of services vary considerably in the individual countries.

In five Member States of the EU (Belgium, Germany, France, Luxembourg and Austria) health care is organised with social insurance institutions, which developed from corporate-style security structures.

Table 4.1: Health care systems – Organisational types

Country	Social Security System	National Health Service	Mixed system
Belgium (BE)	●		
Denmark (DK)			●
Germany (DE)	●		
Finland (FI)		●	
France (FR)	●		
Greece (GR)			●
Great Britain (GB)		●	
Ireland (IE)		●	
Italy (IT)		●	
Luxembourg (LU)	●		
Netherlands (NL)			●
Austria (AT)	●		
Portugal (PT)		●	
Sweden (SE)			●
Spain (ES)		●	

Source: ÖBIG 2001a; information gathering by ÖBIG

In six Member States (Finland, Great Britain, Ireland, Italy, Portugal and Spain) basic health care is guaranteed by National Health Services.

In the remaining Member States of the EU there are mixed systems made up of social insurance institutions and the National Health Service (Denmark, Greece, Sweden). Only in the Netherlands does the health care system consist of a combined system of public and private health insurance. Statutory health insurance against acute diseases is obligatory for persons whose incomes do not exceed a certain limit (insurance obligation); persons with higher incomes as well as self-employed persons may opt for private health insurance. During the 1990s not only the Netherlands but also Germany largely changed the concept of obligatory insurance.

In addition to the institutional framework also the range of services in primary health care is of importance. Normally this is only defined very generally, but in some countries selected medical services are explicitly excluded from primary health care. In the mid-1990s in the Netherlands, for example, dental care for adults as well as the costs of physiotherapeutic treatment were de-listed.

The extent of medical care is not only determined by the exclusion of entire groups of health services from primary health care but also by the amount of co-payment. Co-payments for health care services differ considerably in the Member States. In Finland, for example, co-payments for out-patient and in-patient care are limited to about € 600.- per year. Besides, additional payments for pharmaceuticals up to a limit of about € 600.- per year may have to be made. In other countries, for example Great Britain, co-payments are not required for out-patient and in-patient basic health care, but they are for pharmaceuticals.

4.2 Financing

In the EU countries at present health expenditure amounts to an average of 8.0 per cent of the gross domestic product (cf. Table 4.2). In Germany, France and Belgium a much higher percentage of the gross domestic product is spent on health services, whereas in Luxembourg, Ireland, Finland, Great Britain and Spain this percentage is below the average of the Member States.

Table 4.2: Health care systems – General indicators of the countries

Indicators ¹	Belgium	Denmark	Germany	Finland	France	Greece	Great Britain	Ireland	Ø EU
Demographic indicators									
Inhabitants	10.2 million (1999)	5.3 million (1999)	82.1 million (1999)	5.2 million (1999)	59.1 million (1999)	10.6 million (1999)	59.3 million (1999)	3.7 million (1999)	-
Life expectancy women (at birth)	81.1 years (1998)	78.8 years (1999)	80.5 years (1998)	81.0 years (1999)	82.2 years (1998)	79.4 years (1999)	80.0 years (1998) ²	78.5 years (1996)	81.0 years
Life expectancy men (at birth)	74.8 years (1998)	74.0 years (1999)	74.5 years (1998)	73.7 years (1999)	74.6 years (1998)	74.6 years (1999)	75.1 years (1998) ²	73.2 years (1996)	74.8 years
Economic indicators									
Gross domestic product/ inhabitant	22,700 € (1999)	30,608 € (1999)	24,150 € (1999)	23,360 € (1999)	22,775 € (1999)	11,086 € (1999)	22,486 € (1999)	22,329 € (1999)	22,381 €
Health expenditure/ inhabitant	1,937 € (1998)	2,562 € (1999)	2,532 € (1999)	1,538 € (1998)	2,085 € (1999)	853 € (1998)	1,585 € (1999)	1,360 € (1999)	1,713 €
Health expenditure as per cent of GDP	8.8% (1998)	8.3% (1999)	10.5% (1999)	6.9% (1998)	9.5% (1999)	8.3% (1998)	7.0% (1999)	6.4% (1998)	8.0%
Public health expenditure as per cent of GDP	7.9% (1998)	6.8% (1999)	7.9% (1999)	5.3% (1998)	7.3% (1999)	4.7% (1998)	5.9% (1999)	4.8% (1998)	6.1%
Indicators of health care services									
Acute care beds/1.000 inhabitants	5.2 (1996) ³	3.5 (1998)	7.0 (1998)	2.5 (1999)	4.3 (1998)	4.0 (1997)	2.4 (1998)	3.3 (1997)	4.1
Inhabitants/physician	256 (1998) ⁴	295 (1999)	282 (1999) ⁵	327 (1999)	336 (1998)	244 (1997)	582 (1998)	457 (1998)	350

Note: The EU average has been calculated on the basis of the data of the available years.

GDP = gross domestic product, Ø = average

Source: ¹ OECD 2000, or other source as indicated
² Office of National Statistics England 2000
³ European Observatory on Health Care Systems 2000a
⁴ European Observatory on Health Care Systems 2000a
⁵ BMG 2000

⁶ information gathering by ÖBIG (Statistik Austria), as of April 2001
⁷ European Observatory on Health Care Systems 2000c
⁸ Zornotta 2001
⁹ LIF 2000

☞ table to be continued

Table 4.2 (continued): Health care systems – General indicators of the countries

Indicators ¹	Italy	Luxembourg	Netherlands	Austria	Portugal	Sweden	Spain	Ø EU
Demographic Indicators								
Inhabitants	57.0 million (1999)	0.4 million (1999)	15.8 million (1999)	8.1 million (1999)	10.0 million (1999)	8.9 million (1999)	39.4 million (1999)	-
Life expectancy women (at birth)	81.6 years (1997)	80.0 years (1996)	80.7 years (1998)	80.9 years (1998)	78.8 years (1998)	81.9 years (1999)	82.4 years (1999)	81.0 years
Life expectancy men (at birth)	75.3 years (1997)	73.0 years (1996)	75.2 years (1998)	74.7 years (1998)	71.7 years (1998)	77.0 years (1999)	74.9 years (1999)	74.8 years
Economic indicators								
Gross domestic product/ inhabitant	18,919 € (1999)	40,776 € (1999)	23,521 € (1999)	24,255 € (1999)	10,410 € (1999)	24,145 € (1999)	14,190 € (1999)	22,381 €
Health expenditure/ inhabitant	1,593 € (1999)	2,260 € (1998)	1,909 € (1998)	1,876 € (1999) ⁶	765 € (1998)	1,915 € (1998)	932 € (1998)	1,713 €
Health expenditure as per cent of GDP	8.4% (1999)	5.9% (1998)	8.6% (1998)	8.0% (1999) ⁶	7.8% (1998)	8.4% (1998)	7.1% (1998)	8.0%
Public health expenditure as per cent of GDP	5.6% (1998)	5.4% (1998)	6.0% (1998)	5.7% (1999) ⁶	5.2% (1998)	7.0% (1998)	5.4% (1998)	6.1%
Indicators of health care services								
Acute care beds /1.000 inhabitants	5.2 (1997)	5.5 (1998)	3.6 (1999) ⁷	6.3 (1998)	3.1 (1998)	2.5 (1999)	3.2 (1996)	4.1
Inhabitants/physician	170 (1998)	321 (1999)	788 (1999) ⁸	332 (1998)	321 (1998)	311 (1999) ⁹	230 (1998)	350

Note: The EU average has been calculated on the basis of the data of the available years.

GDP = gross domestic product, Ø = average

Source: ¹ OECD 2000, or other source as indicated
² Office of National Statistics England 2000
³ European Observatory on Health Care Systems 2000a
⁴ European Observatory on Health Care Systems 2000a
⁵ BMG 2000

⁶ information gathering by ÖBIG (Statistik Austria), as of April 2001
⁷ European Observatory on Health Care Systems 2000c
⁸ Zornotta 2001
⁹ LIF 2000

Considering health expenditure per inhabitant, the average EU expenditure for health care is € 1,713.- per head (cf. Table 4.2). Joining Spain at the bottom end of the table are Greece and Portugal with health expenditures per inhabitant below € 1,000.-. France, Luxembourg, Germany and Denmark were at the top of the list with expenditures exceeding € 2,000.-. Considering also purchasing power in the comparison of per capita health expenditure, the ranking of the countries does not change essentially, but the spectrum of expenditure is smaller.

In the majority of EU Member States public health expenditure as a proportion of overall health expenditure declined in the 1990s. This development, i.e. the increase of the share of private health expenditure, was particularly remarkable in Italy, Sweden, Greece and Finland. Also in Austria and Spain the burden for private households increased. In Germany and the Netherlands the share of public sector health expenditure rose in the first half of the 1990s, but then went down again due to public cost-containment. In Ireland and Portugal the share of public sector health expenditure increased a little in the past decade. Great Britain is planning to raise public funds for health care in order to improve the health care situation.

4.3 Out-patient and in-patient health care

The average number of inhabitants per physician in the EU is 350 – considering both practising physicians and physicians working in in-patient care. However the density of physicians varies considerably between the individual Member States. In Italy, 170 inhabitants share one physician, whereas according to statistics in the Netherlands there are 788 inhabitants per physician (cf. Table 4.2).

In the Member States of the EU out-patient health care is organised in individual practices, group practices, health centres and hospital out-patient departments. In countries with National Health Services or mixed systems basic medical care is mainly provided in health centres, while specialist health care normally is guaranteed in out-patient departments of hospitals. In this case general practitioners normally act as gatekeepers “controlling” the access to specialists and in-patient health care. In Member States of the EU with a social security system individual practices preponderate. These countries also offer free choice of physicians and free access to specialists (cf. Table 4.3).

The different types of remuneration imply different kinds of incentives for the care providers. Fee for service implies the incentive to enlarge quantities, thereby maximising income instead of optimising treatment. Capitation fees and fixed salaries, on the other hand, entail the risk of quality deficiencies and insufficient health care for the chronically ill. Member States in which primary health care is organised by National Health Services tend to prefer remuneration by salaries or capitation fees. In countries with social security systems remuneration normally is based on tariffs for individual services, which are fixed after negotiations with the health insurance institutions. In addition, remuneration is also organised as a combination of remuneration through flat rates and fee for service, in an attempt to reduce the disadvantages of both systems (cf. Table 4.4).

In the majority of EU Member States out-patient care is predominantly provided as benefit in kind, i.e. according to the system the health care providers are paid directly by the health insurance or by the public institutions. In Belgium, France, Luxembourg and Ireland – in the latter only for persons whose incomes exceed a determined limit, which is the case for about two thirds of the population – the principle of benefits in cash is used in out-patient primary health care. In such a system the care provider is directly paid by the patient, to whom the full amount or part of it is reimbursed by the health insurance institution.

In only three Member States (Greece, Great Britain and Spain) no co-payment is charged for out-patient primary health care. In all other countries co-payments are the rule, varying in amount and type (social clauses, etc.).

Table 4.3: Health care systems – Services and access

Country	Health care services		Access
	out-patient	in-patient	
BE	individual practices and out-patient departments	predominantly private non-profit and public institutions	free choice of physician, change of physician possible, free access to specialists and in-patient care
DK	individual practices, family physician system	predominantly public institutions	regionally limited choice, gatekeeping to specialists and in-patient care
DE	primarily individual practices	predominantly public and private non-profit institutions	free choice per quarter
FI	primarily health centres, about a fifth of municipalities have a family physician system, specialist health care in hospital out-patient departments	predominantly public institutions, 21 hospital districts	gatekeeping to specialists and in-patient care
FR	primarily individual practices, additionally health centres, pilot project family physician system	predominantly public institutions, the share of private institutions is about a third of the total number of beds	free choice, free access
GR	mainly national health centres, in addition polyclinics of the social insurance institutions and practising physicians	predominantly public institutions, the share of private institutions is about a third of the total number of beds	
GB	primarily individual practices, family physician system, specialist health care in hospital out-patient departments	predominantly public institutions	gatekeeping to specialists and in-patient care

☞ table to be continued

Table 4.3 (continued): Health care systems – Services and access

Country	Health care services		Access
	out-patient	in-patient	
IE	primarily individual practices, specialist health care predominantly in hospital out-patient departments	predominantly public institutions	regionally limited choice for about a third of the population, free choice for the rest of the population, gatekeeping to specialists and in-patient care
IT	primarily individual practices, family physician system	predominantly public institutions	gatekeeping to specialists and in-patient care, free but regionally limited choice
LU	primarily individual practices	public and private non-profit institutions	free choice, free access to specialists and in-patient health care
NL	primarily individual and group practices, family physician system, specialist health care predominantly in hospital out-patient departments	primarily private non-profit institutions	free choice of physician, gatekeeping to specialists
AT	primarily individual practices	primarily public and private non-profit institutions	free choice (per quarter), limited access to specialists
PT	primarily health centres, family physician system, specialist health care in health centres, hospitals and individual practices	primarily public institutions, 50 per cent of private institutions profit-oriented	gatekeeping to specialists, free choice
SE	primarily health centres, in addition public practices of family physicians and individual practices, specialist health care predominantly in hospital out-patient departments	primarily public institutions, six health care regions	direct access to specialists
ES	individual and group practices as well as health centres, family physician system, specialist health care primarily in out-patient clinics	primarily public institutions, plus private profit-oriented institutions	gatekeeping to specialists, free choice

Source: ÖBIG 2001a; information gathering by ÖBIG

As far as in-patient care is concerned, a trend to reduce capacities can be observed in all EU Member States. Thereby the number of long-term care beds has been reduced facilitating at the same time out-patient care. Owing to the inadequate situation as regards in-patient care Great Britain and Ireland plan to increase the number of acute care beds in the coming years. The average number of hospital beds per 1,000 inhabitants in the EU is 6.4, ranging from 3.7 beds per 1,000 inhabitants in Ireland to 11.3 beds in the Netherlands. The EU average is 4.1 acute care beds per 1,000 inhabitants, ranging from 2.4 beds in Great Britain to 7.0 beds in Germany (cf. Table 4.2).

The average length of stay has also decreased in all EU Member States – both when considering all beds and when only considering acute care beds.

In respect of the financing of hospitals there have been changes in nearly all Member States in the course of the 1990s frequently with new financing models being tested.

In general, it can be stated that currently a shift from flat rates to performance-oriented remuneration systems (flat per case fees) is taking place, as well as a shift from retrospective – i.e., based on the extrapolation of past data – budgets to performance or function-oriented budgets and/or a shift from deficit coverage by the state towards fixed prospective – i.e., calculated on the basis of future data - budgets (cf. Table 4.4).

Table 4.4: Health care systems – Remuneration

Country	Remuneration	
	out-patient	in-patient
BE	remuneration according to the scheme of fees fixed by the health insurance institutions, free remuneration for non-contract physicians	Prospective budgets, medical services: fee for services rendered
DK	mixture of capitation fees and fees for service, specialists by fee for service only	performance-oriented annual budgets, in cooperation with the regions
DE	fee for service	combined system of remuneration
FI	primarily employed physicians (salaried), in addition individual physician's practices with remuneration by fee for service	remuneration varies between the hospital districts (flat per case fees, daily rates)
FR	remuneration primarily according to the scheme of fees fixed by the health insurance institutions, in addition salaried physicians	according to diagnosis-related groups
GR	employed physicians (national health centres, polyclinics of social insurance institutions, municipal health centres)	public budgets for public hospitals, private hospitals financed by health insurance institutions and private funds
GB	general practitioners: "cost plus" principle, i.e. remuneration by capitation fee, fee for service, supplementary payments; specialists: salary	annual budget for hospitals (based on demographic structures)
IE	general practitioners: according to the group of insured persons remuneration by variable capitation fees or by fees for service according to the scheme of fees, plus lump sums; specialists: remuneration according to scheme of fees	annual budget for public hospitals
IT	partly salaried physicians, partly contract physicians with remuneration by capitation fees	performance-oriented model based on diagnosis-related groups
LU	fee for service according to the scheme of fees fixed by the health insurance institution	annually negotiated budget for hospitals – does not include remuneration for medical services provided by physicians, these are paid directly by the health insurance institution according to scales of fees

☞ table to be continued

Table 4.4 (continued): Health care systems – Remuneration

Country	Remuneration	
	out-patient	in-patient
NL	capitation fees for insured under the statutory health insurance, fee for services rendered for privately insured persons	“function-oriented” budgeting (considering demographic structure and infrastructure as well as number of out-patients, in-patient days, etc), furthermore pilot projects of a performance-oriented remuneration system
AT	contract physicians: general practitioners are paid via health insurance vouchers and fee for services rendered, specialists: fee for service according to the scheme of fees fixed by the health insurance institution	performance-oriented financing (diagnosis-related groups plus structural factor)
PT	salaried physicians in the National Health Service, fee for service for contract physicians	hospitals in the National Health Service: retrospective budgets
SE	primarily salaried physicians, fee for service for self-employed physicians	form of financing varies between health care regions, partly fixed annual budgets, partly flat per case fees but also fees per service
ES	employed physicians in primary health care: monthly salary plus capitation fees; resident physicians: capitation fees	financing through retrospective global budgets, testing of new forms of financing in some regions

Source: ÖBIG 2001a; information gathering by ÖBIG

4.4 Reforms

The EU Member States have adopted many reform measures in the past decade in order to achieve cost-containment in the health care system and to guarantee the most efficient use of resources possible.

Because of changes of governments or political reorientation, some reform concepts which had been elaborated with firm commitment have never been realised or have been revoked. In Greece, for example, only few governmental interventions were realised in the past decade, due to repeated changes of government. Also in Germany numerous measures were revoked after a change of government.

The cost-containment measures adopted were intended to control the demand and the supply on a micro- and macroeconomic level, and to change the institutional framework.

Demand-side measures include the extension of patient co-payments (Belgium, Germany, Austria, Portugal, Sweden), the exclusion of services (e.g. Belgium, Germany, the Netherlands) and the introduction of market economy elements (choice of health insurance fund in Germany and in parts of the acute care services provided by the statutory health insurance in the Netherlands). At the same time some countries took opposite measures, for example the

reduction of patient co-payments (in Germany after the change of government, in Italy prior to the elections) or extended primary health care (Ireland).

Nearly all Member States adopted supply-side measures at the macroeconomic level (budgeting, limitation of services, integration of different health care services). Also at a microeconomic level numerous measures have been taken by countries (e.g. the introduction of performance-oriented financing for in-patient care).

Changes of the institutional and service-related framework mainly aimed at decentralising responsibility in the health care systems (Denmark, Finland, Ireland, Italy, Portugal, Sweden and Spain). In Denmark and Sweden, for instance the responsibility to provide care infrastructures has been transferred to the municipalities.

In the next few years the financial requirements of the health care system will continue to increase, mainly due to demographic developments, medical progress, the shift of employment towards the services sector as well as the rise of diseases of civilisation. As a consequence further reforms of the European health care systems will be necessary.

Table 4.5: Health care systems – Important reforms

Country	Reforms
BE	<ul style="list-style-type: none"> • 1990 Introduction of a global budget for the health insurance institution and of budgets for individual sectors of the health care system, provision of correction mechanisms for the case of health expenditure exceeding the budget • 1993 Change of structure of the National Institute for Health and Invalidity Insurance (supervises the health insurance funds), reduction of services provided by the social insurance institution and increase of co-payment • 1997 Measures adopted in order to limit the number of physicians, dentists and physiotherapists
DK	<ul style="list-style-type: none"> • Shift of health care provision from the in-patient towards the out-patient sector, municipalities obliged to provide an adequate infrastructure • Since 1993 free choice of hospital (previously obligation for treatment in the local hospital)
DE	<ul style="list-style-type: none"> • Numerous reforms in the health care system aiming to facilitate elements of free market economy and stability of contributions • Cost-containment measures (capped budgets, increase of co-payment, exclusion of services from the list of services paid by the health insurance funds, etc.) • Structural changes in the health care system (for example, since 1996 insured persons may choose which health insurance fund they wish to belong to, introduction of "risk structure equalisation" between the health insurance funds in 1994, integrated health care in 2000)
FI	<ul style="list-style-type: none"> • Decentralisation of the health care system: responsibility for health care is shifted to municipalities • Organisation of out-patient care changed (staged introduction of a family physician system since 1994) • Introduction of an annual upper limit for co-payments in out-patient and in-patient sector (not considering pharmaceutical expenditure)

☞ table to be continued

Table 4.5 (continued): Health care systems – Important reforms

Country	Reforms
FR	<ul style="list-style-type: none"> Reforms of social insurance (Veil Plan 1993, Juppé Plan aiming to impose a ceiling on health insurance expenditure by means of annual budgets adopted by the parliament, introduction of “General Health Insurance” in the year 2000 in order to guarantee health insurance for the entire population) Change in the organisation of out-patient care (test model of a system called “physicians of reference”) Change in the financing of hospitals (introduction of a performance-oriented remuneration system based on diagnosis-related groups)
GR	<ul style="list-style-type: none"> 1983 Introduction of the National Health Service 1992 Numerous reforms announced (e.g. towards more competition), but never realised due to change of government 1998 Introduction of a positive list for pharmaceuticals (step towards harmonisation of inhomogeneous services performed within the health care system)
GB	<ul style="list-style-type: none"> Multitude of reforms aiming to rationalise the National Health Service (NHS), reduction of waiting lists, etc. Health Act from June 1999: basis of far-reaching changes which had retroactive effect from April 1999 and April 2000, e.g. abolition of fund-holding and creation of 481 Primary Care Groups consisting of all general practitioners and members of other out-patient health professions within a region In July 2000 presentation of the plan “Re-inventing the NHS” regarding reforms and investments: with the aim of aligning the health expenditure quota to the EU average
IE	<ul style="list-style-type: none"> Expansion of the services provided by the National Health Service in the 1990s, additionally efforts to facilitate quality assurance measures Measures to reduce waiting lists Regionalisation of health care (expansion of responsibility of Health Boards in 1996, strengthening their obligation of financial accounting)
IT	<ul style="list-style-type: none"> Administrative reform in the National Health Service (reorganisation of local health authorities as autonomous profit-oriented centres and of the respective managements with the installation of private managers according to the principle of competition from 1995 onwards, merger of local health units from 1996 onwards) Introduction of new co-payments (e.g. for specialists as well as laboratory and X-ray tests) and increase of co-payments Change of hospital financing (shift of remuneration from daily rates to a performance-oriented system based on diagnosis-related groups) Decentralisation of financing (from 2000 increased financial responsibility of regions)
LU	<ul style="list-style-type: none"> 1992 reorganisation of health insurance funds, expansion of the competencies of the head organisation, at the same time creation of a list of services (“nomenclature”) for the description and evaluation of all medical services 1992 limitation of government subsidies to the upper limit of 40 per cent of the overall health expenditure, 1999 further reduction of government subsidies to 37 per cent 1998 introduction of a statutory long-term care insurance, extension of programmes for the improvement of home-nursing
NL	<ul style="list-style-type: none"> 1992 Introduction of basic insurance (abolition after two years in 1994) Reforms aiming to promote the competition between acute care health insurance funds (e.g. contracts between health insurance funds and providers, reduction of state subsidies for health insurance funds, etc.) Cost-containment (e.g. de-listing of dental services and physiotherapeutic treatments for adults, cost-containment measures for pharmaceuticals)

☞ table to be continued

Table 4.5 (continued): Health care systems – Important reforms

Country	Reforms
AT	<ul style="list-style-type: none"> • 1997 Introduction of performance-oriented hospital financing (new provisions for the financing of hospitals plus accompanying measures such as the establishment of a national hospital and bio-medical equipment plan) • Expansion of out-patient care (out-patient care given preference over in-patient care) • From the middle of the 1990s cost-containment regarding pharmaceuticals (reduction of wholesale margins and prices as well as increase of co-payments for pharmaceuticals)
PT	<ul style="list-style-type: none"> • Decentralisation (creation of five regional health services provided with comprehensive competences in 1993) • 1993 Introduction of co-payments (income-dependent) • Change of hospital financing (replacement of funding through global budgets based on the updating of past data with budgets agreed after negotiations)
SE	<ul style="list-style-type: none"> • 1993/94 Introduction of a family physician system, subsequently with free choice of the physician (has been restricted again in the year 1996) • Shift of hospital financing towards a remuneration system based on flat per case fees • Establishment of an “internal market” (encouragement of competition) between providers and financiers
ES	<ul style="list-style-type: none"> • Decentralisation (creation of regional health services in all 17 regions, seven of which have been provided with comprehensive competences so far) • New provisions for the financing of the National Health Service (shift from financing with social security contributions towards exclusive funding by general taxation – completed by 1999) • Administrative reform of the NHS (introduction of management structures modelled on the private sector) • Promotion of the private sector (contracting out of services of the National Health Service – services provided by private institutions)

NHS = National Health Service

Source: ÖBIG 2001a; information gathering by ÖBIG

5 Pharmaceutical systems

This chapter outlines the current regulatory framework of pharmaceutical systems in the fifteen EU Member States (status: June 2001). Highlighting relevant regulations for a pharmaceutical on its way to the market, main characteristics in the individual countries are presented and patterns shown.

This chapter is subdivided into the sections registration, reimbursement, pricing, margins and co-payment.

5.1 Registration

As stated in Section 3.1, there have been three registration procedures in the European Union since 1995:

- centralised registration for pharmaceuticals derived from biotechnology (compulsory) and innovative pharmaceuticals (optional),
- decentralised registration on the basis of the mutual recognition of national registrations and
- national registration, which is gradually becoming less important.

Centralised registration is in the hands of the European Medicines' Evaluation Agency (EMA) which has its seat in London, whereas the responsibility for the two other registration procedures lies with national authorities. Only in four EU countries (Belgium, Italy, Luxembourg, Austria) do the Ministries of Health still function as registration authorities, whereas in all other countries registration applications are dealt with by specific institutions. Most of these institutions – usually called medicines agencies or institutes – are subordinated to the Ministries of Health and were established in the course of the 1990s (e.g. in Sweden as early as in 1990, in Spain in 1999). In some countries (Denmark, France, Ireland, Portugal) the competence of such authorities includes not only pharmaceuticals but also medical devices.

5.2 Reimbursement

In many EU countries, the step following registration is the decision on reimbursement, i.e., whether the pharmaceutical is to be supplied at the expense of social security institutions and/or the National Health Service. Reimbursable pharmaceuticals may be reimbursed either in full or in part. In some countries, the price of a pharmaceutical is determined and/or negotiated prior to the decision on reimbursement, in some countries (e.g., Sweden) both questions are dealt with in one and the same procedure.

Basically, the EU countries use two reimbursement systems, which partly co-exist (for different groups of pharmaceuticals):

- the reference price system, which concerns both reimbursement and pricing (for information on the reference price system see section 5.3), and
- a system with various reimbursement rates on a percentage basis, often in combination with pharmaceutical lists.

In some Member States (Germany, Great Britain, the Netherlands, Austria) all reimbursable pharmaceuticals insofar as they are not covered by the reference price system (in Germany and the Netherlands) are fully reimbursed by the public authorities. In other EU countries reimbursement rates differ. The systems are especially detailed in Belgium (six reimbursement rates) and in Portugal (different reimbursement rates for brands and generics).

Not all EU countries have a reimbursement rate of 100 per cent: In three Member States (Denmark, Greece and Spain) pharmaceuticals are never fully reimbursed.

As shown in Table 6.1 in the following chapter, during the 1990s pharmaceutical lists were introduced and/or the number of pharmaceuticals listed was modified. These lists either include pharmaceuticals which can be prescribed at the expense of the social security institutions and/or the National Health Service (in some countries called positive lists) or they are designed as negative lists which explicitly exclude pharmaceuticals from reimbursement.

Nine Member States of the European Union use negative lists, which differ in scope: in some countries (e.g., Sweden) they only include a rather small number of pharmaceuticals, in other countries their scope is more comprehensive. Twelve EU countries have pharmaceutical lists for products which can be supplied at the expense of the public authorities. This enumeration includes the Italian pharmaceutical book "Prontuario" and the Austrian pharmaceutical list "Heilmittelverzeichnis", which automatically qualifies pharmaceuticals listed for reimbursement. The planned positive list for Germany (cf. Table 5.1.) is not included.

Table 5.1: *Pharmaceutical systems – Pharmaceutical lists and reimbursement rates 2001*

Country	Positive list(s)	Reimbursement rates (in %)	Negative list(s)	Note
BE	✓	100, 80, 75, 50, 40, 20	-	-
DK	✓	85, 75, 50	-	-
DE	(✓)	100	✓	positive list planned
FI	✓	100, 75, 50	-	-
FR	✓	100, 65, 35	-	-
GR	✓	75	-	-
GB	-	100	✓	-
IE	✓	100	✓	reimbursement rate: different systems for population groups, in some schemes 100 per cent reimbursement only after payment of a deductible
IT	(✓)	100, 50	✓	“positive list”: pharmaceutical book “Prontuario” lists all pharmaceuticals which are reimbursed. Financial Act 2001 abolishes reimbursement rate of 50 per cent as of 1 July 2001
LU	✓	100, 80, 40	✓	-
NL	✓	100	-	-
AT	(✓)	100	✓	pharmaceutical list: generally, all pharmaceuticals are reimbursable; pharmaceuticals in the “Heilmittelverzeichnis” are reimbursed without further approval of health insurance institution negative list: comprises a few pharmaceuticals only
PT	✓	100, 70, 40, 20	(✓)	reimbursement rates: refer to brands, reimbursement rates for generics are 10 per cent higher; negative list: handbook for information as a basis for prescriptions
SE	✓	100, 90, 75, 50	✓	-
ES	-	90, 60	✓	-

Source: ÖBIG 2001a; information gathering by ÖBIG

Within the European Union, pharmaceutical budgets and measures for the control and review of the prescription patterns of physicians are becoming increasingly important for reimbursement.

One control element which predominantly influences volume is the limitation of pharmaceutical expenditure through budgets. Pharmaceutical budgets can be designed as national budgets (with all actors in the pharmaceutical system having responsibility) or as budgets for certain actors, generally physicians. Pharmaceutical budgets for physicians can provide for individual liability of each physician or for collective liability of a group of physicians (e.g., regional budgets).

Table 5.2: Pharmaceutical systems – Further regulations at reimbursement level 2001

Country	Pharmaceutical budgets	Measures for the control of physicians' prescription patterns
BE	national pharmaceutical budgets (annual target budgets), sanctions may be imposed in the form of repayments	prescription guidelines review of the prescription patterns of physicians review of pharmaceuticals as regards their reimbursement status within three years
DK	upper limit to pharmaceutical expenditure of the health insurance institutions 1998 and 1999	promotion of generics analysis and review of the reimbursement system institute for rational pharmaco-therapy
DE	regional pharmaceutical budgets for physicians (collective and individual liability) abolition of collective liability in 2002	prescription guidelines review of the prescription patterns of physicians promotion of generics
FI	-	analysis and review of the reimbursement system
FR	national pharmaceutical budgets (annual target budgets) release of pharmaceutical companies from a general repayment clause if they had agreed to sales targets in individual contracts	prescription guidelines "physicians of reference": obligation of physicians to economic prescribing review of pharmaceuticals as regards their prescription status
GR	-	pharmaceutical monitoring obligation of the pharmaceutical industry to supply sales figures
GB	global budgets in out-patient health care (including pharmaceuticals)	institute for evaluation review of prescription patterns of physicians
IE	individual pharmaceutical budgets for physicians with financial incentives	promotion of the prescription of generics
IT	national pharmaceutical budgets (annual target budgets, from 1998 to 2000 sanctions could be imposed in the form of repayments), pharmaceutical budgets for physicians (pilot project)	prescription guidelines promotion of generics obligation of regions and pharmacies to supply sales figures
LU	-	guidelines for physicians concerning prescription pattern
NL	national pharmaceutical budgets (annual target budget), without liability provisions	pharma-economic guidelines promotion of generics
AT	-	prescription guidelines list of economical pharmaceuticals co-operation projects for "reasonable use of pharmaceuticals" review of the prescription patterns of physicians
PT	national pharmaceutical budgets (annual target budgets), since 1997 sanctions may be imposed in the form of repayments	handbook for information as a basis for prescriptions review of pharmaceuticals as regards their reimbursement status after three years
SE	-	prescription guidelines institute for evaluation revision of reimbursement system
ES	national pharmaceutical budgets with repayment clauses (contract with the industry) individual pharmaceutical budgets for physicians in pilot projects at regional level	prescription guidelines (pilot projects at regional level) individual pharmaceutical budgets for physicians (pilot project at regional level)

Source: ÖBIG 2001a; information gathering by ÖBIG

In ten of the fifteen Member States of the European Union, a cap has been imposed on public pharmaceutical expenditure with differences in structure and the sanctions imposed if the limits are exceeded. Individual pharmaceutical budgets for physicians exist in Germany, Great Britain, Ireland and in regional pilot projects in Spain. In Belgium, France, Italy, the Netherlands, Portugal and Spain annual target budgets determining the amount of the public pharmaceutical expenditure are prepared at national level on a regular basis. In Denmark, measures for an annual ceiling on pharmaceutical expenditure were taken in the years 1998 and 1999.

Except for the Netherlands, these countries have also provided for repayments on the part of the actors should the target budgets be exceeded. In most cases, however, in spite of exceeded budgets no repayments were made and/or repayments could not be enforced so that the measures have lost their credibility and eventually their effectiveness. For instance, both collective and individual liability of physicians was provided for in the pharmaceutical budgets in Germany. As, however, collective recourse has never been enforced and missing and delayed data impaired the timely information of physicians on their budgets, a new draft bill now provides for the abolition of collective recourse in the future with retroactive effect as of the beginning of 2002. Self-governing bodies will be allowed increased scope, they will be entitled to determine the caps on expenditure for their region and target figures for physicians.

In order to control the prescription patterns of physicians, prescription guidelines and/or recommendations have been adopted in eight countries (in Spain only in certain regions) which, however, are not binding. In all EU countries, the prescription patterns of physicians are reviewed on a regular basis; physicians have to inform the competent bodies of their reasons for major deviations from such guidelines.

Other important regulations at reimbursement level are listed in Table 5.2. The following further trends can be observed in the EU countries: establishment of pharmaceutical monitoring, promotion of generics and investment into Health Technology Assessment (HTA) for instance by creating specific institutes for evaluation (e.g. the National Institute for Clinical Excellence, NICE, in Great Britain).

5.3 Pricing

Generally, manufacturer prices for pharmaceuticals can be fixed in three different ways. Manufacturer prices are either:

- determined by pharmaceutical companies or
- negotiated by pharmaceutical companies and the state, which is mostly represented through special committees in the medicines agencies or Ministries of Health, or with health insurance institutions or
- official prices fixed by the authorities, based on (prices) acts.

During the 1990s some systemic changes could be observed in pricing. Statutory pricing, which has been common for many years, has in some countries, such as France, Italy and Austria, been replaced by negotiations. If, however, negotiations fail, laws safeguarding the pricing power of the state are still in force. In other European countries the opposite trend could be identified: In the Netherlands, which had no statutory price regulation, a prices act was introduced in 1996, and in Denmark, where prices are negotiated, pricing power is exercised by the state if negotiations fail.

In some countries pricing is closely connected with reimbursement, as an “appropriate” price determined or negotiated by the state is frequently a prerequisite for the eligibility for reimbursement. Statutory pricing and/or pricing based on negotiations thus usually applies to reimbursable pharmaceuticals. Non-reimbursable pharmaceuticals which cover most of the OTC-market are generally not subject to price regulations on the manufacturing level (cf. Table 5.3). Only in Greece are the manufacturer prices of all pharmaceuticals fixed by the state, while in Great Britain (with the exception of generics) and Ireland there is no determination of prices by the authorities at all. The regulation applied in Great Britain, the Pharmaceutical Price Regulation Scheme, PPRS, restricts the profits of companies in negotiations between the Ministry of Health and the pharmaceutical industry, and differs from the procedures in other countries as it represents an indirect price regulation.

Parallel to the above-specified procedures prices can be regulated via a reference price system (generally only applies to some of the pharmaceuticals on the market). In a reference price system similar groups of pharmaceuticals are combined; the health insurance funds and/or the National Health Service determine a (maximum) price for reimbursement which is called the reference price. If the retail price of a pharmaceutical exceeds the reference price, the patient has to pay the difference.

Germany was the first country to introduce a reference price system, in 1989; in the early 1990s reference price systems were established in three further countries (Denmark, the Netherlands, Sweden).

In the second half of the 1990s, the introduction of a reference price system was discussed in several EU countries and was also agreed to in part. However, the implementation into practice took years, which was to a large extent due to the insufficient number of generics on the market in these countries, as generics are a prerequisite for a reference price system. It was no coincidence that the countries to first introduce a reference price system were “generics countries”, i.e. countries with a high share of generics prescriptions and sales (ÖBIG 2000b). In Spain, a reference price system was introduced in December 2000, in Belgium and Italy such a system is planned.

Table 5.3: Pharmaceutical systems – Regulation of prices at manufacturing level 2001

Country	Pricing			Reference price system
	free	negotiations	statutory pricing	
BE	OTC	-	POM (de facto price notification for non-reimb. POM)	planned
DK	non-reimb. pharm.	-	reimb. pharm. ¹	since 1993
DE	pharm. under the reference price system	-	-	since 1989
FI	non-reimb. pharm.	-	reimb. pharm. (WS-price fixing as a prerequisite for reimbursement)	-
FR	non-reimb. pharm.	reimb. pharm.	-	-
GR	-	-	all pharm. (criterion for import products: WS-prices in the EU)	-
GB	non-reimb. pharm.	reimb. pharm./brands (profit margin limited by PPRS)	generics (maximum prices)	-
IE	OTC	POM (negotiation of WS-prices, criterion: prices in 5 countries of reference)	-	-
IT	non-reimb. pharm.	reimb. pharm. registered in centralised or decentralised procedures	reimb. pharm. with national registration	planned as of 9/2001
LU	non-reimb. pharm.	-	reimb. pharm. (criterion: price in the country of origin)	-
NL	non-reimb. pharm.	-	reimb. pharm. (criterion: WS-prices in 4 countries of reference)	since 1991
AT	all pharm. (price notification procedure, cf. statutory pricing)	reimb. pharm. (negotiation with social security institutions for inclusion in the pharmaceutical list "Heilmittelverzeichnis")	all pharm. (basically, a legal basis for statutory pricing exists, currently implementation in form of a price notification system)	-
PT	OTC (upon the request of the authorities: notification obligation)	-	POM (criterion: prices in 3 countries of reference)	-
SE	non-reimb. pharm.	-	reimb. pharm. (WS-price fixing as prerequisite for reimbursement) ²	since 1993
ES	EFP ³	-	"Farmacéuticas Éticas" ⁴ (criteria: production and R&D costs)	since 12/2000

EFP = Especialidades Farmacéuticas Publicitarias, EU = European Union, OTC = Over-the-Counter products, pharm. = pharmaceuticals, POM = prescription-only medicines, PPRS = Pharma Price Regulation Scheme, reimb. = reimbursable, WS = wholesale

¹ negotiations and price determination by the state alternately

² negotiations are held before the price is determined

³ non-reimbursable OTC

⁴ prescription-only plus reimbursable OTC products

Source: ÖBIG 2001a; information gathering by ÖBIG

5.4 Margins

In spite of new distribution channels (e.g., mail order business, purchasing via the Internet, cf. ÖBIG 2000c) and new retail outlets (e.g., health food stores, supermarkets for specific pharmaceuticals in some countries, cf. ÖBIG 1998b), the distribution of pharmaceuticals via pharmaceutical wholesalers and the pharmacies as retailer is still the usual distribution channel in the countries of the European Union.

The prices for pharmaceuticals at wholesale and pharmacy level depend to a great extent on statutorily regulated margins (cf. Table 5.4).

Denmark is the only EU country in which wholesale margins are not statutorily regulated. In Finland, the Netherlands and Sweden, the margins have not been explicitly regulated by law either, but are de facto laid down by official determination of "appropriate" wholesale prices which form the prerequisite for eligibility for reimbursement. In Great Britain, the wholesale margins have been regulated by the PPRS (cf. section 5.3 above).

In the ten remaining EU Member States the wholesale margins have been regulated by law. In some countries, the provisions only apply to some pharmaceuticals: in Germany to pharmacy-only pharmaceuticals, in France and Italy to reimbursable pharmaceuticals and in Portugal to prescription-only pharmaceuticals.

The detailed regulation of the margins varies: In most cases, the wholesale margins are fixed as linear rates, there are, however, also degressive schemes with two (France, Spain) to ten or more levels (Germany, Austria).

The pharmacy margins have been statutorily regulated in all Member States of the European Union, in a majority of countries for all pharmaceuticals. In France, Great Britain and the Netherlands, the statutory regulation of the pharmacy margins applies only to reimbursable pharmaceuticals, in Portugal to prescription-only pharmaceuticals.

In some countries, there were changes in the regulation of the pharmacy margins – predominantly in the second half of the 1990s. When implementing various strategies for cost-containment the margins were not merely lowered but the regulations were revised and renewed. Currently the pharmacy margins are regulated as linear rates in five countries (Belgium, Greece, Luxembourg, Portugal and Italy for pharmaceuticals registered in decentralised and national procedures) and in the form of a degressive scheme with two (France, Spain) up to 19 levels (Austria) in seven countries. In Great Britain, Ireland and the Netherlands the services provided by the pharmacies are reimbursed by a lump sum payment.

Table 5.4: Pharmaceutical systems – Regulation of wholesale and pharmacy margins 2001

Country	Wholesale				Pharmacies			
	statutorily regulated for			regulation	statutorily regulated for			regulation
	all pharm.	reimb. pharm.	POM		all pharm.	reimb. pharm.	POM	
BE	✓			linear margin	✓			linear margin
DK				free pricing	✓			degressive scheme with maximum mark-ups
DE	✓ ¹			degressive scheme with maximum mark-ups	✓ ¹			degressive scheme with maximum mark-ups
FI		(✓) ²		determined by "appropriate" WS-price for reimbursement	✓			degressive scheme with maximum mark-ups
FR		✓		degressive scheme		✓		degressive scheme
GR	✓			linear margin	✓			linear margin
GB		✓ ³		linear margin		✓		variable lump sum
IE	✓			linear margin	✓			lump sum/PR for reimb. pharm.; private sale: maximum mark-ups
IT		✓		linear mark-up		✓ ⁴		degressive scheme for centrally registered pharm., linear margin for pharm. registered in decentralised and national procedures
LU	✓			linear margin	✓			linear margin
NL		(✓) ²		determined by "appropriate" WS-price for reimbursement		✓		lump sum/PR plus a third of the savings from the sale of generics
AT	✓			degressive scheme with maximum mark-ups	✓			degressive scheme with maximum mark-ups
PT			✓	linear margin			✓	linear margin
SE		(✓) ²		determined by "appropriate" WS-price for reimbursement	✓			degressive scheme with maximum mark-ups
ES	✓			degressive scheme	✓			degressive scheme

pharm. = pharmaceutical, POM = prescription-only medicines, PR = prescription, reimb. = reimbursable, WS = wholesale,

¹ for pharmacy-only pharmaceuticals

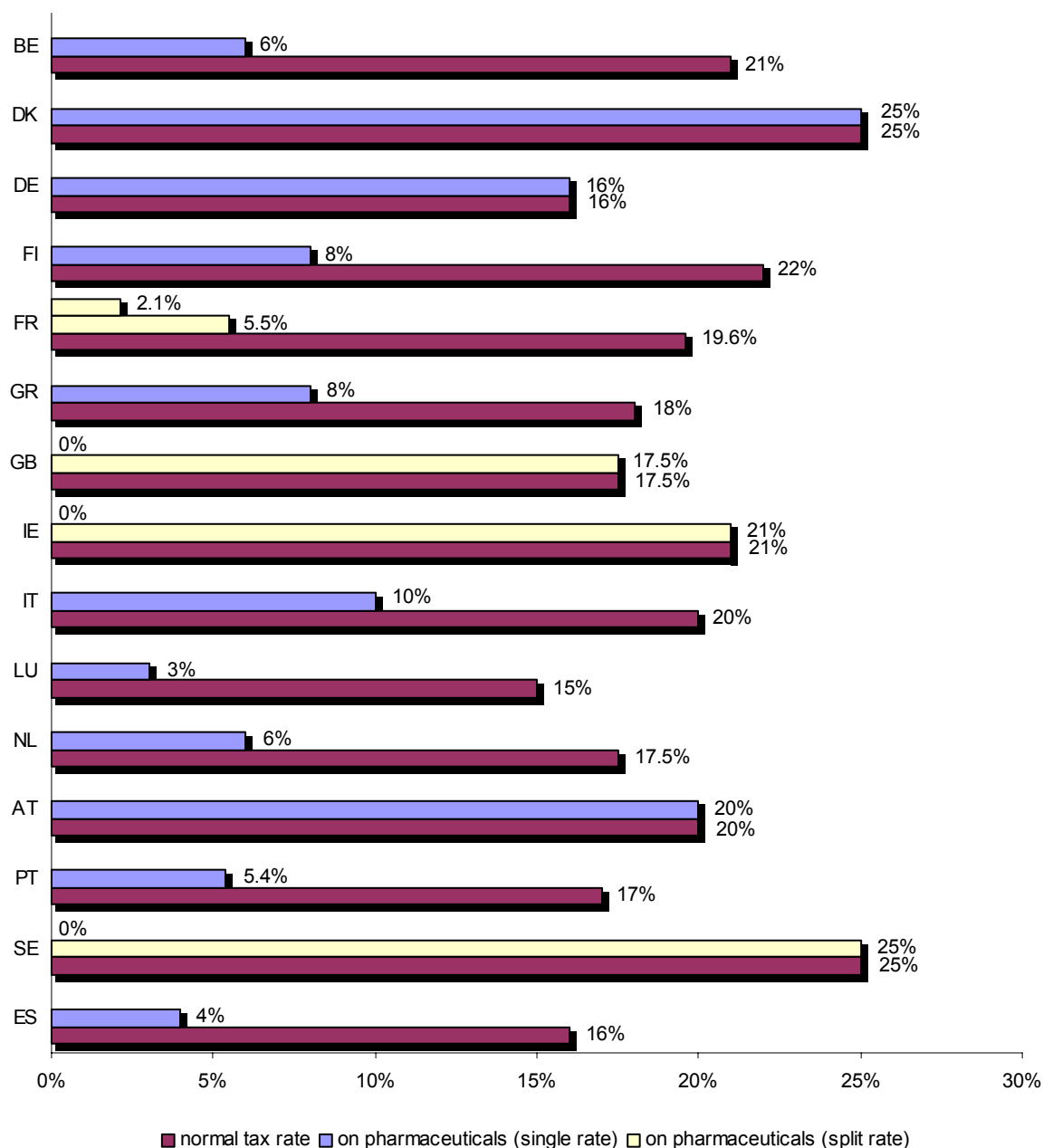
² basically no statutory regulation, but determination of a maximum wholesale price for reimb. pharm.

³ regulated in the framework of the PPRS, except for generics and parallel imports

⁴ the statutory regulation for non-reimbursable pharmaceuticals provides for a minimum margin

Source: ÖBIG 2001a; information gathering by ÖBIG

Figure 5.1: Pharmaceutical systems – Value added tax rates 2001



Note:

Finland: plus 7 per cent pharmacy tax (average)

Portugal: 5 per cent value added tax on pharmaceuticals, plus 0.4 per cent charge for medicines agency INFARMED

Split rates:

France: 2.1 per cent for reimbursable pharmaceuticals and hospital-only pharmaceuticals; 5.5 per cent for non-reimbursable pharmaceuticals

Great Britain: 0 per cent for reimbursable pharmaceuticals; 17.5 per cent for non-reimbursable pharmaceuticals

Ireland: 0 per cent for oral pharmaceuticals; 21 per cent for non-oral pharmaceuticals

Sweden: 0 per cent for prescription-only pharmaceuticals, 25 per cent for OTC products

Source: EFPIA 2000, ÖBIG 2001a; information gathering by ÖBIG

For those financing pharmaceuticals (public authorities and/or patients) the amount of the value added tax on pharmaceuticals is of relevance as such amount co-determines the pharmacy retail price. In Finland, there is an additional pharmacy tax of seven per cent.

Except for Denmark, Germany and Austria, the value added tax rates on pharmaceuticals are lower than the standard tax rate. In four countries the value added tax rates are split: In Great Britain, Ireland and Sweden specific pharmaceuticals (reimbursable, oral, prescription-only) are fully exempt from value added tax and in France reimbursable pharmaceuticals are subject to a lower rate of value added tax.

Figure 5.1 provides an overview of the value added tax rates on pharmaceuticals as compared to the standard tax rate in the EU Member States. The value added tax rates on pharmaceuticals are extremely diverse: they range from 2.1 per cent in France (reduced value added tax on reimbursable pharmaceuticals) to 25 per cent in Denmark.

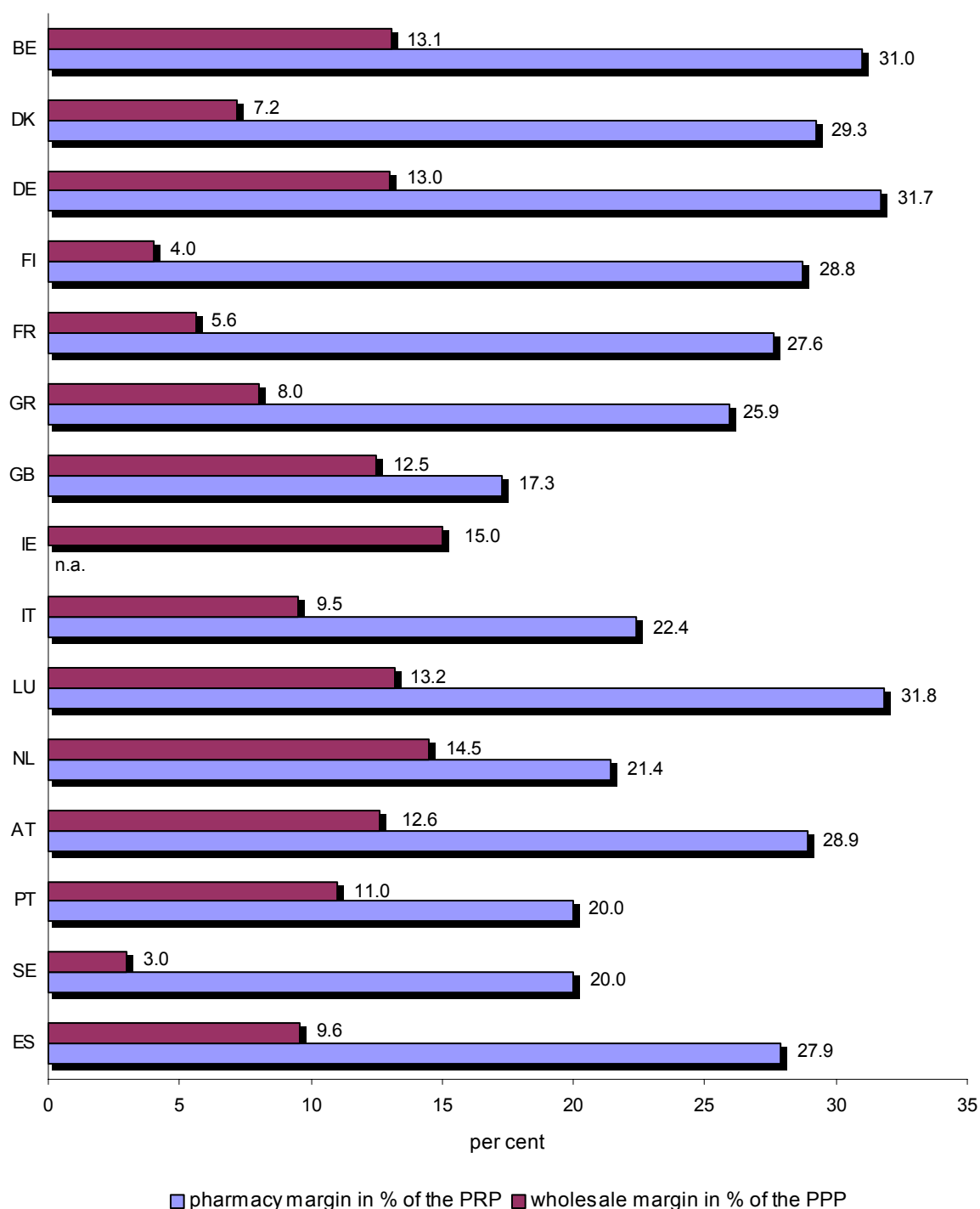
In the course of the present study, the average percentage margins for wholesale and pharmacies were surveyed (cf. Figure 5.2).

When comparing the percentage margins, first the different manufacturer price levels in the individual countries have to be taken into consideration. For instance, it is possible that, in absolute figures, a wholesale company or a pharmacy in a country with high production prices earns more than a wholesale company or pharmacy in a “low price country” although its percentage mark-up rate is lower.

Second, the wholesale systems in the various countries may differ considerably. Comparing wholesale in the individual countries shows that Sweden and Finland have extremely low margins. In these countries the number of both wholesale companies and warehouses is relatively low. For instance, in Sweden there are only two wholesale companies with seven warehouses and in Finland there are three wholesalers with ten warehouses. Furthermore, these two countries use the “single-channel system” which means that a wholesaler is granted the exclusive distribution right for a manufacturer's entire range of products. In Austria, for comparison, there are twelve wholesalers with 27 warehouses, in Germany 16 companies with 102 warehouses and in Ireland five companies with 13 warehouses.

Comparing the average wholesale margins for 1999, Austria ranks in the middle of the EU countries with 12.6 per cent. In mid-2000 the wholesale margins were statutorily lowered as the result of government cost-containment measures. The average margin for the year 2000 – i.e. after reducing the margins – amounted to 11.6 per cent.

Figure 5.2: Pharmaceutical systems – Average wholesale and pharmacy margins 1999



n.a. = not available, PPP = pharmacy purchase price, PRP = pharmacy retail price

Note:

Denmark: wholesale margin for the year 1998

France: wholesale and pharmacy margin refer to the market for reimbursable pharmaceuticals

Great Britain: wholesale margin refers to the market for reimbursable pharmaceuticals; pharmacy margin for the year 1997

Austria: wholesale and pharmacy margin lowered in the year 2000

Denmark, Netherlands, Sweden: pharmacy margins lowered in the year 2000

Source: ÖBIG 2001a; information gathering by ÖBIG

The average pharmacy margins in the European Union ranged from 31.8 per cent (Luxembourg) to 17.3 per cent (Great Britain). Luxembourg, Germany and Belgium showed an average margin of more than 30 per cent, in Portugal, Sweden and Great Britain the average margin was 20 per cent or lower. The average pharmacy margin of 28.9 per cent in Austria sank to 27.9 per cent in the year 2000 as a consequence of the “Agreement on Solidarity Contribution” between the Austrian Chamber of Pharmacists and the Federation of Austrian Social Insurance Institutions. This agreement provides for part of the increases in turnover of the pharmacies to be paid over to the health insurance institutions.

Luxembourg, Germany and Belgium showed high wholesale and pharmacy margins in the 1999 EU-comparison; in Sweden both the wholesale margin and the pharmacy margin was low.

5.5 Co-payment

In the 1990s, the increase in patient co-payments has often been used as an important control instrument (see also chapter 6 below).

There are different co-payment schemes, which are connected to the reimbursement system of a country. Typical co-payment systems for pharmaceuticals are the following:

- payments for pharmaceuticals which are covered by a reference price system. All differences, if any, between the reimbursed reference price and the retail price of a pharmaceutical have to be paid by the patients.
- deductibles (e.g., prescription fees) and
- additional percentage payments for reimbursable pharmaceuticals.

In the European Union, the following co-payment schemes, which often co-exist in one and the same country, are used in the pharmaceutical sector:

- As specified in Section 5.2, reference price systems have been introduced in five countries so far (Denmark, Germany, the Netherlands, Sweden, Spain), in Belgium and Italy they are about to be introduced.
- In six countries, patients have to pay deductibles when purchasing pharmaceuticals in pharmacies. These deductibles are lump sums, either per prescription (Denmark, Great Britain, Austria), or depending on the size of the package (Germany) or related to the indication of the pharmaceutical (Finland, France). In Italy the prescription fee, which was abolished in 2001, depended on the number of items prescribed within a single prescription. The deductibles range from € 0.53 to € 9.25.

- In eleven of the 15 EU Member States the co-payment regulations are percentage based. The amount of the percentage payment mainly depends on the severity and duration of the illness e.g., higher rates of co-payments for pharmaceuticals are demanded for pharmaceuticals which are regarded as less important for therapy. The additional payments can also amount to zero per cent, e.g., in the case of pharmaceuticals for chronic illnesses. On the other hand, in Denmark, Ireland and Sweden the reimbursement regulations currently in force allow for co-payments of 100 per cent for pharmaceuticals which have been classified as reimbursable pharmaceuticals.

Speaking of patient co-payments, we must not forget the non-reimbursable pharmaceuticals which have to be paid for by the patients in full.

Table 5.5 provides an overview of the co-payment regulations in the fifteen EU Member States including upper limits, if any, for co-payments.

The table does not include the exemption provisions by means of which individual population groups are fully or partly exempt from co-payment. Such exemption provisions exist in all EU countries except for Finland. Exemption (in part) from co-payments is possible for the chronically ill and/or certain social groups (persons with low income, senior citizens, unemployed persons, orphans, pregnant women, children, etc.). As a consequence of these exemptions, 85 per cent of the pharmaceuticals in Great Britain are dispensed without co-payments.

In Ireland, approximately one third of the population is exempt from all co-payments (including pharmaceuticals) according to the criteria income, number of family members and age (the so-called GMS Scheme). Persons allocated to other schemes have to make co-payments (up to € 54.30 per month for pharmaceuticals).

In the European Union, the share of co-payments and private spending on total pharmaceutical expenditure differ considerably (cf. also Table 7.1). Comparing the data of the EU Member States showed that Finland has by far the highest share of co-payments, followed by Denmark and Sweden, whereas Spain and France are countries with comparably low co-payment quotas.

Table 5.5: Pharmaceutical systems – Co-payment regulations 2001

Country	Fixed fee / deductible	Co-payment rates for reimbursable pharmaceuticals	Upper limits of co-payments
BE	-	20, 25, 50, 60, 80 per cent	in-patients: € 0.62 for reimb. pharm./day ¹
DK	charge of € 1.04/prescription	15, 25, 50, 100 per cent reference price system: difference between reference and retail price	maximum of € 497.61/year for chronically ill patients
DE	charge depending on package size: € 4.09, € 4.60 or € 5.11	reference price system: difference between reference and retail price	maximum two per cent of the gross income
FI	charge of € 8.41/prescription ("basic refund" category) or € 4.20/prescription ("special refund" category)	25 and 50 per cent	maximum € 593.80/year ²
FR	package charge of € 0.53 (increased charge of € 0.84 for specific pharm.)	35 and 65 per cent	-
GR	-	10 and 25 per cent	-
GB	charge of € 9.25/prescription	-	pre-payment certificate for four months (€ 48.40) or a year (€ 132.90)
IE	-	none or maximum of up to € 53.20 per month	under specific schemes: monthly upper limit of € 3.30
IT	<i>prescription fee abolished</i> ³	50 per cent	-
LU	-	22 and 60 per cent	-
NL	-	reference price system: difference between reference and retail price	<i>co-payment regulation for health care services including pharm. (1997 – 1999), abolished in 2000</i>
AT	charge of € 4.07 per prescribed item ("prescription fee")	-	-
PT	-	brands: 30, 60, 80 per cent generics: 20, 50, 70 per cent	-
SE	<i>planned</i>	10, 25, 50, 100 per cent reference price system: difference between reference and retail price	maximum € 204.31/twelve months
ES	-	10 and 40 per cent reference price system: difference between reference and retail price	-

pharm. = pharmaceutical, PR = prescription, reimb. = reimbursable

¹ in-patients have to pay the full price of non-reimbursable pharm.

² if the annual limit is exceeded, co-payment of € 17.21/item

³ abolished since January 1, 2001. Currently discussion on reintroduction of prescription fee.

Source: ÖBIG 2001a; information gathering by ÖBIG

6 Cost-containment strategies

The current structure of the pharmaceutical systems in the European Union as described in Chapter 5 is the result of numerous savings measures, as different cost-containment strategies were tested in the 1990s: measures having an impact on the prices of pharmaceuticals and activities aiming at consumption and volume were used (for introductory information on control instruments in the pharmaceutical sector see Section 2.3).

For the publication at hand, all control measures taken in EU countries during the time period 1990 to 2001 were surveyed. Table 6.1 gives a chronological overview of important measures taken for the containment of costs, taking into consideration the desired impact of the activities (price vs. volume). An analysis of the measures shows that in spite of country-specific characteristics there are some key trends in the attempts of the European countries to gain control of pharmaceutical expenditure.

6.1 Analysis by countries

Belgium, Germany, Spain, Italy and Denmark are the countries within the European Union which most frequently intervened in the pharmaceutical market in the 1990s.

Compared to these countries, significantly fewer measures were taken in Portugal, Greece, Great Britain and Ireland.

According to the available information, Luxembourg has not imposed any relevant cost-containment measures; obviously the development of pharmaceutical expenditure does not seem to pose a problem in that country.

Basically, analysis of the control measures shows that even countries which are generally regarded as liberal and which usually rely on market instruments for controlling public pharmaceutical expenditure (e.g. Denmark, the Netherlands, Germany) are increasingly using state instruments.

Table 6.1: Cost-containment strategies – Interventions for cost-containment at price and volume level 1990 – 2001

Measures (month/year)	BE	DK	DE	FI	FR	GR	GB
PRICES							
Manufacturers							
Price freezes	1992; 1993; 1995; 5/96; 1997; 1998; 4/00	1994 to 1998; 3/98 to 2/00 ¹ ; 11/00 to 6/01	1993 to 1995	1/94 to 1996 ²	-	1994 to 1996	10/93 to 10/96; 10/99 to 1/01
Price reductions	1995; 5/96; 3/97 ³ ; 2/99; 4/00	4/95	1/93	01/98 to 12/99	9/95; 1/98 ⁴ ; 9/98; 10/00	9/94; 1997	10/93; 10/99; 8/00 ⁵
Wholesalers							
Reduction of margins	5/96	-	7/98	-	9/99	4/96	-
Pharmacies							
Reduction of margins	5/96	9/97; 7/00 ⁶ ; 10/00	7/98	4/98	9/99 ⁷	4/96	-
Pricing							
Introduction of reference price system	2000	6/93	1/89	-	-	-	-
Promotion of generics	8/93 ⁸ ; 4/00	1991; 1993; 1997	1989 ⁹	1993; 3/96	4/96; 1997; 9/98; 1999	-	1995
VOLUME							
Pharmaceutical lists							
Introduction of positive list	-	-	1/00 ¹⁰	-	-	4/98	-
Delisting	1995; 2/97	2/98; 2/00	-	9/92	12/94; 9/98	-	-
Introduction of negative list(s)	-	-	-	-	-	-	1985
Extension of negative list	1995	-	1/91; 10/00	-	-	-	1992; 11/93
Patient co-payments							
Increase	9/92; 10/92; 2/97; 2/98; 7/99	7/90 ¹¹ ; 3/00; 1/01	1/92; 1/93; 1/97; 7/97	9/92; 4/94	1/94	-	-
OTC promotion							
Switches	-	2/98	1992 to 1999	-	12/94	-	on a regular basis
Pharmaceutical budgets							
Introduction of national pharmaceutical budget	1996 ¹²	2/98 ¹³	1/93	-	1/94 ¹⁴	-	4/99 ¹⁵
Introduction of regional pharmaceutical budget	-	-	1/94	-	-	-	-
Introduction of individual pharmaceutical budget	-	-	1/99 ¹⁶	-	-	-	1/90 ¹⁷

¹ partly voluntary and partly statutory prize freezes throughout the years, from 3/98 to 2/00 only for reimbursable pharmaceuticals

² only for reimbursable pharmaceuticals

³ introduction of a special tax of four per cent on turnover of the pharmaceutical industry

⁴ abolition of a turnover-related tax

⁵ determination of statutory maximum prices for generics

⁶ average deduction scale in order to recoup the discount margin negotiated by the pharmacist ("claw-back regulation"), followed by the adaptation of the profit mark-up 10/00

⁷ change of remuneration system for pharmacies

⁸ creation of a statutory basis, information campaign in April 2000

⁹ in the course of the introduction of the reference price system

¹⁰ creation of a statutory basis for the introduction of a positive list

¹¹ increase in prescription charges

¹² without possibility of imposing sanctions

¹³ annual ceiling of the pharmaceutical budget of the state health insurance institution for 1998 and 1999

¹⁴ since 1999 sanctions have been possible, repayments of the industry planned for 2001

¹⁵ global budget for out-patient health care

¹⁶ introduction of a repayment obligation for physicians, changes planned as of 1 January 2001

¹⁷ in the meantime abolished

☞ table to be continued

Table 6.1 (continued): Cost-containment strategies – Interventions for cost-containment at price and volume level 1990 – 2001

Measures (month/year)	IE	IT	LU	NL	AT	PT	SE	ES
PRICES								
Manufacturers								
Price freezes	1993 to 1996	-	-	1994 to 1996	-	1997 to 1999	-	1993 to 1999
Price reductions	1993 to 1996	3/94; 1/95; 7/96; 1/97; 1/99; 7/98; 1/00	-	6/94	1997; 1998; 1999	-	-	1993; 9/1999
Wholesalers								
Reduction of margins	-	2/92; 1/97	-	1996 to 1997 ¹⁸	4/95; 2/97; 6/00	-	-	3/97; 6/99
Pharmacies								
Reduction of margins	-	1/99 ¹⁹	-	10/98 ²⁰ ; 1/00	4/95; 2/97; 1/00 to 1/05 ²¹	-	1/94 ²² ; 2/00	1994 to 1996 ²³ ; 2/97
Pricing								
Introduction of reference price system	-	planned	-	7/91	-	-	1/93	12/00
Promotion of generics	1993; 2000	6/96; 10/98	-	1991	2000 ²⁴	9/98; 9/00	1994; 1997	1997; 12/00
VOLUME								
Pharmaceutical list								
Introduction of positive list	-	-	-	7/91	-	-	-	-
Delisting	-	7/96	-	1/94; 4/96; 1999	1996; 1997	8/98	6/92 ²⁵	-
Introduction of negative list(s)	-	-	-	7/93	-	-	6/92	7/93; 3/98
Extension of negative list	-	-	-	-	-	-	-	-
Patient co-payments								
Increase	-	1/92; 1/93; 1/94; 1/95	-	1/97	8/96 ²⁶ ; 10/00 ²⁶	6/92; 8/98	7/92; 7/95; 1/97; 6/99	1993; 1995
OTC promotion								
Switches	-	6/05	-	10/95	1996	-	2000	-
Pharmaceutical budgets								
Introduction of national pharmaceutical budget	-	1/98 ²⁷	-	-	-	3/97 ²⁷	-	7/95 ²⁸ ; 8/96 ²⁸ ; 1/98 ²⁸
Introduction of regional pharmaceutical budget	-	-	-	-	-	-	-	-
Introduction of individual pharmaceutical budget	1994	-	-	-	-	-	-	-

OTC = Over-the-Counter products, pharm. = pharmaceutical, POM = prescription-only medicines, reimb. = reimbursable, SNS = Sistema Nacional de Salud = National Health Service

¹⁸ statutory fixing of maximum prices

¹⁹ changes in remuneration system for pharmacies

²⁰ purchasing discounts have to be passed on to the health insurance funds, discounts were increased in January 2000

²¹ "Solidarity contribution" of the pharmacists from 1/2000 to 1/2005

²² reduction only referred to POM, margins for OTC were increased

²³ purchasing discounts have to be passed on to SNS; since August 2000 the state has withheld part of the payments to the pharmacies in the case of prescriptions at the expense of the National Health Service

²⁴ by individual health insurance funds

²⁵ OTC

²⁶ extraordinary increase of prescription fee for each pharmaceutical prescribed

²⁷ introduction of possible sanctions

²⁸ at each time stated, a contract providing for a budget was concluded with the pharmaceutical industry

Source: ÖBIG 2001; information gathering by ÖBIG

6.2 Analysis by frequency of interventions

In spite of country-specific differences, it can be said for (almost) all EU countries that in the 1990s barely a year passed without major interventions in the pharmaceutical sector. On average, more than ten radical cost-containment measures were taken in each Member State. The number ranges from no interventions at all (Luxembourg) to 20 (Belgium).

6.3 Analysis by desired impact

The measures targeted both the price level and the volume level (cf. Table 6.1).

6.3.1 Price

At the price level, besides the introduction of reference price systems and the promotion of generics, in particular price reductions played an important role.

Except for Luxembourg and Sweden, all Member States witnessed price freezes or reductions of ex-factory prices in the 1990s. In numerous EU countries with statutory regulation of wholesale margins (cf. Section 5.4), these margins were lowered and in most countries pharmacy margins were reduced – sometimes several times - and/or the remuneration system was changed (France, Italy).

As described in Section 5.3, the introduction of reference price systems is connected to the promotion of generics, as a certain volume of generics on the market is a basic prerequisite for a reference price system. In Europe, the Netherlands, Denmark and Germany are considered “generics countries”, in which less expensive, patent expired products have been strongly present on the market for a long time. In these countries, reference price systems were introduced in the early 1990s and incentive mechanisms for the promotion of generics (e.g. obligatory generic substitution) were created. In recent years, several countries have followed their example: In France, where generic substitution was introduced in 1999, the amount received by pharmacies for the dispensing of generics is the same as for brands, in Ireland, the physicians who have individual pharmaceutical budgets are provided on a regular basis with information on savings potentials from the prescription of generics and in Sweden information campaigns for the public are launched repeatedly.

6.3.2 Volume

Except for Ireland and Luxembourg, all EU Member States have taken one or more measures as regards reimbursement in the 1990s: numerous pharmaceuticals – in particular OTC products – are not (or no longer) reimbursed (delisting) or put on a (newly created) negative list.

During the period under review, nine EU countries limited their pharmaceutical expenditure through budgets. As already described in Section 5.2, different models (at national, regional or individual level, responsibility of the physicians or of several actors within the pharmaceutical system, taking into consideration the possibility of imposing sanctions) were tried out.

A key instrument for the containment of public pharmaceutical expenditure in almost all EU countries (except Greece, Great Britain, Ireland and Luxembourg) was to increase patient co-payments (for the various forms of patient co-payments in the pharmaceutical sector cf. Section 5.5). In some countries co-payments were increased several times (approximately every two or three years). In this respect, Sweden, Germany, Italy and Belgium were clearly in the lead. In Germany and Italy, where co-payments had been massively increased in the mid-1990s, the co-payments were reduced for the first time at the end of the decade.

6.4 Analysis by actors

Considering the shift of the financing burden from public authorities to private households (increase of patient co-payments, delisting of pharmaceuticals) it is not surprising that patients were severely affected by specific cost-containment measures. A significant shift of the financial burden to the patients was witnessed in Italy, Spain, Great Britain and Germany, where the patients have to make increased co-payments and/or pay for an increasing number of pharmaceuticals out of their own pockets (expansion of self-medication).

As regards the actors on the pharmaceutical market, it may be observed that until the mid-1990s it was primarily the pharmaceutical industry which was affected by the measures for the containment of pharmaceutical prices. Thereafter, also the actors in the pharmaceutical distribution sector came under pressure, as is evidenced by the reduction of the profit margins for wholesalers and pharmacies in several Member States. In Austria, the wholesale and pharmacy margins were reduced on several occasions.

6.5 Summary

In spite of the massive savings policy in the pharmaceutical sector during the last decade, there is no end in sight. As can be seen from Table 6.1, the intervals between the individual measures are becoming shorter, as in most cases the success of the cost-containment strategies was only temporary.

Therefore, most of the EU countries plan further interventions. In particular, some countries regard the increased volume of new, expensive pharmaceuticals on the market as a problem. In order to cope with it, they have recently relied on a therapeutic-economic evaluation as one criterion for the decision regarding the inclusion of such pharmaceuticals into the reimbursement scheme (e.g. Great Britain, the Netherlands). Furthermore, the EU countries want to limit the consumption of pharmaceuticals at the expense of the public authorities, for example by increasingly relying on reviews of the prescription patterns of physicians and of pharmaceutical budgets.

7 Benchmarking

In this chapter key indicators of all EU countries, i.e. pharmaceutical expenditure, financing and consumption are compared and ranked in Section 7.1.

In Section 7.2 a detailed analysis of the individual EU Member States is undertaken. It provides an overview of regulations for the listing of pharmaceuticals in the reimbursement system and describes pharmaceutical pricing strategies. Furthermore, a connection between the development of public pharmaceutical expenditure between 1990 and 1999 and cost-containment measures is established and results are analysed.

At the end of the chapter, the central indicators of the countries are listed in Tables 7.1 and 7.2.

7.1 Comparison of indicators

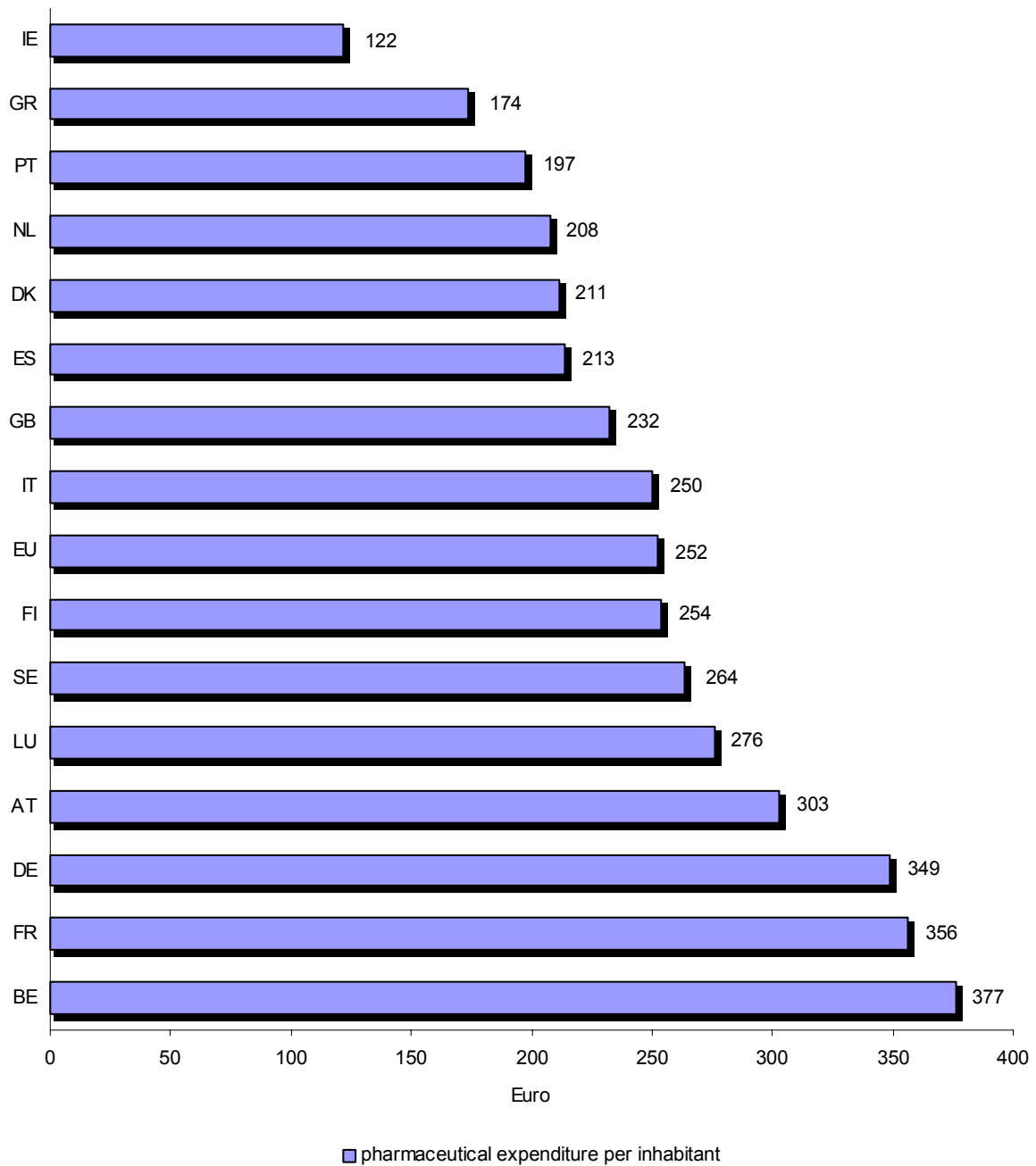
7.1.1 Expenditure

In 1999 the average per capita expenditure on pharmaceuticals within the European Union amounted to € 252.-. Among the individual EU Member States, however, major differences can be observed, as is shown in Figure 7.1.

Reasons for these differences between the EU Member States could be the economic wealth of a country and the age structure of the population. Those countries, for instance, with a very low per capita gross domestic product (cf. Chapter 4, Table 4.2), such as Portugal, Greece and Spain, have a lower pharmaceutical expenditure. Ireland has the lowest per capita pharmaceutical expenditure of all EU Member States. The proportion of elderly people in the population is the lowest of all fifteen EU countries and only five per cent of the population are older than 75 years. Besides, the Irish gross domestic product is only slightly below the EU average.

Richer countries generally display higher pharmaceutical expenditure in comparison with the EU average. Only in Denmark and the Netherlands, both rich countries, pharmaceutical expenditure is below the EU average. This may be caused by the relatively low consumption of medicines (cf. Figure 7.3 and Table 7.1). Those countries with high per capita pharmaceutical expenditure are mostly “social insurance countries”, such as Luxembourg, Austria, Germany, France and Belgium.

Figure 7.1: Benchmarking – Pharmaceutical expenditure per capita in Euro 1999



Portugal, Great Britain, Luxembourg: data for 1998

Ireland: data for 1997

Source: ÖBIG 2001a; information gathering by ÖBIG

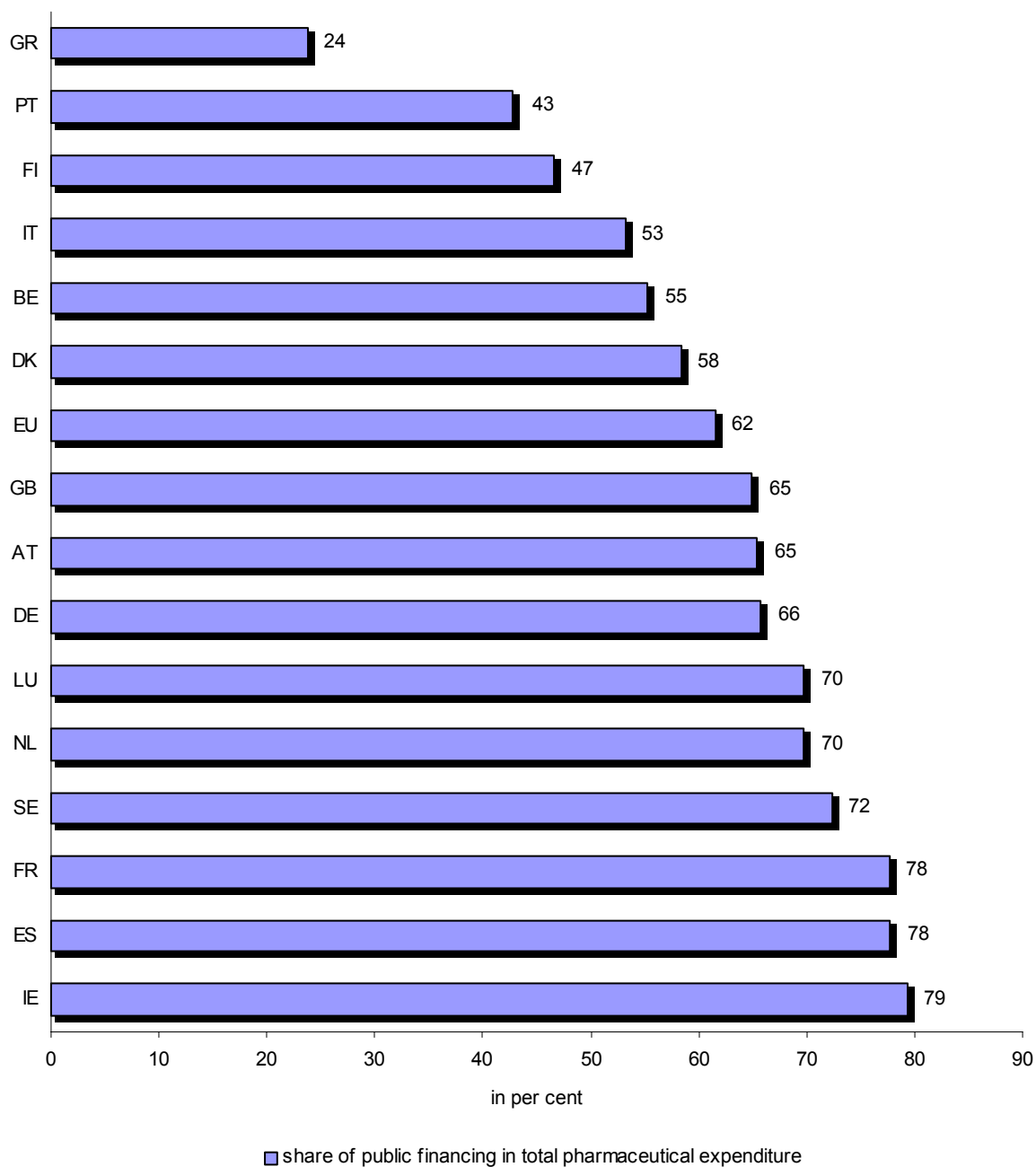
7.1.2 Financing

Within the European Union an average of almost two thirds of pharmaceutical expenditure is borne by the public sector, i.e. social insurance institutions or the National Health Service (cf. Figure 7.2). The remaining third is financed privately, either through co-payments or self-medication.

A public sector share of less than 50 per cent of the financing can be found in Greece, Portugal and Finland. For Greece only the data of the largest health insurance institution, the Social Insurance Institute, which covers approx. half the population, were available. According to these data private financing of pharmaceuticals in Greece has the highest share among all EU countries. In Portugal the share of the public sector contribution increased slightly during the 1990s. However, a large share of pharmaceutical expenditure was still borne by private households in 1999, more than half of the contribution being made via co-payments for reimbursable pharmaceuticals and the rest via self-medication. In Finland the high co-payments made by patients for reimbursable medicines are the main reason for the low public sector share of pharmaceutical expenditure: In 1999 co-payments amounted to 77 per cent of public pharmaceutical expenditure. Co-payment figures have risen considerably since the mid 90s because of the increase in the percentage of co-payments made by patients. For the majority of reimbursable pharmaceuticals patients get only half the costs refunded by the social insurance institution, but only if a deductible of € 8.4 or € 4.2 is exceeded.

In most EU Member States the share of public financing in total pharmaceutical expenditure decreased during the 90s. A notable development occurred in Italy, where the public sector share of pharmaceutical expenditure decreased from about 67 per cent in 1990 to 50 per cent in 1995 and increased to approx. 53 per cent in 1999.

Figure 7.2: Benchmarking – Public spending in per cent of total pharmaceutical expenditure 1999



PE = pharmaceutical expenditure, pharm. = pharmaceuticals

Ireland: data for 1997

Luxembourg, Great Britain, Portugal: data for 1998

Greece: data only for the largest social insurance institution (covers approx. half of the Greek population)

Source: ÖBIG 2001a; information gathering by ÖBIG

7.1.3. Prescriptions

In 1999 there was an average of 8.3 prescriptions per inhabitant in the European Union, without Belgium, France, and Greece, where no data are available (cf. Figure 7.3). The number of prescriptions is comparatively low in Luxembourg, Finland, Denmark, the Netherlands and Italy. Germany, Great Britain, Portugal, Austria and Spain ranked above the EU average.

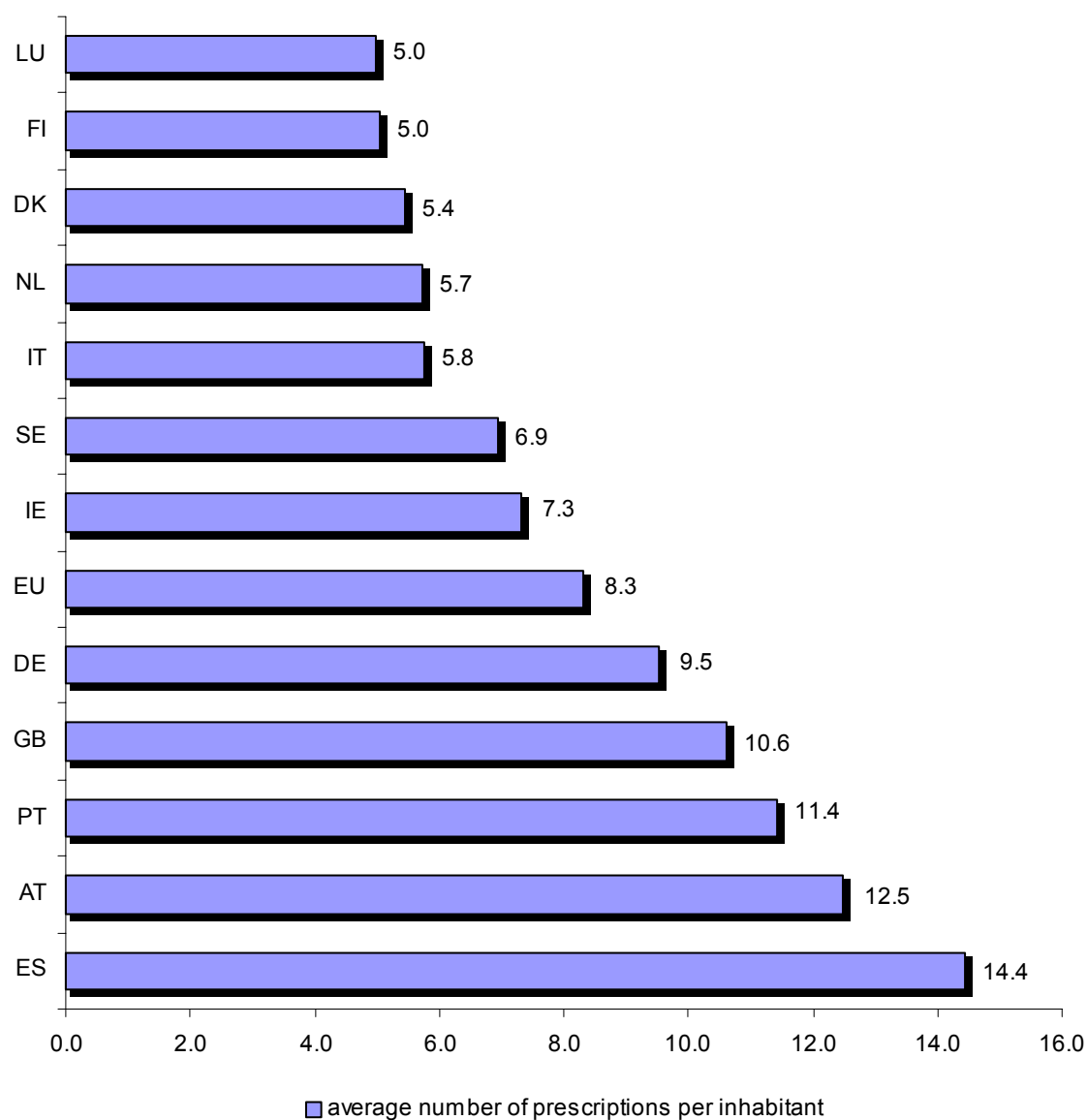
The highest increase in per capita prescriptions could be observed in Sweden with 33 per cent between 1990 and 1999. Among the EU Member States, Sweden is the country with the highest proportion of older people in the total population (nine per cent of the population are older than 75 years). In Italy and Germany the number of prescriptions decreased over the same period due to massive government cuts (cf. Figure 8.1).

Obviously there is no direct connection between the number of prescriptions dispensed at the expense of the social insurance institutions or the National Health Service and the extent of public pharmaceutical expenditure (cf. Figure 7.2). Luxembourg, the Netherlands, Sweden and Ireland, for instance, have a higher share of public financing while the number of pharmaceuticals prescribed is below the EU average.

In the EU Member States an average of € 20.- per prescription is covered by the social insurance institutions or the National Health Service, however, major differences can be observed between the individual countries (cf. Figure 7.4). One factor which has to be considered when analysing the average expenditure per prescription is the level of pharmaceutical prices. Furthermore, it has to be considered whether the public sector finances primarily expensive pharmaceuticals and, for example, delists cheaper pharmaceuticals. Besides, different prescription habits exist in the individual countries, for instance whether large or small packages are usually prescribed. Direct conclusions on the level of prices in different countries are thus almost impossible to draw from the average expenditure per prescription.

Generally, a negative relationship can be established between the average number of prescriptions per inhabitant and the average expenditure per prescription. Countries with an average number of prescriptions below the EU average, such as Luxembourg, the Netherlands, Denmark and Finland, show above-average pharmaceutical expenditure per prescription. Only in Germany are both the number of pharmaceutical prescriptions per inhabitant and the average expenditure per prescription above the EU average. The amount of “admissible” pharmaceutical expenditure seems to be a limiting factor: Control measures relating to public spending on pharmaceuticals are either more strongly aimed at volumes (number of prescriptions) or at prices.

Figure 7.3: Benchmarking – Number of prescriptions per capita at the expense of National Health Service / social insurance institutions 1999

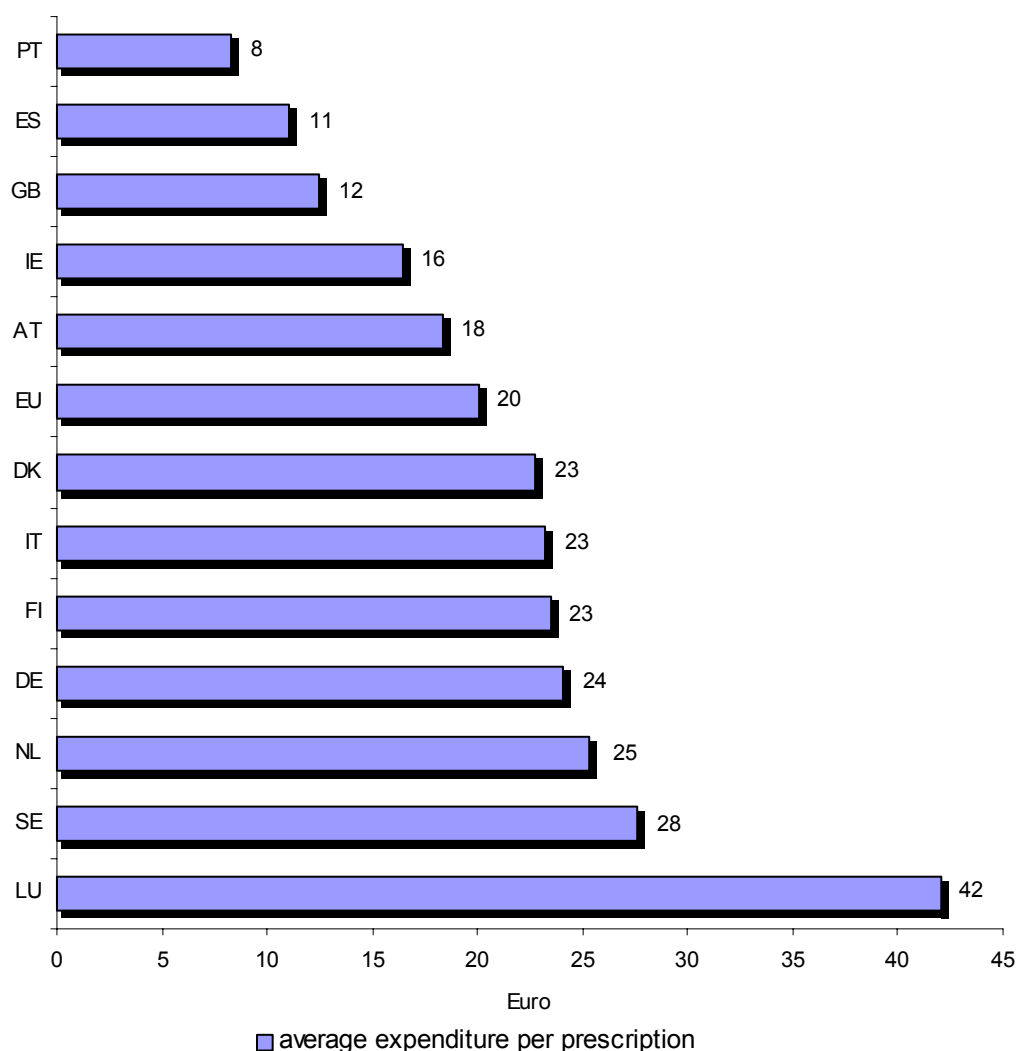


Belgium, France, Greece: no data available

Great Britain: data refer exclusively to England

Source: ÖBIG 2001a; information gathering by ÖBIG

Figure 7.4: Benchmarking – Expenditure per prescription at the expense of National Health Service / social insurance institutions 1999



Belgium, France, Greece: no data available

Great Britain: data refer exclusively to England

Source: ÖBIG 2001a; information gathering by ÖBIG

7.2 Country analyses

7.2.1 Belgium

The central institution in the Belgian pharmaceutical system is the Ministry of Social Affairs, Public Health and the Environment, which is supported by a committee for social insurance.

The Ministry of Social Affairs, Public Health and the Environment decides on listing pharmaceuticals (in the positive list) and on the level of reimbursement. The Ministry of Economic Affairs is responsible for the pricing of prescription-only and reimbursable pharmaceuticals and also fixes maximum prices. The decisions are based on a recommendation of the pricing committee, which consists of, among others, representatives of the pharmaceutical industry, wholesalers, pharmacists, trade unions and health insurance funds.

As compared to the EU average Belgium has the highest pharmaceutical expenditure per inhabitant. A major part of pharmaceutical expenditure is financed privately, the public sector share is relatively low with approx. 55 per cent. Concerning the consumption of pharmaceuticals (only data on the consumption measured in packages is available) Belgium ranks among the upper third of the EU countries.

With a plus of 40 per cent, public pharmaceutical expenditure rose considerably between 1995 and 1999. In the mid 90s public expenditure showed two-digit growth rates. Numerous cost-containment measures followed, such as raised co-payments, multiple price freezes and reductions for pharmaceuticals and the introduction of a national pharmaceutical budget, which was unaccompanied by incentives or sanctions. Further measures were the implementation of a database for the optimisation and documentation of prescription patterns of physicians, a limitation on pharmacy and wholesale margins and the introduction of an extraordinary tax on sales of the pharmaceutical industry. As a consequence the dynamics of expenditure slowed down, but by the end of the 90s the growth rates had again increased considerably. Thus, strategies have been developed in order to reduce pharmaceutical expenditure on a long term basis, such as campaigns to promote so-called “reasonable” prescriptions and increased prescription of generics, as well as the introduction of a reference price system and a new reimbursement scheme as of June 2001.

Belgium took the largest number of cost-containment measures during the period analysed. However, despite numerous interventions it has not succeeded in containing expenditure.

7.2.2 Denmark

An important role in the Danish pharmaceutical system is played by the Medicines Agency. The Medicines Agency decides on listing pharmaceuticals (positive list), on reimbursement rates, which range between 50 and 100 per cent, and on the reimbursement price. Basically the manufacturers of pharmaceuticals are free to decide on pricing, however, they have to report the price to the Medicines Agency after the registration of the product. As a consequence, the Medicines Agency fixes a reference price for equivalent pharmaceuticals – i.e. those for which generics are available. The reference price is calculated from the mean value of the two cheapest pharmaceuticals within a group. For new pharmaceuticals, for which no generics or parallel imports are available, the price is determined on the basis of the European average price, whereby the prices in Italy and Greece are considered less important.

Denmark has a low per capita pharmaceutical expenditure, which can also be attributed to the low pharmaceutical consumption in general in Scandinavian countries. Pharmaceutical

expenditure in relation to the number of inhabitants has decreased considerably as a result of numerous cost-containment measures.

Public pharmaceutical expenditure rose in one year (from 1990 to 1991) by more than 50 per cent. The reason for such an extreme increase was the abolition of the so-called “800-Kroner rule”, which stated that patients were only reimbursed part of the costs of pharmaceuticals if an annual limit of 800 Kroner/€ 101.78 was exceeded. This rule led to massive public protests, and was therefore abolished only 18 months after its adoption. In the following years the development of expenditure could be slowed down considerably through numerous interventions, which affected prices (statutory price freezes, increased promotion of generics, reduction of pharmacy margins) as well as volumes (e.g. delisting of pharmaceuticals). However, the costs have not shifted to private households. The share of public expenditure – which is still relatively low – rose gradually between 1990 and 1999. Private pharmaceutical expenditure has even declined as compared to public expenditure.

At the beginning of 2000 – i.e. after the period of analysis – the co-payment system was changed. Up to an annual total limit of € 484.20 patients have to pay up to € 67.24 for each prescribed pharmaceutical.

In the last decade Denmark has succeeded in controlling pharmaceutical expenditure through a bundle of measures. However, from the point of view of the government the measures have not sufficed; above all prices for pharmaceuticals are still deemed to be too high. Thus, numerous alterations to the system were introduced in the years 2000 and 2001 (adaptation of reimbursement system, increased co-payment, prize freezes and reduction of margins). Furthermore, liberalisation steps have been started in the pharmacy sector. As a consequence, selected OTC products can be sold under certain circumstances at supermarkets and petrol stations. The opening hours of pharmacies have also been liberalised.

7.2.3 Germany

The Ministry of Health has an important role in controlling the pharmaceutical market in Germany. The Ministry is, after consultation of expert committees, responsible for the listing of pharmaceuticals in negative lists or in the planned positive list. Basically, ex-factory prices are determined by manufacturers. Indirectly, prices are influenced by the reference-price system. Firstly, the Federal Standing Committee of Physicians and Sickness Funds groups equivalent pharmaceuticals and then the top associations of the health insurance funds determine the maximum amount which will be reimbursed for a certain pharmaceutical, the so-called reference price. The difference between the reference price and the retail price has to be borne by the insured person.

Public pharmaceutical expenditure developed rather moderately in Germany with a total increase of approx. 30 per cent between 1991 and 1999. As regards consumption of pharmaceuticals (number of prescriptions per inhabitant) Germany ranked slightly above the EU average in 1999. Due to numerous cost-containment measures, however, the number of prescriptions paid for by the compulsory health insurance declined dramatically. With a pharma-

ceutical expenditure of € 349.- per inhabitant, Germany ranked third among EU countries in 1999. In 1990 Germany still had the second highest per capita pharmaceutical expenditure. With a public financing share of approx. two-thirds Germany is close to the EU average.

With numerous cost-containment interventions aimed at stabilising statutory health insurance contributions, Germany succeeded in reducing the increase in public pharmaceutical expenditure considerably between 1992 and 1998. The rigid savings policy tried to control both the prices and the consumption of pharmaceuticals (e.g. multiple rises in co-payments, introduction of a pharmaceutical budget for physicians, price freezes and margin reduction), and burdened the patients. Fewer pharmaceuticals were prescribed and the private share in pharmaceutical expenditure increased. After a new government came into power the financial burden on the patients was relieved for the first time in 1999 (reduction of co-payments).

Faced with currently increasing pharmaceutical expenditure (more than ten per cent growth) the government decided on new cuts in October 2001. As a result pharmacists are in the future to be allowed to dispense less expensive but equivalent pharmaceuticals, if the physician does not prescribe a brand. The legally required discount which pharmacies have to grant to health insurance funds will be increased from five to six per cent and manufacturer prices will be reduced by 4 per cent (valid for the years 2002 and 2003). In the future the patient's report upon discharge from hospital has to include the active substance of the pharmaceutical prescribed and less expensive alternative suggestions for out-patient therapy.

7.2.4 Finland

An authority subordinate to the Ministry of Health, the Pharmaceuticals Pricing Board is responsible for the listing of pharmaceuticals (in the positive list) and has to decide on the reimbursement rate of a pharmaceutical (50, 75 or 100 per cent). It also determines the wholesale price for those pharmaceuticals which are included in the positive list. Decisions are based on a comparison of prices and on health-economic assessment.

Finland ranks near the EU average as regards per capita pharmaceutical expenditure. However the Finish population has to bear more than 50 per cent of the cost of their pharmaceuticals privately. The share of public expenditure is rather low. In Finland co-payments for reimbursable pharmaceuticals are very high. Comparatively few – but mainly expensive – pharmaceuticals have to be refunded by the social insurance KELA. Finland has high average expenditure per prescription.

Between 1990 and 1999 public expenditure almost doubled. Cost-containment measures were originally aimed at the restriction of the already low consumption of pharmaceuticals supported by the public sector. The effect has been that the number of prescriptions has hardly increased and that even more pharmaceuticals have to be financed privately. A counterproductive measure for the development of pharmaceutical expenditure was the end of direct state price control and the increase of VAT in June 1994, which led to a two-digit growth rate. However, since 1998 measures to contain prices have also been taken (price reductions for more than 250 pharmaceuticals and reduction of pharmacy margins). Above all, the

new and expensive pharmaceuticals have been identified as a problem in the development of expenditure. However, cost-containing measures had only short-term effects, and increases soon reached the old level.

7.2.5 France

The Medicines Agency subordinate to the Ministry of Employment and Solidarity is responsible for the listing of pharmaceuticals (in positive lists). The Medicines Agency is supported by a so-called “transparency commission” which consists of representatives of the Ministry, the social insurance organisations and the interest group of the pharmaceutical industry. A prerequisite for listing a pharmaceutical in one of the two positive lists (one for the pharmacy market and one for the hospital market) is its therapeutic benefit. Pharma-economic studies are also critically evaluated by a group of experts. The transparency commission also evaluates the “innovation value” of pharmaceuticals as compared to equivalent products. The assessment by the transparency commission is relevant in the following price negotiations. The transparency commission was asked to check all reimbursable pharmaceuticals for their therapeutic benefit. The result of the evaluation was that one in five reimbursable pharmaceuticals was graded “inadequate”.

The ex-factory prices of reimbursable pharmaceuticals are negotiated with the industry by an interministerial price committee and determined in individual contracts. The system of price negotiations which was introduced in 1994 replaced the former state pricing system.

France stands out because it has the highest pharmaceutical consumption within the EU, more than twice as high as the EU average with approx. 50 packages per inhabitant per year. Correspondingly, per capita pharmaceutical expenditure is also very high: France ranks second, after Belgium. The cost of the majority of pharmaceuticals is borne by the social insurance institutions (public financing of approx. 78 per cent).

Between 1990 and 1999 public pharmaceutical expenditure increased in accordance with the average of EU countries. Therefore, only a few cost-containment measures were taken in France. As the pharmaceutical expenditure of the health insurance funds rose by more than 20 per cent between 1991 and 1992, cost-containment measures started in 1993 (introduction of a nine per cent advertising tax for reimbursable pharmaceuticals, reduction of reimbursement rates, therapy and prescribing guidelines for physicians). Because of the deficits of the health insurance funds cost-containment measures were intensified. Control measures started with volumes and were next also applied to prices (e.g. price reductions, increased support of generics, reduction of margins). Thus, pharmaceutical consumption could be kept at a relatively constant – though rather high – level. As compared to other EU countries France has a low pharmaceutical price level. A tendency can be observed to align prices with European average prices – innovative pharmaceuticals are conceded higher prices.

7.2.6 Greece

In Greece a positive list binding for all health insurance funds was only established in 1998. An expert committee which is part of the Ministry of Health, Welfare and Social Insurance decides on the listing of pharmaceuticals considering criteria such as the cost of treatment compared to effectiveness). In Greece all pharmaceuticals (prescription-only products, OTC, hospital-only pharmaceuticals) are subject to statutory pricing. The Ministry of Trade and Industry is responsible for pricing, but a distinction between import products and national products is made. For import products the lowest wholesale price of the European Union is taken as a basis. For national products with expired patents (generics) a price 20 per cent lower than the original product is set, in case that the pharmaceuticals are sold under their generic names; if a brand name is used, the price has to be 10 per cent lower.

Greece is one of the poorest countries in the EU and has the second-lowest pharmaceutical expenditure per capita after Ireland. Consumption of pharmaceuticals, however, is very high in Greece (measured in packages, the highest after France).

In the past decade Greece has tried to improve the access to health care services. Also in terms of pharmaceuticals Greece had to catch up, which is shown in the highest increases in pharmaceutical expenditure among EU countries. No complete data on the financing structure of pharmaceutical expenditure is available for Greece. Probably, the majority of pharmaceuticals – as with many other health services – is financed privately (high share of self-medication).

Cost-containment measures only became necessary in the mid 90s when economic growth slowed down. Interventions were mostly directed at prices (e.g. price freezes for reimbursable pharmaceuticals, legally fixed price reductions for generics, introduction of a new pricing system in 1997), although Greece has one of the lowest price levels in Europe. When the positive list was introduced (1998) numerous products were excluded from reimbursement, the positive list, however, has been re-filled in the meantime.

7.2.7 Great Britain

The Medicines Control Agency is responsible for registration and licensing of pharmaceuticals in Great Britain. Once registered, all pharmaceuticals are automatically reimbursed by the National Health Service, if they are not listed in the negative lists. The Department of Health, supported by a board of experts, decides on the listing of pharmaceuticals in the negative list considering criteria such as “low therapeutic value”, “excessive cost or availability generics. Especially for innovative and/or expensive pharmaceuticals recommendations by the National Institute for Clinical Excellence (NICE), which was founded for the evaluation of new technologies, are of importance concerning eligibility for reimbursement.

The Department of Health is also responsible for pricing within the Pharmaceutical Price Regulation Scheme. In this scheme prices are not determined for individual pharmaceuticals,

but a maximum allowed (percentage) profit of a company is agreed in individual contracts between the Association of the British Pharmaceutical Industry and the National Health Service.

Per capita pharmaceutical expenditure ranks below the EU average in Great Britain whereas the number of prescriptions ranks slightly above the EU average. Approx. 65 per cent of pharmaceutical expenditure is financed by the National Health Service. Consumption – measured in packages – is low, which is partly due to the very common practice, until 1999, of ‘splitting up’ (dispensing single units from large pharmaceutical packages).

Pharmaceutical expenditure increased in the early 1990s noticeably (two-digit growth rates). Due to cost-containment measures in the mid 1990s (extension of the negative list, price reductions of the industry) the increase in public pharmaceutical expenditure was halted and shifted to private expenditure. As of 1997 private expenditure decreased, and public expenditure increased more substantially. This was partly a result of the growing number of persons exempt from prescription fees.

Great Britain only intervened slightly in the pharmaceutical market, probably because other problems prevailed in the health sector (e.g. long waiting lists, underfinancing of the National Health Service). Since 2000, however, state maximum prices for generics have been fixed for the first time, after their prices had risen sharply and the National Health Service had been confronted with high pharmaceutical expenditure. Another remarkable innovation was the foundation of the National Institute for Clinical Excellence (NICE) in early 1999, with the task of evaluating new and expensive pharmaceuticals, which are still entering the British market in growing numbers. NICE evaluates the therapeutic and economic benefit of new health technologies including pharmaceuticals and the clinical management of specific conditions.

7.2.8 Ireland

In Ireland the Department of Health and Children decides whether or not to list a pharmaceutical (on the positive list). The criteria are therapeutic necessity and generics on the market. Pharmaceuticals which can be easily replaced by generics are not reimbursed and are listed in the National Drug Formulary.

The Department of Health and Children also fixes the prices for prescription-only pharmaceuticals. Since mid-1997 a pricing agreement between the representatives of the industry and the Department of Health and Children has been in force, defining the average wholesale price in Great Britain, Germany, Denmark, the Netherlands and France as a basis for pricing. OTC products are not subject to pricing.

In Ireland per capita pharmaceutical expenditure is very low. In the ranking – data for Ireland from 1997 – Ireland ranked last. Also, pharmaceutical consumption (considering both the number of prescriptions paid for by the National Health Service and the number of packages sold) is below the EU average.

As during the 80s drastic reductions took place in the health care sector, which led to a deterioration of health care provisions. Therefore the primary objective of the last decade has been to improve access to health care services and to pharmaceuticals. Public pharmaceutical expenditure increased between 1995 and 1999 by more than 60 per cent. In the same period the number of prescriptions increased by approx. 28 per cent. The public sector share in pharmaceutical expenditure – with 80 per cent the highest in the EU – also rose. On the other hand the government goal to decrease private pharmaceutical expenditure was achieved.

7.2.9 Italy

After the registration of pharmaceuticals a pharmaceutical commission of the Ministry of Health classifies them. This pharmaceutical commission evaluates pharmaceuticals with regard to their therapeutic benefit and the severity of illness, which is relevant for reimbursement: Since July 2001 there have been only two categories of pharmaceutical products: Class A (essential pharmaceuticals and pharmaceuticals for the chronically ill), which are totally reimbursed, and Class C, which is not reimbursed. Previously, Class B pharmaceuticals had also existed, which were reimbursed at 50 percent. Class B applied to approx. seven per cent of the reimbursable market and mostly comprised oral contraceptives, which are now either allocated to Class A or C.

In connection with the pricing of pharmaceuticals, an important role is played by the so-called Interministerial Committee for Economic Planning, which is part of the Ministry of the Treasury, Budget and Economic Planning, and the Pharmaceutical Commission of the Ministry of Health. The pricing mode differs according to whether a new pharmaceutical has been approved in accordance with an EU procedure (centralised or decentralised registration procedure) or nationally. To nationally authorised pharmaceuticals the “European average price” method is applied, the prices are calculated according to purchasing power and compared with all EU Member States except Denmark and Luxembourg. For pharmaceuticals approved according to the centralised or decentralised procedure prices have been negotiated between the pharmaceutical companies and the pharmaceutical commission since 1998, also applying price comparisons.

Prices of non-reimbursable pharmaceuticals (Class C) can be freely fixed by the companies. However, the prices may only be changed once per year and have to be reported to the Ministry of Health and the Interministerial Committee for Economic Planning in advance. The Ministry can interfere in case of “unjustified” price increases.

In Italy the state has intervened massively in the pharmaceutical market. Especially in the first half of the 90s numerous cost-containment measures were taken, which were first and foremost aimed at volume control (e.g. increases in prescription fees, de-listing of pharmaceuticals), but also at price control (e.g. price reductions, reduction of wholesale margins). Control measures have been so successful that public spending was not only slowed down but also reduced in absolute terms (between 1992 and 1996). Currently, per capita pharma-

ceutical expenditure in Italy is in line with the EU average. At the beginning of the 90s Italy was top of the field in this respect.

Public pharmaceutical consumption (prescriptions) has been reduced drastically. In 1999 almost 40 per cent fewer pharmaceuticals were prescribed than in 1990. This reduction is the biggest among all the countries compared. The reduction of prescriptions has been accompanied by a massive increase in private expenditure for self-medication. As a result, the proportion of private expenditure has risen considerably. In 1999 the National Health Service accounted for only slightly more than half of the overall pharmaceutical expenditure, the other half was financed by the private households. The consumption of pharmaceuticals – measured in average packages per inhabitant – is high as compared with other EU countries, but it has declined slightly.

In the mid 90s when public expenditure increased considerably and prescriptions slightly, cost-containment measures were introduced, which were primarily aimed at the price level (price reductions, reduction of wholesale and pharmacy margins). To take the burden from the population the prescription fee was abolished in early 2001, although a reintroduction is now being considered. These measures and fixing budgets for pharmaceutical expenditure, which, if exceeded, theoretically created an obligation to refund overspending, though these were not consistently implemented, did not produce the desired effects. Thus, the government considers taking new measures to control the development of pharmaceutical expenditure. In 2001, for instance, pharmaceutical budgets for physicians and a reference price system were introduced on a trial basis.

7.2.10 Luxembourg

In Luxembourg the head organisation of the health insurance funds decides to what extent pharmaceuticals are reimbursed by health insurance funds. Pharmaceuticals for certain chronic or very serious diseases are reimbursed totally (no co-payment). For the majority of pharmaceuticals the normal reimbursement rate with a co-payment of 22 per cent applies, for so-called “comfort” pharmaceuticals (e.g. mild pain relievers) co-payment amounts to 40 per cent. The negative list includes pharmaceuticals with disputed active substances, but also OTC and products for general sale. These pharmaceuticals are not reimbursed.

The prices of reimbursable pharmaceuticals are fixed by the Price Office of the Ministry of Economic Affairs, which decides on the basis of the prices in the country of origin.

Public expenditure on pharmaceuticals rose by only approx. a quarter between 1995 and 1999; prescriptions increased by approx. eight per cent. It is rather striking that the average expenditure per prescription is the highest in Luxembourg (probably because of the high price level and the funding of expensive pharmaceuticals by the health insurance institutions). With a public financing share of approx. 70 per cent, Luxembourg is above the EU average.

Luxembourg has the highest per capita gross domestic product in the European Union. Both health care expenditure and pharmaceutical expenditure have increased less than the gross

domestic product in the period of analysis (1995 until 1999). Thanks to the good economic situation Luxembourg has been the only EU member country – according to the information available – with no cost-containment measures.

7.2.11 The Netherlands

In the Netherlands the Ministry of Health, Welfare and Sport, supported by a pharmaceutical commission (independent body of experts), decides on the reimbursement status of pharmaceuticals. There are two different categories: List 1A contains pharmaceuticals which are part of the reference price systems ("exchangeable" pharmaceuticals). For pharmaceuticals in this group the patients have to pay the difference, if any, between the reference price and the actual retail price. If a pharmaceutical is not part of the reference price system, a therapeutic and economic evaluation by the pharmaceutical commission is carried out. The Ministry of Health, Welfare and Sport decides whether or not a pharmaceutical is included in the reimbursement system. In case of a positive decision these pharmaceuticals are listed in List 1B and may be prescribed at the expense of the health insurance funds. Generally, homeopathic and OTC products are not reimbursed, except a few for chronic diseases.

Until the end of 1995 no national regulation of pharmaceutical prices on manufacturers' and wholesale level existed in the Netherlands. Prices were indirectly influenced by the reference price system. After the government had recognised that the reference price system did not suffice to achieve the planned cost-containment, a law on pharmaceutical prices was passed on January 1, 1996. In accordance with this law the Ministry of Health, Welfare and Sport is authorised to fix a maximum pharmacy purchasing price for reimbursable pharmaceuticals. As a basis for the maximum price the Ministry takes the average pharmacy purchasing price for comparable products in the four reference countries Belgium, Germany, France and Great Britain.

In the Netherlands two major alterations to the system took place in the 90s, which also affected the pharmaceutical market. A basic insurance covering almost the entire pharmaceutical expenditure was introduced. However, this measure was abolished in 1996. Furthermore a general co-payment rule was applied between 1997 till late 1999, which stated that the insured persons had to pay a deductible of 20 per cent, up to a limit of € 90.76 or € 45.38 (for people with low income) per year for certain services provided by obligatory health insurance. This regulation also applied to pharmaceuticals thus leading to an enormous increase in pharmaceutical expenditure.

The Netherlands have low pharmaceutical expenditure and low pharmaceutical consumption. Neither pharmaceutical expenditure nor pharmaceutical consumption borne by the health insurance funds have increased extraordinarily.

During the 90s the Netherlands have taken numerous cost-containment measures which were aimed at prices on the one hand and on volumes on the other hand, with the effect that the increase in public pharmaceutical expenditure was kept down. With a public financing share of approx. 70 per cent (1999) the Netherlands rank above the EU average. It is rather

striking however, that the average expenditure per prescription is among the highest. This may be due to increasing prices or to the fact that health insurance funds no longer reimburse OTC products, which are usually less expensive. The cost-containment measures introduced in the mid 90s had positive effects in the Netherlands.

The current government considers the steps taken as short-term cost-containment measures only. For 1999 the government had the ambitious goal of limiting the increase to 2.3 per cent, a limit which was ultimately exceeded, however. In order to achieve long-term effects, the government will in the future rely on the control of new and expensive pharmaceuticals, measures to reduce consumption (e.g. improving prescription patterns) and increased competition between health insurance funds. According to the suggestions of a pharmaceutical commission, for instance, the health insurance funds should offer different service packages and premiums, negotiate pharmaceutical prices directly with the manufacturers and conclude separate agreements with the wholesale industry and with pharmacies.

7.2.12 Austria

According to the Austrian General Social Insurance Act all pharmaceuticals are reimbursable in Austria, if they are required for effective and sufficient medical treatment which does not exceed the necessary level. However, two different types of reimbursement are distinguished: Those pharmaceuticals which are part of the pharmaceutical list “Heilmittelverzeichnis” qualify for automatic reimbursement. Those pharmaceuticals which are not listed in the “Heilmittelverzeichnis” are only funded by the social insurance if they are approved by the health insurance fund (through a so called “head doctor”). The Federation of Austrian Social Insurance Institutions decides whether or not a pharmaceutical should be included in the “Heilmittelverzeichnis”. In the course of the approval procedure the Federation considers formal criteria, medical-therapeutic criteria and economic criteria (e.g. comparison of costs of medical treatment, of price comparison in other European countries) for evaluation. There is a fixed prescription fee for pharmaceuticals which are reimbursed by the social insurance (2001: € 4.07).

Pricing of pharmaceuticals is based on the 1992 Price Act. According to this act the Federal Ministry of Social Security and Generations is authorised to determine a “maximum price which is justified by the national economic situation” after discussion with a consulting body (price commission). Following an agreement between the social partners (representatives of employees and employers) signed in September 1999, the way the Price Act is applied has been changed. Now, the pharmaceutical companies do no longer have to apply for the approval of a price or a price increase by the Federal Ministry for Social Security and Generations. Instead, a notification procedure has been introduced. This means that the maximum price of a pharmaceutical or any price change has to be reported to the Federal Ministry. If required – e.g. in case of an excessive price – the Federal Ministry can fix the price.

In the period of investigation Austria recorded a dynamic increase in public pharmaceutical expenditure and now takes place four in the EU rankings for average per capita pharmaceutical expenditure. Public pharmaceutical expenditure shows the second-highest increase of

all EU countries, immediately after Greece. It must be considered, however, that part of the increase can be attributed to the introduction of VAT on reimbursable pharmaceuticals. However, even VAT-adjusted pharmaceutical expenditure more than doubled between 1990 and 1999, and consequently Austria is still among those countries with the most dynamic increase in public pharmaceutical expenditure.

Regarding consumption Austria also ranks high, with an annual average of 12.5 prescriptions per inhabitant, although the number of prescriptions has increased one quarter less than public expenditure during the period of investigation.

In the face of deficits in the health insurance sector since the mid 90s, cost-containment measures have been started. Primarily, the measures were aimed at curbing price development (multiple price reductions and freezes in the pharmaceutical industry, reduction of pharmacy and wholesaler margins, etc.). The prescription fee was also raised in 1996 by 20 per cent. The effects of the measures lasted only for a short time, and after two to three years the effects vanished and new ones were required. The last government cuts became effective in 2000. Among other measures wholesale margins have again been reduced and a "Solidarity Contribution Agreement" has been concluded with the pharmacies. According to this agreement part of the increase in pharmacy sales has to be refunded to the health insurance funds. The agreement has been concluded for a period of five years. By the end of 2000 prescription fees had again been raised considerably. According to recent data, these measures have resulted in a significant containment of increases in pharmaceutical expenditure by the social insurance funds. It remains to be seen, however, for how long the measures will be effective and when the next will follow, especially as the health insurance funds again show deficits, and also because of the weak development of insurance contribution revenues.

7.2.13 Portugal

In Portugal the Ministry of Health decides on the listing of pharmaceuticals eligible for reimbursement (positive list) and on the reimbursement rates in consultation with the Medicines Agency. Criteria for the listing of pharmaceuticals are legally fixed via decrees. The criteria applied are therapeutic benefit, effectiveness of economic criteria, price comparisons and results of pharma-economic studies, which pharmaceutical companies have to provide since 1999.

Reimbursement is divided into four categories: Category A comprises vital pharmaceuticals and pharmaceuticals for the chronically ill and do not require any co-payment. Category B contains important pharmaceuticals which are used for long, serious diseases, the co-payment amounting to 30 per cent. Category C comprises pharmaceuticals which are not regarded as "priority" but which have a proven therapeutic benefit (e.g. vaccination, serum). For these pharmaceuticals co-payment amounts to 50 per cent. Category D, which was only introduced in September 2000, will be applied as an interim category for new pharmaceuticals with still uncertain therapeutic benefit. Co-payment is 80 per cent. In spring 2001, however, no pharmaceutical product was listed in this category. Another new regulation since

September 2000 is that for generics co-payment is 10 per cent less than for the corresponding brand.

Prices of prescription-only pharmaceuticals are fixed by the Ministry of Economic Affairs. The decision is based on the prices in the reference countries Spain, Italy and France. The ex-factory sales price must not be higher than the lowest price of an identical or similar pharmaceutical with the equivalent active substance in the reference countries. Upon request, manufacturers have to report prices or increases in prices of OTC products which are already on the market to the Ministry of Economic Affairs. The pricing mode for OTC products entering the market is not regulated.

Portugal is the EU country with the lowest per capita gross domestic product. Portugal has the lowest pharmaceutical expenditure per inhabitant after Ireland and Greece. Only a small part of this expenditure (approx. 43 per cent) is covered by the National Health Service. Co-payments for pharmaceuticals are considerable in Portugal. However, pharmaceutical consumption is rather high – similar to many southern countries.

Although public pharmaceutical expenditure has increased significantly in Portugal (many years with two-digit increase rates), only few cost-containment measures have been taken (e.g. prize freezes and increased co-payments). In recent years generics have been increasingly promoted, e.g. by demanding lower co-payments than for brands.

The government regards the dynamic development of public pharmaceutical expenditure at a two-digit rate as the major future problem, as the general economic upswing is also slowing.

7.2.14 Sweden

In Sweden the National Social Insurance Board decides on the inclusion of pharmaceuticals in the "Pharmaceuticals benefit system", i.e. the reimbursement scheme. Apart from therapeutic criteria also the price of a pharmaceutical is a decisive factor for the eligibility for reimbursement. In the year 1993 state pricing for pharmaceuticals was abolished. Since then the National Social Insurance Board has been responsible for fixing an "appropriate" wholesale price for reimbursable pharmaceuticals. These are mainly prescription-only products. Pricing criteria are, among others, prices of pharmaceuticals in other countries – especially in the country of origin – and the prices for similar products in Sweden. In practice, pricing takes place only after negotiations with the industry. Upon request of the Medicines Agency, pharmaceuticals, for which generics or parallel imports are on the market, can be priced within the reference price system.

At the beginning of 1998 major alterations to the system took place in Sweden. In the course of decentralisation the responsibility for pharmaceutical expenditure was shifted from the National Social Insurance Board to local authorities, the county councils. The county councils are allocated an annual budget by the central state, which has to be used for the health care of a region including pharmaceuticals. Because of the continued increase in pharmaceutical expenditure the allocated budget has sometimes been exceeded. Consequently, the county councils are demanding increased power of co-decision in price negotiations between the in-

dustry and the National Social Insurance Board, as they have to bear the pharmaceutical expenditure.

Sweden ranks slightly above the EU-average per capita pharmaceutical expenditure; nonetheless pharmaceutical consumption (both packages and prescriptions) is below the EU average. Sweden stands out with a high increase in public pharmaceutical expenditure and high average expenditure per prescription. In the first half of the 90s the average rate of increase amounted to 12.5 per cent per year, as a consequence many cost-containment interventions were made. These were primarily aimed at a reduction of the number of prescriptions. Consequently, co-payment has been raised five times, co-payment regulations have been changed several times and finally pharmaceuticals have been delisted. These measures only succeeded in containing the massive increase in public expenditure slightly, whereas private expenditure – due to higher co-payments and more self-medication – continued to rise. In the late 90s the pharmacy margins were also reduced and information campaigns for improved use of generics were started.

In October 2000 a report of a government commission containing proposals for alterations of the current reimbursement system was published. According to this report the now rather complicated reimbursement scheme is to be simplified in such way that patients will have to pay the full costs for pharmaceuticals up to a limit of € 204.31 per year. This change would mean that co-payments are to be increased considerably, a fact which has led to massive public criticism. According to further proposals of the government report the county councils would have to monitor the prescription patterns of physicians more closely and develop pharmaco-therapy guidelines. As a high percentage of pharmaceuticals is financed by public spending, the government wants to exercise more rigid control and limit the listing of pharmaceuticals in future. Among other measures, the establishment of an evaluation institute is planned which is to evaluate new therapies, pharmaceuticals and medical technologies.

7.2.15 Spain

The Ministry of Health decides on the listing of pharmaceuticals. The key criteria are the severity of the disease and the therapeutic benefit. In some cases the Ministry of Health demands pharma-economic studies from the companies. The patients generally have to pay a deductible of 40 per cent. For chronic and serious diseases a reduced co-payment rate of ten per cent is applied.

All reimbursable pharmaceuticals are subject to state pricing. An interministerial price committee, which consists of representatives of the Ministry of Economic Affairs, Financial Affairs, the Industry and Health, is responsible for pricing. The price committee fixes the ex-factory sales price on the basis of production and development costs plus a profit margin.

In Spain the high public financing share of pharmaceutical expenditure and the high pharmaceutical consumption (measured in packages and in prescriptions) stands out. Per capita pharmaceutical expenditure lies below the EU average, but has increased tremendously in

recent years. Public pharmaceutical expenditure increased by two and a half times between 1990 and 1999.

Also, in Spain many cost-containment measures – above all on price level – have been taken since the mid 90s. As a result the financial burden of pharmaceutical expenditure has been shifted to the private households. Especially out-of-pocket spending for self-medication has increased drastically. But the numerous cost-containment measures have not succeeded in containing the increasing pharmaceutical expenditure. Thus, reforms continue. By the end of 2000 a reference price system and obligatory generic substitution in pharmacies were introduced. In mid 2001 the Ministry of Health presented a new cost-containment plan, which proposes an obligation for physicians to prescribe pharmaceuticals using their international non-proprietary name, the dispensing of the cheapest pharmaceutical available in pharmacies, a reduction of the wholesale margin and annual refunds of the pharmaceutical industry.

Table 7.1: Benchmarking – Central indicators, 1999

Indicators / Country	BE			DK			DE			FI			FR			Ø EU
Pharmaceutical expenditure																
Total PE / Inhabitant	in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €
	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	
	377	1	1 ¹	211	11	7	349	3	2	254	7	6	356	2	3	
ø pub. PE / PR	in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €
	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	
	n.a.	n.a.	n.a.	23	7	2	24	4	7	23	5	6	n.a.	n.a.	n.a.	
Financing																
Share of pub. PE in total PE	in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %
		1999	1990		1999	1990		1999	1990		1999	1990				
	55.2	11	11 ³	58.4	10	14	65.7	7	6 ⁴	46.6	13	12	77.7	3	9	61.5
Share of priv. PE in total PE	in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %
		1999	1990		1999	1990		1999	1990		1999	1990				
	34.5	7	n.a.	41.6	4	1 ⁵	25.2	11	13 ⁴	53.4	1	2	22.3	12	5	33.7
Pharmaceutical consumption																
ø Number PR ⁶ / Inhabitant	Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number
		1999	1990		1999	1990		1999	1990		1999	1990				
	n.a.	n.a.	n.a.	5.4	10	8 ³	9.5	5	2 ⁴	5.0	11	9	n.a.	n.a.	n.a.	8.3
ø Number pkg. / Inhabitant	Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number
		1999	1989		1999	1989		1999	1989		1999	1989				
	23.2 ⁷	5	3	12.1 ⁸	14	11 ⁹	19.3 ⁷	8	8	15.8 ⁷	9	9	51.5 ⁷	1	1	21.6

Note: descending order, 1 = highest level or share, 15 = lowest level or share

n.a. = not available, PE = pharmaceutical expenditure, pkg. = packages, PR = prescription, priv. = private, pub. = public, ø = average

¹ 1995, corresponds to number 1 in the ranking of 95

² Sum of private and public shares of pharmaceutical expenditure does not always amount to 100 per cent due to data gaps.

³ 1995

⁴ 1991

⁵ 800 Kroner rule (high co-payment, which has been abolished)

⁶ prescriptions financed by public spending

Source: ÖBIG 2001a, OECD 2000; information-gathering by ÖBIG

⁷ 1998

⁸ 1997

⁹ 1993

¹⁰ average cost per package

¹¹ IKA only (= largest health insurance)

¹² data only refer to England

☞ table to be continued

Table 7.1 (continued): Benchmarking – Central indicators, 1999

Indicators / Country	GR			GB			IE			IT			LU			Ø EU
Pharmaceutical expenditure																
Total PE / Inhabitant	in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €
	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	
	174	14	15	232 ⁷	9	11	122 ⁸	15	14	250	8	4	276 ⁷	5	5	
ø pub. PE / PR	in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €
	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	
	6 ¹⁰	13	13	12	10	11	16	9	8	23	6	5	42	1	1	
Financing																
Share of pub. PE in total PE	in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %
		1999	1990		1999	1990		1999	1990		1999	1990		1999	1990	
	23.8 ¹¹	15	15	64.9 ⁷	9	8	79.3 ⁸	1	2 ³	53.3	12	5	69.6 ⁷	6	3 ³	
Share of priv. PE in total PE	in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %
		1999	1990		1999	1990		1999	1990		1999	1990		1999	1990	
	n.a.	n.a.	n.a.	35.1 ⁷	5	6	20.7 ⁸	14	10 ³	46.7	3	8	30.4 ⁷	8	11 ³	
Pharmaceutical consumption																
ø Number PR ⁶ / Inhabitant	Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number
		1999	1990		1999	1990		1999	1990		1999	1990		1999	1990	
	n.a.	n.a.	n.a.	10.6 ¹²	4	6 ⁴	7.3	6	12	5.8	8	4	5.0	12	10 ³	
ø Number pkg. / Inhabitant	Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number
		1999	1989		1999	1989		1999	1989		1999	1989		1999	1989	
	30.7	2	5	14.7 ⁷	10	10	14.7 ⁷	10	13	26.2 ⁷	3	2	n.a.	n.a.	n.a.	

Note: descending order, 1 = highest level or share, 15 = lowest level or share

n.a. = not available, PE = pharmaceutical expenditure, pkg. = packages, PR = prescription, priv. = private, pub. = public, ø = average

¹ 1995, corresponds to number 1 in the ranking of 95

² Sum of private and public shares of pharmaceutical expenditure does not always amount to 100 per cent due to data gaps.

³ 1995

⁴ 1991

⁵ 800 Kroner rule (high co-payment, which has been abolished)

⁶ prescriptions financed by public spending

Source: ÖBIG 2001a, OECD 2000; information-gathering by ÖBIG

⁷ 1998

⁸ 1997

⁹ 1993

¹⁰ average cost per package

¹¹ IKA only (= largest health insurance)

¹² data only refer to England

☞ table to be continued

Table 7.1 (continued): Benchmarking – Central indicators, 1999

Indicators / Country	NL			AT			PT			SE			ES			Ø EU
Pharmaceutical expenditure																
Total PE / Inhabitant	in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €
	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	
	208	12	10	303	4	9	197 ⁷	13	13	264	6	8	213	10	12	252
ø pub. PE / PR	in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €	Ranking		in €
	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	1999	1999	1990	
	25	3	4	18	8	9	8	12	12	28	2	3	11	11	10	20
Financing																
Share of pub. PE in total PE	in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %
		1999	1990		1999	1990		1999	1990		1999	1990				
	69.8	5	7	65.4	8	10	42.7 ⁷	14	13	72.4	4	4	77.7	2	1	61.5
Share of priv. PE in total PE	in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %	Ranking		in %
		1999	1990		1999	1990		1999	1990		1999	1990				
	30.2	9	7	34.6	6	4	47.0 ⁷	2	3 ⁹	27.6	10	9	22.3	13	12	33.7
Pharmaceutical consumption																
ø Number PR ⁶ / Inhabitant	Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number
		1999	1990		1999	1990		1999	1990		1999	1990		1999	1990	
	5.7	9	11	12.5	2	3	11.4	3	5 ³	6.9	7	7	14.4	1	1 ⁹	8.3
ø Number pkg. / Inhabitant	Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number	Ranking		Number
		1999	1990		1999	1989		1999	1989		1999	1989		1999	1989	
	14.0 ⁷	12	15	19.9 ⁷	7	6	22.2 ⁷	6	7	12.5 ⁷	13	12	25.4 ⁷	4	4	21.6

Note: descending order, 1 = highest level or share, 15 = lowest level or share

n.a. = not available, PE = pharmaceutical expenditure, pkg. = packages, PR = prescription, priv. = private, pub. = public, Ø = average

¹ 1995, corresponds to number 1 in the ranking of 95

² Sum of private and public shares of pharmaceutical expenditure does not always amount to 100 per cent due to data gaps.

³ 1995

⁴ 1991

⁵ 800 Kroner rule (high co-payment, which has been abolished)

⁶ prescriptions financed by public spending

Source: ÖBIG 2001a, OECD 2000; information-gathering by ÖBIG

⁷ 1998

⁸ 1997

⁹ 1993

¹⁰ average cost per package

¹¹ IKA only (= largest health insurance)

¹² data only refer to England

Table 7.2: Benchmarking – Central indicators, developments 1990 until 1999

Index: 1990 (or earliest available year) = 100											
Indicators / Country	BE		DK		DE		FI		FR		Ø EU
General economic data											
Gross domestic product	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index
	141.9	12	146.7	11	159.8	6	137.3	14	133.4	15	169.8
	Health expenditure	(163.7) ¹	(10)	145.5	12	191.9	4	(115.4) ¹	(15)	144.5	13
Pharmaceutical expenditure											
Total PE	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index
	(123.8) ²	(14)	149.3	11	(133.3) ³	(13)	201.4	6	157.7	8	180.7
	Pub. pharmac. expenditure	(140.2) ²	(12)	247.3	4	(129.1) ³	(13)	198.4	7	191.4	9
Priv. pharmac. expenditure	(102.5) ⁴	(11)	95.9	14	(183.6) ³	(6)	204.2	5	97.7	12	158.2
Pharmaceutical consumption											
ø Expenditure per PR	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index
	n.a.	n.a.	(106.4) ²	(13)	(167.4) ³	(6)	185.7	3	n.a.	n.a.	158.4
	Total prescriptions	n.a.	n.a.	(111.2) ²	(9)	(77.1) ³	(12)	106.8	11	n.a.	n.a.

Note: descending order, 1 = highest increase, 15 = lowest increase

EU average calculated on basis of years/data available

n.a. = not available, PE = pharmaceutical expenditure, pkg. = packages, PR = prescription, priv. = private, pub. = public, Ø = average

¹ 1990 - 1998

² 1995 - 1999

³ 1991 - 1999

⁴ 1998 - 1999

⁵ 1990 - 1997

⁶ 1995 - 1998

⁷ IKA only (= largest health insurance)

⁸ 1995 - 1997

⁹ average cost per package

¹⁰ data only refer to England, 1991 - 1999

¹¹ packages sold

¹² 1993 - 1998

¹³ partly a result of considering VAT in the insurance market since 1997

¹⁴ 1993 - 1999

Source: ÖBIG 2001a, OECD 2000; information-gathering by ÖBIG

☞ table to be continued

Table 7.2 (continued): Benchmarking – Central indicators, developments from 1990 until 1999

Index: 1990 (or earliest available year) = 100											
Indicators / Country	GR		GB		IE		IT		LU		Ø EU
General economic data											
	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index
Gross domestic product	290.0	1	158.6	8	239.3	2	159.2	7	205.1	4	169.8
Health expenditure	(296.1) ¹	(1)	186.2	5	208.4	3	165.0	9	(173.0) ¹	(7)	171.7
Pharmaceutical expenditure											
	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index
Total PE	412.0	1	(205.0) ¹	(5)	(155.6) ⁵	(9)	146.4	12	(117.2) ⁶	(15)	180.7
Pub. pharmac. expenditure	(332.3) ⁷	(1)	225.0	6	(162.6) ²	(11)	113.7	15	(124.7) ²	(14)	191.9
Priv. pharmac. expenditure	n.a.	n.a.	(215.1) ¹	(4)	(96.5) ⁸	(13)	218.0	3	(124.0) ⁶	(10)	158.2
Pharmaceutical consumption											
	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index
ø Expenditure per PR	(275.9) ⁹	(1)	(160.1) ¹⁰	(7)	(126.8) ²	(10)	183.4	4	(115.4) ²	(12)	158.4
Total prescriptions	(149.4) ¹¹	(2)	(130.3) ¹⁰	(5)	186.8	1	62.0	13	(108.0) ²	(10)	116.2

Note: descending order, 1 = highest increase, 15 = lowest increase

EU average calculated on basis of years/data available

n.a. = not available, PE = pharmaceutical expenditure, pkg. = packages, PR = prescription, priv. = private, pub. = public, Ø = average

¹ 1990 - 1998

² 1995 - 1999

³ 1991 - 1999

⁴ 1998 - 1999

⁵ 1990 - 1997

⁶ 1995 - 1998

⁷ IKA only (= largest health insurance)

⁸ 1995 - 1997

⁹ average cost per package

¹⁰ data only refer to England, 1991 - 1999

¹¹ packages sold

¹² 1993 - 1998

¹³ partly a result of considering VAT in the insurance market since 1997

¹⁴ 1993 - 1999

Source: ÖBIG 2001a, OECD 2000; information-gathering by ÖBIG

☞ table to be continued

Table 7.2 (continued): Benchmarking – Central indicators, developments from 1990 until 1999

Index: 1990 (or earliest available year) = 100											
Indicators / Country	NL		AT		PT		SE		ES		Ø EU
General economic data											
Gross domestic product	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index
	158.1	9	149.3	10	211.4	3	138.7	13	185.6	5	169.8
	(146.4) ¹	(11)	165.5	8	(244.9) ¹	(2)	(126.6) ¹	(14)	(177.0) ¹	(6)	171.7
Pharmaceutical expenditure											
Total PE	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index
	178.0	7	233.3	4	(154.1) ¹²	(10)	244.3	3	258.8	2	180.7
	pub. pharmac. expenditure	183.5	10	(272.9) ¹³	(2)	(193.3) ¹⁴	(8)	251.7	3	246.7	5
priv. pharmac. expenditure	166.3	8	183.2	7	(140.9) ¹²	(9)	226.9	2	312.0	1	158.2
Pharmaceutical consumption											
Ø Expenditure per prescription	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index	Ranking 1999	Index
	140.8	9	208.1	2	(124.0) ²	(11)	183.0	5	(151.7) ²	(8)	158.4
	Total prescriptions	130.3	4	125.0	6	(124.9) ²	7	137.5	3	(112.7) ²	(8)

Note: descending order, 1 = highest increase, 15 = lowest increase
 EU average calculated on basis of years/data available

n.a. = not available, PE = pharmaceutical expenditure, pkg. = packages, PR = prescription, priv. = private, pub. = public, Ø = average

¹ 1990 - 1998

² 1995 - 1999

³ 1991 - 1999

⁴ 1998 - 1999

⁵ 1990 - 199

⁶ 1995 - 1998

⁷ IKA only (= largest health insurance)

⁸ 1995 - 1997

⁹ average cost per package

¹⁰ data only refer to England, 1991 - 199

¹¹ packages sold

¹² 1993 - 1998

¹³ partly a result of considering VAT in the insurance market since 1997

¹⁴ 1993 - 1999

Source: ÖBIG 2001a, OECD 2000; information-gathering by ÖBIG

8 Conclusion

The most important findings of this study on the pharmaceutical systems within the EU and on the cost-containment strategies including their impacts can be summarised as follows:

Pharmaceutical markets are subject to a multitude of regulations both at the Community and at the national level. In order to safeguard the principle of the free single market, the European Union has meanwhile gained great influence on the registration of pharmaceuticals. The relevant regulations have been implemented in all countries and harmonisation within the European Union has been achieved.

Basically, the individual EU countries are responsible for pricing and reimbursement of pharmaceuticals. Therefore, the Member States have very different regulations in this area, some of which are very complex. In recent years, however, a growing influence of the European Union on this sector could be observed. For instance, the individual countries have to prove that reimbursement decisions are based on transparent criteria and that there is no discrimination or preferred treatment, for example, of the national pharmaceutical industry.

Member States are strongly interested in controlling public pharmaceutical expenditure. Thus, in most Member States manufacturer prices as well as wholesale and pharmacy margins are regulated for reimbursable pharmaceuticals only.

In almost all EU Member States, the increase in pharmaceutical expenditure was significantly higher than the increase in the gross domestic product and in health expenditure. As a consequence, all EU Member States, except Luxembourg, have taken a multitude of cost-containment measures. However, the scope, intensity and control measures used varied as the problems and “control strategies” were country-specific.

The following conclusions can be drawn with regard to the cost-containing measures and their impacts:

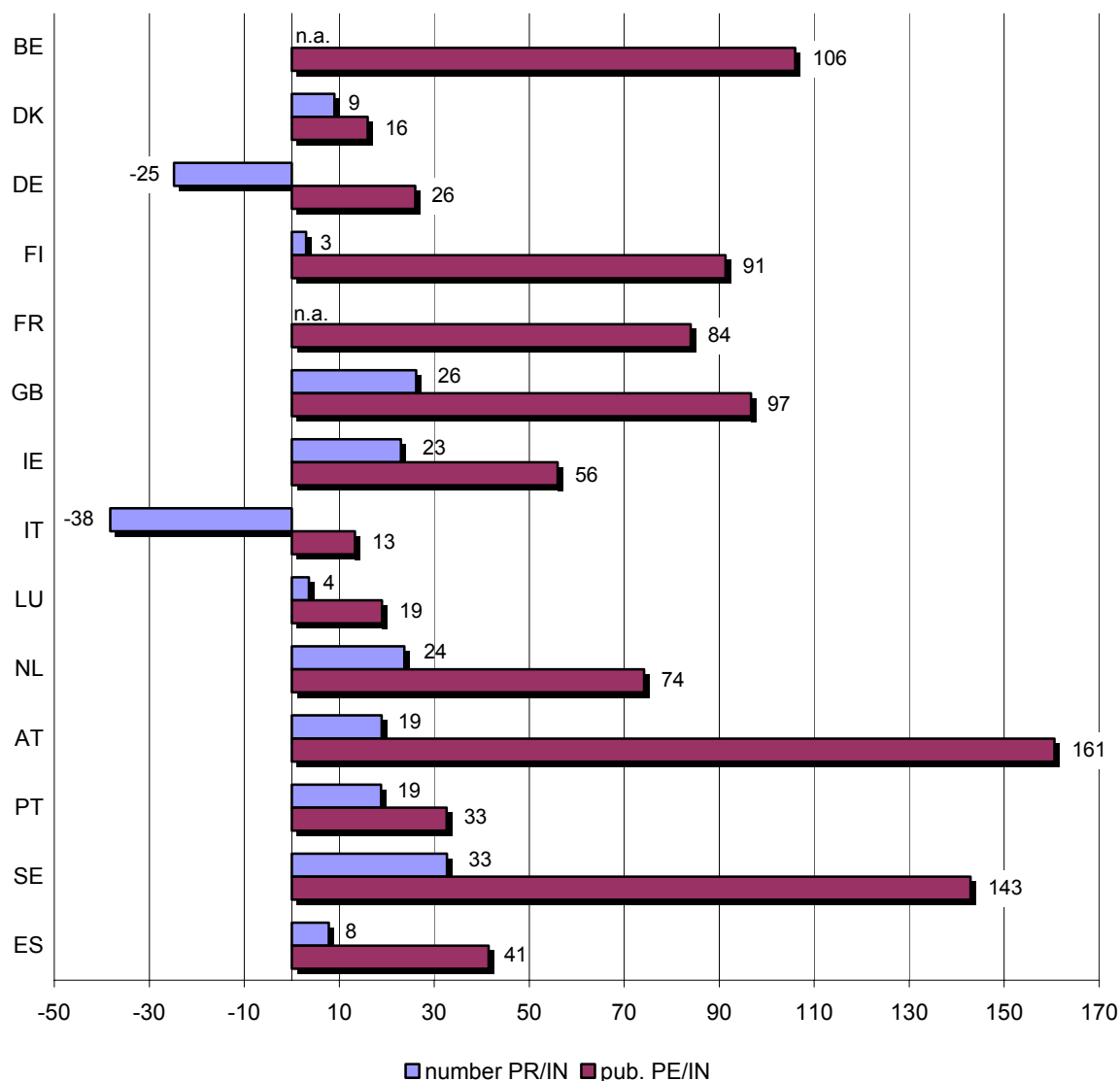
- Except for Luxembourg, all EU countries intervened more or less strongly in order to control of pharmaceutical expenditure.
- The cost-containment measures focused on publicly funded pharmaceuticals. The measures became urgent whenever the general economic situation had deteriorated and/or the health care funds had run into a deficit.
- Less containing measures were taken by countries with a low level of per capita health and pharmaceutical expenditure and a need for investment in pharmaceutical care.
- The countries which intervened most frequently were Belgium, Germany, Spain and Italy, Denmark and the Netherlands. The measures actually had an impact. It could be observed that those countries which intervened at the price level and at the volume level at the same time, were “more successful”.

- The success of the cost-containment measures was, however, mostly to the detriment of the patients, who have to make increased co-payments and/or have to pay for an increasing number of pharmaceuticals out of their own pockets (expansion of self-medication).
- Compared to public pharmaceutical expenditure the number of pharmaceuticals prescribed fell or rose less (cf. Figure 8.1). This is especially true for Germany and Italy, where massive savings have been made.
- In most countries, the increase in average public expenditure per prescription was considerably higher than the increase in the number of prescriptions. This is an indication that more new and expensive pharmaceuticals are entering the market. Many countries try to react with counter-strategies as the price-containing effect of less expensive pharmaceuticals such as generics obviously does not suffice to compensate for the price increase of the new pharmaceuticals.
- Some countries (Great Britain, the Netherlands) have already reacted to the increasing number of new, expensive pharmaceuticals on the market by evaluating the therapeutic-economic benefit of such pharmaceuticals.
- Another trend is to improve the prescription habits of physicians by continuous reviewing and enhancing prescription patterns which also contributes to cost-containment.

Again, the conclusions regarding control strategies as expressed in the ÖBIG-study "Pharmaceuticals. Market Control in nine European Countries" (ÖBIG 1998a) have been confirmed in this study. A "pendulum effect" typical of many fields of policy could be observed. Discontentment with the original situation leads to a number of fundamental changes causing the pendulum to swing in the desired direction. If deficiencies or problems occur or the government changes, the pendulum begins to move back towards the initial situation. Some more liberal countries had moved back to state interventions (e.g. Denmark, Great Britain, the Netherlands). Other countries, which had used rigid state control attempted to attain their goals by means of market instruments (e.g. Spain and Italy with the introduction of reference price systems). The Scandinavian countries and the Netherlands, known as pioneers in many fields, have combined both strategies lately. All in all, many countries – due to budgetary restrictions – give the impression of a certain insecurity and helplessness when it comes to controlling the pharmaceutical systems.

Furthermore, the assessment of the short-term impact of measures made in the above-cited ÖBIG-study (ÖBIG 1998a) was confirmed: There are loopholes in every control approach. Therefore, its effect is limited in time, i.e. until the market participants have adjusted to the new situation and have learned to take advantage of the loopholes. No system for cost-containment in the health care sector will be effective in the long run, but all systems are permanently subject to change.

Figure 8.1: Conclusion – Changes in public pharmaceutical expenditure and in the number of prescriptions (figures adjusted to demographic development), 1999 compared to 1990¹ (indexed)



IN = inhabitant, n.a. = not available, pub. PE = public expenditure on pharmaceuticals, PR = prescriptions

Note for Austria: increase in public PE per capita, VAT-adjusted, amounts to 116 per cent for 1990

¹ DK, IE, LU, ES 1999 compared to 1995; DE, GB 1999 compared to 1991, PT 1998 compared to 1995

Source: ÖBIG 2001a; information gathering by ÖBIG

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ANNEX

List of available publications

An up-dated list of publications can also be found at our homepage <http://www.oebig.at>

Information on ÖBIG

Jahresbericht 2000 / Annual report 2000 (in German)
90 p., fig., spiral binding
ÖBIG, Vienna 2001, available free of charge at ÖBIG

OLD-AGE AND LONG-TERM CARE

Wie behindertengerecht sind Österreichs Kultureinrichtungen? / How barrier-free are Austria's cultural institutions? (in German)

304 p., numerous tab., charts, plans, colour photographs, spiral binding
ÖBIG and Institut für soziales Design, Vienna 1993, ATS 440.-- / € 31.98

IGSS - Integrierte Gesundheits- und Sozialsprengel/Handbuch / Integrated health care and social services districts/Handbook (in German)

308 p., 41 fig., samples and work sheets, spiral binding
ÖBIG, Vienna 1993, ATS 175.-- / € 12.72

Approaches to co-operation and co-ordination between medical and social services in five European countries (Germany, the Netherlands, Austria, Sweden, Czech Republic):

New Forms of Health and Social Care - Five National Reports (in English)

100 p., 3 tab., 11 fig., spiral binding
ÖBIG, Vienna 1994, ATS 255.-- / € 18.53

Kultur ohne Barrieren - Hinweise für Kulturveranstalter / Culture without barriers – Guidelines for cultural event managers (in German)

87 p., numerous fig., list of addresses, literature and acts prepared by ÖBIG and Institut für soziales Design, published by the Federal Ministry of Science, Research and Cultural Affairs, Vienna 1995, available free of charge at ÖBIG

Pflegevorsorge in der Steiermark / Nursing provision in Styria (in German)

Teil A: Seniorenbereich/Kurzfassung / Part A: Senior Citizens/Abridged Version

51 p., numerous tab., fig. and maps, spiral binding
ÖBIG, Vienna 1996, ATS 145.-- / € 10.45

Teil B: Behindertenbereich/Kurzfassung / Part B: Disabled Citizens/Abridged Version

87 p., numerous tab., fig. and maps, spiral binding
ÖBIG, Vienna 1996, ATS 180.-- / € 13.08

Teil A: Seniorenbereich/Langfassung / Part A: Senior Citizens/Long Version

573 p., comprehensive annex, numerous tab., fig. and maps, spiral binding
ÖBIG, Vienna 1996, ATS 595.-- / € 43.24

Teil B: Behindertenbereich/Langfassung / Part B: Disabled Citizens/Long Version

287 p., annex, numerous tab., fig. and maps, spiral binding
ÖBIG, Vienna 1996, ATS 350.-- / € 25.44 /

Partnerschaften zur Förderung des sozialen Zusammenhalts - Länderbericht Österreich / Partnerships for the support of social co-operation – country report Austria (in German)

127 p., tab. and fig.

prepared by ÖBIG, publ. by the Federal Ministry of Labour, Health and Social Affairs, series "Soziales Europa" no. 7, Vienna 1997, available free of charge at the Federal Ministry of Social Security and Generations

Report to the Austrian Chapter of the Club of Rome:

Alte Menschen in Österreich. Lebensverhältnisse, Probleme, Zukunftsperspektiven / The elderly in Austria. Their life situation, problems, future perspectives (in German)

65 p., numerous tab. and charts, spiral binding
ÖBIG, Vienna 1998, available free of charge at ÖBIG

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