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Pharmaceutical Pricing and Reimbursement Information

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Pharmaceutical Pricing and Reimbursement Information

CYPRUS

Pharma Profile

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PPRI Participant(s)

Mrs. Xenia Ashikales and Dr. Athos Tsinontides, Department of Pharmaceutical Services (PhS) and Health Insurance Organisation (HIO)

PPRI Pharma Profile - Authors

Mrs. Xenia Ashikales and Dr. Athos Tsinontides, Department of Pharmaceutical Services (PhS) and Health Insurance Organisation (HIO)

PPRI Pharma Profile - Editorial team

WHO Regional Office for Europe: Trine Lyager Thomson (editor-in-chief), Nicole Satterly (copy-editing), Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG: Sabine Vogler, Christine Leopold

Executive summary

Background

In Cyprus the provision of health care is divided into public and private sectors. The private sector is financed with out-of-pocket payments (OPPS) by the patients and there is no reimbursement for the services provided. The public sector falls under the Ministry of Health and it is block-funded by the Ministry of Finance. It provides a wide range of health services, including: out-patient care by general practitioners (GPs); in- and out-patient care by specialists; dental care; pharmaceutical care according to a pre-approved pharmaceuticals list; medical rehabilitation, etc., to eligible patients according to the Medical Institutions and Services Laws of 1978 and 2000. The private sector offers mainly out-patient and in-patient specialist care. Patients have to pay out-of-pocket payments (OPPs) for their pharmaceuticals.

In 2001, a Law on the implementation of a General Health Care Scheme (GHS) was passed, as a result of which the Health Insurance Organisation (HIO) was established. The General Health Care Scheme (GHS) is expected to be launched in 2008. It will cover all Cypriot citizens living in Cyprus, irrespective of their level of income. Contributions to the Scheme will be mandatory for all citizens that have an income.

Currently, under the public sector system, patients are divided into five groups (A-E), according to which they are eligible for free services or services at a reduced fee, either because of their income or because they suffer from a specific chronic disease.

The public and the private health expenditure (HE) levels are almost equal. This is probably because of the absence of a national health scheme.

Pharmaceutical system

Organisation

Cyprus has not yet adopted and implemented a comprehensive policy in the pharmaceuticals field. However, there is a set of policies and regulations that govern the pharmaceutical sector in terms of the availability of pharmaceuticals and their prices in the private sector, the availability of pharmaceuticals to eligible patients in the public sector and the implementation of a National Health Insurance Scheme.

The most relevant key players in the Cypriot pharmaceutical system are: the Ministry of Health; the Drugs Council, which acts as a medicines agency responsible for (a) issuing market authorisation licences, (b) classification of pharmaceuticals, (c) pharmacovigilance and (d) inspection of manufacturers; the Price Control Committee appointed by the Ministerial Council as a consultative body to the Minister of Health on the prices of pharmaceuticals; the Pharmaceutical Council responsible for recognising pharmacists' qualifications and registering pharmacists, as well as for the opening and licensing of new pharmacies; the Department of Pharmaceutical Services (PhS) acting as the Secretariat of the Drugs Council, of the Price Control Committee, of the Drugs Committee and of the Pharmaceutical Council, and responsible for the procurement and distribution of pharmaceuticals to all public pharmacies; the Drugs Committee, an in-

ternal committee in the Department of Pharmaceutical Services (PhS), which is responsible for the catalogue of the List of Approved Pharmaceuticals¹; and finally, the Health Insurance Organisation (HIO), responsible for the implementation of the General Health Care Scheme (GHS) in Cyprus.

Pharmaceutical market

In 2006, there were approximately 2,900 registered pharmaceuticals in Cyprus, but only 2,300 are available for sale on the market due to the fact that many products authorised through a Mutual Recognition Procedure (MRP) or through the Centrally Authorised Procedure (CAP) are not introduced into the market because many market authorisation holders (MAH) are not interested in marketing those products on the small Cypriot market.

The number of registered products has decreased since the introduction of the Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act, mainly because market authorisation holders (MAH) could not upgrade their dossiers and renew their market authorisation licences. The number of generics available on the market is not known, but most of them are used in the public sector, contributing substantially to cost-containment.

Currently, pharmaceuticals are classified as prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals, based on the guidelines of the Council of Europe, in the form of a Ministerial Decree.

Market players

In Cyprus the pharmaceutical industry has been mainly comprised of five generic manufacturers. In addition, there is one manufacturer of raw materials. A substantial part (95%) of the production from local manufacturers is exported, and therefore the local industry does not play a major role in the local market, but on the other hand this makes the Cypriot pharmaceutical industry an important source of foreign income. Research and development (R&D) is limited due to the nature of the industry (generics).

The majority of wholesalers distribute pharmaceutical products through distributors, although some of them have their own distribution network. They are important key players as they distribute 90% of the pharmaceuticals on the market. The Cyprus Association of Pharmaceutical Companies (Syndesmos Farmakeytikwn Etaireiwn Kyproy, SFEK) is the wholesalers association, which is represented in the Price Control Committee.

Pharmaceuticals are dispensed through community pharmacies, 430 of which are private and 35 are public (in 2006). There are also 8 public hospital pharmacies (in 2006). There are no restrictions on establishing pharmacies. Neither Internet nor mail-order pharmacy are allowed.

Doctors are represented in the Drugs Council through the Doctors Association and therefore they have a say in the registration of new products on the market. The majority of doctors prescribe by brand name and pharmacists are obliged to dispense what is prescribed. Doctors are only allowed to dispense pharmaceuticals when the nearest pharmacy is located at a distance

¹ Pharmaceuticals available from public pharmacies to all eligible patients through prescriptions, only from the public sector doctors.

of more than 30 km. Public sector doctors are involved in the process of inclusion of pharmaceuticals in the List of Approved Pharmaceuticals and they prescribe by brand less than often than private doctors.

Pharmaceutical expenditure

The total expenditure (approximately CYP 88 Mio. in 2005) on pharmaceuticals has been increasing dramatically especially in the public sector¹, mainly due to the addition of expensive treatments into the List of Approved Pharmaceuticals. The share of generics in the public sector is about 20% in terms of value, whereas in the private sector it is about 5%. The main source of health care expenditure for the public sector comes from the government budget (through taxation). In the private sector, health care is financed by out-of-pocket payments (OPPs) by patients. Expenditure in the private sector is increasing due to the lack of regulation, planning and health policy.

Pricing

Organisation

In Cyprus, prices of pharmaceuticals are regulated according to the Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act of 2001-2006 [L.70(I)2001-2006].

The Minister of Health, following the recommendations of the Price Control Committee, which operates as a consultative body, sets prices of pharmaceuticals. However, the Minister of Health is not bound by the Price Control Committee recommendations in (her/his) final decision.

As of 2005, the prices of imported pharmaceuticals are set through external price referencing (only for the private sector). The price set is the wholesale price and on top of that the pharmacist's margin is added. This price does not include a specific profit margin for the wholesalers. The prices of imported generics after external price referencing cannot exceed 80% of the price of the original branded product marketed in Cyprus. For locally manufactured generics the ex-factory price is set on the basis of the production cost plus a mark up of 20%, which should not exceed 80% of the original product. The public sector buys pharmaceuticals through tenders and achieves prices many times lower than the prices in the private sector price list.

At the time of writing, pricing is not interlinked with reimbursement due to the current organisation of health care and of the pharmaceutical system.

Pricing policies

Statutory pricing is applied to all pharmaceuticals with a market authorisation licence that are available in the private sector. The market authorisation holder (MAH) has to apply to the Price Control Committee and the Department of Pharmaceutical Services (PhS) (as the secretariat of the Committee). The method of external price referencing is applied for all imported pharmaceuticals (original, generics, prescription-only medicine(s) (POM) and over-the-counter (OTC)) and the method of cost-plus pricing is used for locally produced pharmaceuticals (all generics). The

¹ Expenditure in the public sector: 2001 = CYP 19 Mio., 2004 = CYP 37 Mio.

results of the external pricing method are presented to the Price Control Committee, which makes recommendations to the Minister of Health, who set the prices. A price list including the pharmacy retail prices (PRPs) of all the products available in the market is published once a year. Currently, value-added tax (VAT) is not applied for pharmaceuticals, except in the case of diagnostic agents which bear a 15% value-added tax (VAT) level. Price negotiation is not used, whereas free pricing may be applicable at manufacturer level for imported pharmaceuticals in the private sector. Moreover, according to the law, the Minister of Health has to set the price of a pharmaceutical within 90 days of receipt of a fully completed application. In some cases this period might be extended by 60 days. However, if the Minister fails to set a price within this time frame, the applicant may freely set the price her/himself.

As far as the pharmaceuticals used in public pharmacies are concerned, a public procurement method is used. According to the existing laws and regulations, the Government can purchase goods (including pharmaceuticals) through tendering process, by which lower prices are usually achieved (or at least when there is competition).

Pharmacy remuneration

Pharmacists receive a flat mark-up margin on the wholesale price which is regulated by ministerial decree. When the new pricing system was introduced in 2005, causing an average decrease of approximately 15% in prices, for the majority of products (for which the price was decreased) the profit mark up was increased from 33% to 38% on the pharmacy purchasing price (PPP), and for the products for which the price did not decrease, the profit mark up remained the same (33%).

Remibursement

Organisation

In Cyprus the provision of health care is divided into two distinct sectors: private and public. The private sector is financed by out-of-pocket payments (OPPs) on the part of the patients and there is no reimbursement for any services provided. The Government finances the public sector, which provides health care services including pharmaceuticals to eligible patients, according to the Medical Institutions and Services General Regulations.

The reimbursement scheme used in the public sector is a population-specific system. There are no reimbursement categories for pharmaceuticals, but rather categories of patient eligibility. Patients are divided into five groups (A-E). The legal framework for this scheme is the Public Institutions and Foundations Law. The services provided to the five categories of eligible patients include the provision of pharmaceutical care. Individuals who are entitled to services free of charge fall under category A; individuals who are entitled to services provided at a reduced fee fall under category B; and category C is comprised of patients who are not covered under categories A and B. Some patients, who fall under specific disease or treatment categories, are entitled to free medical care irrespective of their income levels (category D) and category E includes patients entitled to free medical care for the treatment of their specific medical condition only, irrespective of income.

The pharmaceuticals provided to the eligible patients must be included in the List of Approved Pharmaceuticals, prepared by the Drugs Committee. In order for a new product to be added to the List of Approved Pharmaceuticals, a formal pharmaceutical request form has to be submitted by a specialist physician practising in a public hospital. The criteria for inclusion of a pharmaceutical in the List of Approved Pharmaceuticals include: product-specific criteria (e.g. medical and therapeutic value, safety, lack of alternative therapies); economic criteria (e.g. cost-effectiveness, budget impact); patient-specific criteria (e.g. age, sex, chronically or terminally ill patients); and disease-specific criteria (e.g. severity of illness, special medical needs). The Drugs Committee assesses all of the above criteria. Upon entry to the List of Approved Pharmaceuticals, the pharmaceutical's reimbursement level is based on the eligibility criteria of the patient.

Reimbursement lists

Only the products that are included in the List of Approved Pharmaceuticals are reimbursed. The Drugs Committee manages the List, which is updated constantly, as the Drugs Committee finishes each assessment, and it is communicated to all the public sector physicians.

Payments

Direct payments may be made by patients according to their eligibility category, but not based on the type of pharmaceutical. Out-of-pocket payments (OPPs) are also based on the eligibility group of the patient. Some patients may need to pay 50% of the pharmacy purchasing price (PPP). There are no fixed co-payments and no deductibles are used in Cyprus.

Rational use of pharmaceuticals

Prescription guidelines

There are no treatment guidelines for doctors in the private sector. There are some guidelines available for the doctors working in government hospitals and out-patient clinics. The Drugs Committee prepares the guidelines, which are not extensive and have been implemented since the mid-1990s. Adherence to the guidelines is monitored through the pharmacies in the public sector. In cases where a specific protocol has been set, the pharmaceutical is not dispensed unless the protocol is followed. In cases where the protocol is vague, no one monitors it. There are no sanctions for not following the protocols, apart from refusal to dispense the pharmaceutical.

The Ministry of Health recently introduced the Health Booklet to be used in the public sector. Physicians write the patient's prescriptions in this booklet and the pharmacy can monitor prescribing as well as the quantities dispensed. The aim of this is to limit the quantities of pharmaceuticals stocked at home by patients, as the pharmacist can refuse to fill a prescription if (s/)he realises that the patient has sufficient quantities of the pharmaceuticals at home. The booklet is used only by the public sector physicians and pharmacists and it is distributed to patients who fall under any of the five eligibility categories. The eligibility category of the patient is indicated on the booklet.

Information to patients / doctors

The “Marketing Directives”, as stipulated in Directive 2001/83/EC, have been implemented in Cyprus through the enactment of the Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act which is implemented by the Drugs Council.

Generics

Generics and generic substitution are used widely in the public sector. The use of generics provides a lot of cost savings in the public sector. The use of generics in the private sector is limited. Pharmacists in the private sector are not allowed to substitute branded pharmaceuticals for generics.

Generic promotion is limited in Cyprus and there are no incentives for doctors and pharmacists. Even though generics are cheaper and affect the patients who pay out of pocket, still they prefer to pay for the original product prescribed by the doctor.

Current challenges and future developemtns

The main challenges the pharmaceutical system in Cyprus currently faces are the lack of a National Drug Policy, access to pharmaceuticals and the uncontrolled increase in pharmaceutical expenditure (PE).

Lack of a National Drug Policy

As a result of the current system of health care provision (public and private sector), including pharmaceutical care, the private pharmacies are underutilised and the public pharmacies are overloaded, resulting in inferior pharmacy services to public sector patients. The segregation of the sectors does not allow for uniform utilisation of resources, nor does it allow the application of a National Drug Policy that will provide access, safety and cost savings.

The fact that all pharmaceuticals are provided free to most patients, without a co-payment, leads to over-consumption of pharmaceuticals. Although the centralised procurement method enables lower prices of pharmaceuticals, it fails to estimate the needs and as a result there are shortages of pharmaceuticals in the public sector.

Access to pharmaceuticals

Owing to the small and segregated market there is a problem of access to pharmaceuticals. Particularly since the harmonisation of the regulations with Directive 2001/83/EC, there has been a dramatic decrease in the number of pharmaceuticals in the private sector. In addition, pharmacies in the public sector often have to obtain pharmaceuticals that are not available on the Cypriot market.

Uncontrolled increase in pharmaceutical expenditure

Pharmaceutical expenditure (PE) has been increasing at a fast pace. This is mainly due to the addition of new expensive therapies in the public sector and the absence of a drug policy in the private sector.

Future developments

Cyprus is working towards the introduction of a General Health Care Scheme (GHS). The Scheme will be based on the solidarity principle, with all citizens that have an income contributing.

The beneficiaries will be all Cypriot citizens living permanently in Cyprus. The General Health Care Scheme (GHS) will unite the provision of health care by buying services under the same conditions from the private and the public sectors, and it will create competitive conditions and raise the quality of the services provided. The unification of the market will move the responsibility of planning of quantities to the private sector, and may stimulate the entry of more products onto the market and improve accessibility.

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Abbreviations

CAP	Centrally Authorised Procedure
CY.PHA.M.A	Cyprus Pharmaceutical Manufacturers Association
DC	Drugs Council
DG SANCO	(European Commission) Directorate General for Health and Consumer Protection
GDP	Gross Domestic Product
GGE	General Government Expenditure
GHS	General Health Care Scheme
GP	General Practitioner
HE	Health Expenditure
HIO	Health Insurance Organisation
HOM	Hospital-Only Medicine(s)
NCU	National Currency Unit
MAH	Market Authorisation Holder
Mio.	Million
MoH	Ministry of Health
MRP	Mutual Recognition Procedure
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter (pharmaceuticals)
PE	Pharmaceutical Expenditure
PhS	Pharmaceutical Services
POM	Prescription-Only Medicine(s)
PPP	Pharmacy Purchasing Price

PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
SFEK	Syndesmos Farmakeytikwn Etaireiwn Kyproy / Cyprus Association of Pharmaceutical Companies
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value-Added Tax
WHO	World Health Organization

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbe- reich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other,
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”,
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information,
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU) and,

disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from competent authorities, Medicines Agencies, Social Insurance Institutions, research institutes) and edited by experts of the PPRI project coordination.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI website at <http://ppri.oebig.at>. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available at the PPRI website.

1 Background

Chapter 1 aims to provide an overview on the country, in particular on the health care system. As the focus on the PPRI Pharma Profiles is on pharmaceutical pricing and reimbursement, the authors of this Profile did not write a full chapter like for the following ones, but opted for the presentation of some key figures on health care systems presented in 2 tables, accompanied by a brief description of the health care system.

In Cyprus the provision of health care is divided into two distinct sectors, the private and the public. The private sector is financed through out-of-pocket payments (OPPs) by the patients and there is no reimbursement for any services provided. The public sector falls under the Ministry of Health and is financed by the Government. The public sector is block-funded by the Ministry of Finance and provides: out-patient care by general practitioners (GPs); in-patient and out-patient care by specialists; diagnostic and paramedical examinations; hospitalisation; dental care¹; medical rehabilitation and provision of prosthetic and orthopaedic appliances; transport of patients; and necessary pharmaceuticals and pharmaceutical material, according to a pre-approved pharmaceutical list. The staff working in the public sector are on a salary whereas medical services in the private sector are paid on a fee-for-service basis.

The public sector provides health care services to eligible patients according to the Medical Institutions and Services Laws of 1978 and 2000. The current system, however, dates back to the colonial era (1950s), with several modifications over the years.

In 2001, a Law on the implementation of a General Health Care Scheme (GHS) was passed, as a result of which the Health Insurance Organisation (HIO) was established. The Organisation has the mandate of the implementation and management of the General Health Care Scheme (GHS), which is expected to be launched in 2008. It will cover all Cypriot citizens living in Cyprus, irrespective of their level of income. Contributions to the Scheme will be mandatory for all citizens that have an income.

Currently, under the public sector system, patients are divided into five groups (A-E). Individuals who are entitled to services free of charge fall under category A, which includes active and retired civil servants and their dependants (including government ministers, and members of the education service, police, and armed services); families with four or more children; students; war pensioners; welfare recipients; and low-income individuals (people living alone with an annual income below CYP 9,000/€ 15,600 and families with an annual income below CYP 18,000/€ 31,200 plus CYP 1,000/€ 1,730 per dependent child). A dependent child is a non-married child under the age of 18. These patients are required to pay a co-payment of CYP 1/€ 1.733 per out-patient visit.

Services are provided at a reduced fee rate for individuals with low income, i.e. people living alone with an annual income between CYP 9,000/€ 15,600 and CYP 12,000/€ 20,800 and families with an annual income below CYP 22,000/€ 38,130 plus CYP 1,000/€ 1,730 per dependent child (category B). These individuals are required to pay 50% of the fees charged to paying pa-

¹ not including dentures, although these are provided to some low-income groups.

tients (see later, under category C explanation). However, in the case of the medical ailment being caused under circumstances creating a legal liability for damages to be paid by a third person, the right to free care is waved and fees must be paid by the person liable for the damages.

Category C is comprised of patients who are not covered under categories A and B. They must pay a fee for the use of government medical services. Each visit to a general practitioner (GP) or specialist requires a fee of CYP 7/€ 12.10 and CYP 10/€ 17.30, respectively. Additionally, fees are compulsory for laboratory, radiology and all examinations and tests. The charge for expensive in-patient treatment may be reduced in accordance with individual income levels.

Some patients, who fall under specific disease or treatment categories, are entitled to free medical care irrespective of their income levels (category D). This group includes: patients with multiple sclerosis; patients with Alzheimer's disease; transplant patients; patients on hemo- or peritoneal dialysis; patients suffering from myasthenia gravis and other genetic neurological diseases, thalassaemia, idiopathic thrombocytopenic purpura, haemophilia, chronic immunodeficiency syndrome, congenital heart disease, and cystic fibrosis; paraplegics and tetraplegics; and patients up to the age of 18 with autism, diabetes type I, or congenital somatic anomalies.

Category E includes patients entitled to free medical care for the treatment of a specific medical condition only, irrespective of income. An example would be patients suffering from diabetes mellitus II. These patients are entitled of free health care for issues regarding diabetes only. For any other conditions they may develop, they are not eligible.

It is estimated that 70-75% of the population fall in Categories A, D and E and are eligible for free health care. Approximately 5-10 % of the population falls into category B.

The private sector offers mainly out-patient and in-patient specialist care. Most physicians in the private sector are specialists and work out of private practices, and many of them provide primary care, since there are very few specialists in general medicine. Private hospitals and clinics offer a wide range of in-patient services for patients not eligible for free health care, or for eligible people who choose to pay out of pocket.

Public health expenditure (HE) is almost 50% of the total health expenditure (THE) (cf. Table 1.1). This is probably because the importance of the private sector has given the opportunity for high and unregulated expansion of the private health care sector.

Table 1.1: Cyprus – Key figures in the health care system 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total population (Mio.)	0.690	0.697	0.705	0.715	0.730	0.749	n.a.
Life expectancy at birth, total	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Life expectancy at birth, females	79.8	81.0	n.a.	81.4	81.4	81.4	n.a.
Life expectancy at birth, males	75.3	76.1	n.a.	77.0	77.0	77.0	n.a.
GDP in NCU	n.a.	5,679.0	6,103.6	6,370.3	6,836.2	7,292.1	n.a.
GDP in billion €	n.a.	9,894.7	10,597.8	11,072.3	11,703.9	12,531.1	n.a.
GGE in NCU	n.a.	2,139.4	2,373.4	2,586.6	3,096.7	3,167.7	3,426.4
GGE in €	n.a.	3,727.6	4,120.0	4,496.0	5,301.8	5,443.5	5,940.0
THE in NCU	n.a.	330.4	356.8	390.5	438.8	449.2	n.a.
THE in Mio. €	n.a.	575.7	619.5	678.7	751.3	771.9	n.a.
Public HE in NCU	n.a.	137.2	151.2	175.6	215.4	214.6	n.a.
Public HE in Mio. €	n.a.	239.0	262.5	305.2	368.8	368.8	n.a.
Private HE in NCU	n.a.	193.2	205.6	214.9	223.4	234.6	n.a.
Private HE in Mio. €	n.a.	336.6	356.9	373.5	382.5	403.1	n.a.
Total no. of hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	15 ¹	n.a.
No. of acute care beds	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total no. of doctors	1,607	1,800	1,839	1,864	1,879	1,965	n.a.
No. of visits to GPs per patient per year	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exchange rate (NCU per €1)	n.a.	0.57394	0.57593	0.57531	0.58408	0.58192	0.57683

GDP = gross domestic product, GGE = general government expenditure, NCU = national currency unit (CYP), HE = health expenditure, THE = total health expenditure, GP = general practitioner

¹ There are 6 public hospitals and 9 private hospitals. The private hospitals have more than 40 beds. In addition, there are 78 private hospitals with fewer than 40 beds each. The number of acute care beds and doctors is not available.

Sources: Health & Hospital Statistics 2004, Statistical Services, Austrian National Bank.

Table 1.2: Cyprus - Diseases with highest morbidity levels (2004) and leading causes of mortality (2005)

No.	Top 5 diseases with highest morbidity levels * (1 = most common)	ICD-10 code	No.	Top 5 leading causes of mortality (1 = most common)	ICD-10 code
1	External causes of injury and poisoning	V01-Y89	1	Myocardial infarction	I21
2	Diseases of the circulatory system	I00-I99	2	Diabetes mellitus	E14
3	Diseases of the digestive system	K00-K93	3	Chronic ischaemic heart disease	I25
4	Diseases of the respiratory system	J00-J99	4	Cerebrovascular accident	I64
5	Neoplasms	C00-D48	5	Heart failure	I50
Source: Health and Hospital Statistics			Source: Health Monitoring Unit		
Year: 2004			Year: 2005		

* There are no data available at the 3rd ICD-10 character level.

1.1 Demography

Table 1.3: Cyprus - Demographic indicators 1995, 2000, 2003 and 2004

Variable	1995	2000	2003	2004
Total population	n.a.	697,500	730,400	749,200
Population density per km ²	n.a.	n.a.	n.a.	n.a.
Population aged 0-14 (as a % of total)	n.a.	22.3	20.0	19.2
Population aged 15-64 (as a % of total)	n.a.	66.4	72.0	72.8
Population aged > 64 (as a % of total)	n.a.	11.3	8.0	8.0
Life expectancy at birth, total	n.a.	n.a.	n.a.	n.a.
Life expectancy at birth, females	n.a.	81.0	81.4	81.4
Life expectancy at birth, males	n.a.	76.1	77.0	77.0

n.a. = not available

Source: Health and Hospital Statistics, 2004

1.2 Economic background

Table 1.4: Cyprus - Macroeconomic indicators 1995, 2000-2005

Variable (in NCU or percentage)	1995	2000	2001	2002	2003	2004	2005
GDP in NCU (Mio.)	n.a.	5,679.0	6,103.6	6,370.3	6,801.7	7,292.1	n.a.
GDP per capita in NCU	n.a.	8,141	8,651	8,907	9,316	9,733	n.a.
GDP per capita in PPPa	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Growth rate from 1995 to 2000	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Growth rate from 1995 to 2005	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
GGE	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
GGE as a % of GDP	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exchange rate (NCU per €), annual rate	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

GDP = gross domestic product, GGE = general government expenditure, n.a. = not available, NCU = national currency unit (CYP), PPPa = purchasing power parity

Source: Health and Hospital Statistics 2004

1.2.1 Funding

Table 1.5: Cyprus - Health expenditure 1995, 2000-2005

Health expenditure (HE)	1995	2000	2001	2002	2003	2004	2005
THE in NCU	n.a.	330.4	356.8	390.5	438.8	449.2	n.a.
THE as a % of GDP	n.a.	5.6	5.6	5.9	6.3	6.2	n.a.
THE per capita in NCU	n.a.	455	485	531	583	599	n.a.
Public HE as a % of THE	n.a.	43.0	44.0	40.0	50.0	47.6	n.a.
Private HE as a % of THE	n.a.	57.0	56.0	60.0	50.0	52.4	n.a.

GDP = gross domestic product, HE= health expenditure, THE = total health expenditure, n.a. = not available, NCU = national currency unit (CYP)

Source: Health and Hospital Statistics, 2004

1.2.2 Access to health care

Table 1.6: Cyprus – Out-patient care 1995, 2000, 2002, 2004 and 2005

Variable	1995	2000	2002	2004	2005
Total no. of doctors	n.a.	n.a.	1,864	1,965	n.a.
No. of doctors per 1,000 inhabitants ²	n.a.	n.a.	2.6	2.62	n.a.
Total no. of out-patient doctors	n.a.	n.a.	n.a.	n.a.	n.a.
<i>of which GPs</i>	n.a.	n.a.	n.a.	n.a.	n.a.
<i>of which dentists</i>	n.a.	n.a.	n.a.	n.a.	n.a.
No. of out-patient doctors per 1,000 inhabitants	n.a.	n.a.	n.a.	n.a.	n.a.
No. of out-patient clinic departments ("ambulatories")	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available, GP = general practitioner

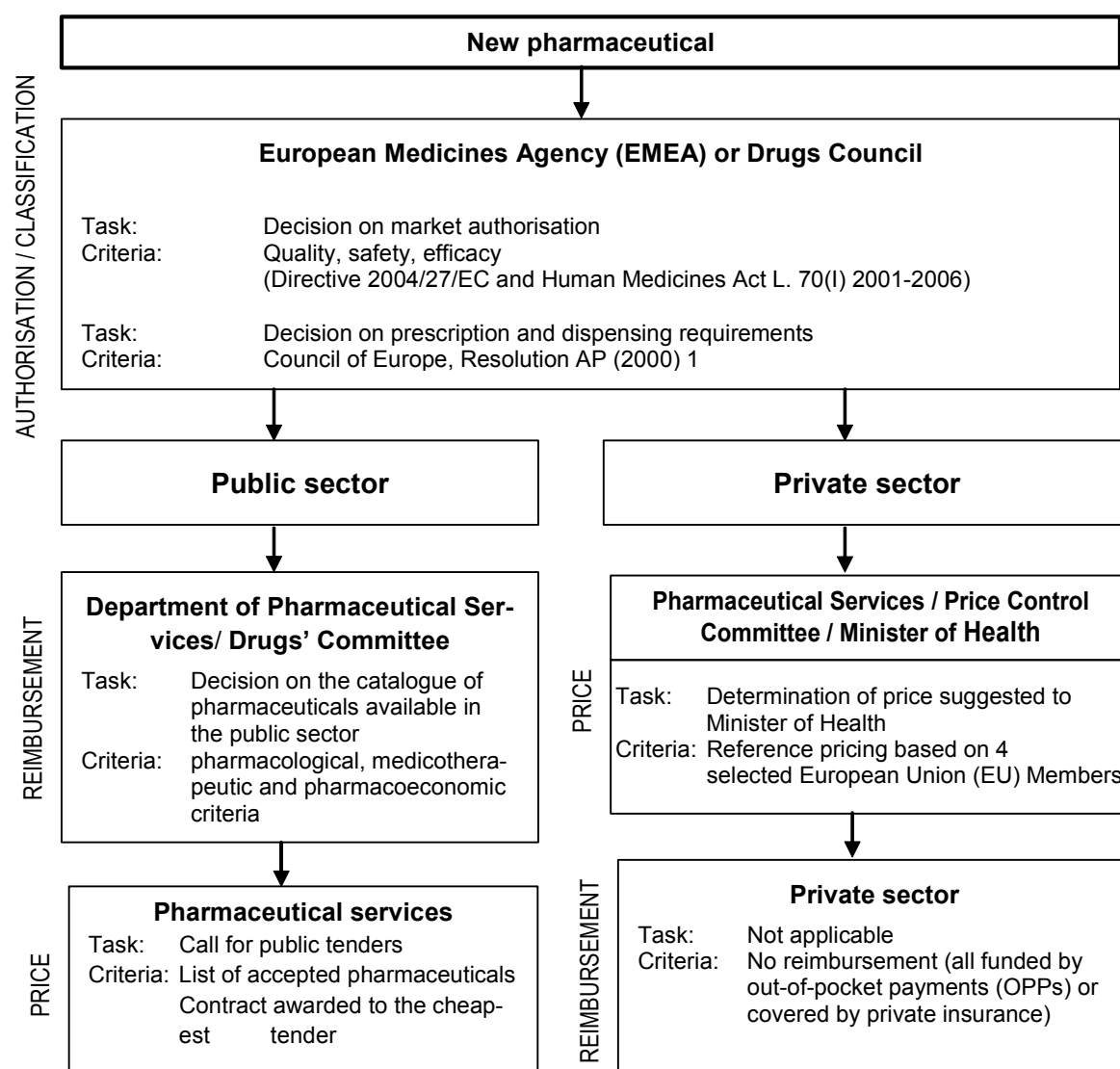
Source: Health and Hospital Statistics 2004

2 Pharmaceutical system

2.1 Organisation

Figure 2.1 provides a comprehensive overview of the Cypriot pharmaceutical system.

Figure 2.1: Cyprus - Flowchart of the pharmaceutical system 2006



Source: Department of Pharmaceutical Services, Ministry of Health

2.1.1 Regulatory framework

2.1.1.1 Policy and legislation

Cyprus has not adopted and implemented a comprehensive policy in the pharmaceuticals field. However, there is a set of policies and legislation that govern the pharmaceutical sector, as listed here.

- Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act L.70(I)/2001
- Pharmacy and Poisons Law Cap 254 N.184(I)/2004
- The General Health Care Scheme Law N.89(I)/2001
- Medical Institutions and Services Laws of 1978 and 2000
- Medical Institutions and Services General Regulations 225/2000
- Medical Institutions and Services General Regulations of 660/2002
- Medical Institutions and Services General Regulations of 364/2005
- Ministerial Decree on the prices of pharmaceuticals for the year May 2006 to April 2007, dated 29 May 2006

The Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act and the Ministerial Decree on the prices of pharmaceuticals regulate the availability of pharmaceuticals and their price in the private sector. The Public Medical Foundations and Institutions Act and Regulations regulate the availability of pharmaceuticals to eligible patients in the public sector.

2.1.1.2 Authorities

The most relevant players in the Cypriot pharmaceutical system are listed here.

- The Ministry of Health, which has overall regulatory and planning authority.
- The Drugs Council, acting as the Pharmaceuticals Agency in charge of (a) issuing market authorisation licences; (b) classification of pharmaceuticals; (c) pharmacovigilance; and (d) inspection of manufacturers.
- The Department of Pharmaceutical Services (PhS), within the Ministry of Health. The department has four roles:
 - Secretariat of the Drugs Council. Its responsibility is to assess all market authorisation applications, renewals, variations and anything relevant to the regulatory aspect.
 - Secretariat of the Price Control Committee. It determines the proposed prices using external price referencing and submits them to the Price Control Committee for discussion. The prices are then passed to the Minister of Health for approval. The final prices are set by ministerial decree.
 - Secretariat of the Pharmaceutical Council and performs pharmacy inspections.

- Responsible for the preparation of the catalogue of pharmaceuticals that are available in the public sector, as well as for the procurement and distribution of pharmaceuticals to all pharmacies in the government hospitals and health centres.
- The Price Control Committee is appointed by the Ministerial Council and is a consultative body to the Minister of Health on the prices of pharmaceuticals.
- The Drugs Committee is an internal committee in the Department of Pharmaceutical Services (PhS), responsible for the catalogue of pharmaceuticals available in the government hospitals and health centres serving in-patients and out-patients in the public sector. Pharmaceuticals are assessed based on their efficacy and cost.
- The Pharmaceutical Council is responsible for recognising pharmacists' qualifications and registering pharmacists. In order to become a registered pharmacist in Cyprus you need to have a university degree in pharmacy, recognised by the Pharmaceutical Council, and have passed the law examination. The Council is also responsible for the opening and licensing of new pharmacies.
- The Health Insurance Organisation (HIO) is responsible for the implementation of the General Health Care Scheme (GHS) in Cyprus. The development of the Organisation started in 2006 and it currently has a staff of 20 people (in 2006).

Table 2.1: Cyprus - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English (Abbreviation)	Description	Responsibility
Υπουργείο Υγείας (ΥΥ)	Ministry of Health (MoH)		Overall planning authority
Συμβούλιο Φαρμάκων (ΣΦ)	Drugs Council (DC)	Regulatory body	In charge of market authorisation, classification, pharmacovigilance. Deals with prescription and non-prescription status of pharmaceuticals.
Φαρμακευτικές Υπηρεσίες (ΦΥ)	Pharmaceutical Services (PhS)	Secretariat of the Regulatory Body (subordinate to the MoH)	Processes market authorisation issues (including preliminary assessment of applications for market authorisations, pharmacovigilance, variations, etc.). Procures pharmaceuticals included in the List of Approved Pharmaceuticals for use in the public sector. Secretariat for pricing of pharmaceuticals in the private sector.
Επιτροπή Ελέγχου Τιμών (ΕΕΤ)	Price Control Committee	Consultative body to the Minister of Health on price setting	Examines applications on pricing of pharmaceuticals and other issues relevant to pricing and makes recommendations to the Minister of Health.

Επιτροπή Φαρμάκων (ΕΦ)	Drugs Committee	Consultative body to the Minister of Health on the List of Approved Pharmaceuticals	Makes recommendations for the inclusion of pharmaceuticals in the List of Approved Pharmaceuticals that are used in public sector health care institutions.
Συμβούλιο Φαρμακευτικής	Pharmaceutical Council	Regulatory body	Responsible for the licensure of pharmacists and private pharmacies.
Οργανισμός Ασφάλισης Υγείας (ΟΑΥ)	Health Insurance Organisation (HIO)	Implementation body of the General Health Care Scheme (GHS)	Responsible for the implementation of the General Health Care Scheme (GHS), which will cover all Cypriot citizens living in Cyprus.

Source: Department of Pharmaceutical Services, Health Insurance Organisation

Pricing of pharmaceuticals in the private sector

The market authorisation holder (MAH) submits an application to the Price Control Committee in order to set of the maximum wholesale and/or retail price. The Department of Pharmaceutical Services (PhS) of the Ministry of Health, which is the Secretariat of the Price Control Committee, applies the external price referencing method and each case is presented to the Committee for assessment and evaluation of the application. The Price Control Committee then makes its recommendation to the Minister of Health. The market authorisation holder (MAH) must be informed of the decision of the Minister within 90 days. In the event that the Minister fails to set the price within the required time frame, the applicant may set the price her/himself.

A price list is published once a year and includes the maximum wholesale and retail prices. Supplementary price lists for new pharmaceuticals are published three times a year. The prices included in the price lists are applicable to the private sector only. There are no reimbursement schemes for pharmaceuticals purchased from the private sector.

Catalogue of pharmaceuticals (List of Approved Pharmaceuticals) in the public sector

The hospitals and health centres in the public sector belong to the Government and are under the supervision of Ministry of Health. The pharmaceuticals available in the public sector are only dispensed from public pharmacies in public hospitals or health centres. The pricing of pharmaceuticals, as described earlier, does not apply to the public sector because it buys the pharmaceuticals on the List of Approved Pharmaceuticals through a tendering process. The Drugs Committee only accepts applications for the inclusion of new pharmaceuticals to the List of Approved Pharmaceuticals from public sector doctors. Following assessment, based on efficacy, safety and cost criteria, the Drugs Committee makes recommendations to the Minister of Health on the inclusion of the particular pharmaceutical in the List of Approved Pharmaceuticals. Upon approval by the Minister, the Department of Pharmaceutical Services (PhS) calls for tenders for the purchase of the pharmaceutical. These pharmaceuticals are provided to eligible patients through the public sector pharmacies. Reimbursement of 100% is provided to public servants and pensioners. In addition, reimbursement is either 100% or 50% according to the eligibility status of the patient, which is based on annual income and disease criteria (cf. 4.2.1).

Market authorisation

The Department of Pharmaceutical Services (PhS) accepts applications for national market authorisations. Following evaluation and assessment of applications, they are forwarded to a subcommittee of the Drugs Council to be assessed for new market authorisation. Based on the recommendation of the subcommittee, the Drugs Council issues a market authorisation. There is no available data on the average time for issuing a national market authorisation.

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

The number of authorised products on the market has decreased since the introduction of the Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act. The reason for this is that for a large number of old products the market authorisation holders (MAH) could not upgrade their dossiers, therefore their market authorisation licence could not be renewed. Currently, only registered products are available on the private market. Some exceptions occur in the public sector where pharmaceuticals are purchased, which are indicated for special or rare medical conditions.

Table 2.2: Cyprus - Number of pharmaceuticals 1995, 2000-2006¹

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised ²	n.a.	5,735 ^{3,4}	5,064 ^{3,4}	4,105 ⁴	2,334 ⁴	1,624	n.a.	2,592
On the market ²	n.a.	3,868 ^{3,4}	3,401 ^{3,4}	3,000 ⁴	2,474 ⁴	2,354	2,209	2,107
POM	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Reimbursable	n.a.	574 ⁵	n.a.	n.a.	650 ⁵	n.a.	n.a.	700 ^{5,6}
Generics ²	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Parallel traded	0	0	0	0	0	0	0	0
Hospitals-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

POM = prescription-only medicine(s), n.a. = not available

¹ as of 1 January

² Data refer to pharmaceuticals in the private sector

³ Includes the veterinary products

⁴ Includes food supplements

⁵ Active substances (include hospital and out-patient pharmaceuticals)

⁶ This is an approximate number

Source: Department of Pharmaceutical Services, Catalogue of Hospital Drugs 2000 and 2003

Pharmaceuticals in Cyprus are only divided into two broad classes, prescription-only medicine(s) (POM) and over-the-counter (OTC) products, based on the guidelines of the Council of Europe. The body responsible for the categorisation of pharmaceuticals into these classes is the Ministry of Health, which usually adapts the recommendations of the Council of Europe unless special local conditions exist, at which point it may change an over-the-counter (OTC)

pharmaceutical to a prescription-only medicine (POM). The classification of pharmaceuticals is set by ministerial decree. There are no special names for the classifications of these products.

In 2006, there were approximately 2,900 registered pharmaceuticals in Cyprus, but only 2,300 are available for sale on the market due to the fact that many products authorised through a Mutual Recognition Procedure (MRP) or through the Centrally Authorised Procedure (CAP) are not introduced into the market because many market authorisation holders (MAH) are not interested in marketing those products on the small Cypriot market. Most of the products that are registered but are not on the market are for a small number of patients with rare conditions. The number of generics available on the market is not known, but most of them are used in the public sector, contributing substantially to cost-containment. The use of generics in the private sector is limited (cf. 5.5).

2.1.2.2 Market data

Table 2.3: Cyprus - Market data 1995, 2000-2005

Pharmaceutical industry in Mio. CYP / €	1995	2000	2001	2002	2003	2004	2005
<i>Prescriptions</i>							
No. of annual prescriptions by volume in the private sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual prescriptions by volume in the public sector	n.a.	n.a.	n.a.	n.a.	n.a.	1,350.0000	n.a.
<i>Pharmaceutical sales</i>							
Sales at ex-factory price level in Mio. CYP	n.a.	n.a.	n.a.	n.a.	26.00	n.a.	n.a.
Sales at ex-factory price level in Mio. €	n.a.	n.a.	n.a.	n.a.	45.07	n.a.	n.a.
Sales at wholesale price level in Mio. CYP	n.a.	n.a.	n.a.	n.a.	32.50	32.90	n.a.
Sales at wholesale price level in Mio. €	n.a.	n.a.	n.a.	n.a.	56.34	57.03	n.a.
Sales at PRP level in Mio. CYP	n.a.	n.a.	n.a.	n.a.	43	44.80	n.a.
Sales at PRP level in Mio. €	n.a.	n.a.	n.a.	n.a.	75.54	77.66	n.a.
Sales at public hospitals in Mio. CYP **	n.a.	n.a.	19.30	23.10	33.80	37.90	n.a.
Sales at public hospitals in Mio. € **	n.a.	n.a.	33.45	40.04	58.59	65.70	n.a.
Sales of generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of parallel traded pharmaceuticals							
<i>Exports and imports</i>							
Total pharmaceutical exports *	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total pharmaceutical imports in Mio. CYP *	n.a.	n.a.	n.a.	n.a.	CYP 66,300,000 / € 14,900,000	CYP 70,800,000 / € 122,724,000	n.a.
Total pharmaceutical imports in Mio. € **	n.a.	n.a.	n.a.	n.a.			n.a.

* Finished products

** Includes all products in the public sector (in-patient and out-patient)

PRP = pharmacy retail price, n.a. = not available, NCU = national currency unit (CYP)

Source: Department of Pharmaceutical Services, Ministry of Health Annual Report 2003, 2004

Table 2.4: Cyprus - Top 10 best-selling pharmaceuticals, by active ingredient, 2005 or latest available year.

Position	Pharmaceutical, by active ingredient
1	Atorvastatin 10 and 20 mg
2	Alendronate 70 mg
3	Paracetamol 500 mg
4	Deferipron 500 mg
5	Interferon β -1a 30 mcg
6	Olanzapine 10 mg
7	Mycophenolate mofetil 250 mg
8	Desferrioxamine 2g injection
9	Raloxifene 60 mg
10	Candesartan 16 mg

Source: Department of Pharmaceutical Service (2005 consumption in the private and public sector)

2.1.2.3 Patents and data protection

Patent protection in Cyprus is harmonised with European Union (EU) legislation under the European Patent Convention and guarantees market protection for original pharmaceuticals for 20 years. Under European Union (EU) legislation there is the possibility of extending this for a further five years under a Supplementary Protection Certificate.

Under the recently adopted European Union (EU) legislation, authorities are also obliged to provide for data protection for an 8 + 2 + 1 year period. This provides for an additional protection period for patented pharmaceuticals. Only after eight years can the pharmaceuticals agency process applications for generic pharmaceuticals under the European Commission (EC) Bolar amendment, which can then be marketed when the 10-year data protection period ends (provided that by that time the patent has also expired). Authorities may provide for an additional year of data protection (and thereby delay generic market entry) for additional innovative indications (e.g. for paediatric indications).

There is no provision in the national legislation for compulsory market authorisation, parallel importing or "government use" of patented products, nor any recent court cases in relation to patent protection of pharmaceuticals, that the authors are aware of at the time of writing.

2.1.3 Market players

2.1.3.1 Industry

In Cyprus, the pharmaceutical industry is mainly comprised of generics manufacturers. There are five local generics manufacturers. In addition, one raw materials manufacturer has been established recently. Pharmaceutical manufacturers in Cyprus belong either to the Cyprus Pharmaceutical Manufacturers Association (CY.PHA.M.A) or to the Cyprus Association of Pharmaceutical and Chemical Industries.

Pharmaceuticals distribution in the private sector in Cyprus is usually channelled via wholesalers, whereas the Government has its own network for distributing the pharmaceuticals to the government pharmacies.

A substantial part (95%) of the production from local manufacturers is exported, and therefore the local industry does not play a major role in the local market. However, the Cypriot pharmaceutical industry is an important source of foreign income.

Due to the nature of the industry (generics), research and development (R&D) is limited. In addition, the small size of the industry means that it is not a major employer in the country.

International pharmaceutical companies have 90% of the local market. The local pharmaceutical industry, along with the local agents of international pharmaceutical companies is represented in the Pricing Control Committee, which acts as a consultative body to the Minister of Health. However, industry does not play a major role in policy-making. Market prices are determined through external price referencing. Capping and reimbursement are not used in price setting in Cyprus.

Table 2.5: Cyprus - Key data on the pharmaceutical industry 1995-2005 ¹

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	5	5	5	5	4	4	5
- research-oriented	0	0	0	0	0	0	0
- generic producers	5	5	5	5	5	5	5
- biotech	0	0	0	0	0	0	0
No. of persons employed ²	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	950

n.a. = not available

¹ as of 1 January

² counted per head

Source: Department of Pharmaceutical Services, Ministry of Health

2.1.3.2 Wholesalers

The majority of wholesalers distribute pharmaceutical products through distributors. However, some distribute their products through their own distribution network. The distribution companies

are joint ventures between the wholesalers and some of them include repacking units. There are no parallel trade wholesalers operating in Cyprus at the time of writing.

There is one wholesalers association, the Cyprus Association of Pharmaceutical Companies (SFEK). Members of this Association are wholesalers and/or local agents of multinational companies. They are members of the Price Control Committee and they play a major role in the pharmaceutical system as they supply approximately 90% of the local pharmaceutical market. They also had a key role in the negotiations concerning the reform of the pricing system.

Table 2.6: Cyprus - Key data on pharmaceutical wholesale 1995, 2000-2005¹

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total no. of wholesale companies	n.a.	n.a.	n.a.	n.a.	60	60	60
Total no. of outlets	n.a.	n.a.	n.a.	n.a.	n.a.	433	430

n.a. = not available

¹ as of 1 January

Source: Department of Pharmaceutical Services, Ministry of Health

2.1.3.3 Pharmaceutical outlets / retailers

Pharmaceuticals are dispensed through community pharmacies. In 2005 there were approximately 430 private pharmacies, 35 public community pharmacies and 8 public hospital pharmacies. There are no restrictions on establishing pharmacies and most of them are concentrated in urban areas. Neither Internet nor mail-order pharmacy are allowed.

2.1.3.3.1 Pharmacies

There are four types of community pharmacy in Cyprus: those owned by the Government, those privately owned, those that are union owned, and chain pharmacies. Currently there is only one chain of pharmacies. However, a pharmacist has to own at least 51% of the shares of each pharmacy belonging to the chain (only one pharmacy per pharmacist). There is a very small number of Labour Union-owned pharmacies. The government-owned pharmacies only dispense to patients if they have a prescription from a government doctor. All other pharmacies can dispense pharmaceuticals to patients with a prescription from a licensed doctor.

There is freedom of establishment in the private sector. However there should be only one pharmacy per pharmacist and the pharmacist has to hold 51% of the shares of that pharmacy. There are no incentives for pharmacists to establish pharmacies in rural areas and therefore most of them are concentrated in urban areas. There are currently no regulations to guarantee a geographical spread across the country.

- There are 430 private community pharmacies, of which 11 are owned by Labour Unions. There are 8 hospital pharmacies that dispense pharmaceuticals for out-patients as well and 35 government-owned pharmacies. Approximately 50% (by value) of pharmaceuticals are dispensed in private community pharmacies.
- There is one organisation, the Pancyprian Pharmaceutical Association, of which all registered pharmacists are members by law. Its role is to represent officially the pharmacists in all

relevant issues concerning policy-making. However, it is already represented as part of the Pharmaceutical Council and the Price Control Committee.

*Table 2.7: Cyprus - Retailers of pharmaceuticals 1995, 2000-2006*¹

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
No. of community pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	473	473
No. of private pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	430	430
No. of public pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	35	35	35
No. of hospital pharmacies for out-patients	n.a.	n.a.	n.a.	n.a.	n.a.	8	8	8
No. of other POM dispensa-ries	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total no. of POM dispensa-ries ²	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	473	473
No. of Internet pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of OTC dispensaries, such as pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

OTC = over-the-counter, POM = prescription-only medicine(s); n.a. = not available

¹ as of 1 January

² Doctors are allowed to dispense pharmaceuticals in rural areas where a pharmacy is not available

Source: Department of Pharmaceutical Services, Ministry of Health

2.1.3.3.2 Other pharmacy outlets

There are no other pharmacy outlets in Cyprus. Pharmaceuticals are only available from pharmacies (either private or public community pharmacies or public hospital pharmacies dispensing to out-patients eligible for reimbursed pharmaceuticals).

2.1.3.3.3 Internet pharmacies

There are no Internet pharmacies operating in Cyprus.

2.1.3.3.4 Dispensing doctors

Doctors in Cyprus are allowed to dispense pharmaceuticals only when the nearest pharmacy is located at a distance of over 30 km. Dispensing of pharmaceuticals by doctors is very rare in Cyprus (anecdotal evidence) but there is no actual information as to whether any doctors are doing so.

2.1.3.4 Hospitals

Hospital pharmacies can only be found in government-owned hospitals. There are no pharmacies in private hospitals and clinics, because the law does not allow private pharmacies to operate in a hospital setting.

There are eight government hospital pharmacies which are allowed to dispense pharmaceuticals to out-patients. These pharmacies do not have a budget. Salaries and pharmaceuticals are

covered by a block budget allocated by the Ministry of Health. Out of that budget the pharmaceuticals are purchased and are provided to the patients.

The government hospitals work with a limited pharmaceuticals list which is the government List of Approved Pharmaceuticals (cf. 4.2.3). The List is generated centrally by the Drugs Committee composed of experts working for the Department of Pharmaceutical Services (PhS), in collaboration with the Department of Medical Services. There are no hospital committees.

Pharmaceuticals for all government hospitals are purchased centrally by the Department of Pharmaceutical Services (PhS). There is a procurement sector in the Department responsible for the purchase of pharmaceuticals through public tenders following public procurement regulations (cf. 3.2.4). The Department of Pharmaceutical Services (PhS) receives block funding from the Ministry of Finance through the national budget, which is approved by the House of Representatives. Pharmaceutical companies exert pressure on physicians to request the inclusion of their products into the List of Approved Pharmaceuticals.

Private hospitals do not have pharmacies; they therefore purchase pharmaceuticals from private pharmacies at a discounted pharmacy retail price (PRP). The private pharmacies sell pharmaceuticals to the private hospitals with a 15% profit mark up. Private hospitals do not work with a List of Approved Pharmaceuticals, but rather use pharmaceuticals according to the doctors' choice. There are no incentives to reduce costs since all costs are transferred to the patients.

2.1.3.5 Doctors

The Doctors Association is represented in the Drugs Council and has a say in the market authorisation process of new products on the market. Other than this, the Doctors Associations do not have an impact on pharmaceutical policy-making. The majority of doctors prescribe by brand name and pharmacists are obliged to dispense what is prescribed.

Doctors in the public sector are represented within the Drugs Committee by a member of the Department of Medical Services and are involved in the process of inclusion of pharmaceuticals in the List of Approved Pharmaceuticals. Public sector doctors prescribe by brand name less often than private doctors (although no actual data are available). In the public sector the pharmacists dispense by active ingredient, no matter what product is available. There is no option of free choice of pharmaceutical on the part of the pharmacists in the public sector.

2.1.3.6 Patients

Patients are represented in the Price Control Committee. They are also involved in lobbying, exerting pressure for the introduction of pharmaceuticals in the List of Approved Pharmaceuticals in the public sector. However, they are not represented in the Drugs Committee. There is industry funding to some patient groups, but there is no available information on how extensive this is. The most important patient organisations are those of heart, multiple sclerosis, rheumatoid arthritis, diabetes, cancer, Alzheimer's disease, thalassaemia and haemophilia patients.

In the private sector patients have no role in deciding which pharmaceuticals are to be prescribed/dispensed. The price of pharmaceuticals is the same in every private pharmacy and the

choice of pharmacists therefore depends on factors other than pricing, although pharmacies do offer discounts to their customers.

The List of Approved Pharmaceuticals is available in every pharmacy, on the Internet and at the Cyprus Consumers' Association.

2.2 Funding

2.2.1 Pharmaceutical expenditure

The total expenditure on pharmaceuticals in Cyprus has been increasing dramatically, especially in the public sector. Pharmaceutical expenditure (PE) in the public sector increased from CYP 19 Mio. in 2001 to CYP 37 Mio. in 2004. The share of generics in the public sector is approximately 20% in terms of value, and very limited (approximately 5%) in the private sector.

Table 2.8: Cyprus - Total pharmaceutical expenditure (TPE) 1995, 2000-2005

Pharmaceutical Expenditure (PE)	1995	2000	2001	2002	2003	2004	2005
TPE in NCU ¹	n.a.	n.a.	n.a.	n.a.	66,300,000	70,800,000	87,700,000
TPE as a % of THE	n.a.	n.a.	n.a.	n.a.	15.1%	16.1%	n.a.
TPE per capita in NCU	n.a.	n.a.	n.a.	n.a.	95.90	108.80	n.a.
Public PE as a % of THE	n.a.	4.7%	5.4%	6.1%	7.7%	8.4%	n.a.
Private PE as a % of THE	n.a.	n.a.	n.a.	n.a.	9.3%	9.7%	n.a.

n.a. = not available, NCU = national currency unit (CYP), GDP = gross domestic product, TPE = total pharmaceutical expenditure, PE = pharmaceutical expenditure, THE = total health expenditure

¹ Does not include the consumption of locally manufactured generics which account for approximately 5% of the private pharmaceutical expenditure (PE)

Source: Ministry of Health Annual Reports 2002 & 2004, Health & Hospital Statistics 2004

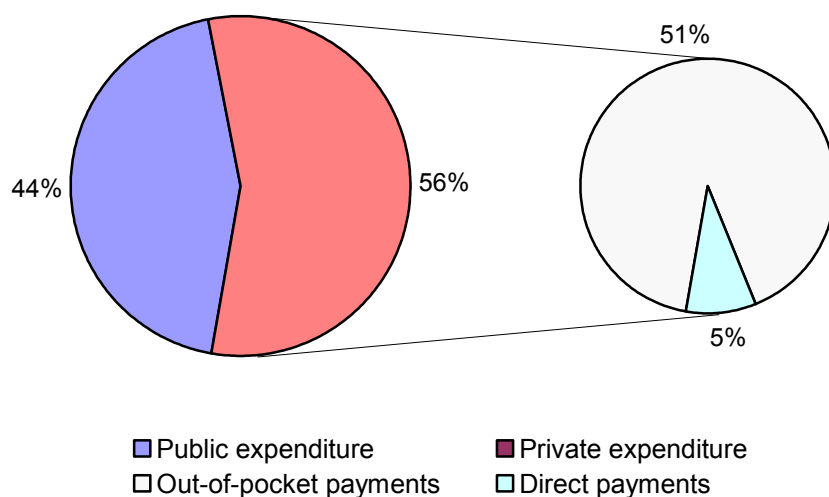
2.2.2 Sources of funds

The main source of funding for health care expenditure is the government budget (taxes) for the public sector. Public pharmaceutical expenditure (PE) is increasing due to the addition of new and expensive treatments in the List of Approved Pharmaceuticals and the lack of control over prescribing. In the private sector, health care is financed via out-of-pocket payments (OPPs) by the patients. Expenditure in the private sector is increasing due to the lack of regulation, planning and health policy.

Although a large percentage of the population is entitled to free health care (approximately 70%), more than 50% of health care spending is out of pocket. The total pharmaceutical expenditure (TPE) in the private sector amounts to CYP 43,000,000, of which 10% is covered by private health insurance funds and the rest from out-of-pocket payments (OPPs).

With the implementation of the General Health Care Scheme (GHS), funding of the health care system is to be based on the contributions of employees (2%), employers (2.5%), the self-employed (3.5%) and the Government (4.5%).

Figure 2.2: Cyprus - Share of private and public pharmaceutical expenditure (PE) 2004



Sources: 2004 Annual Report and Information from Pharmaceutical Services and Insurance Companies

2.3 Evaluation

At the time of writing there is no established system to monitor of the outcomes of pharmaceutical policy. However, with the introduction of the General Health Care Scheme (GHS) by the Health Insurance Organisation (HIO), it will be possible to assess the effectiveness of the pharmaceutical policy that is to be introduced.

3 Pricing

3.1 Organisation

According to the Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act of 2001-2006 [L.70(I)2001-2006], prices of pharmaceuticals are regulated. As of 2005, the prices of imported pharmaceuticals are set by means of external price referencing, with the use of four reference countries. The prices of imported generics after external price referencing cannot exceed 80% of the price of the original (branded) product marketed in Cyprus. For locally manufactured generics the ex-factory price is set on the basis of the production cost plus a mark up of 20%. In any case, the price of generics should not exceed 80% of the price of the original product.

The price of pharmaceuticals is set by the Minister of Health, following the recommendations of the Price Control Committee. The role of the Price Control Committee is to provide consultation to the Minister of Health on any matter regarding pricing, either on its own initiative or on the Minister's request. The Committee is appointed by the Ministerial Council and is composed of nine members, as follows:

- two officers from the Department of Pharmaceutical Services (PhS) of the Ministry of Health;
- one officer from the Ministry of Finance;
- one officer from the Ministry of Commerce, Industry and Tourism;
- one pharmacist from the private sector;
- one person with knowledge and experience in wholesale, designated by the importers of pharmaceutical products in Cyprus;
- one person with knowledge and experience in the manufacture of pharmaceutical products, designated by the manufacturers of pharmaceutical products in Cyprus;
- one person designated by the Cyprus Consumers Association;
- one person representing the patients.

Meetings of the Price Control Committee are not regulated and its members meet on an ad-hoc basis, when necessary. The Minister of Health is not bound by the recommendations of the Committee in (her/his) final decision(s) on setting the prices.

The prices set by the Minister of Health are only for the private sector. The public sector buys pharmaceuticals through a tendering process and obtains prices many times lower than those in the price list for the private sector. As a result of the current organisation of the health care and pharmaceutical system (split into a public and a private sector), pricing is, at the time of writing, not interlinked with reimbursement.

The average time for the pricing process is not known. However, according to the law, the Minister of Health has to issue a decision within 90 days of receipt of a fully completed application. This may be extended in special cases by 60 days. In the event that the Minister fails to set the price within the above time frame, the applicant may set the price her/himself.

3.2 Pricing policies

There are basically two methods of pharmaceutical pricing in Cyprus: statutory pricing and public procurement. Statutory pricing has been in effect since 1964. In the past it involved a fixed mark up on the ex-factory price, but since 2005 the prices are determined using the external price referencing method. Prices set by this method are only applicable in the private sector. The Government buys pharmaceuticals through public procurement.

Table 3.1: Cyprus - Ways of pricing pharmaceuticals

	Manufacturer level	Wholesale level	Pharmacy level
Public procurement	Public procurement through tenders for all pharmaceuticals used in government pharmacies (not only HOM but also for others)		Not applied because pharmaceuticals are dispensed by government-employed pharmacists that are paid a salary. There is no mark up in the government pharmacies
Statutory pricing	Locally produced pharmaceuticals (generics) available in the private sector This price is not published	External price referencing for all imported pharmaceutical products (HOM, POM, OTC) available in the private sector Mark up of 20% for locally produced pharmaceuticals (generics) available in the private sector	Profit mark up according to ministerial decree (currently up to 38% of the wholesale price)
Free pricing	Pharmaceuticals in the private sector, as prices are set at the wholesale level This price is not known	Only in case the wholesale price for pharmaceuticals in the private sector is not statutorily set in the legal time frame	n.app.
Institution in charge of pricing	<ul style="list-style-type: none"> ➤ Price Control Committee (Department of Pharmaceutical Services (PhS), Ministry of Health as the secretariat) and the Minister of Health for pharmaceutical products available in the private sector ➤ Department of Pharmaceutical Services (PhS), Ministry of Health for public procurement through tendering 		
Legal Basis	➤ Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act of 2001-2006 [L.70(I)2001-2006]		

HOM = hospital-only medicine(s), POM = prescription-only medicine(s), OTC = over-the-counter (pharmaceuticals)

Source: Department of Pharmaceutical Services, Ministry of Health

3.2.1 Statutory pricing

Statutory pricing is applied for all pharmaceuticals with a market authorisation licence that are available in the private sector. The prices for imported pharmaceuticals are set at the wholesale price level and, on top of that, the pharmacist's margin is added.

For the pricing of any pharmaceutical, the market authorisation holder (MAH) has to apply to the Price Control Committee of the Ministry of Health. The Department of Pharmaceutical Services (PhS) (as the secretariat of the Pricing Control Committee) applies the method of external price referencing, as described in the Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act of 2001-2006 [N.70(I)2001–2006] for imported pharmaceuticals, and for locally produced pharmaceuticals it applies the method of cost-plus pricing. It then presents the results to the Price Control Committee. The Committee makes a recommendation to the Minister of Health, who sets the prices. A price list with the pharmacy retail price (PRP) of each product is published once a year. Prices are monitored by inspections carried out by the Department of Pharmaceutical Services (PhS).

3.2.2 Negotiations

Price negotiation is not used as a method of pricing in Cyprus.

3.2.3 Free pricing

Free pricing may be applicable at manufacturer level for imported pharmaceuticals in the private sector. In addition, if the wholesale price of a pharmaceutical (imported or locally manufactured) is not set by the Minister of Health within the legal time frame (within 90 days of receipt of application), then the market authorisation holder (MAH) is free to set the price her/himself.

3.2.4 Public procurement / tendering

Public procurement of all pharmaceuticals used in the public hospitals, and rural and urban health centres, is carried out centrally, through a tendering process. The Department of Pharmaceutical Services (PhS) of the Ministry of Health has a tendering department and procures, stores and distributes pharmaceuticals to all government health institutions.

According to the laws and regulations in place, the Government can only purchase goods through the tendering process. Tendering, even though it is a time consuming process and may result in delays in obtaining pharmaceuticals, achieves lower prices on most occasions, at least when there is competition.

3.3 Pricing procedures

Table 3.2: Cyprus - Pricing procedures

Pricing procedure	In use: Yes / No	Level of pricing ¹	Scope ²
Internal price referencing	No	n.app.	n.app.
External price referencing	Yes	At wholesale level	Imported POM and OTC pharmaceuticals available in the private sector
Cost-plus pricing	Yes	At manufacturer level	Locally produced pharmaceuticals (generics) available in the private sector
Other, e.g. indirect profit control	No	n.app.	n.app.

¹ Level of pricing = at what stage of the pricing process does the pricing take place (e.g. at the pharmaceutical retail price (PRP) level)

² Scope = A pricing procedure does not always refer to all pharmaceuticals: e.g. a pricing procedure could only refer to reimbursable pharmaceuticals, since for over-the-counter (OTC) pharmaceuticals there is free pricing.

POM = prescription-only medicine(s), OTC = over-the-counter

Source: Department of Pharmaceutical Services

3.3.1 External price referencing

External price referencing is used for all imported pharmaceutical products in Cyprus, including over-the-counter (OTC) products, and is applied at the wholesale price (pharmacy purchasing price (PPP)) level.

External price referencing is the sole method of price determination for imported pharmaceuticals in the private sector in Cyprus. However, according to the law other methods may be used. In addition, locally manufactured products are priced based on cost-plus pricing (cf. 3.3.3).

The law does not indicate which countries are to be used for comparison. The countries were chosen based on a study on pricing conducted by the London School of Economics, on behalf of the Ministry of Health of Cyprus. The study recommended that the basket of countries includes one country with high prices, two countries with medium prices and one with low prices. The countries are Sweden (high), Austria and France (medium), and Greece (low). In the event that a product is not found in the above countries, there are alternative countries: Denmark and Germany (high), Italy and Belgium (medium), Spain and Portugal (low). In the event that there are no data in some of the selected countries, the price is set based on the rest of the available data. So, the price may be determined with data from a maximum of four countries and with the minimum of one country. In the event that no data is available for old products from the selected countries, the price remains the same as it was before the implementation of the external price referencing in March 2005. For products that are new on the market, the price may be set de-

pending on the actual cost of manufacture or on the cost of the product that is sold in the country of manufacture, or on the cost of a product with the same active ingredient.

Comparisons are made based on the published price and they are not adjusted according to purchasing power parity (PPPa). Based on the available published price, i.e. the pharmacy retail price (PRP), the pharmacist's margin and the value-added tax (VAT) are deducted and the price is reduced to the pharmacy purchasing price (PPP). This is the price that is used for the determination of the reference price. The exchange rates used are the average exchange rates for the previous year. In the event that the price in one of the reference countries changes, the price is reviewed and it also changes accordingly.

The country price information is obtained from the official price lists of the selected countries. The manufacturers are asked to declare the prices and these prices are checked against the prices included in the official price lists.

3.3.2 Internal price referencing

Internal price referencing is not applicable in Cyprus.

3.3.3 Cost-plus pricing

For locally manufactured generics the wholesale price is set by adding 20% on to the ex-factory price, which is set on the basis of the production cost. The wholesale price should not exceed 80% of wholesale price of the original product.

3.3.4 (Indirect) Profit control

(Indirect) Profit control is not applicable in Cyprus.

3.4 Exceptions

There are no exceptions in the pricing of pharmaceuticals for the private sector. Pharmaceuticals in the public sector are purchased through tenders as explained earlier (cf. 3.2.4).

3.4.1 Hospitals-only

The pharmaceuticals for all public hospitals are purchased centrally through tenders by the Department of Pharmaceutical services (PhS) (cf. 3.2.4). Private hospitals purchase pharmaceuticals from private pharmacies at the pharmacy purchasing price (PPP), plus 15%. The prices of hospital-only pharmaceuticals in private hospitals are set in a different way.

Private hospitals cannot have a pharmacy on their premises. Therefore, based on the regulation that pharmaceuticals have to be dispensed only by pharmacists, private hospitals are forced to purchase pharmaceuticals from private pharmacies.

3.4.2 Generics

The method of external price referencing, as described earlier, is applied for all imported generic pharmaceuticals. For locally manufactured generics, the wholesale price is based on the cost of manufacture plus a 20% mark up. However, the wholesale price of a generic pharmaceutical (imported or locally manufactured) cannot exceed the 80% of the wholesale price of the original.

3.4.3 Over-the-counter pharmaceuticals

The same method of external price referencing is applied for all imported pharmaceuticals, including over-the-counter (OTC) products. The legal framework does not distinguish between prescription-only medicine(s) (POM) and over-the-counter (OTC) products.

3.4.4 Parallel traded pharmaceuticals

There are no parallel imports at the moment.

3.4.5 Other exceptions

No exceptions.

3.5 Margins and taxes

Table 3.3: Cyprus - Regulation of wholesale and pharmacy mark ups 2006

Wholesale mark up			Pharmacy mark up		
Regulation (Yes / No)	Content	Scope	Regulation (Yes / No)	Content	Scope
No	None	Imported pharmaceuticals in the private sector	Yes	Flat mark up	All pharmaceuticals in the private sector
Yes	20%	Locally produced pharmaceuticals in the private sector			

Source: Department of Pharmaceutical Services, Ministry of Health

3.5.1 Wholesale remuneration

The new pricing system in Cyprus ensures that the wholesale price of all imported pharmaceuticals, i.e., the price they should sell to the pharmacy, is set. This price does not include a specific profit margin for the wholesalers. However, there are contractual agreements between manufacturers and wholesalers. Locally manufactured pharmaceuticals are usually distributed by the manufacturers and, in the event that they are not, the manufacturers have contractual agreements with the wholesalers (in this case they are the distributors).

For locally manufactured generics the wholesale price is set by adding 20% on to the ex-factory price, which is set on the basis of the production cost. The wholesale price should not exceed 80% of wholesale price of the original product.

3.5.2 Pharmacy remuneration

In Cyprus pharmacists receive a flat mark-up margin on the wholesale price. The profit margin is regulated by a ministerial decree. The pharmacy mark up was increased from 33% to 38% on the pharmacy purchasing price (PPP) for the majority of products in March 2005, when the new pricing policy was implemented and caused an average decrease in prices of approximately 15%. For those products for which price did not decrease, the pharmacist's profit mark up remained at 33%.

3.5.3 Remuneration of other dispensaries

There is no remuneration of other dispensaries – this is not applicable in Cyprus.

3.5.4 Value-added tax

Currently the value-added tax (VAT) on pharmaceuticals is zero, except on diagnostic agents, which carry a 15% value-added tax (VAT) rate.

3.5.5 Other taxes

There are no other types of taxes.

3.6 Pricing-related cost-containment measures

3.6.1 Discounts / Rebates

There are no official discounts or allowances granted to pharmacists by wholesalers in Cyprus. However, they are allowed to include cash discounts or discounts in kind, and may do so, but there is no official information available on this matter. The only entities that can receive a discount from pharmacists are private hospitals, which buy pharmaceuticals from pharmacies at a 15% mark up, rather than at 38%.

3.6.2 Margin cuts

The pricing system changed in 2005 and the wholesale mark up has been eliminated. Currently, the wholesale price for imported pharmaceuticals is set and there are contractual agreements between wholesalers and manufacturers. The pharmacy mark-up margin was increased from 33% to 38% on the wholesale price.

3.6.3 Price freezes / Price cuts

With the introduction of the new pricing system there has been an overall average decrease in prices of all pharmaceuticals on the market by approximately 15%. Products for which the price within the new system would have increased were fixed at the old price.

3.6.4 Price reviews

Methods of pricing and pricing procedures in Cyprus have recently been changed. The Price Control Committee reviews the procedures and offers suggestions where necessary to the Minister of Health.

4 Reimbursement

4.1 Organisation

In Cyprus the provision of health care is divided into two distinct sectors, the private and the public. The private sector is financed through out-of-pocket payments (OPPs) by the patients and there is no reimbursement of any services provided. The public sector is financed by the Government. The public sector provides health care services, including pharmaceuticals, to eligible patients according to the Medical Institutions and Services General Regulations.

Individuals who are entitled to services free of charge fall under category A, which includes active and retired civil servants and their dependants (including government ministers, and members of the education service, police, and armed services); families with four or more children; students; war pensioners; welfare recipients; and low-income individuals (people living alone with an annual income below CYP 9,000 and families with an annual income below CYP 18,000 + CYP 1,000 per dependent child). These patients are required to pay a CYP 1 co-payment per out-patient visit.

Services are provided at a reduced fee rate for individuals with low income, i.e. people living alone with an annual income between CYP 9,000 and CYP 12,000 and families with an annual income below CYP 22,000 + CYP 1,000 per dependent child (category B). These individuals are required to pay 50% of the fees charged to paying patients (see later, under category C explanation). However, in the case of the medical ailment being caused under circumstances creating a legal liability for damages to be paid by a third person, the right to free care is waved and fees must be paid by the person liable for the damages.

Category C is comprised of patients who are not covered under categories A and B. They must pay a fee for the use of government medical services. Each visit to a general practitioner (GP) or specialist requires a fee of CYP 7 and CYP 10, respectively. Additionally, fees are compulsory for laboratory, radiology and all examinations and tests. The charge for expensive in-patient treatment may be reduced in accordance with individual income levels.

Some patients, who fall under specific disease or treatment categories, are entitled to free medical care irrespective of their income levels (category D). This group includes: patients with multiple sclerosis; patients with Alzheimer's disease; transplant patients; patients on hemo- or peritoneal dialysis; patients suffering from myasthenia gravis and other genetic neurological diseases, thalassaemia, idiopathic thrombocytopenic purpura, haemophilia, chronic immunodeficiency syndrome, congenital heart disease, and cystic fibrosis; paraplegics and tetraplegics; and patients up to the age of 18 with autism, diabetes type I, or congenital somatic anomalies.

Category E includes patients entitled to free medical care for the treatment of a specific medical condition only, irrespective of income. An example of this category is diabetes mellitus II patients that are entitled to free pharmaceuticals for diabetes but not for any other condition.

Public sector health services include: out-patient care by general practitioners (GPs); in-patient and out-patient care by specialists; diagnostic and paramedical examinations; hospitalisation; dental care¹; medical rehabilitation and provision of prosthetic and orthopaedic appliances; transport of patients; and necessary pharmaceuticals and pharmaceutical material according to a pre-approved pharmaceuticals list.

The pharmaceuticals provided to the eligible patients must be included in the List of Approved Pharmaceuticals, prepared by the Drugs Committee. In order for a new product to be added to the List of Approved Pharmaceuticals, a formal pharmaceutical request form has to be submitted by a specialist physician practising in a public hospital. The request is evaluated by the Drugs Committee based on the product's efficacy, safety and cost.

Although they are not involved in the decision-making process, patients' associations/organisations can potentially influence reimbursement decisions, i.e. whether or not a product is included in the List of Approved Pharmaceuticals.

The pharmaceuticals in the List of Approved Pharmaceuticals are procured through tenders. Therefore, when generics enter the market the acquisition cost falls. In the event that therapeutically equivalent products enter the market, either all patients will receive the cheapest equivalent or all new patients will receive the cheapest equivalent and old patients will continue their treatment with the product they started.

4.2 Reimbursement schemes

The reimbursement scheme as described in 4.1 above was introduced in 1980, with subsequent changes in the eligibility criteria of patients. The legal framework for this scheme is the Public Institutions and Foundations Law.

4.2.1 Eligibility criteria

The criteria for inclusion of a pharmaceutical in the List of Approved Pharmaceuticals include: product-specific criteria (e.g. medical and therapeutic value, safety, lack of alternative therapies); economic criteria (e.g. cost-effectiveness, budget impact); patient-specific criteria (e.g. age, sex, chronically or terminally ill patients); and disease-specific criteria (e.g. severity of illness, special medical needs). The Drugs Committee assesses all of the above criteria. Upon entry to the List of Approved Pharmaceuticals, the pharmaceutical's reimbursement level is based on the eligibility criteria of the patient (cf. 4.1).

4.2.2 Reimbursement categories and reimbursement rates

There are no reimbursement categories, but rather categories of patient eligibility, as described earlier (cf. 4.1). Patients in categories A, D and E enjoy 100% reimbursement and those in category B are entitled to 50% reimbursement.

¹ not including dentures, which are provided to some low-income groups.

In the event that a pharmaceutical is not in the List of Approved Pharmaceuticals, patients or doctors can apply to the Drugs Committee for inclusion or provision on a named patient basis, explaining the reasons for their request.

Table 4.1: Cyprus - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate	Characteristic of category
Category A	100%	Active and retired civil servants and their dependants (including government ministers, and members of the education service, police, and armed services); families with four or more children; students; war pensioners; welfare recipients; and low-income individuals (individuals living alone with an annual income below CYP 9,000 and families with an annual income below CYP 18,000 + CYP 1,000 per dependent child)
Category B	50%	Individuals with low income, i.e. people with an annual income between CYP 9,000 and CYP 12,000 and families with an annual income below CYP 22,000 + CYP 1,000 per dependent child
Category C	0%	Does not fall into categories A, B, D and E
Category D	100%	Patients with multiple sclerosis; patients with Alzheimer's disease; transplant patients; patients on hemo- or peritoneal dialysis; patients suffering from myasthenia gravis and other genetic neurological diseases, thalassaemia, idiopathic thrombocytopenic purpura, haemophilia, chronic immunodeficiency syndrome, congenital heart disease, and cystic fibrosis; paraplegics and tetraplegics; and patients up to the age of 18 with autism, diabetes type I, or congenital somatic anomalies
Category E	100%	For the treatment of the specific medical condition only, irrespective of income. An example of this category is the diabetes mellitus II patients that are entitled to free pharmaceuticals for diabetes but not for any other condition

Source: Public Medical Foundations and Institutions Act 1978 and resulting regulations

4.2.3 Reimbursement lists

In Cyprus, only the products that are in the List of Approved Pharmaceuticals are reimbursed. The List is managed by the Drugs Committee. It is updated constantly, as the Drugs Committee finishes each assessment. The Drugs Committee meets on an ad-hoc basis, as needed. A cumulative list is published by the Department of Pharmaceutical Services (PhS) every three years.

The changes in the List of Approved Pharmaceuticals are mainly communicated to the doctors working in the public sector through government pharmacies and sometimes via circulars.

4.3 Reference price system

There is currently no reference price system in place for reimbursement.

4.4 Private pharmaceutical expenses

As explained earlier, the health care system in Cyprus is split into two distinct sectors, private and public. In the private sector pharmaceutical expenses are financed solely through out-of-pocket payments (OPPs). Pharmaceutical expenditure (PE) in the private sector is almost 50% of the total pharmaceutical expenditure (TPE).

There are no controls applied in the private sector. Physicians prescribe based on their preference and patients have to pay the pharmacy retail price (PRP), apart from those that hold private insurance. Some 10% of the private pharmaceutical expenditure (PE) is covered by private health insurance funds (cf. 2.1.3.5).

4.4.1 Direct payments

Direct payments may be made by patients according to their eligibility category and not based on the type of pharmaceutical. There are no data on the amount of money paid by these categories of people.

4.4.2 Out-of-pocket payments

Out-of-pocket payments (OPPs) are based on the eligibility group of the patient. Some patients, who are eligible for reimbursement, may need to pay 50% of the pharmacy purchasing price (PPP) of the pharmaceutical (Category B) (cf. 4.2). There are no data available how many patients this applies to and how much they pay each year.

4.4.2.1 Fixed co-payments

There are no fixed co-payments.

4.4.2.2 Deductibles

No deductibles are used.

4.5 Reimbursement in the hospital sector

Reimbursement in the hospital sector depends if the setting is public or private. There is no reimbursement in private sector hospitals. Reimbursement in public sector hospitals is the same

as in the public out-patient setting. Public hospitals provide the pharmaceuticals in the List of Approved Pharmaceuticals based on the eligibility categories of patients.

4.6 Reimbursement-related cost-containment measures

Cost-containment measures include the introduction of the List of Approved Pharmaceuticals, which includes generic pharmaceuticals where possible, and the pharmacists in the government pharmacies can only dispense these, no matter what the physician prescribes. One could say that the pharmacists exercise generic substitution; however, this is not strictly true since they do not have an option because the original is not available.

Using pharmacoeconomic criteria the Drugs Committee tries to evaluate new pharmaceutical applications for inclusion in the List of Approved Pharmaceuticals. In addition, expensive therapies are monitored and some are only provided once approved by a member of the Drugs Committee.

Recently, the Ministry of Health has introduced the Health Booklet for every patient eligible for health care in the public sector, in which the physician writes the patient's prescriptions. Before dispensing, the public sector pharmacists check the previous prescriptions (date and quantity dispensed) and can prevent wastage by refusing to dispense the prescription if the patient has enough supplies at home (cf. 5.2).

4.6.1 Major changes in reimbursement lists

The Drugs Committee was established in 1996, and has been responsible for editing the List of Approved Pharmaceuticals ever since. The List has been updated constantly and a cumulative list, in the form of a booklet, is published every three years.

4.6.2 Introduction / review of reference price system

This is not applicable in Cyprus.

4.6.3 Introduction of new / other out-of-pocket payments

There are no recent changes in the system of out-of-pocket payments (OPPs).

4.6.4 Claw-backs

There are no claw-back mechanisms operating in the Cypriot pharmaceuticals system.

4.6.5 Reimbursement reviews

The eligibility criteria for patients were last reviewed by the Government and approved by the Parliament in 2003.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

There are no obligatory budgetary constraints for prescribing doctors in the public or in the private sectors.

5.2 Prescription guidelines

There are no treatment guidelines for doctors in the private sector. There are some guidelines, prepared by the Drugs Committee, available for the doctors working in government hospitals and out-patient clinics. These guidelines, which are not extensive, have been implemented over the last 10 years and are intended for doctors working in the public sector only.

The above-mentioned guidelines are not structured, but rather are developed according to need. Some require specific lab exams before a pharmaceutical is dispensed and some require the use of one specific pharmaceutical before another is dispensed. Adherence to the guidelines is monitored through the pharmacies in the public sector. In the case of a specific protocol, the pharmaceutical is not dispensed unless the protocol is followed. In the cases the protocol is vague then no one is monitoring it. There are no sanctions for not following the protocols apart from refusal to dispense the pharmaceutical.

The Ministry of Health recently introduced the Health Booklet to be used in the public sector. Physicians write the patient's prescriptions in this booklet and the pharmacy can monitor prescribing as well as the quantities dispensed. The aim of this is to limit the quantities of pharmaceuticals stocked at home by patients, as the pharmacist can refuse to fill a prescription if (s/)he realises that the patient has sufficient quantities of the pharmaceuticals at home. This booklet is used only in the public sector doctors and pharmacists.

5.3 Information to patients / doctors

The "Marketing Directives", as stipulated in Directive 2001/83/EC, have been implemented in Cyprus through the enactment of the Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act which is implemented by the Drugs Council.

The above-mentioned Act stipulates the conditions under which the advertising of pharmaceuticals can be carried out in Cyprus. In addition, the Act also restricts the use of any type of gifts of significant value to prescribers, as well as the provision of samples to the doctors. Samples can be given only after a written request by the physician and the market authorisation holder (MAH) has to keep a log of all samples given.

5.4 Pharmacoeconomics

Health economics are used in the assessment and evaluation of products to be added to the List of Approved Pharmaceuticals. The Drugs Committee, which is responsible for managing the List, takes into account the cost-effectiveness of each new pharmaceutical as well as the total cost of the treatment. Health economics are not used for any other purposes.

The official national source for health economics analysis is the Ministry of Finance and the Department of Statistical Services. They are the key data source, from which many data included in this report have originated. However, they do not undertake any health economics studies.

5.5 Generics

Generics and generic substitution are used widely in the public sector. The use of generics is known to provide significant cost savings in the public sector. However, there are no data available on the volume and the value of the generics market share in Cyprus. The use of generics in the private sector is limited, as pharmacists in the private sector are not allowed to substitute original pharmaceuticals for generics.

5.5.1 Generic substitution

Generic substitution is only allowed in the public sector and is always exercised by the pharmacists in public pharmacies. Generic substitution is not allowed in the private sector. However, even if it was allowed, it is unlikely that it would be used, since there are no incentives to do so in the private sector. Public sector pharmacists are obliged to substitute originals for generics since they do not have access to the original products, when the generic is available on the market.

Public sector pharmacies are also allowed, in some cases, to substitute therapeutically (i.e. to dispense a pharmaceutical with equal therapeutic benefits, known as analogous substitution).

5.5.2 Generic prescription

Generic prescribing is only carried out by doctors working in the public sector. Even if they prescribe the original brand name product, generic substitution is applied.

5.5.3 Generic promotion

Generic promotion is limited in Cyprus. There are no incentives for doctors or pharmacists to use generics. Even though generics are cheaper and this affects the patients who pay out of pocket, many people still do not believe in them, or they do not want to take something else other than what the doctor prescribed (usually the original). Pharmacists in the private sector are not allowed to substitute.

5.6 Consumption

The consumption of pharmaceuticals, in terms of value, has been increasing steadily in recent years. The greatest increase can be seen in the public sector, since it covers all the expensive biotechnology therapies provided.

6 Current challenges and future developments

6.1 Current challenges

The main challenges that the pharmaceutical system in Cyprus currently faces are:

- lack of a National Drug Policy
- access to pharmaceuticals
- uncontrolled increase in pharmaceutical expenditure (PE).

6.1.1 Lack of a National Drug Policy

The pharmaceutical sector is divided into two distinct sectors, public and private. Owing to the current system of health care provision, including pharmaceutical care, the 43 pharmacies of the public sector provide services for approximately 75% of the population in Cyprus and the 430 pharmacies in the private sector provide for the other 25%. As a result, the private pharmacies are underutilised and the public pharmacies are overloaded, resulting in inferior pharmacy services for the patients. In addition, there are long queues in public pharmacies daily.

The segregation of the sectors does not allow for uniform utilisation of resources, nor does it allow the application of a National Drug Policy that will provide access, safety and cost savings.

The fact that all pharmaceuticals are provided free to most patients, without a co-payment, leads to over-consumption of pharmaceuticals. Although the centralised procurement method enables lower prices of pharmaceuticals, it fails to estimate the needs and as a result there are shortages of pharmaceuticals in the public sector.

6.1.2 Access to pharmaceuticals

As a result of the small and segregated market there have been problems relating to access to pharmaceuticals. Particularly since the harmonisation of the regulations with Directive 2001/83/EC, there has been a dramatic decrease in the number of pharmaceuticals in the private sector. In addition, pharmacies in the public sector often have to obtain pharmaceuticals that are not available on the Cypriot market.

6.1.3 Uncontrolled increase in pharmaceutical expenditure

Pharmaceutical expenditure (PE) has been increasing at a fast pace. This is mainly due to the addition of new expensive therapies in the public sector and the absence of a drug policy in the private sector.

6.2 Future developments

As already mentioned, Cyprus is working towards the introduction of a General Health Care Scheme (GHS). The Scheme will be based on the principle of solidarity, with all citizens that

have an income contributing. The contributions will be as follows: employees (2%), employers (2.5%), self-employed people (3.5%) and the Government (4.5%).

The beneficiaries will be all Cypriot citizens living permanently in Cyprus. The General Health Care Scheme (GHS) will unite the provision of health care by buying services under the same conditions from the private and the public sectors, and it will create competitive conditions and raise the quality of the services provided. The unification of the market will move the responsibility of planning of quantities to the private sector, and may stimulate the entry of more products onto the market and improve accessibility.

7 Appendixes

7.1 References

Ministry of Health Annual Reports 2002, 2003 and 2004.

Health & Hospital Statistics 2004, www.mof.gov.cy/cystat.

Laws and Decrees

Pharmaceuticals for Human Use (Control of Quality, Supply and Prices) Act N.70(I)/2001

Pharmacy and Poisons Law Cap 254 N184(I)/2004

The General Health Care Scheme Law N.89(I)/2001

Medical Institutions and Services Laws of 1978 and 2000

Medical Institutions and Services General Regulations 225/2000

Medical Institutions and Services General Regulations of 660/2002

Medical Institutions and Services General Regulations of 364/2005

Ministerial Decree on the prices of pharmaceuticals for the year May 2006 to April 2007, dated 29 May 2006

7.2 Further reading

Golna C, Pashardes P, Allin S, Theodorou M, Merkur S, Mossialos E. *Health care systems in transition: Cyprus*. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004.

<http://www.euro.who.int/Document/E85255.pdf>

7.3 Web links

Ministry of Health of the Republic of Cyprus: www.moh.gov.cy

Statistical Service of the Republic of Cyprus: www.mof.gov.cy/cystat

7.4 Authors

Mrs. Xenia Ashikales, Pharmacist, Department of Pharmaceutical Services (PhS), Ministry of Health.

Dr. Athos Tsinontides, Senior Officer, Health Insurance Organisation (HIO).