Pharmaceutical Health Information System

PHIS Hospital Pharma Report

CYPRUS

Commissioned by the European Commission, Executive Agency for Health and Consumers (EAHC) and the Austrian Federal Ministry of Health (BMG)

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Executive Summary

In Cyprus, the hospital market consists of private and public hospitals. Public hospitals belong to the Ministry of Health (MoH), they are funded and consequently all of their procedures are centrally coordinated by the MoH. Private hospitals, on the other hand, are funded through the services they provide in form of out-of pocket payments.

The price setting mechanism in public hospitals is borne by the tender system. The hospital price is the price of the tender awarded to a specific product. This price is influenced by factors such as competition and generic penetration.

In the private sector, there is no official price, although according to law, private hospitals purchase their medicines through private pharmacies at the pharmacy purchasing price plus 15% pharmacy mark-up (instead of 37% in the public sector). That corresponds to the pharmacy retail price.

Regarding reimbursement, the social insurance law annotates 5 patient categories, and each one has its specific percentage of reimbursement (100% or 50%). This is applied only in public hospitals.

In public hospitals pharmaceutical consumption is monitored however, it is very difficult to distinguish between medicines dispensed for out-patients and medicines used for in-patients. In private hospitals due to the medicine supply chain operated and pattern of purchasing, monitoring of pharmaceutical consumption is not feasible.

The MoH procures medicines at substantially lower prices, due to the big number of beneficiaries that are entitled to free medical care by the state. As a result, this leads to big competition between the companies with a consequent price reduction.

Currently an IT programme is being installed and it will substantially facilitate the tracking of medicines dispensed, regardless of its usage (in-patients or out-patients).

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List of abbreviations

AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
ATC	Anatomical therapeutic chemical classification
BMG	Bundesministerium für Gesundheit / Austrian Ministry of Health
CIVAS	Centralised intravenous admixtures service
DDD	Defined daily doses
DG SANCO	Health and Consumer protection Directorate General
DRG	Diagnosis related group
EAHC	Executive Agency for Health and Consumers
EMA	European Medicines Agency
EU	European Union
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG
GDP	Gross domestic product
HE	Health expenditure
HIO	Health Insurance Organisation Cyprus
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals
HPF	Hospital pharmaceutical formulary
HTA	Health technology assessment
IHHII	International Healthcare and Health Insurance Institute
MAH	Marketing authorisation holder
MoH	Ministry of Health
Mio.	Million
NCU	National currency unit
NHIS	National Health Insurance System
NICE	National Institute for Health and Clinical Excellence
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development

OPD	Out-patient department(s)
OPP	Out-of pocket payments
OTC	Over-the-counter medicines
PE	Pharmaceutical expenditure
PHIS	Pharmaceutical Health Information System
POM	Prescription-only medicines
PPP	Pharmacy purchasing price
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy retail price
SUKL	Statny Ustav pre Kontrlu Lieciv / State Institute for Drug Control (Slovakia)
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
VAT	Value added tax
WP	Work package

Introduction

PHIS research project

PHIS (Pharmaceutical Health Information System) is a research project commissioned under the call for proposals 2007 in the priority area “health information” of the European Commission, DG SANCO. It has been commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project aims at increasing knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union (EU) Member States, covering both the out-patient and the in-patient sector.

This will be done via different work packages (WP) resulting in the following deliverables:

- the PHIS Glossary with key terms related to pharmaceuticals,
- the PHIS Library offering country specific information on out-patient and in-patient pharmaceutical pricing and reimbursement for the EU Member States
- the PHIS Indicators and the PHIS Database, containing major data for the developed indicators in the Member States,
- the PHIS Hospital Pharma Report with information on pharmaceutical policies in the in-patient sector in the EU Member States, including a price survey

The PHIS project management is a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG), which is a research institute situated in Vienna, Austria, and four associated partners:

- the Italian Medicines Agency (AIFA)
- the International Healthcare and Health Insurance Institute (IHHII), Bulgaria
- SOGETI Luxembourg SA., which is a services provider, and
- the State Institute for Drug Control (SUKL), Slovakia

SUKL is the WP leader of Hospital Pharma.

Further key stakeholders of the PHIS project management are the PHIS Advisory Board covering EU Commission services and agencies and other international organisations, and the PHIS network, which comprises national representatives from competent authorities and further relevant institutions from the EU Member States and associated countries.

The PHIS project runs from September 2008 to April 2011 (32 months). Further information and all deliverables is available at the PHIS project website http://phis.goeg.at.

PHIS Hospital Pharma

The aim of the work package “Hospital Pharma” is an in-depth investigation of the in-patient sector, as systematic knowledge of pharmaceutical policies in this sector has been rather poor.

The survey is divided in two phases:

- Phase 1: General survey

Country reports on pharmaceuticals in hospitals (“PHIS Hospital Pharma Reports”), designed to describe specific pharmaceutical policies in the in-patient sector in the EU Member States (summer 2009)

- Phase 2: Case studies

A specific survey, including a price survey, provided by means of case studies, in a limited number of hospitals in a few countries (autumn 2009).

The final PHIS Hospital Report, covering information from the general survey (phase 1) and the case studies (phase 2), is scheduled for February 2010.

Methodology of the General Survey

The production of the country-specific PHIS Hospital Pharma Reports is based on three steps:

1. Development of a uniform PHIS Hospital Pharma Report Template

The PHIS Hospital Pharma Report Template offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in-patient sector of a country. The Template was developed by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader) and further members of the PHIS project management. It is based on literature and internet reviews as well as interviews with experts in the hospital sector in the EU Member States. Members of the PHIS network received the draft Template for feed-back, and had an opportunity to discuss and provide personal feed-back during a meeting.

2. Collecting information and data and drafting the PHIS Hospital Pharma Report

The country-specific PHIS Hospital Pharma Reports were written by members of the PHIS network. In order to get the needed information and data, hospital experts were contacted and involved in several countries. They provided information and data in written form and during telephone conservations and personal talks. In some countries the reports (or parts of it) were written by hospital experts. In several countries, the preparatory work for drafting the PHIS Hospital Pharma Reports also included study visits of the authors to hospitals and hospital pharmacies. Information on persons and institutions involved can be found in the

“Acknowledgements” at the beginning of this PHIS Hospital Pharma Report and in section 8 “References and data sources”, listing “Literature and documents” (section 8.1) and “Contacts” (section 8.2).

3. Editorial process

The draft PHIS Hospital Pharma Reports were submitted to the project management for review, which was undertaken by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader). The review focused on checking clarity and consistency in general and with regard to the outline of the Template and terminology (PHIS Glossary). In the course of the editorial process, the reviewers contacted the authors for providing feed-back on language and content, offering suggestions for rephrasing and change and clarified open and/or misunderstanding points.

1 Background

1.1 Definition and scope

The hospital system in Cyprus is divided into a public and private sector such as the whole health care in the country. The scheduled enforcement of a new legislation on 1 January 2010 (which is now postponed to 1 January 2011) regarding the minimum number of nurses per number of patients aggravated by the shortage of nurses forced many small clinics to consolidate and create bigger private hospitals, which are owned, in their majority, by doctors-stakeholders. The majority of the qualified nurses prefer to join the public sector, due to the better benefits and working conditions.

Definition of a hospital
The law 90(1) 2001 governs the operation of *private* health institutions. A private institution "refers to any health provider unit, which serves for admission and stay of patients, in order to be treated. However, any hospital, health centres and health institutions that belong to the government are exempted from this law". This definition is similar, albeit not as descriptive as the one provided by OECD.

The law 40 (1978) dictates the operation of *public* hospitals. According to the terminology it is the "public medical institution established for diagnosis and treatment of patients". Currently all public hospitals offer out-patient services and first- aid services (there is one hospital that offers first-aid services only upon referral from other hospitals, due to the fact that it houses specialised units such as haematology and ophthalmology).

This law classifies health institutions in 4 categories, according to medical specialities and number of beds available:

I. Day care clinic that operate from 07.00-19.00 hours, are not allowed to keep patients overnight and must have at least 2 beds per each medical specialty.
II. Clinics that must have no more than 2 medical specialties and have at least 3 beds per specialties.
III. Polyclinics that have 3 to 5 medical specialties and 3 beds per each specialty.
IV. Private hospitals that have more than 5 specialties and at least 30 beds. It is obligatory for private hospitals to have an ambulance vehicle.

Hospital out-patient services
The out-patient services are of major importance in the public sector and dominate the function of private hospitals. Usually severe chronic and complicated to treat patients are referred to the public sector.

Public hospitals provide out-patient services in every specialty in addition to the in-patient services that they operate. Consequently every department offers both in-patient and out-

patient care on a daily rotational basis. As a result, every doctor usually spends half of his/her time on in-patient service and half on out-patient care. In public hospitals apart from primary out-patient services, specialised doctors, such as orthopaedics, visit smaller hospitals or health care centres, exclusively for out-patient service, although the operations are carried out in their base hospital.

A major difference between private and public hospitals is that in public hospitals a patient does not book an appointment with a specific doctor. Although he/she may request a specific doctor, this is not obligatory. He/she books an appointment with a certain specialty, and usually may not visit the same doctor on consecutive visits. Moreover, the vast majority of the public hospitals offer first aid services.

On the contrary, the private hospitals do not have dedicated doctors for in-patient services. The private hospitals operate primarily as out-patients services. A patient requests an appointment with a specific doctor, and given than he/she needs in-patient service, the specific doctor is in charge of this patient as well. All doctors have their out-patient programme, and between their appointments they consult their in-patients. There is usually one doctor in charge of first aid. Therefore in a private clinic, the patient is primarily (if not exclusively) treated by his/her doctor, while in public hospitals the on duty doctor treats the patient. Private hospitals offer first aid services but not to the extent and coverage of the public hospitals.

1.2 Organisation

The Ministry of Health (MoH) is the competent authority for the accreditation and operation of all health institutions. In addition to this the MoH is also the competent authority for the supervision on running and budget for public hospitals. Currently there are 95 health institutions in Cyprus. Among them, 8 are public hospitals and 87 are private health institutions. According to the definition of private hospitals in the relevant law, only 16 out of the 87 private health institutions are classified as private hospitals. 21 are defined as polyclinics, 39 as clinics and 11 as day care centres. The private hospitals are profit organisations. The shareholders of the private hospitals are usually the doctors that are employed there, although one investment company penetrated this field.

As seen in table 1.1 there is a reduction in the acute care beds. This reduction is mainly due to consolidation of smaller clinics into bigger hospitals. Specifically, the law 90(2001) states that each hospital must employ a certain number of nurses in accordance to their bed capacity. Due to the shortage of nurses in Cyprus, some hospitals consequently reduced their acute care beds. Currently, there are 2 public hospitals with more than 300 acute care beds. There are 1 private and 3 public hospitals with more than 100 acute care beds.

Regarding the location of the public hospitals, there is one public hospital in every city, apart from Nicosia that has 2 hospitals. These 2 hospitals do not offer overlapping services. More-

over, there is one public hospital in each one of the 2 remote villages that serves as regional centre. The private hospitals are evenly dispersed among the major cities.

The most complete hospital, in terms of functional departments, is the Public General Hospital of Nicosia which offers the whole spectrum of services and several patients are referred there, due to nonexistence of the respective services in their home hospital or due to disease severity. The Nicosia Hospital is considered to be the reference centre, mainly due to the fact that some departments are fully functional and staffed only in this hospital. In order to assist and facilitate access to medical care, specialists visit smaller hospitals or care centre for outpatient only services. In Cyprus there are no university hospitals.

There are currently 3 medicine rehabilitation centres in Cyprus. However, they are not classified as hospitals.

Pharmaceutical legislation

The legislation and execution of pharmacy and pharmaceutical services are in the hands of the state, respectively through the department of Pharmaceutical Services within the MoH.

Table 1.1: Cyprus – Key data on in-patient care, 2000 and 2004–2008

In-patient care	2000	2004	2005	2006	2007	2008
No. of hospitals[1]	n.a.	n.a.	n.a.	24	24	n.a.
Classified according to ownership						
- thereof public hospitals	n.a.	n.a.	n.a.	8	8	n.a.
- thereof private hospitals[2]	n.a.	n.a.	n.a.	16	16	n.a.
- thereof other hospitals (please specify)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Classified according to subtypes[1]						
- thereof general hospitals	n.a.	n.a.	n.a.	23	23	n.a.
- thereof mental health and sub-stance abuse hospitals	n.a.	n.a.	n.a.	1	1	n.a.
- thereof specialty (other than mental health and substance abuse) hos-pitals	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of acute care beds	3,147	3,075	2,847	2,864	2,911	n.a.
- thereof in the public sector	1,510	1,438	1,445	1,430	1,456	n.a.
- thereof in the private sector (all private health institutions including private hospitals)	1,637	1,637	1,402	1,434	1,455	n.a.
- thereof in the private sector (private hospitals only)	n.a.	n.a.	n.a.	755	755	n.a.
Average length of stay in public hospitals[3]	5.9	5.9	6.1	5.8	5.8	n.a.
Average length of stay in private hospitals[4]	n.a.	2.5	2.7	2.9	2.7	2.3
No. of hospital pharmacies	8	8	8	8	8	8
thereof no. of hospital pharmacies that serve out-patients	8	8	8	8	8	8

n.a. = not available, n.app. = not applicable

Note: Data are indicated as of 31 December

1 According to OECD definition and its subtypes

2 Currently, 86 private health institutions including 16 private hospitals operate in Cyprus

3 This applies only to public hospitals.

4 These are not published data.

Source: Statistical Services, Annual Report 2003, 2004, 2005, 2006, 2007

Ownership

Public hospitals are owned by the State and governed by the Ministry of Health, while private hospitals are owned by doctors and in one case by an investment company.

Hospital pharmacies

All public hospitals have pharmacies while on the contrary no private hospital has a pharmacy. The public pharmacies serve both in-patients and out-patients exactly under the same regulations and rules. Beneficiaries (both in-patient and out-patients) to free medical care by the State get their medicines from public pharmacies, including hospital pharmacies. Consequently public pharmacies are overloaded and have reached their optimum output capacity.

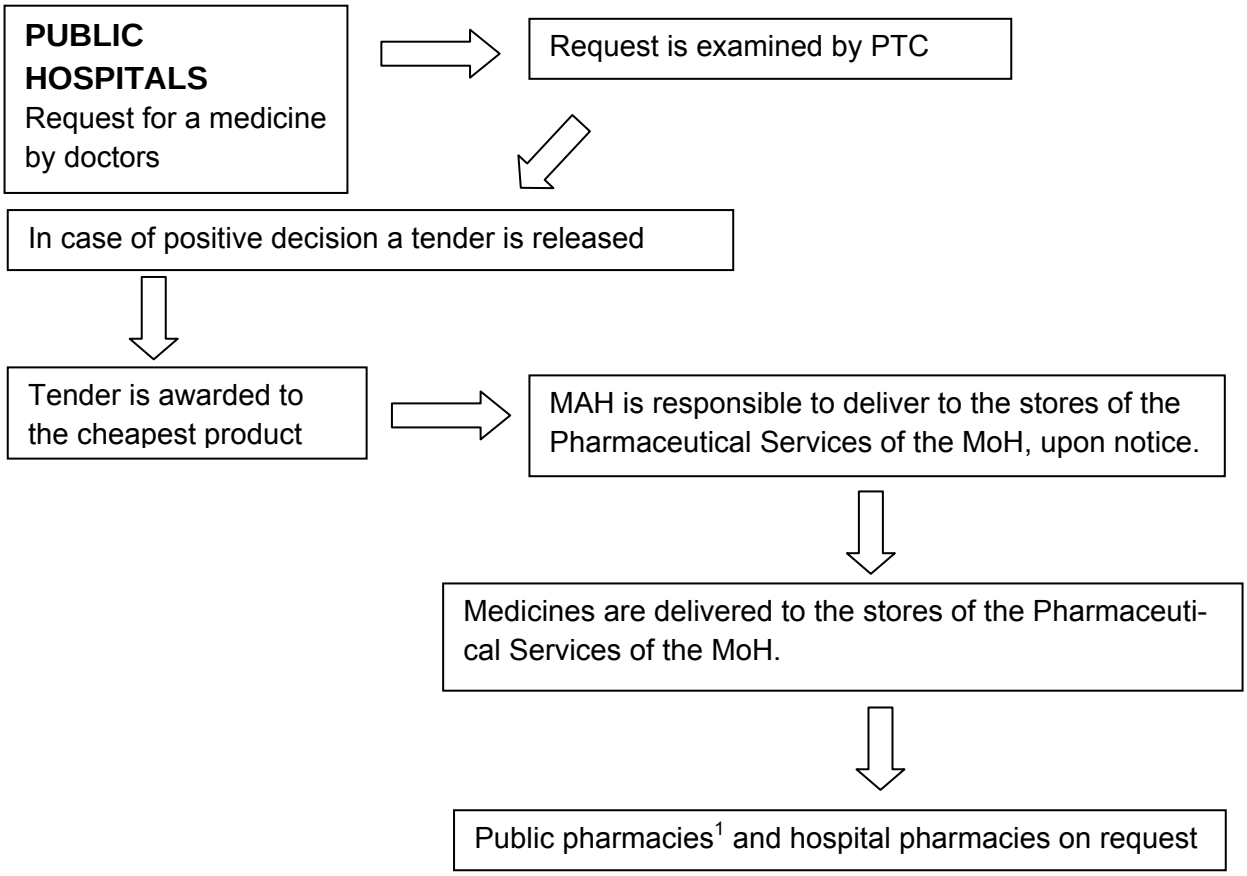
The law 90(1)2001 dictates the storage of medicines in private hospitals. It describes the storage conditions (temperatures of injectables, vaccines etc. and special conditions for narcotic substances) but this law does not mandate the presence of a pharmacist. Alternatively a doctor or a nurse can be assigned for this position.

Delivery chain

The public sector procures medicines through tenders. The marketing authorisation holder (MAH), upon the award of the tender is obliged to deliver the requested amount of medicines to the stores of the Pharmaceutical Services of the MoH which then deliver medicines to hospital pharmacies upon request. Usually the product is delivered every 5 months to the Pharmaceutical Services and the duration of the tender is 2 years.

The private hospitals usually purchase medicines from private out-patient pharmacies. In case of non availability they can get their medicines from public pharmacies.

Figure 1.1: Cyprus – Flowchart of medicines delivery chain in public hospitals, 2009

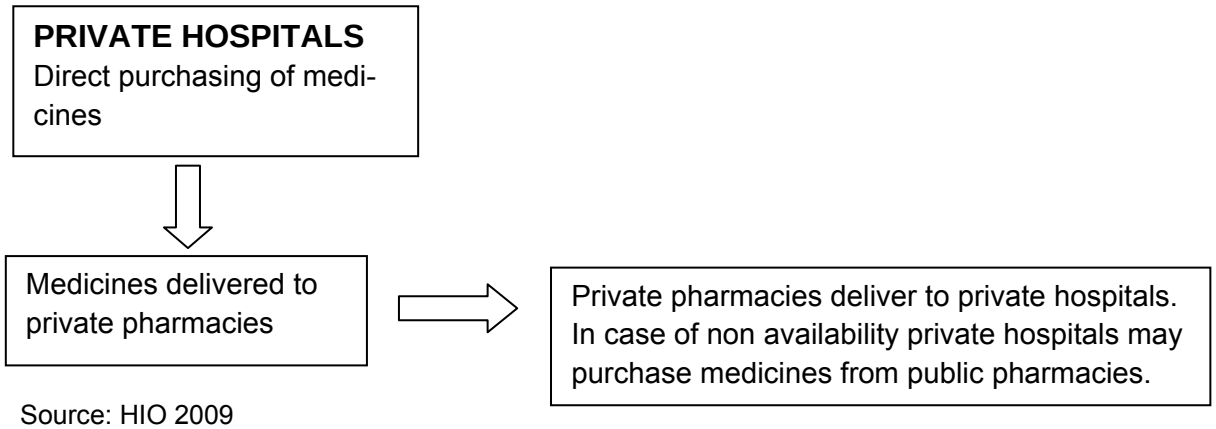


MAH = marketing authorisation holder, MoH = Ministry of Health, PTC = pharmaceutical and therapeutic committee

[1] Public pharmacies are community pharmacies that operate in public hospitals and public health care centres (HCC) owned by the Ministry of Health

Source: HIO 2009

Figure 1.2: Cyprus – Flowchart of medicines delivery chain in private hospitals, 2009



Source: HIO 2009

Table 1.2: Cyprus – Pharmaceuticals in the public sector, 2000 and 2005–2009

Number of pharmaceuticals	2000	2005	2006	2007	2008	2009
Authorised pharmaceuticals in total	n.a.	1,669	1,616	1,987	n.a.	n.a.
- thereof hospital-only pharmaceuticals	n.a.	n.a.	n.a.	542[1]	n.a.	n.a.

[1] In Cyprus there is neither an official definition of hospital-only medicines, nor a relevant list. This number was inserted to demonstrate the number of products that according to their summary of product characteristics should be administered in a hospital setting. For 2008 Pharmaceutical Services estimate this number to be around 20% of authorised medicines.

Note: Since the sales of private sector hospitals cannot be monitored the above numbers refer to the hospitals of the public sector.

The method of counting is in packages (i.e. including different pharmaceutical forms, dosages and pack sizes)

Source: Data on file, MoH (sales are not freely available)

Hospital pharmacists are not involved in the reimbursement process. In general the role of hospital pharmacists is the following:

- Hospital pharmacists are in charge of the preparation of products for parenteric use;
- Supply of medicines to wards;
- Monitor rational use of medicines by implementing guidelines, checking the personal medical book of the patient to avoid stockpiling and by keeping registry for expensive products;
- They are in charge of supplying and are responsible for requesting medicines from the Pharmaceutical Services, in order to ensure a prompt provision of medicines to beneficiaries;
- They ensure that certain guidelines are implemented and they can even refuse to dispense a product in case that the corresponding therapeutic guidelines were not followed;
- Communication and interaction with other professionals within the hospital;
- Currently, only certain expensive and subject to abuse medicines are monitored regarding the consumption by in-patient.

Publications

The private hospitals are obliged to submit the annual report until 31 January, for the previous year to the commissioner (who is a public servant) of the private hospitals that falls under the Ministry of Health.

The data submitted include:

- Number of beds
- Annual admission number
- Annual discharge number
- Annual deaths occurred in the institution
- Annual number of bed days
- Annual number of day cases.
- Annual number of minor operations (patients does not spend night in the institution)
- Annual number of operations
- Annual number of deliveries
- Annual number of caesarean sections.

The above mentioned data are categorised by each specialty. The total number is submitted as well. In addition to the above the annual number of patients treated in the specialised units such as hemodialysis, intensive care units, endoscopy etc., has to be submitted separately. Along with the above, all the personnel data (name, specialty and registry number) has to be submitted as well.

Public hospitals submit a detailed report to the MOH that consists of the following:

- List of medical and paramedical personnel per specialty
- Number of out-patient visits per specialty
- Number and type of in-patient and out-patient diagnostic radiology tests performed
- Number and type of nuclear physics test performed
- Number and type of oncology interventions performed
- Number and type of operations performed per department
- List of services provided by maternity and child welfare department.
- List of vaccinations performed per age group bands (0-12, 0-18, adults)
- Number of in-patient admissions per specialty and length of hospital stay
- List of pharmacy staff
- Number of prescriptions issued and number of prescriptions filled
- List of laboratory staff
- Number and type of laboratory tests performed
- Number of beds per specialty

1.3 Funding

Payers

The MoH is the regulating and financial authority for public hospitals. The MoH is funded through the Ministry of Finance, according to the budget that MoH submits to the Ministry of Finance. In case of excess of actual expenses, in July the MoH may request an additional budget, in order to meet its financial liabilities.

There are 5 major categories of beneficiaries (A-E).The legal framework is the Public Institutions and Foundations Law. The services provided to the 5 categories of eligible patients include the provision of medicines.

Individuals who are entitled to services free of charge fall under category A which includes all people with annual income less than € 15,400 for an individual, or € 30,754 for a family. The amount can be increased by 1,708 for each dependant. This category includes all public servants, families with more than five members and people who present with specific conditions (e.g. dialysis patients, myasthenia patients, Alzheimer diseases, idiopathic thrombocytopenic purpura, cystic fibrosis, vaguez disease, autism, etc.).

Individuals who are entitled to services provided at a reduced fee fall under category B which include all patients with annual income less than € 20,500 or € 37,500 for a family. This amount can be increased by € 1,708 for each protégé. Category B patients must contribute 50% of the total expenses.

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 (for more information please consult the PPRI Pharma Profile Cyprus 2007).

Therefore, due to the large number of eligible categories, in public hospitals the majority of the patients are beneficiaries. In 2007, 668,825 people were entitled to free medical coverage by public hospitals. This contributes to 85% of the total population. Out-patients that belong to the above mentioned categories are served by public pharmacies that are located outside hospitals (e.g. in public health care centers). The non beneficiaries who visit public hospitals fully pay for their treatments and medications. However the prices are lower than in the private sector. In the private sector the patients pay the full amount out-of pocket, unless the patient is covered by a private insurance or referred by a public hospital.

Remuneration of hospitals

The MoH issues a price list for public hospitals, which annotates separately each part of the treatment. In private clinics, the final invoice of the whole treatment is described analytically (e.g. room cost, anaesthesiologist fee, surgeon fees, medicine fees). There is no diagnosis related group (DRG) system in Cyprus.

Table 1.3: Cyprus – Health and pharmaceutical expenditure, 2000 and 2004–2008

Expenditure (in million EUR)*	2000	2004	2005	2006	2007	2008
Total health expenditure (THE)	n.a.	792.4	846	905.9	976.8	n.a.
- thereof THE public	n.a.	394	408.6	451.4	518.5	n.a.
thereof THE private	n.a.	398.4	437.4	454.5	458.3	n.a.
THE in hospitals (HOSHE)	n.a.	n.a	n.a.	n.a.	n.a.	n.a.
thereof HOSHE public	n.a.	n.a	n.a	n.a.	n.a.	n.a.
thereof HOSHE private	n.a.	n.a	n.a	n.a.	n.a.	n.a.
Total pharmaceutical expenditure (TPE)	n.a.	125.95	139.15	156.47	176.89	n.a.
- thereof TPE public	n.a.	60.80	77.38	75.15	84.6	n.a.
- thereof TPE private*	n.a.	65.15	61,77**	81.32	92.29	n.a.
Pharmaceutical expenditure in hospitals (HOSPE)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof HOSPE public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof HOSPE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

HOSHE = health expenditure in hospitals, HOSPE = pharmaceutical expenditure in hospitals, n.a. = not available, NCU = national currency unit, PE = pharmaceutical expenditure, THE = total health expenditure, TPE = total pharmaceutical expenditure
Note: Data are indicated as of 31 December

* Expenditure data in the private sector are expressed in the pharmacy purchasing prices in million Euros.

** The reduction of private TPE, as noted in 2005 is due to the price reduction that was implemented in 2005.

Source: Health Statistics 2004, *Health and Hospital Statistics 2004 (Series1,No 25),* Statistical Services, Republic of Cyprus

Health Statistics 2005, *Health and Hospital Statistics 2005 (Series1,No 26),* Statistical Services, Republic of Cyprus

Health Statistics 2006, *Health and Hospital Statistics 2006 (Series1,No 27),* Statistical Services, Republic of Cyprus

MOH data on file

2 Pricing

2.1 Organisation

2.1.1 Framework

The relevant laws for the pricing of medicines are:

- Drug`s and medicine´s law 90(1) 2000
- Regulation for requirements, establishment and operation for pharmacies 281/2000
- Drug´s provision law 75(1) 2006
- Pharmaceutical pricing law 184(1)2004.

Price regulation
In Cyprus the medicine prices for the private sector (also for private hospitals) are set by the Ministry of Health, following the recommendations of the Drug Price Control Committee, by means of external price referencing, based on reference prices among one expensive, 2 medium and one cheap EU countries. Public hospitals procure their medicines through tenders by the Pharmaceutical Services of the Ministry of Health (public procurement), so the price is determined through competition for each tender.

In general prices in public hospitals are usually significantly lower than the pharmacy wholesale price set by the MoH for the private sector. Depending on the medicine (level of competition, generic entry, etc.) the reduction usually ranges from 15-80%. As a result, public hospital pharmacies do not sell medicines to non beneficiaries, in order to avoid competition with private pharmacists, since this is a sensitive issue. Nevertheless, they sell products that are only available at public hospitals to non beneficiaries. As stated in section 1.3 certain patients categories are eligible for free medical treatment in public hospitals. Consequently, the relevant medicines are consumed almost exclusively in public hospitals. Therefore, no business interest exists from many marketing authorisation holders to market their product in the private sector, once they get a tender for a product, especially if the product has a high price. In this case, as certain products are only available in public pharmacies, public hospitals can sell these products to non beneficiaries at a price which is the tender price plus a 20% mark-up which contributes to their administrative costs.

Decision-taking bodies/persons and process
Private hospitals, since they shift the cost to patients, do not have strict rules and procedures regarding medicines´ provision. On the other hand, public hospitals are cost sensitive and therefore several procedures must be followed .The competent body is the Drug Committee of the Ministry of Health. The Drug Committee consists of:

- the director of the Pharmaceutical Services or his/her representative;
- the director of the medical services and services of public health, or his/her representative;
- the director of the mental health services or his/her representative;
- clinical pharmacists;
- 2 public hospital´s specialists, among them one general practitioner.

The committee decides upon the inclusion or not of a medicine in the hospital pharmaceutical formulary (which is the same for all public hospitals). In case of a positive recommendation outcome, a tender is released. The actual price is set according to the price of the tender awarded to each product. The hospitals cannot alter this price, apart from the 20% mark-up profit. The hospital pharmacists cannot influence the process, since this is centrally originated and directed.

Pricing policies
The dominant pricing policy in public hospitals is tendering and in private hospitals direct purchasing (cf. section 2.2).

Exceptions
For certain products such as orphan medicines, the reimbursement is performed on a patient basis. For emergency cases and for non significant amounts, the Pharmaceutical Services can directly buy a specific medicine (small quantities) without issuing a tender.

2.1.2 Hospital prices

In Cyprus, the term hospital price in public hospitals describes the wholesale price of the product, as set by the tender outcome. The term “tender price” is usually used unofficially. It is more similar to the perception of the wholesale price. The hospital medicines also have a retail price which is the hospital price plus a mark-up profit of 20%, which is assigned as administrative cost. Pharmaceutical Services publish a book with the prices of pharmaceutical products that are included in the formulary.

Private hospitals directly purchase their medicines from private pharmacies. A mark-up of 15% is added to the pharmacy wholesale price (instead of the official pharmacy mark-up profit which is 37%). In addition to this, if private hospitals purchase medicines from a public hospital (only in case that the specific product is not available on the private market) the payable price is the tender price plus a 20% mark-up profit. It has to be clarified that public pharmacies do not compete with private pharmacies, regarding the provision of the private hospitals. Medicines used in hospitals are not subject to VAT.

Discounts
Discounts may occur in the provision of medicines by private hospitals There are no mandatory discounts granted to public hospitals. However due to the fact that the tender´s volumes are guaranteed for a period of 2 years, there is enough competition that leads to significant

price reduction. Even in categories without competition and the tender has virtually no effect, usually a discount occurs, because the committee can decline the purchase of one medicine due to high prices. For innovative medicines there is an average of 10% discount on the wholesale price, while for me-too and generics the discount is even higher. For instance:

- Valsartan 80mg has a wholesale price of € 18.79 / The hospital price is € 13.- (43% discount).
- Infliximab has a wholesale price of € 596.- / The hospital price is € 504.- (18% discount).
- Actylise has a wholesale price of € 517.- / The hospital price is € 412.- (25% discount).
- Diclofenac 25mg/ml injection has a wholesale price of € 2.3 / The hospital price is € 0.4.
- Basiliximab has a wholesale price of € 1,311 / The hospital price is € 1,115 (19% discount).

Level of hospital prices: The hospital prices are considerably lower compares to the official pharmacy retail prices in the out-patient sector. This is due to the inexistence of margin profit in the hospital prices and due to the competition which is originated by the big number of beneficiaries to free medical care by the State.

The price of a medicines in public hospitals is the same regardless its use.

Every year the MoH publishes and distributes the formulary with the hospital prices to all hospitals.

2.2 Pricing policies

2.2.1 Procurement

Tendering is the major pricing policy for hospital medicines in the public sector. The Pharmaceutical Services fully comply with the EU legal framework. In addition to this, Pharmaceutical Services comply with the national laws which are the following:

1. The co-ordination of procedures for the award of public contracts, public supply contracts and public service contracts and related matters Law 12(I)/2006. This law converges with the EU directives.
2. The Award of Contracts (Supplies, Works and Services) Regulations 201/2007
3. The Execution of Contracts (Supplies, Works and Services) Regulations 115/2004
4. The Award of Contracts (Supplies, Works and Services) Regulations for the Tender Review Authority 745/2003

5. Part IV - Tender Review Authority of the Award of Contracts (Supplies, Works and Services) Law 101(I)/2003.

There are three forms of tendering:

- Tendering
- Simplified Procedure (occurs usually in urgent cases and when the cost is between € 8,543 and € 85,430
- Negotiating procedure (occurs after a cancellation of the tender. It is obligatory to sustain the same terms as the first tender)

Free of charge goods are accepted only if they are included in the quantity already requested by MoH.

The MoH tenders all medicines for all public hospitals and distributes them according to their needs. Private hospitals directly buy their medicines either from private pharmacies or only in case of non availability from public pharmacies. The Pharmaceutical Services of the MoH are primarily involved in the procurement process, following decision by the Drug Committee.

Criteria: The prices of medicines in public hospitals are set through the tender system. Consequently, factors such as competition and generic entrance affect the price submitted by the MAH. In fast developing categories with intense competition, there is a relevant decrease of the prices. However, in order for a tender to be released, there must be clear evidence to the Drug Committee that the new medicine possesses medical and therapeutic benefits and that the inclusion in the medicines list will help to control the expenses through its superior efficacy or safety compared to other products. Therefore cost (pharmacy purchasing price) and efficacy are important factors as well. Moreover, recommendations from international agencies such as the National Institute for Health and Clinical Excellence (NICE) are taken into consideration. In certain cases, a Health Technology Assessment (HTA) may be elaborated. The committee may reject the proposal for the introduction of a new product mainly due to the price. There are financial limitations, especially with new products that have not been budgeted. The prices of similar products directly affect the prices of competing products through the tender system.

The most important decision criterion is the price. The tender system obliges the government to buy the cheapest product. If there are significant benefits demonstrated by a more expensive product, then the tender should ask only for the most expensive product, otherwise a tender cannot be awarded to any product if a cheaper product has entered the same tender. When a tender is released, it usually calls for a basket of product, mainly for the same ATC category (muscle system, neurological system etc.).

Frequency: A tender is released every 2 years. Upon the award of a tender, the MoH is obliged to buy the requested quantities at the determined price. There is flexibility on behalf of the MoH that allows a fluctuation ranking from -30% up to +30% on the requested quantity.

Publication: When the sales estimation of a given product is above € 133,000 the tender must be published in the TED Europe[1]. Both the announcement and the result of the tender is awarded to the MAH not later than 48 days after the tender. Moreover, the competent authority is obliged to inform all tender participants of the outcome.

Information on prices: The price for an innovative product is usually 10% lower compared to the wholesale price, while for a generic they may reach as low as 80% of the pharmacy wholesale price. For me-too medicines usually there is a 25% price reduction, compared to the pharmacy wholesale price.

2.2.2 Others

In the private sector, private hospitals directly purchase their medicines from private pharmacies at the official pharmacy purchasing price plus 15% mark-up profit. Besides direct purchasing private hospitals may negotiate prices with marketing organisation holders (MAH). The Drug Price Control Committee sets the official prices for the medicines in the private sector.

In public hospitals negotiations are possible in case a tender is cancelled (cf. section 2.2.1).

[1] http://ted.europa.eu/

3 Reimbursement

3.1 National hospital reimbursement procedure

The system described below only applies to public hospitals.

Legal framework: The primary legal framework is the Public Institutions and Foundations Law. The law for Medical Institutions and Medical services (1978) annotates the beneficiaries' categories. This law consists of the regulations for the Governmental Medical Insitutions (225/2000, 660/2002, 455/2004, 364/2005, 629/2007).

Payers: The MoH fully pays for medicines for category A in-patients when they are treated in public hospitals and partially (50%) for category B in-patients (cf. section 1.3). Non beneficiaries pay the whole amount out-of pocket. Regarding private hospitals, patients have to pay out-of pocket for the whole treatment. The majority of private patients have private insurances. The MoH may compensate patients for health care provided by private hospitals, given that the specific treatment is not available in public hospitals, or if there is a considerable long waiting list.

The reimbursement products of the public formulary are available both to in-patients and out-patients. The reimbursement procedure is the same for in-patients and out-patients, although certain medicines, due to their indications and administration requirements are not dispensed to out-patients.

Currently there is no national positive or negative list. However, a common public hospital formulary exist and there is usually one medicine from each ATC level 4 categories (although in many cases there

is more than one).

The Drug Committee (cf. section 2) is the competent authority to evaluate the application for the introduction of a product in the formulary. Moreover this committee is in charge of evaluating specialised cases, for which there is no alternative treatment in the formulary. Five votes of the representatives of this committee are required for a positive result.

Evaluation Criteria

The sector of clinical pharmacy prepares, upon application, a report with the following parameters:

Therapeutic:

- current medicines of the formulary for the same disease (cost/consumption);
- epidemiologic data of the relevant disease;

- registration status of the requested product;
- international guidelines and the position of the pharmaceutical products in these guidelines.

Pharmacoeconomic evaluations:

- conclusions of assessment by other European competent authorities such as NICE;
- budget impact analysis, cost-effectiveness analysis etc.

When the Drug Committee deems fit, it appoints ad-hoc committees for specialised cases. During the evaluation process the Drug Committee may elaborate therapeutic guidelines or impose limitations in order to establish the rational use for new and existing medicines as well.

The evaluation is based on:

- evidence based medicine;
- evaluation by independent reliable bodies;
- inclusion in international guidelines;
- approval by the European Medicines Agency (EMA);
- financial evaluation based on the basic principles of pharmacoeconomics and on the budget of the MoH.

The Drug Committee does not accept experimental products (that are in clinical trials) or products that are not officially approved by EMA. On exceptional cases, and on a name basis, the Drug Committee may approve the use of a pharmaceutical product for off-label use, under the condition that there is satisfactory medical evidence supporting this use.

Co-payments for medicines in hospital care: As mentioned above there is no co-payment for medicines for in-patient care for category A patients, while category B patients pay 50 % of the total expenses. For other patient categories, medicines, medical care and laboratory tests that are related to their disease are fully reimbursed. Currently there are no deductibles or any other form of co-payment.

Specific budgets: MoH derives its funds from the Ministry of Finance, through the government budget. There are no specific budgets for specific products, although the MoH may request an adjunctive amount from the Ministry of Finance, in order to meet its financial obligations.

3.2 Hospital pharmaceutical formularies

There is only one hospital pharmaceutical formulary (HPF) in Cyprus in public hospitals, although some specialised medicines are available only in certain hospitals. In Cyprus, negative lists do not exist.

In public hospitals, the MoH pays for the medicines, if the patient is eligible as beneficiary. There are several categories as described in section 1.3. Regarding the private hospitals, the patient pays, unless he/she has a private insurance.

As already mentioned the Drug Committee is the competent authority to evaluate the introduction of a product in the formulary (cf. section 2).

The role of hospital pharmacists is rather advisory, meaning that they can only recommend the introduction of a specific product, however this rarely occurs.

Doctor may freely prescribe, however if the product cannot be provided at the hospital pharmacy, then the patient has to visit a private pharmacy and pay the whole amount out-of pocket.

4 Consumption of pharmaceuticals

Currently, it is not possible to quantify consumption by department due to inexistence of an I.T. system. In the table below, the figures refer both to private and public hospitals.

Table 4.1: Cyprus – Pharmaceutical consumption in hospitals, 2000 and 2004-2008

Pharmaceutical consumption	2000	2004	2005	2006	2007	2008
Annual pharmaceutical consumption in total						
in packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
in DDD (Defined Daily Doses)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In other measures units (e.g. unit doses)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Annual pharmaceutical consumption in public hospitals						
in packs	n.a.	n.a.	13,500,622	14,975,279	16,877,217	n.a.
in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In other measures units (e.g. unit doses)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

DDD = Defined Daily Doses, n.a. = not available

Source: MoH, Data on file

Table 4.2: Cyprus – Top 10 pharmaceuticals by pharmaceutical expenditure and consumption in public hospitals, 2007

Position	Top pharmaceuticals used in hospitals, indicated by active ingredient, ranked with regard to consumption	Position	Top pharmaceuticals used in hospitals, indicated by active ingredient ranked with regard to expenditure
1	FactorVIIIF/D1000IU,1IU	1	Trastuzumab (Hercep)150mgInj,1V
2	MicroenemaRectalEnema,1Tube	2	RituximabInj500mg/50ml,1Vial
3	FactorIX(Konyne),1IU	3	FactorVIIRecombAct.2.4mg,1V
4	Potassium Chlor. IVINF10%,10ml	4	InterferonB-1a30mcg,1Vial
5	Ranitidine50mg/2ml,1Amp	5	Infliximab (Remicade)Inj100,1Am
6	EpoetinAlfa4000IU,1X0,4ml	6	HumanImmunog.IV2.5g5%,1Vial
7	Imipen&CilastatInj500mg,1Vial	7	Docetaxel80mg/2ml,1Vial
8	Pethidine100mg,1Amp	8	FactorVIIIF/D1000IU,1IU
9	Albumin HumanI.VInj20%,1Vial	9	Epoetin Alfa 4000IU,1X0,4ml
10	Fentanyl Citr50mcg/ml,1AmpX2ml	10	Tirofiban Inj0.25mg/ml,50ml,1V

Source: Pharmaceutical Services, Ministry of Health

5 Evaluation

5.1 Monitoring

There is no monitoring in private hospitals. In public hospitals, pharmaceutical expenditure and consumption is monitored and it is done by the clinical pharmacy department of the Pharmaceutical Services. The clinical pharmacy department divides the formulary´s medicine into the ATC level 1 categories and each clinical pharmacist is allocated to one (or more categories) for better monitoring.

Hospital pharmacists can monitor the expenditure, however they cannot interfere or control the budget. The monitoring is done centrally and regularly in the Pharmaceutical Services and not in hospitals individually. The clinical pharmacy department deals with excess in the expenditure through implementation of guidelines that usually limit prescription of a product to a specific specialty, certain indications and severity of the disease. The Pharmaceutical Services publish and disseminate guidelines for certain therapeutic areas to all public doctors. If patients do not follow the guidelines the public pharmacist may not dispense the prescribed product to the patient and refer him/her back to the doctor for a new prescription. Currently it is not possible to quantify the expenditure of pharmaceuticals for a given disease however this issue will be addressed upon the installation of the I.T. system, which is in progress.

This new I.T. system is currently being installed in all public pharmacies, aiming to coordinate all functions of Pharmaceutical Services such as tendering, provision to hospitals, dispensing to out-patients and in-patients and monitoring expenditure.

5.2 Assessment

Several cost-containment measures have been implemented in hospitals. Implementation of guidelines, that dictate the provision of expensive medicines, the personal medical book in which all the medicines prescribed for each patients are documented and the constraint of specialty products to be prescribed only by the relevant specialty. Moreover, the Drug Committee specifies and limits indications for certain expensive products, it defines disease severity, create registry of patients and check whether a patient is eligible for this treatment. At tender system level, the aim of the Pharmaceutical Services is to have as many participants as possible, in order to obtain lower prices.

The use of tendering has lead to a reduction up to 40% of the public pharmaceutical expenditures, compared to the amount that the public sector would have spent given that the prices utilised were the pharmacy retail prices. In addition to the above, several other interventions that contained expenditure were implemented such as guidelines in costly therapeutic areas such as diabetes and rheumatoid arthritis. The savings derived by these approaches cannot be estimated, due to inexistence of an I.T. system.

6 Interface Management

A new I.T system is currently being installed in all public hospitals (cf. section 7).

7 Developments and Outlook

An I.T system is currently being installed in public hospitals. The rationale is to connect all health care providers in order to track down prescribed and dispensed products. Moreover, this will enable pile-stocking reduction by the patients, since pharmacists will be able to check existing quantities of each medicine the patient possesses. Pile-stocking has been a significant source of medicines waste during the years. The introduction of the patient´s book by the Ministry of Health led to reduction of this issue. Each patient is provided with a book that contains prescriptions (in duplicate form) that are filled by the doctor. The patient must display this to the pharmacist, which keeps the prescription. In this way, all past medicinal history can easily be seen by the physician and stock piling can be avoided.

Moreover, since the implementation of the National Health System is getting closer (planned in the 2nd half-year 2011), public hospitals will have to be autonomous and separated by the Ministry of Health according to the rules of fair competition. Therefore each hospital must develop its own pathways for medicine provision, because it will be reimbursed directly from funds of National Health System.

8 References and data sources

8.1 Literature and Documents

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Confidential

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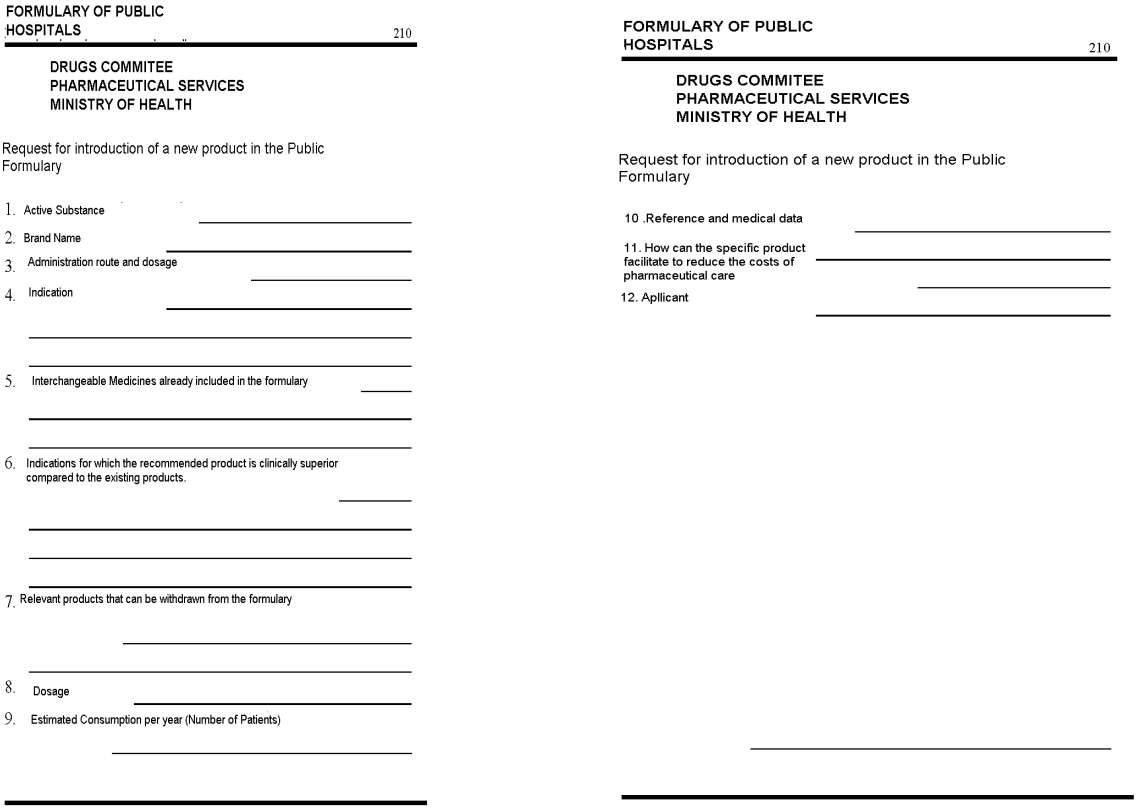
Sample of request for introduction of a new product in the public formulary



FORMULARY OF PUBLIC HOSPITALS 210

DRUGS COMMITEE
PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH

Request for introduction of a new product in the Public Formulary

1. Active Substance
2. Brand Name
3. Administration route and dosage
4. Indication
5. Interchangeable Medicines already included in the formulary
6. Indications for which the recommended product is clinically superior compared to the existing products.
7. Relevant products that can be withdrawn from the formulary
8. Dosage
9. Estimated Consumption per year (Number of Patients)

FORMULARY OF PUBLIC HOSPITALS 210

DRUGS COMMITEE
PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH

Request for introduction of a new product in the Public Formulary

10 .Reference and medical data
11. How can the specific product facilitate to reduce the costs of pharmaceutical care
12. Apllicant

8.2 Contacts

Several persons assisted in the elaboration of this report. To begin with Aphrodite Kasini, a nurse officer at Ministry of Health has provided priceless support regarding the function and obligations of hospitals. Antonis Kontemeniotis and Maro Papademetriou, pharmacists at Pharmaceutical Services assisted regarding the tasks of the Drug´s Committee and the procedures for tendering. Within HIO, Christos Paschalides, Gnosia Achniotou, Christos Symeonides and Chrystalla Lambrou eagerly supported the elaboration of this report. Finally Maria Michaelidou´s input regarding the legal aspects of tendering was equally important.