



Pharmaceutical Health Information System

PHIS Hospital Pharma Report 2009

MALTA

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PHIS

Pharmaceutical Health Information System

MALTA

PHIS Hospital Report

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Executive Summary

Hospitals services in Malta fall within international (e.g. OECD) definitions of “hospitals” and “hospital care”. General hospitals provide both in-patient care and also specialised out-patient services for diagnostic and pre-hospitalisation purposes. Within general hospitals, services also include the Emergency and Admitting Department for cases requiring urgent management. Day care forms a substantial part of hospital activity of the general hospital services delivered in Malta.

Health care services in Malta, including the provision of medicines are the responsibility of the Health Care Services Directorate within the Ministry for Social Policy (MSOC) at a national level which includes the responsibility for the implementation and provision of medical services. The Public Health Regulation Directorate within the MSOC is the regulatory counterpart to this.

The public health care system is funded through central taxation and provides a comprehensive basket of health services. The private sector acts as a complementary mechanism to this and is funded either from private insurance schemes or through out-of pocket payments. Health insurance is not compulsory in Malta and patients can move without restrictions between the public and private sector.

All hospital services, including in-patient stays, are provided free at the point of use to eligible clients. The cost of medicines required for out-patient use are only supplied at no cost to patients eligible under entitlement for chronic illness or low household income schemes. When required, patients discharged from in-patient hospital care are entitled to a free 3-day supply of medicines.

The public health services and the pharmaceuticals consumed therein are funded by the Government through budget allocations to hospitals and the Government Pharmaceutical Services.

The Availability of Medicinal Products within the Government Health Services Regulations (L.N. 58 of 2009) within the Medicines Act (Cap. 458) regulates the availability of adequate supplies of medicines at a reasonable cost in the Government Health Services. This legal notice details the application processes for a medicinal item to be included in the government formulary list (GFL), decisions on inclusion and exclusion of specific medicines on this list and to apply pricing measures to any pending and new applications for the introduction of medicines.

Medicines listed in the GFL are procured centrally by the Government Health Procurement Services (GHPS) via a tendering process. This process is price driven, the cheapest option being chosen. This procurement department centrally procures and hence supplies all government hospitals. The L.N. 58 of 2009 applies pricing measures using external price

referencing for new medicines introduced in the GFL. A maximum reference price will be calculated on a basket of reference countries¹.

When in-patients are treated in a public hospital, pharmaceuticals listed on the GFL used are free-of-charge for all patients. Pharmaceutical expenses are covered from the annual budget specifically allocated to GHPS. These finances are determined by the government in an annual budget plan for the country. Any pharmaceutical listed on the GFL may be used for the treatment of an in-patient at the expense of the National Health Service if the criteria specified in medicinal protocols are satisfied.

Out-patients may be eligible to free pharmaceuticals by virtue of the Social Security Act Cap 318 Article 23 and the Fifth Schedule to the same Act that set down necessary criteria for eligibility. These criteria include household income level, diagnosis of specific medical chronic conditions and certain population groups such as members of religious orders, members of the police and the armed force.

Information and data on the utilisation of pharmaceuticals in hospitals at a national level were not obtained in time. Expenditure, prices and consumption of pharmaceuticals used in the Mater Dei Hospital (MDH) are monitored by the Mater Dei Hospital Pharmacy Department (MDHPD), the regularity of this depending on the item concerned. The MDHPD also quantifies the expenditure of pharmaceuticals by disease category within the hospital. The data are assessed regularly by the MDHPD and discussed internally with the relevant stakeholders. This information however is not publicly available.

The stock management programme allows the MDHPD to keep track of all pharmaceuticals from point of entry to point of use. Medicine usage (individual or by category), expenditure of medicines, and in-patients and out-patients expenditure, expenditure by ward or departments e.g. surgical, medical, intensive care etc. can be monitored and assessed.

The review of government formulary is an ongoing process and consists of inclusions, deletions, the development of new protocols with amendments of prescribing criteria, etc.

¹ There is external reference pricing in Malta which is applied to new medicines when processed through the Transparency Directive. The basket of reference prices varies according to the GDP of Malta and the other countries (a GDP of +/-20% of the local GDP).

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List of abbreviations

| | |
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| ATC | Anatomic Therapeutic Chemical classification |
| DPPM | Directorate For Pharmaceutical Policy And Monitoring |
| EU | European Union |
| GDP | Gross Domestic Product |
| GFL | Government Formulary List |
| GFLAC | Government Formulary List Advisory Committee |
| GHPS | Government Health Procurement Services |
| HE | Health Expenditure |
| HOM | Hospital-Only Medicines |
| HOSHE | Health expenditure in hospitals |
| HOSPE | Pharmaceutical expenditure in hospitals |
| HP | Hospital Protocol |
| INN | International Non-Proprietary Name |
| L.N. | Legal Notice |
| MDH | Mater Dei Hospital |
| MDHPD | Mater Dei Hospital Pharmacy Department |
| MP | Medicine Protocol |
| MSOC | Ministry of Social Policy |
| NCU | National Currency Unit |
| NHS | National Health Service |
| OTC | Over-The-Counter pharmaceuticals |
| PE | Pharmaceutical Expenditure |
| PHIS | Pharmaceutical Health Information System |
| POYC | Pharmacy of Your Choice |
| THE | Total Health Expenditure |
| TPE | Total Pharmaceutical Expenditure |
| VAT | Value Added Tax |

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 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 are made 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 (spring 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 conversations 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 re-phrasing and change and clarified open and/or misunderstanding points.

1 Background

1.1 Definition and scope

Malta does not have an official definition of the terms “hospital” and “hospital care”. However, hospitals services in Malta fall within international definitions (e.g. OECD) of “hospitals” and “hospital care”. General hospitals provide both in-patient care and also specialised out-patient services for diagnostic and pre-hospitalisation purposes. Services within these hospitals also include the Emergency and Admitting Department for cases requiring urgent management. Day care, which forms a substantial part of hospital activity nowadays, is not mentioned e.g. in the WHO definition² but plays an important role in the general hospital services delivered in Malta. There is no specified minimum number of beds required for an establishment offering such medical services to be licensed as a hospital.

Maltese hospitals can be classified similarly to the OECD system of health subtypes of hospitals, that is, into general (acute) hospitals, mental health and substance abuse hospitals and other speciality hospitals. There is a strict differentiation between public hospitals and private hospitals.

The following description on hospital pricing, reimbursement and monitoring in this PHIS Hospital Pharma Report refer to Maltese public hospitals only. All Maltese citizens are eligible to free public health care services including hospital care. Other categories of clients entitled to free services by the public sector include holders of the European Health Insurance Card (EHIC), mainly citizens European Economic Area (EEA), Switzerland, and all persons residing in Malta covered by the Maltese social security legislation. Those who opt for private health services, including hospitalisation, have to pay the full price out-of pocket or through private health insurance covering part or all treatment. The Government does not monitor hospital pricing and reimbursement systems in private hospitals.

1.2 Organisation

Health care services in Malta, including the provision of medicines are the responsibility of the Health Care Services Directorate within the Ministry for Social Policy (MSOC) at a national level. The Public Health Regulation Directorate within the Ministry for Social Policy is responsible for the monitoring of standards, licensing, inspection of all health care services and where necessary, enforcing regulations through its various departments.

² The term “hospital” is defined by the WHO as a “residential establishment equipped with in-patient facilities for 24-hour medical and nursing care, diagnosis, treatment and rehabilitation of the sick and injured, usually for both medical and surgical conditions, and staffed with at least one physician. The hospital may also provide out-patient services” (WHO, 2000a).

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The public health care system is funded through central taxation and provides a comprehensive basket of health services to all persons residing in Malta who are covered by the Maltese social security legislation. The private sector acts as a complementary mechanism for health care coverage and is funded either from private insurance schemes or through out-of-pocket payments. Health insurance is not compulsory in Malta. Patients can move without restrictions between the public and private sectors. It is estimated that around 7.5% of the gross domestic product (GDP) is spent on health care in the public sector. Total health expenditure (that is, also including expenditure in the private sector) amounts to 9.3% of the GDP.

There is one large general hospital on the main island of Malta and a medium-sized one on the second largest island, Gozo. Mater Dei Hospital (MDH), the main (and largest) general hospital in Malta, started operating in November 2007 and has a complement of 854 beds. This new hospital completely replaced another acute general hospital, St Luke's Hospital (SLH), part of which now functions as an intermediate residential care unit for elderly patients awaiting admission to a long-term residential unit or discharge to the community. Mater Dei Hospital also houses the University of Malta Medical School. The Gozo General Hospital is a general hospital with 279 beds catering for residents of the Island of Gozo. Both of these general hospitals include in-patient and out-patient services, including day care management for diagnostic and therapeutic procedures not requiring over-night stays in hospital.

Sir Paul Boffa Hospital is an 85-bed hospital specialising in oncology and convalescence. It also caters for dermatological cases. Mount Carmel Hospital is a large hospital of 609 beds catering for persons with mental health problems that require specialist treatment and care. Another publicly funded hospital (Zammit Clapp Hospital) is a specialised geriatric hospital with 60 beds with a remit of rehabilitation and early return to the community of its users. These three hospitals incorporate specialised out-patient services within their speciality. Karen Grech Hospital is a specialised geriatric hospital with 155 beds.

There are three acute general hospitals within the private sector. These are all small hospitals with less than 80 beds each. The general population is more inclined to utilise public hospitals over private hospital services.

All public in-patient services, including pharmaceutical treatment, are free in Malta. On discharge from hospital care, all patients receive a free 3-day pharmaceutical supply. Persons who suffer from one or more of a schedule of chronic illnesses listed under the fifth schedule of the Social Security Act are entitled to obtain (without charge and irrespective of income) the necessary medicines under the Schedule V scheme (also known as Yellow Card). Other population groups entitled to free pharmaceuticals (on an out-patient basis) include those below a specified income threshold (Schedule II scheme, also known as Pink Card) where patients benefit under the Medical Aids grant under the Social Security Act. Such cards are issued from the Department of Social Security and entitlement is based on an assessment of the total household income. Patients who are diagnosed with certain specific medical conditions and certain population groups such as members of religious orders, members of the police and the armed forces are also entitled for a Pink Card.

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The Government through the Ministry for Social Policy and the Ministry for Gozo is the owner of public hospitals. Private companies or groups are the main stakeholders of private hospitals.

All the above-mentioned hospitals except one privately owned hospital have a hospital pharmacy.

The table below provides detailed information about in-patient care in Malta.

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

| In-patient care | 2000 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|----------------|----------------|----------------|----------------|----------------|----------------|
| No. of hospitals¹ | 8 | 8 | 8 | 8 | 9 | 9 |
| <i>Classified according to ownership</i> | | | | | | |
| - thereof public hospitals | 5 | 5 | 5 | 5 | 6 | 6 |
| - thereof private hospitals | 3 | 3 | 3 | 3 | 3 | 3 |
| - thereof other hospitals | 0 | 0 | 0 | 0 | 0 | 0 |
| <i>Classified according to subtypes¹</i> | | | | | | |
| - thereof general hospitals | 5 | 5 | 5 | 5 | 5 | 5 |
| - thereof mental health and substance abuse hospitals | 1 | 1 | 1 | 1 | 1 | 1 |
| - thereof speciality (other than mental health and substance abuse) hospitals | 2 ² | 2 ² | 2 ² | 2 ² | 3 ³ | 3 ³ |
| No. of acute care beds | n.a. | n.a. | 1,129 | 1,155 | 1,102 | 1,102 |
| - thereof in the public sector | n.a. | n.a. | 965 | 991 | 938 | 938 |
| - thereof in the private sector | n.a. | n.a. | 164 | 164 | 164 | 164 |
| Average LOS in hospitals | 4.63 | 4.64 | 4.73 | 5.32 | 4.30 | n.a. |
| No. of hospital pharmacies | n.a. | 7 | 7 | 7 | 7 | 8 |
| thereof no. of hospital pharmacies that serve out-patients | n.a. | 6 | 6 | 6 | 6 | 6 |

LOS = length of stay, n.a. = not available

¹ according to OECD definition and its subtypes

² Sir Paul Boffa Hospital (cancer, skin and convalescence hospital); Zammit Clapp Hospital (specialized geriatric hospital)

³ Sir Paul Boffa Hospital (cancer, skin and convalescence hospital); Zammit Clapp Hospital (specialized geriatric hospital); Karen Grech Hospital (specialized geriatric hospital)

Source: WHO Health for all (HFA) Database

The table below provides information on the share of hospital-only medicines (HOM). The method of counting includes different pharmaceutical forms, different pack sizes and different dosages. There is no legal classification for HOM in Malta.

In the table below, the total number of authorised pharmaceuticals refers to the total number of authorised pharmaceuticals in Malta. The total number includes medicines from both the

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public and private sector. The number of HOM refers to hospital pharmaceuticals used in the NHS.

Table 1.2: Malta – Pharmaceuticals, 2000 and 2005–2009

| Number of pharmaceuticals | 2000 | 2005 | 2006 | 2007 | 2008 | 2009 |
|--|------|------|-------|-------|-------|-------|
| Authorised pharmaceuticals in total | 0 | 365 | 1,352 | 1,835 | 1,995 | 1,995 |
| - thereof HOM | n.a. | n.a. | n.a. | n.a. | 489 | 489 |

HOM = hospital-only medicines, n.a. = not available

Note: Data are indicated as of 1 January

Source: Medicines Authority; Government Formulary List

The pharmaceutical services within the public sector are provided through a number of hospitals and health centre pharmacies, and also through some retail pharmacies. Private pharmacies do not operate in public hospitals.

The Government Health Procurement Services (GHPS) within the Ministry of Social Policy is responsible for the provision of good quality medicines for pharmaceutical preparations and medical devices which are safe and effective, in a timely, quality-approved and cost-effective manner, with the aim of achieving optimal and effective pharmaceutical care in relation to expenditure. The Directorate of Pharmaceutical Policy and Monitoring (DPPM) within the Ministry of Social Policy is responsible for the Government Formulary List (GFL). Pharmaceuticals on that list are fully reimbursed for entitled patients, as explained in Section 1.2. The Ministry of Social Policy decides, on advice of the Government Formulary List Advisory Committee (GFLAC), which pharmaceuticals shall be added to the national formulary, and then procures these substances via public tendering. This public procurement process is managed by the GHPS.

Private wholesalers deliver pharmaceuticals to the Government Health Pharmaceutical Stores (GHPS). The GHPS is then responsible for the distribution of these medicines to public hospital pharmacies and other public out-patient pharmacies.

In the private system there is a direct distribution from the wholesalers to the private hospital pharmacies or private hospital stores.

As mentioned above, the main general hospital in Malta covering all the Maltese population is the Mater Dei Hospital. The following information will focus on the pharmacy operating within this hospital.

Mater Dei Hospital Pharmacy Department

The Mater Dei Hospital Pharmacy Department (MDHPD) serves both in-patients and out-patients. It provides a 24-hour service to hospital in-patients and an emergency service to the community sector outside opening hours.

The out-patient categories served include:

- Patients entitled to non-formulary items which are medicines approved under the Exceptional Medicines Treatment Policy on a named-patient basis.
- Patients receiving stoma-care items
- Patients who require medicines not available from retail pharmacies (supplied against payment)
- Patients requiring medicines not in stock or not available from other public pharmacies
- Patients who require anti-malarial treatment, HIV medication and anti-TB medication
- Patients discharged from hospital requiring 3 days supply
- Patients requiring oxygen supply

The mission of MDHPD is “to deliver an efficient, professional and patient-oriented pharmaceutical care service at Mater Dei Hospital”. MDH covers a wide range of specialties necessitating a highly specialised pharmaceutical care service that goes beyond the stocking, distribution and dispensing of medicines. The pharmaceutical service includes a number of functions that follow internal quality systems. These include ordering and stocking of medicines, distribution service to all hospital wards and departments, dispensing service to both in- and out-patients, compounding of medicines including both non-aseptic and aseptic dispensing, repackaging, and the provision of a clinical pharmacy service and a poisons-and medicines information service. The services are provided through four main sections, namely Stores & Distribution, Pharmacy Section, Quality Assurance & Compounding Section and Clinical and Medicines Information Section.

The main objectives for MDHPD are to increase the quality of the various services offered, and to introduce new services with the aim of improving the quality of service offered to the patient. This department provides a ward topping up system on a number of wards on pilot basis with the aim of minimising stock wastage on wards. The preparation of biologically derived products and ophthalmic preparations are centralised at the Reconstitution Unit and there is an annual physical validation by the Pharmacy Reconstitution Unit and Microbiological Monitoring Service to ensure that this unit is operating according to the required standards. The internal processes within Stores and Pharmacy are being revised with the aim of minimising wastage, whilst avoiding stock-out situations. The clinical pharmacy services are also in the process of being expanded with the aim of achieving rationale prescribing in other clinical areas.

An annual report for the MDHPD is included in the Mater Dei Hospital annual reports.

1.3 Funding

The public health services and the pharmaceuticals consumed therein are funded by the Government through budget allocations to the different health divisions. All hospital services, including in-patient stays, are provided free at the point of use by eligible clients. In the private hospitals scenario, the patients have to pay for all services out-of pocket or through health insurance coverage.

Table 1.3: Malta – Health and pharmaceutical expenditure, 2000 and 2004–2008 in Euros

| Expenditure (in million €) | 2000 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--|-------------|-------------|-------------|-------------|-------------|-------------|
| Total health expenditure (THE) | 271 | 375 | 405 | 423 | 407 | n.a. |
| -thereof THE public | 196 | 274 | 309 | 326 | 315 | n.a. |
| -thereof THE private | 75 | 101 | 96 | 97 | 92 | 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) | 56.8 | 63.8 | 70.7 | 73.4 | 74.5 | n.a. |
| -thereof TPE public | 19.8 | 28.8 | 35.7 | 37.4 | 43.5 | 45.5 |
| -thereof TPE private | 37.0 | 35.0 | 35.0 | 36.0 | 31.0 | n.a. |
| Pharmaceutical expenditure in hospitals (HOSPE) | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| -thereof HOSPE public | 13.4 | 23.1 | 27.5 | 25.7 | 31.5 | 27.0 |
| -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, NCU = national currency unit, PE = pharmaceutical expenditure, THE = total health expenditure, TPE = Total pharmaceutical expenditure

Note: Data are indicated as of 31 December.

- Yearly accruals not included
- Medical and Surgical devices not included
- Nutritional feeds/foods included

Source: Government Health Procurement Supplies, Ministry for Social Policy (2000, 2006–2008), Financial Monitoring and Control Unit, Ministry for Social Policy (2004–2005)

2 Pricing

2.1 Organisation

2.1.1 Framework

The Availability of Medicinal Products within the Government Health Services Regulations (L.N. 58 of 2009) within the Medicines Act (Cap. 458) regulates the availability of adequate supplies of medicines at a reasonable cost in the Government Health Services. This legal notice details the application processes for a medicinal item to be included in the Government Formulary List (GFL), decisions on inclusion and exclusion of specific medicinal products on this list and to apply pricing measures to any pending and new applications for the introduction of medicines.

The GFL is a list of pharmaceuticals which includes medicines, vitamins, food supplements and borderline substances. Medicines are either listed as non-proprietary medicines according to the International Non-proprietary Name (INN), or are listed as a therapeutic class (for those products that are deemed therapeutically or clinically, equivalent or similar). Each medicine is classified according to the Anatomical Therapeutic Chemical Classification (ATC Code), depending on the indications for which it is approved. A medicine may at times be approved for one or more indications.

Currently the Government Formulary List consists of the INN name of the medicines, the dosage form and dosage strength, the disease category and the ATC code. The list contains further information such as the prescriber criteria, which is the category of physicians who are entitled to prescribe a particular medicine, the specific department for which a medicine is being procured, and the entitlement to a particular medicine (Schedule II or Schedule V entitlement). At times a hospital protocol (HP) or a medicine protocol (MP) is attached to a medicinal product, restricting its use within the Government Health Services. The protocol is written in a defined format and stipulates the use of such a medicine. Moreover the list provides information as regards the licensing status of a medicinal product; the products which are unlicensed are marked so on the list. The GFL is available on <http://www.sahha.gov.mt>.

Under L.N. 58, an increase in the price of a medicinal product is permitted only after approval from the Superintendent of Public Health acting on the advice of the Government Formulary List Advisory Committee. If this change in price is not accepted, reasons based on objective and verifiable criteria are referred to the applicant. The Minister responsible for health may request that the price being charged by the holder of the marketing authorisation be reviewed according to the exigencies of the Government Health Services. The pricing unit together with the standard operating procedures are currently being developed within the Directorate of Pharmaceutical Policy and Monitoring (DPPM) in order to uphold these regulations.

2.1.2 Hospital prices

The end-price i.e. the “hospital price” corresponds to the “wholesale price” with no mandatory or voluntary discounts, the process being a tendering process. The prices of hospital pharmaceuticals are lower than pharmaceuticals from retail pharmacy since they are at wholesale prices. Presently, there is no VAT on pharmaceuticals. There are no mark-ups with reference to hospital pharmaceuticals. Because of these reasons, prices of hospital pharmaceuticals are lower than pharmaceuticals from retail pharmacy. However, there is a 15% mark-up when pharmaceuticals are sold to out-patients resorting to MDHPD in circumstances when a specific item is unavailable from retail pharmacies.

There are no legal obligations for government hospitals to publish pharmaceutical prices to the public or other competent authorities. No price surveys are presently available.

2.2 Pricing policies

2.2.1 Procurement

Pharmaceuticals for all hospital use listed in the government formulary list (GFL) are procured centrally by the Government Health Procurement Services (GHPS) via a tendering process. This process is price driven, the cheapest option being chosen. This procurement department centrally procures and hence supplies all government hospitals.

Each contract agreed through the tendering process is valid for a three-year period although one-year contracts are also awarded in specific circumstances such as a very high price. As mentioned, pharmaceuticals are free for in-patient health care users.

2.2.2 Others

There are no other pricing policies besides procurement.

3 Reimbursement

3.1 National hospital reimbursement procedure

Running costs of all public hospitals, including pharmaceuticals and medical devices are sustained by public funds, mainly derived from central taxation and social security contributions. When in-patients are treated in a public hospital, pharmaceuticals listed on the government formulary list (GFL) used are fully reimbursable for all patients. Reimbursement is covered from the annual budget specifically allocated for pharmaceuticals. These finances are determined by the government in an annual budget plan for the country. The allocated finances fall under the budget allocated to the health sector for the specified year with no specific budgets formulated for specific hospital pharmaceuticals (e.g. for orphan medicines, for specific diseases, for high cost pharmaceuticals).

In the private sector, in-patients have to pay the full price of pharmaceuticals out-of pocket or through private health insurance coverage. However, as mentioned above, when in-patients are treated in a public hospital pharmaceuticals listed on the GFL are free of charge for all patients. Hence, any pharmaceutical listed on the GFL may be used for the treatment of an in-patient at the expense of the National Health Service if the criteria specified in medicinal protocols are satisfied.

In conclusion, all GFL items are fully reimbursed for all in-patients in public hospitals, including a 3-day supply following discharge. However out-patients may be eligible to free pharmaceuticals by virtue of the Social Security Act Cap 318 Article 23 and the Fifth Schedule of the same Act. These legal instruments set down the necessary criteria, such as the household income level, diagnosis of specific medical chronic conditions and certain population groups such as members of religious orders, members of the police and the armed force, that determine eligibility.

3.2 Hospital pharmaceutical formularies

In Malta, the government formulary list (GFL) includes medicines, vitamins, food supplements, borderline substances, and medical devices that are available throughout the public health service i.e. is common to all public hospital and community services. Protocols are attached to pharmaceuticals specifying and restricting their use to specific circumstances within the in-patient and out-patient sectors.

Currently the GFL consists of the international non-proprietary name (INN) of the medicine, the dosage form and dosage strength, the disease category and the ATC code depending on the indications for which it is approved. A medicine may at times be approved for one or more indications. The list contains further information such as the prescriber criteria which

are the category of medical practitioners who are allowed to prescribe a particular medicine. There are also listed the speciality departments which can use certain medicines, and the drugs which can be supplied to low-income patients and certain special population groups. Some medicines can be dispensed only according to hospital protocols or a medicinal protocol listed in the GFL. The list also provides information on the licensing status of a medicine; unlicensed products are indicated on the list.

The Directorate of Pharmaceutical Policy and Monitoring (DPPM) is responsible for the establishment, maintenance and periodical review of the GFL. Updating of the list is carried out approximately twice a year. This list is published on an official website and is accessible to professionals and the public. Only items listed on the formulary can be prescribed by medical practitioners operating in public hospitals. The Government Formulary List Advisory Committee recommends whether a medicine is included or not into the formulary list (as per L.N. 58 of 2009). The final decision is taken by the Minister of Social Policy.

The following criteria are taken into account for the inclusion of pharmaceuticals in the GFL:

- entitlement
- clinical efficacy;
- safety of the pharmaceutical;
- licensing status;
- a comparison of the pharmaceuticals with alternative treatments on the GFL;
- economic evaluation;
- recommendations by international agencies offering reimbursement guidelines.

The DPPM is responsible for the deletion of a pharmaceutical from the GFL, as allowed by the above-mentioned L.N. and after consulting the various stakeholders. This may be carried out for various reasons, for instance when the consumption of a specific medicine is low or if an alternative therapy with a better cost-effectiveness is introduced. Substances may also be deleted when the manufacturer discontinues supply of the pharmaceutical and no other source is found. Currently there are 1,305 pharmaceuticals on the GFL and 489 of them are indicated for hospital use only. The GFL is updated at least twice yearly and the updated lists are published on the DPPM website (<http://gov.mt/frame.asp?1=http://www.sahha.gov.mt>).

Hospital pharmacists have an advisory role and may give information about current pharmaceutical guidelines which in-turn provides the basis for developing of the formulary. They also liaise with the specialist consultants for necessary feedback giving information about possible increases or decreases in consumption.

Private hospitals have their own individual formularies.

4 Consumption of pharmaceuticals

Information and data on the utilisation of pharmaceuticals in hospitals at a national level could not be obtained from the GHPS in time for finalising this report.

Table 4.1 Malta – Pharmaceutical consumption, 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, please specify) | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Annual pharmaceutical consumption in hospitals | | | | | | |
| 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, please specify) | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |

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

The top pharmaceuticals used in hospitals, as indicated by active ingredient, and ranked with regard to consumption and expenditure is shown in table 4.2. This list includes data from the in- and out-patient sector.

Table 4.2 Malta – Top 10 pharmaceuticals by pharmaceutical expenditure and consumption in the in- and out-patient sector, 2008

| Position | Top pharmaceuticals indicated by active ingredient, ranked with regard to consumption | Position | Top pharmaceuticals indicated by active ingredient ranked with regard to expenditure |
|----------|---|----------|--|
| 1 | Metformin 500mg Tablets | 1 | Etanercept Vials With Water For Injections |
| 2 | Perindopril 4mg Tablets | 2 | Immunoglobulin Normal 5g |
| 3 | Bumetanide 1mg Tablets | 3 | Interferon Beta 1a 6miu Injection |
| 4 | Aspirin 75mg Ec Tablets | 4 | Meropenem 1g Injection |
| 5 | Trimetazidine 20mg Tablets | 5 | Infliximab 100mg Injection |
| 6 | Amlodipine 5mg Tablets | 6 | Imatinib 100mg Tablets |
| 7 | Simvastatin 20mg Tablets | 7 | Anti Haemophiliac Factor Viii 1000u |
| 8 | Omeprazole 20mg Capsules | 8 | Atorvastatin 20mg Tablets |
| 9 | Paracetamol 500mg Tablets | 9 | Teicoplanin 200mg Injections |
| 10 | Ranitidine 150mg Tablets | 10 | Perindopril 4mg Tablets |

Source: Mark L. Zammit, Principal Pharmacist, MDHPD

5 Evaluation

5.1 Monitoring

Expenditure, prices and consumption of pharmaceuticals used in Mater Dei Hospital (MDH) are monitored by the Mater Dei Hospital Pharmacy Department (MDHPD). The regularity of this monitoring depends on the item concerned. The MDHPD also quantifies the expenditure of pharmaceuticals by disease category within hospitals.

The data are assessed regularly by the MDHPD and discussed internally with the relevant stakeholders. This information however is not publicly available.

The MDHPD is represented in the Clinical Practice Guidelines Committee within MDH and other relevant sub-committees. This representative gives valuable input and liaises with the relevant stakeholders to manage necessary amendments to formulary.

Product services

The compounding services are performed in the Reconstitution Unit, which operates Pharmacy Clean Room Technology. The Pharmacy Clean Rooms include three areas, one for aseptic compounding (Central IV additive Service), one for cytotoxic drug aseptic compounding and the non-aseptic area, where all non-sterile products are prepared. The nonaseptic area includes the re-packaging function of oral formulations from bulk. At present, Central IV additive service is not provided, however, there are plans to start the preparation of ophthalmic products in the Central IV additive suite. All operations within the Pharmacy Clean Rooms are monitored by the Quality Assurance Section so to ensure that the required standards and procedures are followed.

Support services

Purchasing and supply

The Stores and Distribution Section within MDHPD is responsible for ordering of pharmaceuticals from the central government purchasing department (GHPS) based on reorder levels. The section is also responsible for the supply of medicines to the wards. Each ward has an approved custom list of medicines. Orders are assembled and delivered to the ward in lockable boxes. A scheduled system is followed and the ward nurse places the order for stock items via an online requisition system. The plans are to introduce a ward-topping up system provided that the necessary resources are made available. Protocol-regulated and non-formulary (products not on the GFL) medicines are dispensed to the ward on a named-patient basis from the pharmacy.

The section is also responsible for the ordering and supply of medical gases in cylinders to wards. The medical gases are ordered from the medical gas supplier in line with the contract

between the GHPS and the supplier. Medicines stocked at MDHPD are those listed on the government formulary list (GFL) and are dispensed according to the entitlement and prescribers' criteria set by the Directorate Pharmaceutical Policy & Monitoring (DPPM). A number of medicines are governed by a protocol, and therefore are dispensed if the prescription and application form from the Hospital Consultant³ meet the protocol. However, requests can be made by Hospital Consultants for medicines not listed on the GFL which are approved by DPPM on an individual named-patient basis.

Therefore for out-patients, medicines are dispensed to out-patients in possession of the necessary entitlement card and permit issued by DPPM for protocol-regulated and non-formulary medicines. For in-patients, protocol-regulated and non-formulary medicines are ordered from the ward and supplied on a named-patient basis against request from the Hospital Consultant.

Computer services

The pharmacy operates a stock-control management system which keeps track of all medicines stocked by the pharmacy. An invoice is issued with each supply to the ward/department. Supplies to out-patients are recorded in the Dispensing Module and the patient is issued with a label of the medicines dispensed, including date of dispensing, ID card, name and quantity of medicine and equivalent days supplied.

Education and training

MDHPD is actively involved in training undergraduate and postgraduate health care professionals, including pharmacy technicians, pharmacists, nurses and doctors. Continuing professional development is a must for all health care professionals in fact all pharmacists take the initiative to keep themselves adjourned with the latest guidelines and development of new medicines.

Research and development

Prior to embarking on new developments or projects, the area under development is well researched and the necessary resources are identified. Pharmacists undertaking post-graduate studies are generally involved in such projects. The Pharmacy Department is also involved closely in clinical trials sponsored by the company.

Clinical services

The Clinical and Medicine Information Section operating within the MDHPD offers a variety of services centred on providing excellence in pharmaceutical care.

Services provided include a Clinical Pharmacy Service aimed at maximising the effectiveness and efficiency in the use of pharmaceuticals within Mater Dei Hospital. Clinical pharma-

³ A Hospital Consultant is a position within the hospital setting. A consultant must be specialised in a certain area of medicine and occupies a high-ranking post within the hospital administration.

cists are also involved in the operations of the Antiretroviral Clinic as well as Rheumatology Clinic at the out-patients department. Oncology pharmacists also cover paediatric cancer and haematology services.

A clinical pharmacy service is presently being provided to seventeen consultants within the Department of Medicine which is part of the MDH. This service is aimed at delivering individual pharmaceutical care which is *the responsible provision of medicine therapy for the purpose of achieving definite outcomes that improve a patient's quality of life*. Interventions made by clinical pharmacists amount to an average of 1,000 interventions monthly and have been proven to be cost effective not only in reducing patient bed-stay by enhancing early discharge and preventing readmissions but also by reducing pharmaceutical expenditure. This is represented when an intravenous preparation is switched to the less expensive oral preparation or when a cheaper medicine of the same efficacy is chosen as first line treatment. A small exercise was carried out in 2008 by the clinical pharmacists to estimate cost savings. The clinical pharmacists analysed the following four interventions:

Change of administration route of a medicine e.g. from intravenous to oral;

Stopping unnecessary medication;

Stopping duplicate treatment;

Selecting a cheaper medicine of the same class and efficacy

and cost was estimated on the fact that if the clinical pharmacist did not intervene the intervention would have been delayed by one day only. In 2008 the amount saved exceeded €°26,000.

The Medicines and Poisons Information Section is a specialised section within the Pharmacy Department which offers support regarding the effective, efficient and safe use of medicines through the provision of advice and specialised information regarding the use of medicines. This service is given both to patients as well as to patients and is a national service. A specialised aspect of this service is the provision of a poisons information service. This is very important in cases of poisonings presenting at Emergency Department.

Communication and interaction

Pharmacists work closely with other professionals e.g. nursing department through working committees and meet regularly with the aim of improving the service provided. Oncology pharmacists work hand in hand with clinicians and are directly involved in the management of cancer patients. Clinical pharmacists form part of the clinical team and attend ward rounds regularly with clinicians with the aim of optimising pharmaceutical care. Clinical pharmacists work closely with pharmacists with the Directorate Pharmaceutical Policy and Monitoring (DPPM) and with various consultants and head of departments to revise the government formulary list (GFL) and draw up medicine protocols. Clinical pharmacists are also involved in hospital and national committees related to clinical practice guidelines.

Traceability / tracking of pharmaceuticals

The stock management program allows the pharmacy to keep track of all pharmaceuticals from point of entry to point of use. Reports can be issued regarding drug usage (individual or by category), expenditure of medicines, and in-patients and out-patients expenditure, expenditure by ward or departments e.g. surgical, medical, intensive care etc. This allows the pharmacy to monitor medicines usage trends and take proactive approach in formulary management.

5.2 Assessment

Cost-effectiveness/HTA reports

MDH Pharmacy assists the DPPM in the drawing up of protocols and clinical practice guidelines which involve cost evaluation of the medicinal product or service. In addition, new services being introduced within MDH are approved by Director General Strategy and Sustainability and Director General Health Care Services and the clinician is to fill in the "Request for introduction of new Health Technology/Service" form. The form includes the following details:

- Indications (protocol with eligibility criteria)
- Benefits of new technology (over existing technology where applicable)
- Relevant Literature on proposed technology
- Financial considerations including:
 - Cost per patient per year
 - Projected annual cost over a 3 year period
 - Infrastructural/equipment requirements
 - Additional staff requirements
 - Training requirements
 - Maintenance requirements

If the new service/technology involves the use of pharmaceuticals, the pharmacy is requested to evaluate the service and provide its recommendations.

Audit reports

The National Audit Office had undertaken an in-depth performance audit on inventory policy and distribution of pharmaceutical products across public pharmacies including the pharmacy at St. Luke's Hospital in 2004. This report is publicly available on the National Audit Office website: <http://www.nao.gov.mt/>

Cost-containment/stock management

Over the past years, the Pharmacy Department, St. Luke's Hospital (SLH), Mater Dei Hospital (MDH) introduced effective control mechanisms based on good stock management principles. This involved:

1. Re-organisation of the functions which involved separation of the stores functions from dispensing functions.
2. Setting up of procedures for all pharmaceutical activities, thus ensuring that all pharmacy staff adheres to the standard operating procedures.
3. Regular stock takes (at least on an annual basis) in stores and pharmacy areas.
4. Out of stock reporting, so as to ascertain that essential medicines are available, thus preventing prescribing of more expensive medicines.
5. Redistribution of stocks due to expire but which will not be utilised in time
6. Regular updating of the list of medicines included or deleted from the government formulary list, thus not retaining any stock unnecessarily.
7. Quality management with regards to storage conditions and expiry dates such that first expiry first out procedure is maintained, thus ensuring that medicines retain their stability and are safe and effective for use.
8. Introduction of access accounts stock management program such that there is traceability of goods from point of entry to point of dispensing/supply.
9. New requisition forms (serial numbered) and in duplicate for manual ordering from wards to provide better accountability.
10. An online ordering system (ORS) to allow online ordering between wards and pharmacy was rolled out to all hospital wards within SLH/MDH. For this to be achieved, the pharmacy has revisited its practices and reorganised its systems of work. This also required staff to take on new functions such as data inputting. Pharmacy staff has been trained on the system and the pharmacy is also involved in training ward staff on the ORS.
11. All transactions are recorded in the access accounts program
12. A dispensing module was developed which provides an interface to achieve full traceability to the individual out-patient without increasing the dispensing time window. The dispensing module allows recording of all medicines dispensed to out-patients on an individual basis, such that a medication history is retained on an individual patient basis. The dispensing module is interfaces with the access accounts stock management program, such that stock levels within access accounts are updated at end of day.
13. All issues to wards/departments are accompanied by an invoice which includes the expenses of medicine/s supplied, thus increasing awareness of costs among health care professionals. All invoices must be signed by the receiving officer.
14. Protocol-regulated medicines and non-formulary medicines continue to be ordered on a named-patient basis and are to be accompanied by consultant's request form on first time order.

15. The provision of a clinical pharmacy service on a number of medical wards has also attributed to the control on use of medicines, as clinical pharmacists have now integrated well in a number of clinical consultant firms and play a very important role in rationale prescribing, where they advise the doctors on medicines to be prescribed and provide advice to patients on discharge. Interventions by clinical pharmacists on wards resulting in cost savings of € 26,000 in 2008.
16. Assistance in the organisation of clean utility rooms at all wards within MDH prior to migration and the setting up of re-order levels for each ward/entity within MDH.
17. Setting up of re-order levels at each section within the pharmacy department, i.e. stores, pharmacy and compounding section. The re-order levels are revised regularly so as to reflect the consumption trends.
18. Close liaison with clinical pharmacists to utilise stock of due to expire – for example cost savings of € 7,200 for one product alone.
19. Pharmacoeconomic evaluation of different classes of drugs presented to DPPM thus aiming at maximising the efficient utilisation of medicines by helping the clinician in choosing cheaper treatment options. In 2008 this project has been implemented in the following pharmaceutical classes – cardiovascular medicines; respiratory medicine as well as analgesia and anti-inflammatory medications.
20. Audit of clean utility rooms at wards, for example cost savings of € 11,580 for one audit alone.

The future plans are:

1. To purchase a database system for tracking all medical gas cylinders by cylinder number.
2. Introduce a ward-topping up service provided that the necessary resources are in place. The preparatory work for this service was completed in 2008 and agreement was reached with the Nursing Services Department on the role of the pharmacy technicians. The service can be initiated on a pilot basis once the necessary resources are provided.
3. To provide a Central IV additive service.
4. To purchase a pharmacy computer system at MDH through the IHIS tender. In the interim, the MDHPD will continue to operate using the access accounts program, which is not a pharmacy computer system and has a number of limitations.
5. Expansion of clinical pharmacy services to other clinical areas.

The benefits are numerous but can be summarised as follows:

- Better stock management with better forecasts and data on consumption patterns;
- Better accountability;
- Support to pharmacy activities e.g. batch recalls and report generation, reduced stock-out situations and reduction in value of expired medicines.

6 Interface management

Need for interface management

The entitlement policy is such that the Schedule V card (cf. section 1.2) for chronic conditions can only be applied for by the consultant working with the public health sector. Generally, patients get their treatment changed either following an in-patient episode or attendance to the out-patient clinic. Therefore pharmaceutical prescribing within hospital strongly impacts on the out-patient sector. Patients discharged from hospital are usually given an out-patient appointment following discharge.

Interface management

The clinical pharmacist provides counselling on discharge and ensures that all the necessary documents are filled in prior to discharge from hospital to those patients under the care of consultants with a clinical pharmacist attached to the firm. This allows the patient to obtain medicines from the public health centre pharmacy or pharmacy of your choice. Clinical pharmacists also endorse the prescription thus notifying the out-patient pharmacist that the patient has all the entitlement documents in process.

Clinical pharmacists already provide a service at HIV clinic and rheumatology clinic, where the pharmacist takes a full medicine history and wherever needed identified pharmaceutical care issues which are then referred to the consultant.

7 Developments and outlook

Plans are being developed for the setting up of a Medicinal Entitlement Unit that will be responsible for the review of the medicinal entitlement system for Malta.

Another unit, the Medicinal Pricing Unit, will also be set up. This unit will complement the new L.N. 58 described previously (cf. section 2.1.1) and incorporating legal procedures for the pricing for new medicines.

In the out-patient sector, the POYC Scheme (Pharmacy-of-your-Choice) has been introduced in several localities around Malta. Persons entitled to free medicines are now able to choose from which registered pharmacy they prefer to collect their medicinal supply. This is aimed at increasing accessibility to prescribed medicines for the population within the community and at decreasing dispensing of medicines from health centre and hospital pharmacies. The scheme will roll out for the whole Maltese population in the near future. The logistics, including planning, developing, delivery and monitoring of pharmaceutical services within this scheme is centralised and depends on the central budgeting and pricing mechanisms. Following these initiatives, a new integrated IT system needs to be introduced to collect data for monitoring purposes.

No specific developments are planned in the in-patient sector in the near future.

8 References and data sources

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8.2 Contacts

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