



# **Performance Audit**

## **Inventory Strategy and Distribution of Pharmaceutical Products - Health Division**

**Ministry of Health, the Elderly and Community Care**

Report by the Auditor General

---

## Table of Contents

---

<b>Abbreviations used within the report</b>	<b>4</b>
<b>Foreword</b>	<b>5</b>
<b>Executive Summary</b>	<b>7</b>
Inventory Strategy at the Government Pharmaceutical Services (GPS)	8
Stock Management in Government Pharmacies	9
<b>Part 1 - Introduction</b>	<b>11</b>
Background	12
Audit Objective	13
Methodology	13
The Pharmacies in the Health Care Network	15
Organisational and Functional Changes at GPS, Government Hospitals and Health Centres	16
Report Structure	16
<b>Part 2 - The Inventory Strategy at GPS</b>	<b>17</b>
Introduction	18
Costs	18
Inventory-related functions of GPS	19
Description of GPS inventory strategy	19
NAO case study results	19
Assessment of the Inventory process	20
Issues conducive to inconsistency	23
A more efficient approach to inventory modelling	24
Conclusions	27
Recommendations	27



<b>Part 3 - Stock Management in Government Pharmacies</b>	<b>29</b>
Introduction	30
A. The Regulatory Framework	31
B. Organisational Structure	32
C. Resources and Technical Support Available to Government Pharmacies	32
D. Written standards and procedures	34
Conclusions and Recommendations	35
<b>Appendix A - Methodology</b>	<b>38</b>
<b>Appendix B - Modelling Demand for Pharmaceuticals</b>	<b>40</b>
<b>Appendix C - Current setup of GPS and Government Pharmacies</b>	<b>45</b>

## Abbreviations used within the report

<b>DAS</b>	Departmental Accounting System
<b>DDA</b>	Drugs of Dependence and Abuse
<b>DH</b>	Health Division
<b>ECB</b>	European Central Bank
<b>EOQ</b>	Economic Order Quantity
<b>GPS</b>	Government Pharmaceutical Services
<b>IHD</b>	Institutional Health Department
<b>INCB</b>	International Narcotic Control Board of Vienna
<b>IT</b>	Information Technology
<b>LN</b>	Legal Notice
<b>MHEC</b>	Ministry for Health, the Elderly and Community Care
<b>NAO</b>	National Audit Office
<b>NI</b>	National Insurance
<b>NMPAU</b>	National Medicine Policy and Audit Unit
<b>PHCD</b>	Primary Health Care Department
<b>SOP</b>	Standard Operating Procedure



## Foreword



---

## Foreword

---

The procurement and distribution of free medicine is a critical part of Malta's public health services. This activity is the responsibility of the Ministry for Health, the Elderly and Community Care (MHEC) and is carried out by the Health Division comprising of various departments.

The Government Pharmaceutical Services (GPS, the main store) is the department which is responsible for the procurement, storage, distribution to government pharmacies and for the inventory control of pharmaceuticals, surgical equipment and other health consumables.

The Institutional Health Department (IHD) is responsible for the storage and management of stocks, as well sub-distribution and dispensing of pharmaceuticals from hospital pharmacies to inpatients, outpatients and/or wards. The Primary Health Care Department (PHCD) is responsible for stock management in pharmacies located in health centres, issues to pharmacy dispensing areas, and dispensing to outpatients.

Payments for running the main store, that is procuring and stocking health consumables amounted to over Lm15 million during 2003. Of these, payments for health consumables amounted to Lm14 million. The cost of operations regarding the distribution of health consumables from government pharmacies within hospitals and health centres to the final patient is not available due to the lack of allocation of costs in the accounting systems applied by the Health Division.

This report is concerned with various aspects of operations regarding pharmaceuticals only. Payments for pharmaceuticals during 2003 amounted to over Lm9 million.

Value for money audit issues concern three types of costs. There are costs related to economic issues, costs related to efficiency issues and costs related to effectiveness and risk issues.

Costs related to economic issues are located both at GPS, or the main store, and at the government pharmacies. These costs concern the procurement, inventory models and operations in place. **The adequacy and cost of the inventory strategy applied by GPS, is the first objective of this report.**

Costs related to efficiency issues are found across the storage and distribution system. These efficiency-related costs are the function of structures and staff requirements. GPS has outsourced a consultancy firm to report on its state of operations in keeping and handling stock and recommend a reengineering exercise of the whole operation within GPS (main store) itself. Operations at pharmacies in hospitals and health centres were only addressed in this report as far as stock control issues were concerned.

Costs related to effectiveness issues can be both social and pecuniary. These costs include the risks of stock outs, obsolescence, public health hazards and pilferage. **The second objective of the report is concerned with effectiveness issues. It addresses management issues and inherent risks in the stock management and distribution systems at government pharmacies.**

There are various areas within the service of supplying free medicine where audit and assessment is required. However, this report concentrates on the two critical objectives: (i) costing the inventory strategy at GPS and (ii) assessing management and control risk issues at government pharmacies.

A blue-tinted photograph of a hand pouring white, round pills from a glass bottle into another hand. A pill cap is visible on the left. The background is a solid blue color.

## Executive Summary

## Executive Summary

1. This Performance Audit, carried out by the Value for Money Section of the National Audit Office (NAO), covers various aspects related to the procuring, storage, stock management and distribution of pharmaceuticals. Its scope includes operations within the Government Pharmaceutical Services (GPS), the Primary Health Care Department (PHCD), and the Institutional Health Department (IHD), all within the Health Division.

2. Of all operations related to stock management and distribution, this report covers two particular areas, namely (a) the adequacy and cost of the inventory strategy applied by GPS at central stores and (b) management issues and inherent risks in the stock management and distribution systems at government pharmacies.

3. The findings in this report reflect conditions up to August 2004.

### GPS Inventory Strategy

4. GPS procures pharmaceuticals, surgical equipment and other health consumables on behalf of the Health Division. It also acts as main stores and distribution centre, supplying hospitals and health centres.

5. During 2003, GPS made payments of over Lm15 million, of which over Lm14 million were spent on procurement of its stock items. Of these, Lm9 million were spent on the procurement of pharmaceuticals, the scope of this audit. GPS carried a daily average stock of pharmaceuticals of Lm4.3 million.

6. GPS owns a defined inventory model at the central stores of maintaining a maximum of six months' stock monitored every two months for reordering purposes.<sup>1</sup>

<sup>1</sup> GPS has outsourced a consultancy firm to report on its state of operations in keeping and handling stock. The relevant terms of reference included the formulation of a new inventory policy.

7. In this study, a frequently-transacted stock item was selected to assess the inventory model in terms of stockouts and holding costs. The assessment indicated inconsistent results in stock management, conducive to high holding costs and/or a high incidence of stockouts. Factors conducive to inconsistency in results included:

- Limited information on demand and critical stock levels;
- Lack of completeness / accuracy of the computerized system records;
- Irregular periods during which stock items received are kept on hold for compliance tests prior to release;
- Non-adherence to contracted delivery periods;
- The inventory strategy itself.

8. The inconsistency in managing stock levels in this case revealed that GPS did not maintain its inventory strategy as per Para 5 above. At some stage, a decision was taken that a good ordering strategy which would minimise keeping unnecessarily high stocking levels would be to abandon the model adopted by GPS as per Para. 5.

9. NAO carried out further analysis, using computerised simulations of stock movements, in order to understand GPS behaviour. This analysis showed that consistent implementation of the fixed inventory strategy currently owned by GPS seems to lead to higher holding costs and stockouts than the actual GPS results.

10. However, the simulations also showed that reducing maximum level of stock held from six to three months' supply and a delivery lead time of one month, reduced holding costs by half, at the expense of higher stockouts.

11. Notwithstanding, the adopted ordering strategy was erratic in that it gave little thought to



the problem of deciding whether stocking levels are too high or too low except when the situation was getting or had already gone out of hand.

12. GPS contends that it is still not satisfied with the overall results and is constantly trying to develop a more economic inventory strategy.

13. NAO proposes the adoption of a better inventory strategy and is recommending guidelines on how this can be realised.

14. These are:

a) The definition of an objective function that includes estimates of the costs for:

- o Obsolescence;
- o Holding Costs;
- o Pricing by quantity schemes;
- o Variation of prices over time;
- o Stockouts;
- o Ordering costs.

b) Incorporation of these costs into a cost function that is meaningful and reflects reality;

c) Identification and quantification of constraints governing the nature of the inventory, to include:

- o Acceptable level of stockouts;
- o Maximal storage;
- o Maximal demand;
- o Minimal order quantity;
- o Maximal and minimal delivery lead times.

d) Adoption of superior strategies triggered by tracking stock levels rather than by a fixed review period;

e) Consideration of the recruitment of professional help on a regular basis to assist in the initial implementation and subsequent update of the new strategy;

f) The implementation of a computerized system that allows GPS to view the inventory system in its entirety, covering items stocked within the entire Health Division.

15. GPS has already taken up NAO's advice to study stock behaviour in detail, enabling the identification of an optimal inventory strategy. However it is acknowledged that implementing such a strategy involves an exercise that is lengthy in nature. Priority can be assigned to high value and/or fast moving items.

16. Furthermore, strategic decisions, including a new adequate IT system, effecting GPS operations are currently being assessed by the MHEC Health Policy Board.

### Stock Management in Government Pharmacies

17. GPS directly supplies pharmaceutical products to pharmacies in eight health centres, a store and six hospitals. According to its records, in 2003, GPS processed invoices to pharmacies with a total value of Lm11.26 million. Eighty-one per cent of this value is related to invoices to pharmacies in hospitals managed by the IHD, and the remaining nineteen per cent is related to invoices to pharmacies in health centres managed by the PHCD.

18. During fieldwork in 2003 in nine government pharmacies attached with both departments, NAO identified gaps and weaknesses in the control and documentation concerning the stock management and distribution of pharmaceuticals to final consumers, after being received from the GPS.

19. The weaknesses and operational risks identified in the studied stock management and distribution processes, included:

- i an organisational structure which lacked clarity on accountability, responsibility and reporting relationships;
- ii outdated job descriptions;
- iii ineffective communication of organisational changes;
- iv insufficient monitoring of management initiatives;
- v an overall absence of written procedures or standard practices;
- vi the prevalence of inadequate stock control;
- vii incomplete records; and

xiii an unsatisfactory audit trail of documents and records from the pharmacies to the patients.

20. The critical risks arising out of these weaknesses include unacceptable levels of obsolescence and pilferage. These risks could not be assessed due to lack of stock movement information available.

21. Over the past year, IHD and PHCD have introduced limited changes in some of the government pharmacies with the aim of enhancing stock control and advancing good pharmacy practice. In addition, two major hospital pharmacies are in the process of implementing Standard Operating Procedures, although the other pharmacies are still without clear and well-documented procedures. Significant work still needs to be done to ensure that all pharmacies have an adequate and reliable stock management system with the necessary procedures, premises, day-to-day controls and documentation. The observations listed in Part 3 of the Report show that there are barriers to effective management and control which should be addressed by MHEC. Management argues that these shortcomings are the result of lack of resources – human, finance, IT and physical assets such as premises etc.

22. To address these weaknesses and manage these risks, NAO recommends the need to:

- a) introduce, standardise and enforce licensing requirements, operational guidelines, policies, and written procedures applicable to all pharmacies;
- b) strengthen the management and supervisory structure and determine clear lines of accountability and responsibility within the stock management and distribution processes;
- c) determine and provide adequate resources and technical support to government pharmacies to ensure effective stock management;
- d) expedite the installation of holistic and integrated management information systems in all pharmacies;
- e) improve the documentation and authorisation processes in order to provide a reliable audit trail within the pharmacies;
- f) enhance learning and communication amongst pharmacy staff; and
- g) introduce an internal function which monitors and audits, for example, standards, procedures, and stock discrepancies.



## Part 1 - Introduction

## Part 1 - Introduction

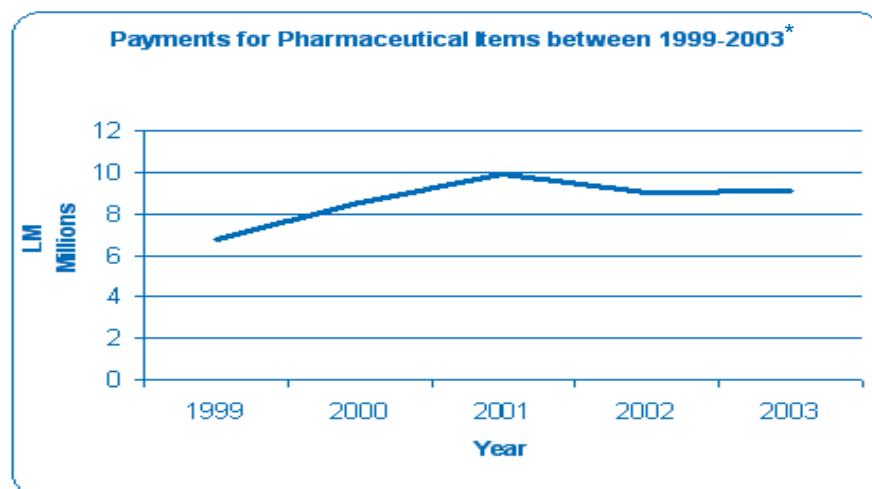
### Background

1.1 Over a five year period, between 1999 and 2003, the annual value of total payments for pharmaceutical products by the Ministry of Health, the Elderly and Community Care (MHEC) increased considerably, by 34 per cent, from Lm6.77 million in 1999 to Lm9.10 million in 2003 (Figure 1).<sup>1,2</sup> The highest total payment (Lm9.89 million) was reached in 2001. The MHEC predicts that the expenditure on pharmaceutical products will continue to increase over the years.

the expenditure on pharmaceutical products in the public sector, although the Division attributes the steady increases to four main causes, namely to:

- a) an increase in the prices of a broad range of pharmaceutical products;
- b) demographic changes (an ageing population requires more treatment over a longer period);

**Figure 1: Total payments for pharmaceutical products by the MHEC has increased by 34 per cent, from Lm6.77 million in 1999 to Lm9.10 million in 2003**



Source: GPS (Government DAS Accounting System, 2004)

\* Values include arrear payments.

1.2 It seems that no conclusive studies have been carried out by the Health Division on the factors contributing to the increases in

- c) new services introduced in the national health system, such as the introduction of cardiac services and the introduction of treatment for HIV/AIDS which led to a greater number of people requiring long term medication; and
- d) an increased number of patients and medical cases.

<sup>1</sup> The Ministry of Health, the Elderly and Community Care, prior to March 2004 was known as the Ministry of Health. For the purposes of this report, the acronym "MHEC" refers to both Ministries.

<sup>2</sup> Source: GPS records on the Government DAS accounting system.



1.3 Similar conclusions had been identified in Europe, where the following factors are considered as the main causes of the increased expenditure:<sup>3</sup>

- a) an increase in the number of items prescribed;
- b) the introduction of new expensive products in areas where no treatment was available (e.g. cancer, AIDS);
- c) the switch from inexpensive to expensive drugs for greater effectiveness or improved side-effect profiles;
- d) the increasing number of elderly people;
- e) an absolute increase in population size; and
- f) increasing public expectations.

1.4 The public health care sector procures pharmaceutical products through the Government Pharmaceutical Services (GPS) – a central organisation within the Health Division. GPS is responsible for sourcing, purchasing, storing and providing medical and hospital supplies to a network of government-run pharmacies in hospitals and community-based health centres, collectively offering comprehensive health care services to an extensive range of patients.<sup>4,5</sup> (The current set-up of GPS and the government pharmacies is described in Appendix C).

1.5 The distribution of pharmaceutical products is regulated by various laws and regulations, some of which have been recently updated to include EU Directives.

1.6 The Value for Money Section within the National Audit Office (NAO) carried out a performance audit on the economy of the current inventory strategy at GPS, as well as the adequacy and effectiveness of procedures and practices that manage and control the flow of pharmaceutical products through government pharmacies.

1.7 The decision to conduct the audit was instigated by the materiality of the increased expenditure and by concerns expressed by policy-makers, by members of Parliament and by the media on the rising costs and incidents of stockouts.

<sup>3</sup> A Review on Entitlement to Free Medicines, Internal Report of the Health Division, February 2000.

<sup>4</sup> Medical and hospital supplies include e.g. pharmaceutical products, food, infection control items, laboratory supplies, surgical items, sterilisation items, special clothing, collars, splints, slings, bandages, dressings, drapes, needles, syringes, medical gases, chemical and raw materials, instruments and medical equipment.

### Audit Objective

1.8 The objective of this report was to determine, in the case of pharmaceutical products, whether:-

- a) The inventory strategy currently in use at the GPS is economic.
- b) The stock management systems at government pharmacies are adequate, robust and reliable.

### Methodology

1.9 Details of the methodologies used to carry out this study are summarised in Appendix A.

### A Broad Range of Pharmaceutical Products

1.10 Table 1 overleaf provides an indication of the wide range of pharmaceutical products purchased and distributed by GPS within the public health care network over the past five years. The total amount of stock items held fluctuates over time according to, for example, changes in demand and supply and other considerations such as new treatments.

1.11 GPS classifies most of its pharmaceutical products by type of disease. Every product within each disease category is further divided into different store items according to differences in, e.g. strength, formulation or packaging. For example, a pharmaceutical product containing warfarin can be dispensed in six different forms (as a 1mg, as a 3mg or as a 5mg item, each in packets of 28 units or 500 units). Hence, if all items are in stock, GPS has six different codes for the six different forms of the pharmaceutical product containing warfarin.

1.12 Another distinction by GPS relates to the pharmaceutical products that are listed collectively as “Dangerous Drugs” or “Drugs of Dependence and Abuse” (hereon referred to as DDA products) by the world regulatory body INCB, (International Narcotic Control Board of Vienna) or by the Director

<sup>5</sup> The published draft Pharmacy License Regulations, defines “pharmacy” as any premises from which any medicinal substances are sold, dispensed or otherwise supplied directly to the public by retail, irrespective of whether such sale, dispensing or supply is carried out on the presentation of a prescription given for the purpose by a medical practitioner, dental surgeon or veterinary surgeon, or otherwise.



**Table 1: A list of categories of pharmaceutical items supplied to the public health care network by GPS, including the number of different items purchased over the last five years. \***

	<u>Number of different items</u>
• <i>Gastro Intestinal System</i>	(92)
• <i>Cardiovascular System</i>	(234)
• <i>Respiratory System</i>	(60)
• <i>Central Nervous System</i>	(196)
• <i>Dangerous Drugs</i>	(72)**
• <i>Infections</i>	(203)
• <i>Endocrine System</i>	(137)
• <i>Obstetrics, Gynaecology, and Urinary Tract Disorders</i>	(22)
• <i>Malignant Disease &amp; Immunosuppressant</i>	(103)
• <i>Nutrition and Blood</i>	(149)
• <i>Musculoskeletal and Joint Disorders</i>	(73)
• <i>Eye</i>	(71)
• <i>Ear, Nose and Oropharynx</i>	(37)
• <i>Skin</i>	(173)
• <i>Immunological Products and Vaccines</i>	(35)
• <i>Anesthesia</i>	(42)
• <i>Antidotes</i>	(23)
• <i>Radiopharmaceuticals</i>	(24)
• <i>Contrast Media</i>	(11)
• <i>Sterile Manufacturing Unit</i>	(28)
• <i>Renal Products</i>	(35)

**Total: 1,820 different items \*\*\***

\* GPS classifies pharmaceutical products by type of disease and records different forms of the same product (e.g. different strength, formulation or packaging) as separate items in its inventory system.

\*\* Another distinction by GPS relates to the pharmaceutical products that are listed collectively as "Dangerous Drugs" or "Drugs of Dependence and Abuse" (hereon referred to as DDA products) by the world regulatory body INCB, (International Narcotic Control Board of Vienna) or by the Director General, Health. These products are mainly psychotropic and narcotic products and are not grouped by type of disease by GPS.

\*\*\* The total amount of stock items held fluctuates over time according to, e.g., changes in demand and supply and other considerations such as new treatments.

**Source: GPS, March 2004**

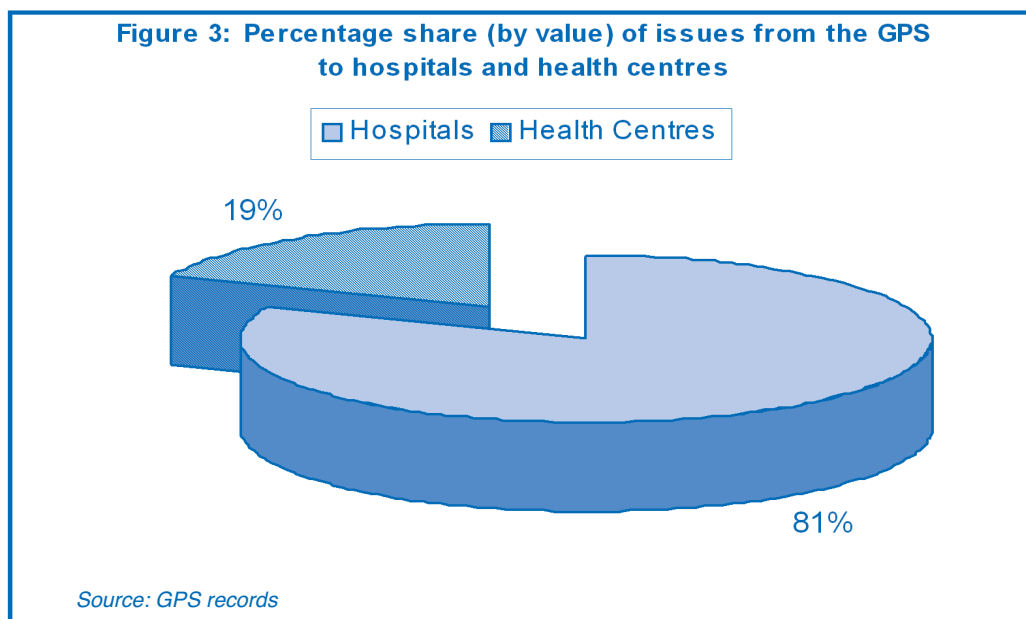
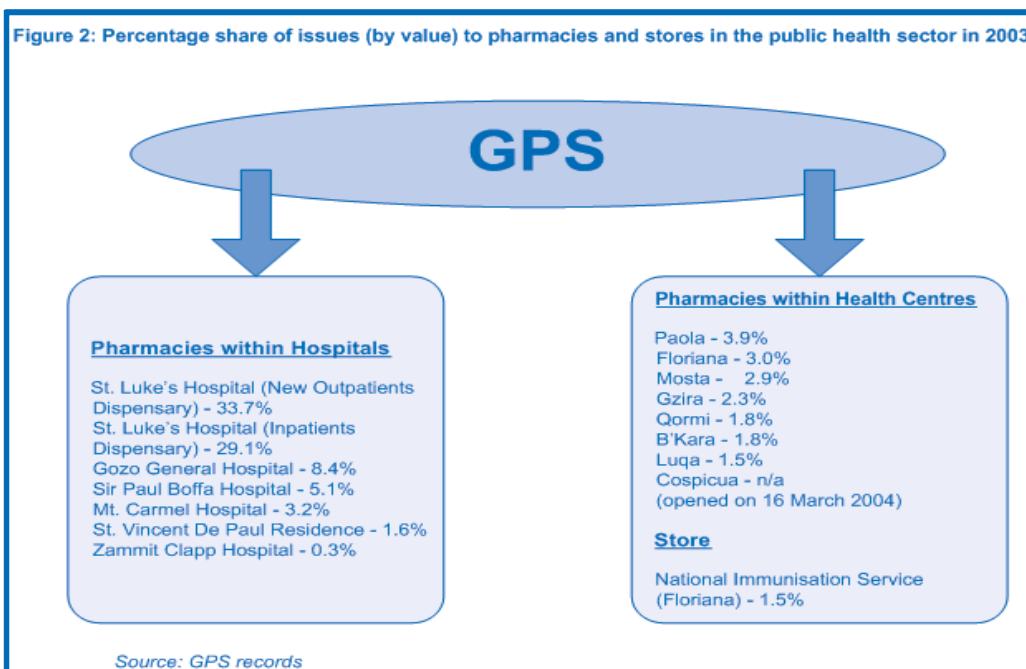
General, Health. These products are mainly psychotropic and narcotic products and are not grouped by type of disease by GPS.

### The Pharmacies in the Health Care Network

1.13 GPS directly supplies pharmaceutical products to pharmacies in seven health centres, a store and six hospitals (Figure 2).<sup>6</sup> A brief

description on each of these entities is provided in Appendix C.

1.14 According to its records, in 2003 GPS processed invoices to pharmacies in hospitals and health centres with a total value of Lm11.26 million. Eighty-one per cent of this value is related to invoices between GPS and hospitals and nineteen per cent is related to invoices to health centres (Figure 3).<sup>7</sup>



<sup>6</sup> An additional new pharmacy was opened in the Cospicua Health Centre in March 2004.

<sup>7</sup> The current information systems at government pharmacies

do not provide data on pharmaceutical products dispensed from each pharmacy but only data of products supplied to the pharmacies by GPS.

1.15 A detailed assessment of the requisition, storage and issue processes and procedures followed by government pharmacies is given in Part 3 of the report.

### Organisational and Functional Changes at GPS, Government Hospitals and Health Centres

#### GPS

1.16 One of the major challenges being faced by GPS is the organisational and functional changes required following a review of workflows and procedures by an external private business consultancy firm.

1.17 The results of the outsourced assignment, which was awarded in May 2001 and extended through separate agreements, have been:

- a) Three reports on the required business process re-engineering at GPS, addressing requirements related to structure, infrastructure and processes.
- b) The provision of the services of a full-time Financial Controller and an Administrative Assistant.
- c) Consultancy on Systems and Stores processes.
- d) Assistance in the implementation of the process re-engineering exercise.
- e) Support in the procurement of a new IT system.

1.18 The exercise identified the following main areas of implementation:

- a) A new organisational set-up for GPS.
- b) The need for a comprehensive off-the-shelf IT package to cover and facilitate all operations within GPS.
- c) The need to centralise and upgrade storage facilities to European standards.

1.19 The conclusions of the exercise are being assessed by the MHEC Health Policy Board and decisions have still to be taken.

### Government Hospitals and Health Centres

1.20 The public health care environment within which government pharmacies operate is changing. Several factors can have impact on the flow of pharmaceutical products through government pharmacies, including new government policies, revised laws and regulations, reviewed organisational structures, resources available and expectations of stakeholders.<sup>8</sup>

1.21 In addition, several changes are being proposed to the organisational structure, staff complement, IT systems and the physical layout of the future Pharmacy Department at the new hospital currently under construction (Mater Dei Hospital).

### Report Structure

1.22 The structure for the report is as follows:

- a) Part 2 analyses the inventory strategy of the GPS and the ways of how this strategy can be improved.
- b) Part 3 studies management issues and inherent risks in the stock management and distribution systems at government pharmacies.

<sup>8</sup> Government pharmacies are currently managed by three different entities, namely:

- *The Department of Institutional Health* responsible for hospital services and clinics;
- *The Department of Primary Health Care* responsible for primary health care and community care services; and
- *The Ministry of Gozo*, responsible for hospital services in Gozo.

The background of the slide is a blue-tinted photograph. It shows a silver spoon lying on a white document. The document has a hole punch on the right side. The spoon is positioned diagonally, with the bowl of the spoon pointing towards the bottom left. The text 'Part 2 - The Inventory Strategy at GPS' is overlaid on a dark blue rounded rectangle in the upper middle part of the image.

## **Part 2 - The Inventory Strategy at GPS**

## Part 2 - The Inventory Strategy at GPS

### Introduction

2.1 Apart from procuring pharmaceuticals, surgical equipment and other health consumables on behalf of the Health Division, the Government Pharmaceutical Services (GPS) acts as main stores and distribution centre, issuing products to its clients, mainly hospitals and health centres<sup>1</sup>, against demand.

2.2 The objective of this section is to assess the adequacy and economic aspects of the inventory policy applied at the GPS Main Stores.

### Costs

2.3 The total costs of running GPS, procuring and stocking pharmaceuticals and other health consumables during 2003<sup>2</sup>, were as follows:

**Table 2 – GPS running costs for 2003**

Nature of Cost	Amount
Materials (pharmaceuticals and other health consumables) <sup>2</sup>	14,555,621
Operational Costs	405,936
Salaries and NI	730,563
<b>Total</b>	<b>15,692,120</b>

Source: DAS figures, GPS Departmental data

2.4 Costs given in Table 2 above are considered as sunk and are very marginally affected by changes in inventory strategy. GPS has outsourced consultants to assess the efficiency of its structure and operation and to recommend a business process re-engineering which is bound to impinge on Salaries and NI figures in Table 2 above.

<sup>1</sup> Collectively referred to as pharmacies. These pharmacies are listed in Appendix C.

<sup>2</sup> The cost of materials reflects payments effected through DAS.

2.5 The scope of this report concerns pharmaceuticals only. Payments for pharmaceuticals amounted to over Lm 9 million during 2003.

2.6 The robustness of an inventory strategy is concerned with levels of holding costs, ordering costs and cost of stockouts and obsolescence.

2.7 In this specific case, ordering costs were of little materiality to report upon.

2.8 Value of expired drugs at GPS only for years 1999 to 2003 is given in Table 3.

**Table 3 – Expired Pharmaceutical items at GPS**

Year	Expired Pharmaceuticals Lm
1999	97,854
2000	124,132
2001	236,651
2002	362,171 <sup>3</sup>
2003	142,284

Source: GPS Departmental data

2.9 The focus of this section is on the adequacy of the inventory strategy to minimise holding costs and stockouts.

2.10 When considering holding costs, only relevant costs were taken into consideration.

2.11 Relevant holding costs considered in the study are opportunity costs arising out of funds tied up in stocks held. During 2003, GPS carried an average stock of Lm4.3 million<sup>4</sup>. At an interest rate for the year 2003 of five per cent<sup>5</sup>, total holding

<sup>3</sup> Includes a specific medication, costing Lm179,654, imported in 1998 for a patient who passed away.

<sup>4</sup> Value of stocks held by GPS in December 2002 amounted to Lm4.7 million.

<sup>5</sup> Source: ECB statistics – Long-term interest rate statistics for the acceding countries (30 April 2004).



opportunity cost of stock during 2003 amounted to circa Lm215,000.

### Inventory-related functions of the Government Pharmaceutical Services

**2.12** Government acquires the majority of its medicines and medical devices against period contracts, typically covering three years. The mechanism conforms to Government Procurement Regulations, and is initiated via a departmental call for quotations, a departmental tender or a Department of Contracts tender, depending on the contract value.

**2.13** Apart from the technical aspect of the items being acquired, the tender covers prices of goods, for which bidders have the option to submit up to three levels of prices, one for each of the three years being covered. Maximum delivery lead time is also specified during the tendering process, albeit not always enforced. On its part, Government gives an indication of the quantity it intends purchasing during the span of the contract, enabling suppliers to determine an appropriate pricing structure. However, actual delivery occurs on an on-demand basis, and is triggered by a request for goods from the GPS Procurement Section. This request follows the stock review exercise described below.

**2.14** Review of contracts, with the aim of ensuring a continuous supply of goods, is the prerogative of the Procurement Officers. Main tasks of the Procurement Officers are to maintain stocks, monitor the status of contracts, trigger replenishment and advise on renewal contracts 18 months prior to expiry of the one in force.

### Description of GPS inventory strategy

**2.15** Up to August 2002, GPS adopted a strategy of holding up to twelve months' equivalent consumption as maximum stock level<sup>6</sup>. Since August 2002, GPS has endeavoured to adopt an inventory strategy<sup>7</sup> that reduced maximum stock levels to the equivalent of six months' consumption<sup>8</sup>.

<sup>6</sup> Consumption in this regard is considered by GPS to be the volume issued (by GPS) to the pharmacies and does not reflect actual end-user consumption.

<sup>7</sup> Excluding exceptional items.

<sup>8</sup> Six months' amounts are calculated by dividing the previous twelve months' issues by two.

**2.16** GPS procuring officers, responsible for maintaining sufficient stock within GPS to be able to supply the pharmacies (but not too high a stock to cause unnecessary waste of resources), since August 2002 were instructed to follow GPS strategy to store a maximum of six months stock. The procurement officers are expected to implement this strategy by reviewing items under their charge periodically, at least once every two months. During the review, they calculate the annual consumption (based on the figures for the previous twelve months). Next they determine the amount in stock and any stocks due to arrive (ordered but not yet delivered). The formula used to maintain the six-month stock is:

$$O = E - ((S + P) - D)$$

where:

- O** is the amount to be ordered (in months)
- E** is the equivalent of six months stock demanded (in months)
- S** is the stock position at GPS (in months)
- P** is the quantity on order (in months)
- D** is the maximum delivery period as per the contract with the supplier

**2.17** Through this exercise, GPS endeavours to meet two objectives: to ensure that it has adequate stock and, simultaneously, minimise stock holding.

**2.18** As a parallel process, GPS has outsourced a consultancy firm to report on its state of operations in keeping and handling stock. The relevant terms of reference included the formulation of a new inventory policy. In the interim, the six-month consumption policy is still currently in use.

### NAO case study results

**2.19** In order to assess the inventory strategy in terms of relevant holding costs and stockouts, NAO selected a frequently-transacted GPS stock item – Salbutamol 100mcg Inhaler BP dispensed in a pressurised metered-dose inhaler, being a first-line drug used in the treatment and prevention of asthmatic attacks and particularly important to treat acute asthmatic attacks. Various tests were carried out on receipts and issues over the years 1999 to 2003.

**2.20** The initial exercise consisted of computerising the bin card entries. These were opted for, in favour of the computerised records, given the time lag built into computer record entries (as explained in Paras 2.31 and 2.32 below). Entries were corrected for mathematical errors and errors of omission. In addition, stock availability dates following receipts were amended to include the quarantine period as receipt transactions in the bin card exclude this quarantine period.

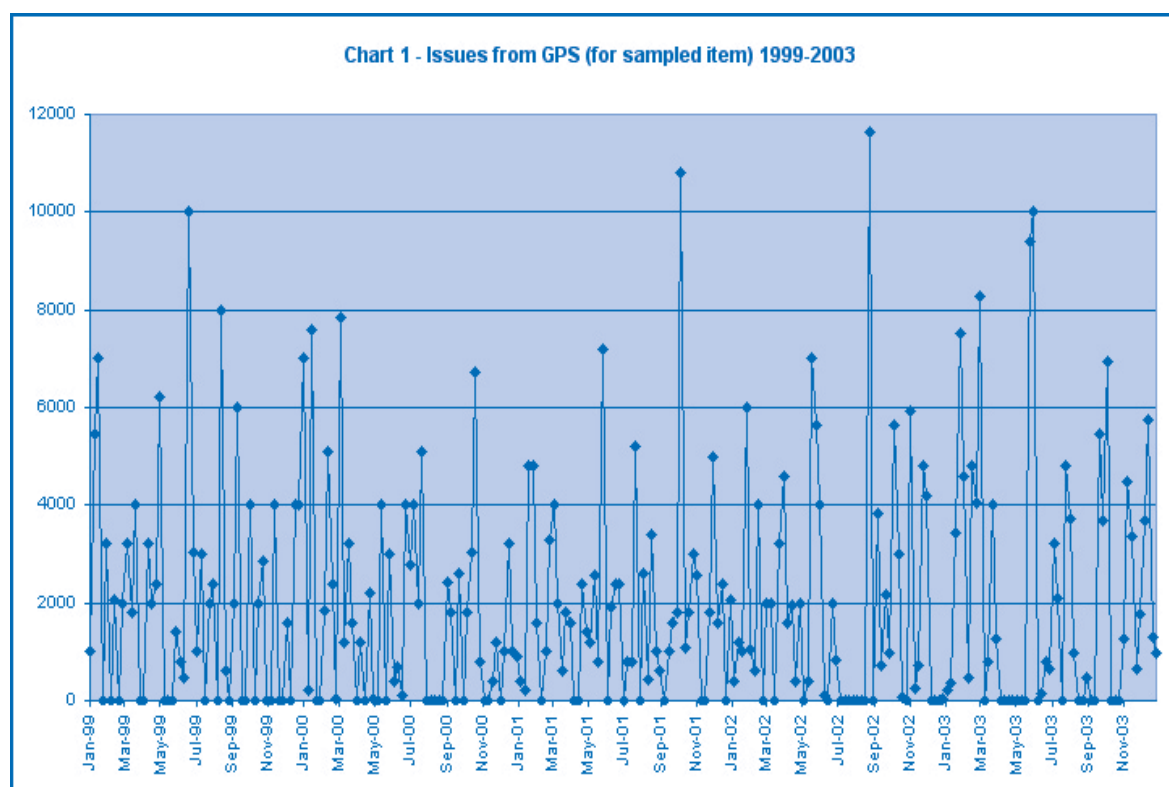
**2.21** An analysis of GPS issues to pharmacies for years 1999 to 2003 (Chart 1 below) revealed that these did not follow a pattern or trend and were random, even without any element of seasonality.<sup>9</sup> However, demand has been stable during these years – no significant changes were observed in demand levels during the period in question.

**2.22** The study then focused on the ability of GPS to manage stock economically by minimising holding costs and increasing stock turnover ratio<sup>10</sup> while reducing the risk of stockouts.

### Assessment of the Inventory process

**2.23** As stated in the introduction, only the relevant holding costs are being considered in this assessment. These costs are being assumed to be the cost of holding funds tied up in stock on a daily basis, that is at the 2003 going rate of five per cent of value of stock in hand. Weighted average unit cost of the item in question, as at end 2002<sup>11</sup>, was taken as the basis for (item-specific) calculations.

**2.24** Table 4 opposite shows annual holding costs, stock turnover and stockout days, for years 1999 to 2003.



<sup>9</sup> This led NAO to eliminate any consideration of the Economic Order Quantity (EOQ) model in its evaluation. EOQ models assume a deterministic and continuous demand. Given the random pattern of issues experienced at GPS, EOQ models do not fit the processes at GPS.

NAO's exercise was limited to GPS issues to pharmacies, as it was not possible to include stock levels and transactions of pharmacies, given the lack of data available at the pharmacies.

<sup>10</sup> Stock turnover ratio is defined as Annual Consumption divided by the Average Daily Stock held. Dividing Daily Average Stock by Annual Consumption and multiplying by three hundred sixty five days gives the number of days an item is stocked before issue.

<sup>11</sup> Cost of the item taken into consideration was Lm0.4831 per unit.

Table 4 – Actual GPS activity for the studied item 1999 – 2003

Year	Holding cost for the year Lm	Average number of days stock item was held on shelf	Stockouts (days)
1999	386.19	55	8
2000	1467.22	236	0
2001	1172.45	175	0
2002	468.71	74	54
2003	811.03	106	48

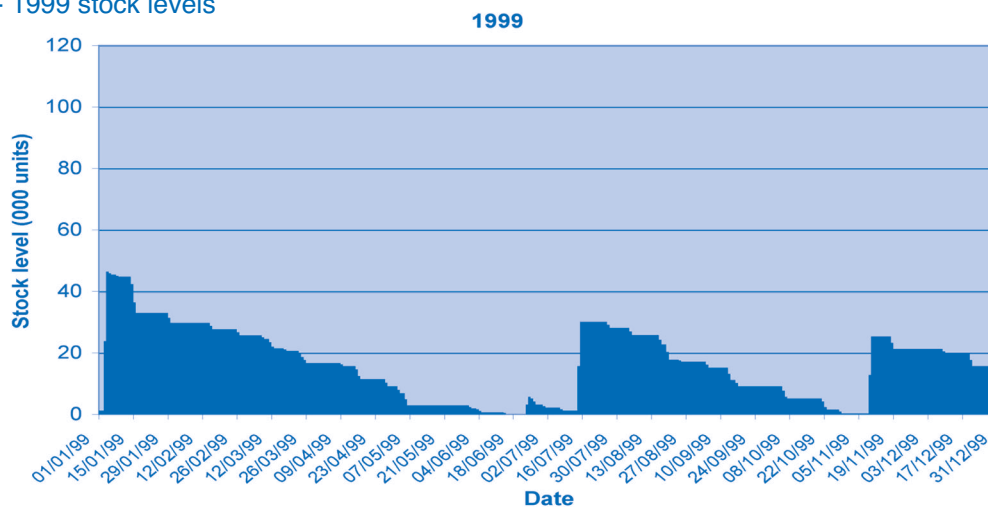
2.25 The table indicates that 1999 was the year when GPS handled this pharmaceutical item most economically and efficiently. The worst year was 2000, when costs and the number of days stocks were held on the shelf were the highest. On the other hand, the worst years for stockouts were 2002 and 2003 when the inventory policy described in Para 2.16 started being applied.

2.26 This inconsistent approach to managing stocks is more evident when the distributions of daily stock levels for the years in question are graphically presented, as per Chart 2 (a to e) below.

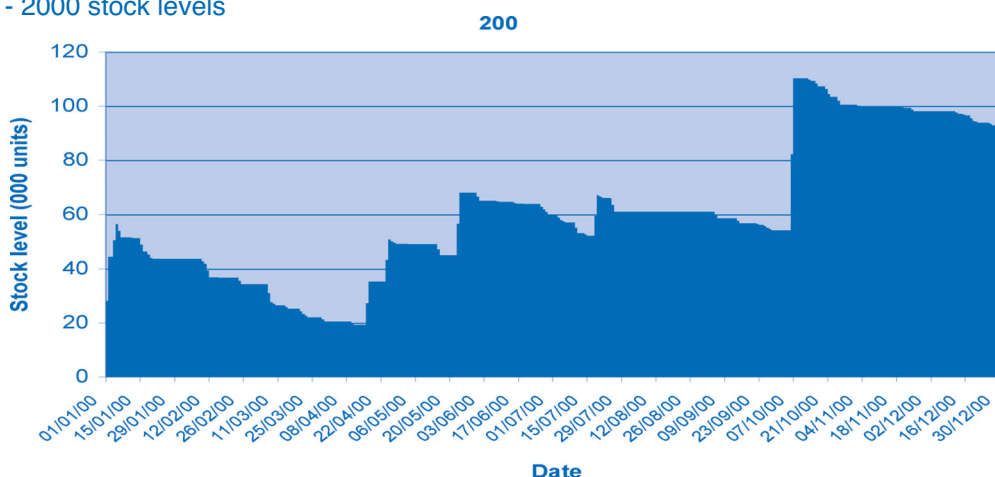
2.27 Inconsistent results indicate that GPS did not or could not follow its own strategy even after August 2002 when the current strategy as described in Para 2.16 was determined.

Chart 2 - Daily stock levels for the years 1999 - 2003

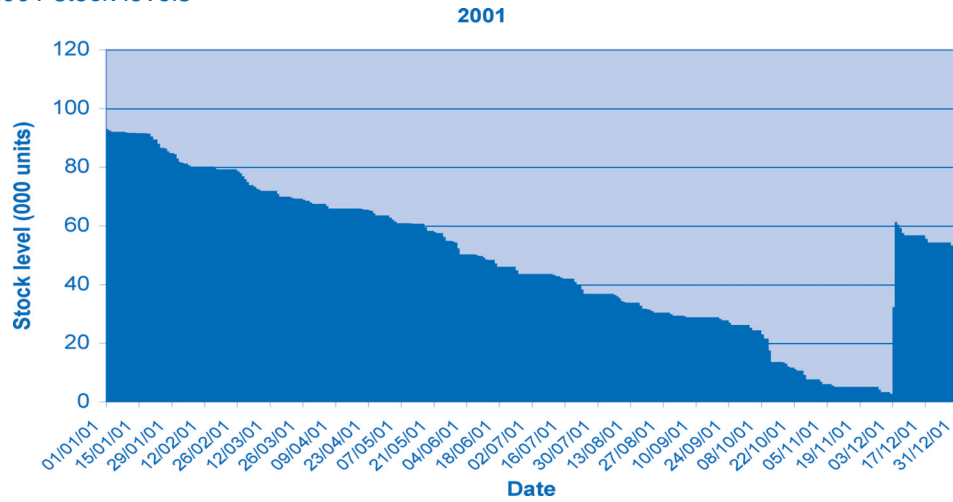
(a) - 1999 stock levels



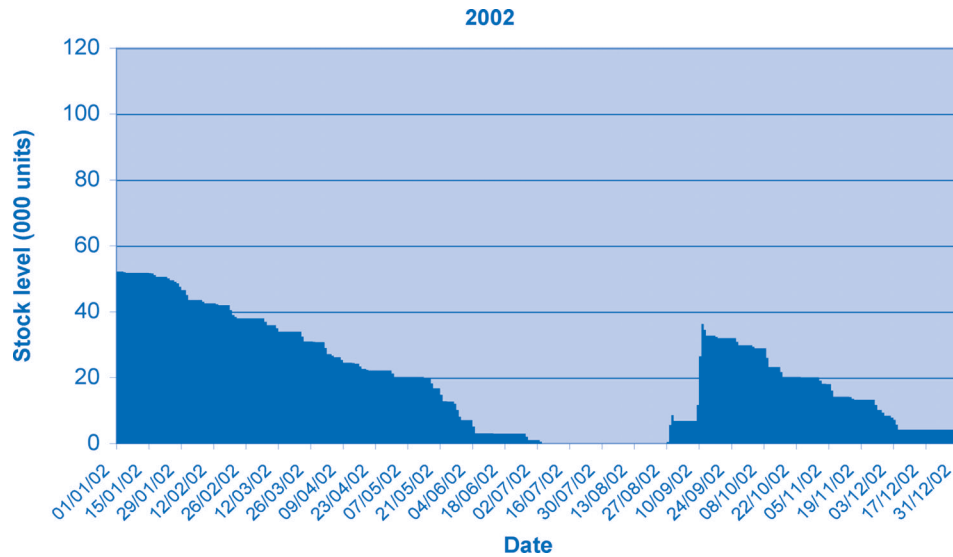
(b) - 2000 stock levels



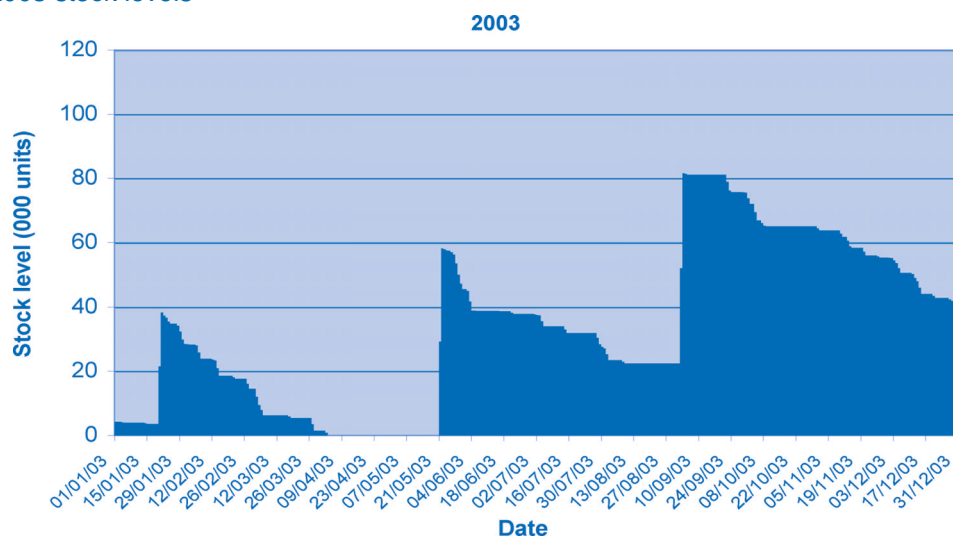
(c) - 2001 stock levels



(d) - 2002 stock levels



(e) - 2003 stock levels



### Issues conducive to inconsistency

2.28 The current operating system of stock control has in-built deficiencies that may be contributing to a less than optimal result in stock control and costs.

#### Limited information on demand and critical stock levels

2.29 GPS suffers from a limited knowledge on the nature of the demand. Demand pattern of the case study was random (as per Chart 1). If this randomness is present in all stock items, the issue becomes critical. Relevant demand patterns for the sampled item are illustrated in Para 2.21.

2.30 Moreover, GPS lacks readily available information on critical stock levels such as minimum, maximum and re-order levels.

#### Lack of completeness / accuracy of the computerized system records

2.31 While stock movements are recorded in real-time mode on the manual bin cards held by the storekeepers, reflecting actual movements as these occur, twenty-five per cent of 2002 computerized records were not posted in real-time mode.<sup>12</sup> This rendered some computerized records, on which the Procurement Officers partly base their reorder review, inaccurate due to the inherent time lag. Mismatches between transactions as recorded on-line on the bin cards and the computerized system are bound to arise, as audit tests have confirmed.

2.32 The computerized system currently in use carries incomplete and/or inaccurate information for re-ordering purposes. This compels Procurement Officers to resort to manual documents, apart from computerized records, during the execution of stock control and the re-order process, thus complicating the exercise which, by nature, should be more straightforward.

#### Interval-based stock control

2.33 An interval based approach to reordering is conducive to delayed response in cases of low stocks at hand. In extreme situations, GPS could very easily run out of stock, taking

<sup>12</sup> Computerised records pertaining to items stored and issued through Ta' Qali depot were not posted in real time mode as, up to 2002, GPS main offices at G'Mangia did not have a permanent IT link with Ta' Qali, its largest depot.

remedial action only when the item in question comes up for review. The problem is further compounded by the element of uncertainty or randomness in issues illustrated in Chart 1. Interval-based stock control every two months may be leading GPS to keep a higher stock than necessary in order to minimise the risk of running out of stock.

#### Quarantine

2.34 Physical receipt of a consignment does not lead to immediate availability of stocks for distribution. Given the nature of the goods in question, GPS tags receipts as quarantine. This triggers off a process, during which the goods in question are kept on hold, dedicated to the testing of the specifications of the goods delivered against those specified when ordered. While the process, given normal conditions and absolute compliance on the part of the supplier, takes a relatively short period of time, there were instances, in the reviewed case study, when due to abnormal conditions<sup>13</sup>, quarantine extended to a considerably longer period. Table 5 below lists quarantine periods as recorded for 2002 and 2003.

**Table 5 – Quarantine periods for consignments received in the period 2002-2003.**

Consignment receipt	Consignment release from quarantine	Days in quarantine
22 Aug 02	27 Aug 02	5
23 Aug 02	27 Aug 02	4
4 Sep 02	12 Sep 02	8
6 Sep 02	12 Sep 02	6
17 Dec 02	20 Jan 03	34 <sup>14</sup>
19 May 03	21 May 03	2
25 Aug 03	2 Sep 03	8

*Source: GPS computer records*

2.35 The quarantine period increases the delivery lead time, but is not taken into account by GPS in the re-order process.

<sup>13</sup> Such as non-compliance on the part of the supplier with the specifications previously agreed to when the contract was awarded.

<sup>14</sup> In this instance, GPS had procured the item from a new supplier for the first time.



### Contract conditions

2.36 This audit does not cover the policy to procurement (relationships with suppliers, middlemen, etc). However, it is evident that GPS, contrary to its own set Tender Technical and Special Conditions<sup>15</sup>, is committing itself to a wide range of delivery periods. In the case of the item under study, the prevailing contracted delivery date is set at six to fourteen weeks. This imposes the problem (for GPS) of having to maintain high buffer stocks in order to bridge long delivery periods.

### Other flaws at Division level

2.37 Apart from stocks held by GPS, the pharmacies in hospitals and health centres maintain their own stocks as well. However, due to lack of a comprehensive computerized system encompassing GPS and pharmacies, GPS does not have access to levels held at these pharmacies. In their review of stock levels GPS Procurement Officers can base their workings on GPS levels only.

2.38 In this way, GPS may experience fictitious stock-outs, with stocks being available within pharmacies, but not at GPS.

2.39 The non-availability of a complete picture on stocks held system-wide potentially leads to over-stocking from a Division perspective.

2.40 Given the limited shelf lives<sup>16</sup> of items and the lack of comprehensive knowledge of stock in hand, NAO doubts whether items with earlier expiry dates are being issued to patients.

### GPS Inventory Strategy

2.41 The inventory strategy itself, as described in Para 2.16, is problematic. A detailed explanation of this problem is given in Paras 2.54 to 2.59.

2.42 These drawbacks impinge negatively on the ability of GPS to adopt a consistent inventory strategy effectively.

### A more efficient approach to inventory modelling

2.43 NAO approached the search for better methods in two stages. The first stage of NAO's test consisted of simulating the strategy which should have been adopted strictly to the letter by GPS as per the formula described in Para 2.16. The second stage consisted of deeper evaluation of the robustness of the inventory strategy.

### Simulation with 2003 demand data

2.44 NAO assumed the current GPS strategy with a six-month maximum stock level, a two month review and a two month delivery lead time (6/2/2). The demand adopted in the simulation was the actual 2003 demand. The results are shown in Table 6 and Charts 3a and 3b below.

2.45 Table 6 below gives holding costs, stock turnover and stockout incidences for the simulation together with a comparison of the actual 2003 performance.

2.46 Results for the simulation, that is when abiding by the policy, do not show significant

**Table 6 – Actual GPS activity for the studied item and implementation (simulation) of six months stock levels – demand is that for year 2003**

Year/Scenario	Holding cost (per annum) Lm	Items' days on shelf (Stock turnover)	Stockouts (days)
2003 actual	811	106	48
Simulation with 6 months' equivalent max stock level and 2 months review and delivery lead times	893	117	0

<sup>15</sup> Delivery period as indicated in Para 10.2 of the Procurement Conditions is set at 3-4 weeks from order.

<sup>16</sup> The inventory system currently in use keeps track of stock expiry dates only for stocks at GPS.

## Part 2 - The Inventory Strategy at GPS

savings from actual operations – while the simulation proved more costly, actual handling resulted in a substantial stock out. This conclusion

requires that the inventory strategy is further analysed and evaluated as discussed in Paras 2.47 to 2.49.

Chart 3a - GPS 2003 (actual) daily stock levels

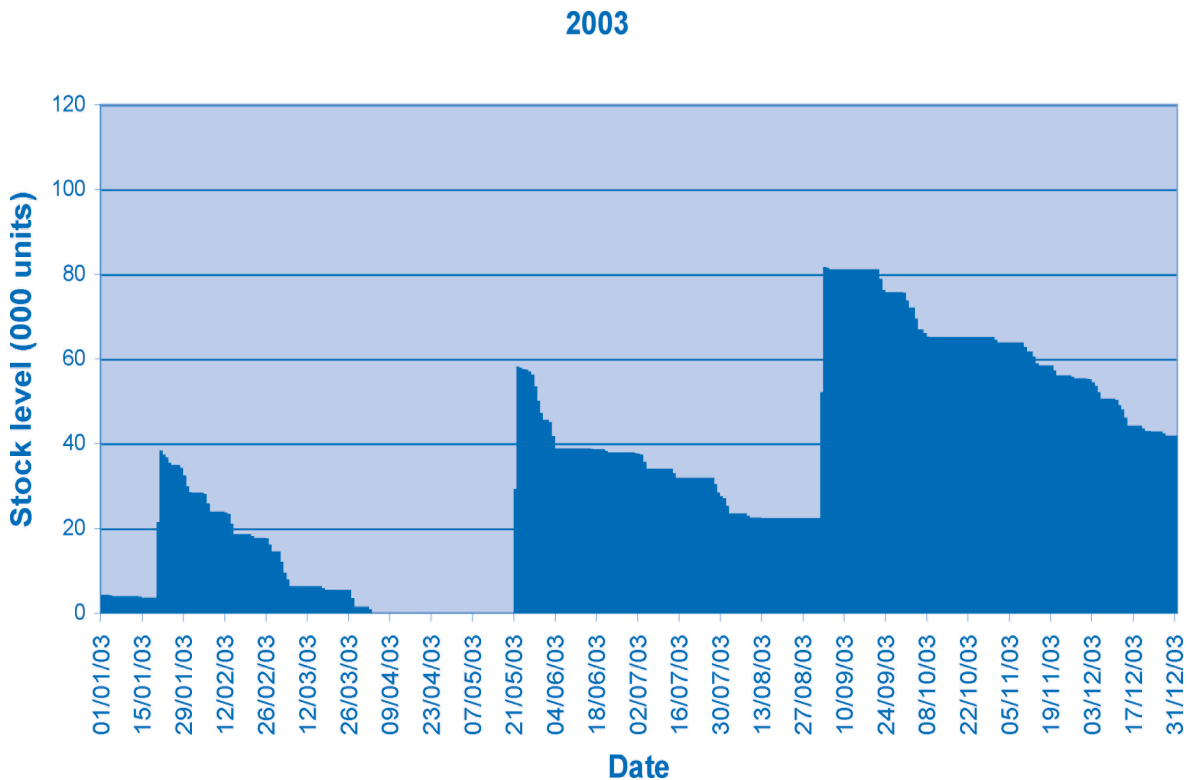
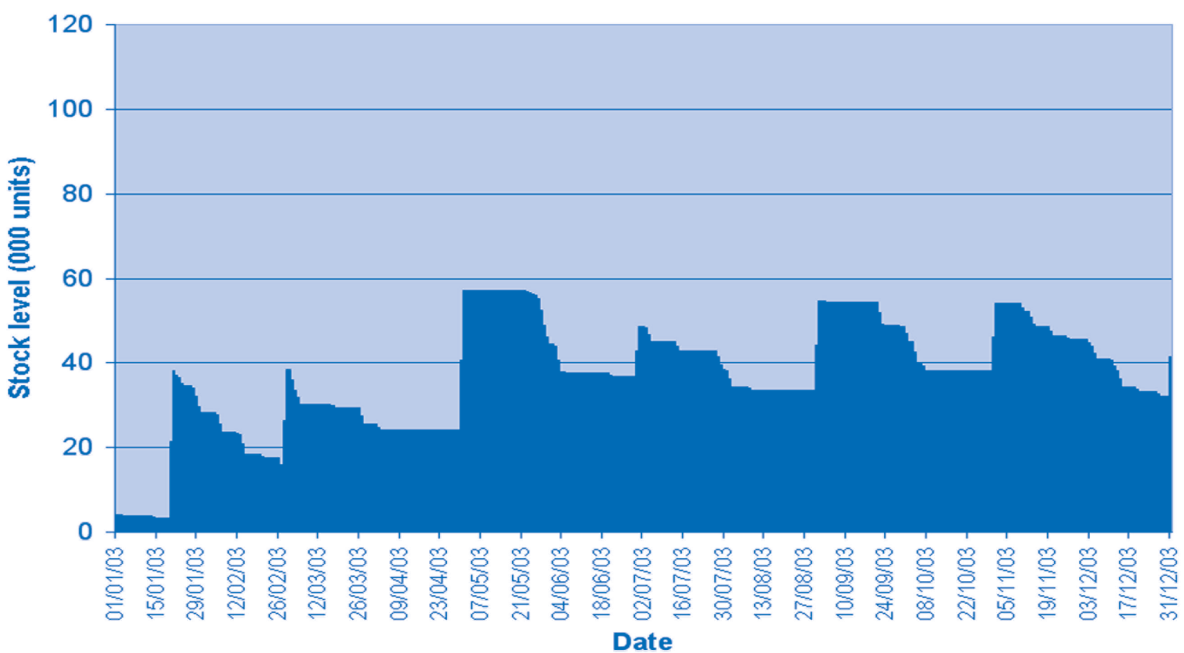


Chart 3b - Simulation of daily levels based on 6 months maximum stock level and 2 months review and delivery lead time as per GPS policy in Para 2.16



### Building a robust inventory strategy

2.47 The second stage of the analysis was testing the performance of the current inventory strategy as explained in Para 2.16 through the use of a large number of simulations, inspired by patterns of demand experienced between 1999 and 2003 of one stock item, namely Salbutamol 100mcg inhaler dispensed in a pressurised metered-dose inhaler. Simulations provide a cheap and evocative way of creating a deeper insight into the workings of relevant inventory systems and of illustrating how strategies implemented consistently flesh themselves out in daily performance. A stochastic model of the demand was defined and its parameters estimated from past records. A brief account of the model specification and estimation exercise conducted is included in Appendix B.

2.48 A large number of demand scenarios following the designated pattern were generated and the strategy in question was implemented on each one of these scenarios. Through the calculation of various performance statistics it was possible to compare a number of characteristics. Changes in the parameters (described in Para 2.52 below) of the ordering strategy were also effected and simulations made to run again to study corresponding changes in performance.

2.49 The simulation exercise in this instance provided a number of results and indications which need to be put forward and discussed. These are explained below:

### Results and conclusions from simulations

2.50 Performance measurements calculated included

- Average number of stockouts per year
- Average number of days with zero stock during a year
- Average holding costs per year
- Average number of orders per year<sup>17</sup>
- Average Ordering costs per year<sup>17</sup>

2.51 Ordering costs and holding costs were estimated through a number of techniques involving accounting principles and other relevant

<sup>17</sup> Ordering costs are not considered in this study due to their low materiality (as per Paras 2.4 and 2.7).

economic considerations. The initial stock could be varied but as the number of days over which the simulations were run exceeded 4000, this might as well have been left equal to the initial stock registered at GPS at the beginning of the period of the true records used in the estimation of the demand.

2.52 The parameters which were systematically changed were:

- Span of previous months for determining demand;
- Top-up stock in terms of monthly estimated demand based on demand over previous months;
- Lead time;
- Length of review period.

2.53 Maximal demand was limited to 12,000 so that demand was clipped to this figure when maximal demand as generated exceeded this limit.

2.54 Examination and comparison of holding costs and stockouts resulting from simulations has an element of arbitrariness and lack of precision because GPS are practically unable to define social and practical costs involved during stock-outs. Furthermore there are no fixed rules for determining the urgency with which the policy of elimination of stock-outs should be pursued. It is immediately obvious that this consideration is of paramount importance.

2.55 The main observations derived from studying simulation results of current GPS inventory strategy were:

- a) Increasing the top-up level of stock has an obvious negative impact on holding costs with a relatively small improvement on stock-out frequency diminution;
- b) Orders based on estimated span of previous demand have a large impact on determining whether or not the inventory tends to overstock over long periods. The stochasticity of demand generates periods of low demand and others of abnormally high demand. Responsiveness to these fluctuations would ensure smaller probabilities of stockouts but also a general tendency leading invariably to

overstocking. Averaging over longer periods from previous data tends to smoothen out kinks of high demand, but it makes the inventory less sensitive to high demand as it arises.

- c) Long lead times are obviously completely undesirable but the costs of having very short lead times is not known, though it should also be mentioned that in practice lead times tend to have a stochastic element in them.
- d) The length of the review period, and hence of potential ordering instances, is also very influential in “causing” overstocking to develop over time. It is clear that shorter review periods can allow GPS to keep smaller top-up levels. However fixed period review methods are not suitable in the presence of stochastic demand. It is clearly much more suitable to keep a constant check on stock-level and place an order once estimated demand and present stock level deem it propitious. This observation is referred to again in recommendations included in this section.

### Conclusions

2.56 The inconsistency in managing stock levels in this case revealed that GPS did not maintain its inventory strategy as per Para 2.16. At some stage, a decision was taken that a good ordering strategy which would minimise keeping unnecessarily high stocking levels would be to abandon the policy adopted by GPS as per Para 2.16.

2.57 Analysis performed through the computerised simulations, showed that consistent implementation of the fixed inventory strategy currently owned by GPS seems to lead to higher holding costs and stockouts than the actual GPS results.

2.58 However, the simulations also showed that reducing maximum level of stock held from six to three months’ supply and a delivery lead time of one month, reduced holding costs by half, at the expense of higher stockouts.

2.59 Notwithstanding, the adopted ordering policy was erratic in that it gave little thought to the problem of deciding whether the stocking levels are too high or too low except when the

situation was getting or had already gone wout of hand.

2.60 GPS contends that it is still not satisfied with the overall results and is currently trying to develop a more economic inventory strategy.

2.61 NAO proposes the adoption of a better inventory strategy and is recommending guidelines on how this can be realised. Therefore, the following comments should be seriously considered.

### Recommendations

2.62 GPS has already taken up NAO’s advice to study stock behaviour in detail, enabling the identification of an optimal inventory strategy. It is acknowledged that implementing such an inventory strategy involves an exercise that is lengthy in nature.

2.63 Recommending guidelines to determine such a strategy are given below.

2.64 An optimal inventory strategy can only be worked and evaluated with some degree of precision when the objective function and the accompanying set of constraints which need to be satisfied are specified with clarity and unambiguously.

2.65 First, a suitably defined objective function should include fairly accurate estimates of the following costs:

- a) Obsolescence,
- b) Holding Costs (including opportunity costs),
- c) Pricing by Quantity Schemes within the Pharmaceutical Industry (Bulk Buying rebates),
- d) Variation of Prices over time,
- e) Costs of Stockouts, and
- f) Ordering Costs (administrative and logistic costs involved in having an order placed and delivered within a stipulated time)

2.66 A good method of incorporating such costs by means of a suitable formula into an aggregate cost function which is meaningful and faithfully reflects reality to an acceptable degree is advisable.

2.67 Secondly, constraints governing the nature of the inventory have to be identified and possibly quantified. These would nominally focus on one major condition: to never face a demand without the ability to deliver the required quantity - that is no stockouts. In a deterministic scenario this would be possible but in a stochastic setting as in the case study, it is technically impossible.

2.68 Constraints impinging on this sole major condition which need to be identified include:

- Maximal Storage
- Maximal Demand
- Minimal Order Quantity
- Maximal and Minimal Lead times (also probabilistic in nature and at times highly fluctuating)

2.69 The nature of demand, being stochastic, is the critical challenge in generating better operations at GPS. This is compounded by the nature of items themselves which are often in packages and/or doses of different sizes. This problem has to be tackled through experimenting with various multi-term formulations and analyzing past data available.

2.70 One consideration which should be emphasized is that it should be clear to planners

at GPS that superior strategies would be triggered by tracking stock levels rather than by fixed review periods, as currently practiced by GPS.

2.71 It is clear that in trying to build a model to fit from scratch a complex situation like the pharmaceutical procurement system one needs to go about the task in a gradual, incremental manner. One needs to start from the over-simplistic as a point of departure and progress on to a more sophisticated model as more realism is built in. Priority can be assigned to high value and/or fast moving items.

2.72 The inventory system at GPS carries high costs, both monetary and social. The task of improving on current inventory strategy is critical to GPS and may require suitable professional help on a regular basis with the major task of updating such a strategy continuously.

2.73 Moreover, it is critical for GPS to view the inventory system in its entirety. It would be futile to address the inventory policy without including in the assessment, the substantial stocks found within the distribution system down the line to the final consumer or patient.

2.74 The next chapter will deal with problems encountered in the distribution system which need to be addressed in conjunction with the development of a more robust inventory strategy.





## Part 3 - Stock Management in Government Pharmacies

## Part 3 - Stock Management in Government Pharmacies

### Introduction

3.1 Part 3 of the report:<sup>1</sup>

- a) focuses on the adequacy and reliability of stock management systems in government pharmacies;<sup>2</sup>
- b) studies the impact that the broader environment has on the studied processes; and
- c) evaluates how stock control systems and pharmacy practices can be strengthened through:
  - i. the creation, communication and enforcement of written internal procedures;
  - ii. the determination of responsibilities of key managerial and supervisory positions;
  - iii. better access to sufficient resources and support.

3.2 Analytical fieldwork to assess stock controls in a sample of nine government pharmacies was undertaken in 2003, as part of the performance audit.

3.3 The fieldwork focused on the pharmacies' stock control measures with respect to the receipt, stock-keeping and dispensing / re-distribution of pharmaceutical items to outpatients / hospital wards. The following were the main findings:

- a) Documents and records kept by the pharmacies did not permit a satisfactory audit trail to be traced through the reviewed systems;

- b) The requisition procedures and paperwork between GPS and pharmacies were found to be reasonably uniform and controlled by a single central body (GPS);
- c) There were weaknesses in the systems that control and document stock movements in pharmacies. Shortcomings included:
  - i. no uniformity in the stock management system, with pharmacies adopting different levels of control and type of documentation;
  - ii. an overall absence of written procedures;
  - iii. the prevalence of inadequate and, at times, unreliable stock control; and
  - iv. an unsatisfactory audit trail of issues to outpatients and hospital wards.

3.4 Changes have been introduced over the past year by some government pharmacies with the aim of enhancing stock control and advancing good pharmacy practice. However, the nature and pace of this progress has varied considerably in each pharmacy and overall the Departments concerned are still planning or developing the essential framework and infrastructure (such as clear managerial and supervisory responsibilities, standard operating procedures and adequate resources) that can eventually sustain an adequate and reliable stock management system.

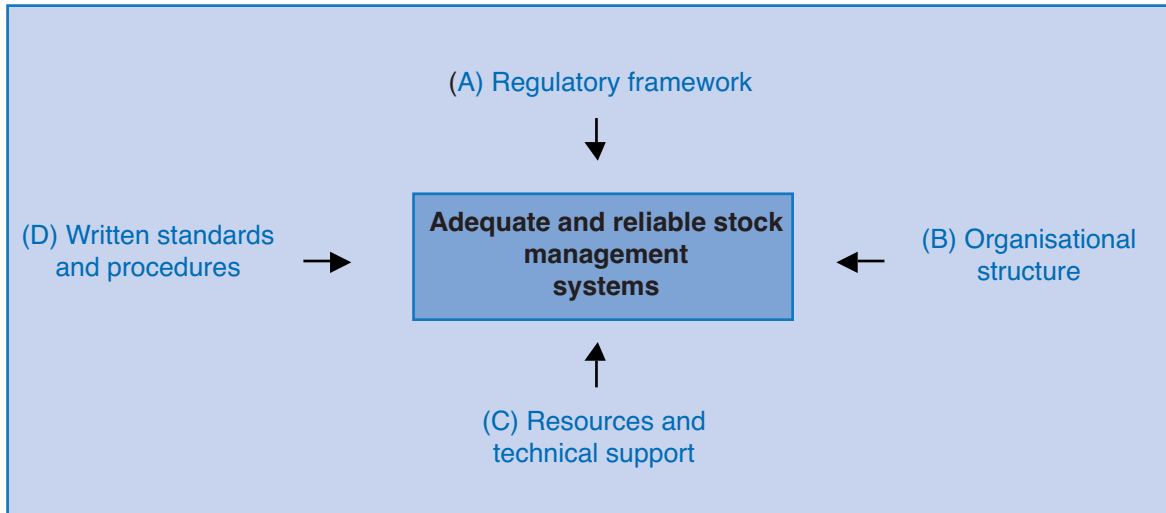
3.5 The analysis below also shows that significant work still needs to be done to ensure that all government pharmacies have written procedures (SOPs) that establish adequate stock control and minimise risks.

3.6 This part of the report is divided into four sections, each focusing on a factor influencing

<sup>1</sup> A detailed overview on the methodology applied during the performance audit is presented in Appendix A of the report.

<sup>2</sup> Government pharmacies are managed by the Institutional Health Department, the Primary Health Care Department and the Ministry of Gozo.

Figure 3.1 Four factors that are influencing the degree of stock control and good pharmacy practice in government pharmacies



the degree of internal stock control and good pharmacy practice within government pharmacies (depicted in Figure 3.1 above). At the end, the main conclusions and recommendations are presented.

3.7 These sections are:

- A. **The regulatory framework** which should ensure that government pharmacies comply with regulations and standards governing the keeping and movement of pharmaceutical stocks (section A below).
- B. **The organisational structure** which must facilitate leadership and management and ensure there are clear lines of responsibility and accountability within the organisation. (section B below).
- C. **The resources and technical support** available to management and pharmacy staff to ensure effective stock management (section C below).
- D. **Written standards and procedures** which should guide and control activities related to requisition, stock-keeping, and dispensing / distribution of pharmaceutical stocks in government pharmacies (section D below).

### A. The Regulatory Framework

3.8 Enhanced regulatory requirements should help strengthen controls over the distribution of pharmaceutical items through government pharmacies. However, progress still remains to be achieved by the Licensing Authority, the Medicines Authority and the Departments concerned in order to ensure adequate compliance with licensing and regulatory requirements.

3.9 The distribution process of pharmaceutical products is subject to a national legal framework, in particular the Medicines Act, 2003.

3.10 The national legislation establishes the minimum standards required when stocking and dispensing pharmaceutical products such as the obligation to have:

- a) qualified personnel,
- b) suitable premises, and
- c) appropriate registers, records, and documents.

3.11 The revised legislation also stipulates that government pharmacies will be required to hold a license to be able to operate and enables the Licensing Authority, through the Medicines Authority, to conduct regular inspections by an



inspecting officer authorised by the Superintendent of Public Health to ensure that regulatory requirements are being observed.

**3.12** However, official communication between the effected Departments responsible for government pharmacies, the Licensing Authority and / or the Medicines Authority has not yet been established. Moreover, the management of government pharmacies has expressed concern on whether it will be possible to ensure that these regulatory requirements and standards can be met due to a number of constraints.

**3.13** The following issues were raised by the Departments concerned as possible barriers or limitations to compliance with the regulations:

- a) Internal policies of the Health Division in response to these new regulations have not been finalised and communicated to the departments and pharmacies concerned.
- b) Consequently, plans and programmes by the departments to achieve compliance have not been drawn up.
- c) New investment is required to ensure that government pharmacies have the required premises and infrastructure.
- d) Additional funds are also required to ensure regular maintenance of premises.
- e) Adequately trained personnel and management positions need to be allocated to ensure compliance.

### B. Organisational Structure

**3.14** Since July 2001, the Health Division has introduced gradual, albeit protracted, changes to the organisational setup and the management of pharmaceutical activities in government hospitals and health centres.

**3.15** More changes are envisaged by the Health Division as health institutions are empowered with greater autonomy and changes are made to the systems in the respective hospitals and health centres.

**3.16** One of these changes has been the decentralisation of pharmaceutical services in hospitals and health centres, with the units within the IHD, the PHCD and the Ministry for Gozo taking over the technical and staffing

responsibilities from the GPS as part of the overall management of pharmacy operations.<sup>3</sup>

**3.17** The current organisational structure is presented in Figure 3.2 opposite.

**3.18** Throughout the audit, however, it was observed that there were weaknesses and risks in the way the changes have been implemented and concerns remain on the current *modus operandi*:

- a) The changes introduced by the Health Division were not being adequately communicated to the staff concerned, leading to uncertainties on the role, accountability and reporting relationships of certain positions in the organizational structure.
- b) Coordination amongst all the government pharmacies has been gradually phased out with no alternative coordination unit being created to develop and monitor pharmacy practices in the public health care sector. The Health Division has indicated that these shortcomings should be addressed with the eventual creation of a Department for Pharmaceutical Affairs. No specific timelines have, however, been set.
- c) Job descriptions introduced with the 1993 agreement with the union representing pharmacists have not been updated to reflect these new developments. Consequently, members of staff responsible for pharmaceutical services are not clearly aware of the responsibilities their respective posts entail and how the changes being introduced are affecting their duties and tasks.

### C. Resources and Technical Support Available to Government Pharmacies<sup>4</sup>

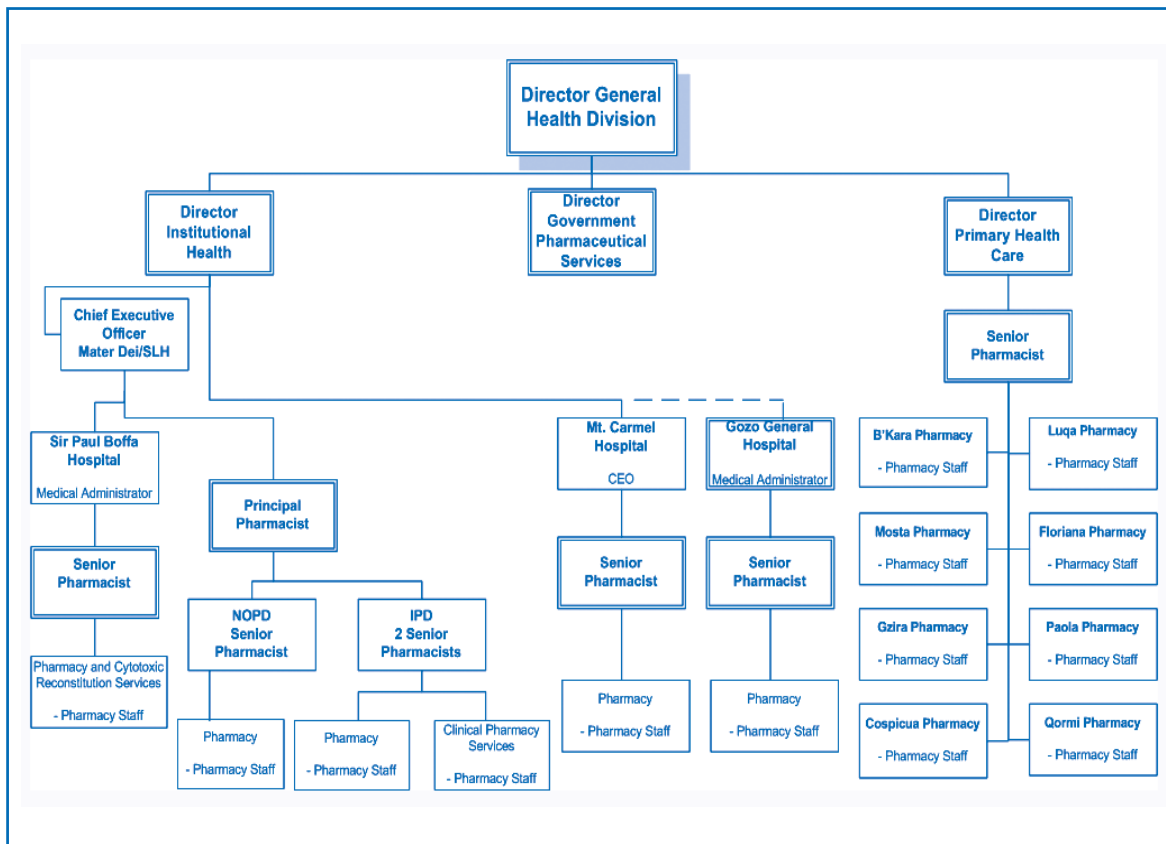
**3.19** The resources and technical support available to the government pharmacies in order

<sup>3</sup> Prior to 2002 technical issues related to the coordination of pharmacy activities including staff movements and procedures were being centrally managed by GPS, whilst administrative issues were being decided by the Directors responsible for the Department of Primary Health Care and the Department of Institutional Health.

<sup>4</sup> Preparatory work that will lead to the re-organisation of the framework that will support the future Pharmacy Department at Mater Dei Hospital is currently being undertaken by the Foundation for Medical Services. At this early stage, the effect of these changes on the distribution of pharmaceutical products in government pharmacies could not be assessed by NAO.

## Part 3 - Stock Management in Government Pharmacies

Figure 3.2 An organisational chart showing only the management of government pharmaceutical services in the public health care sector



Source: Health Division, 2004

to implement an effective stock control system were also taken into consideration during the study. The following are the main findings:

- a) The IHD and the PHCD have both indicated that limitations on available financial and human resources may prevent them from introducing new measures and standards in government pharmacies. (refer to Section A above);
- b) There is the need of better coordination and monitoring of pharmacy activities. (refer to Section B above);
- c) In the past, initiatives to promote good pharmacy practices were not successful as the proposed systems were not monitored and maintained by all the pharmacies. Two such cases were the Pharmacy Manual (introduced in 1998 but never fully developed) and the guidelines for good pharmacy practice (drafted in 1999, circulated amongst staff but never officially endorsed). These two documents were intended to provide guidance to pharmacy staff on official policies, standards and procedures.
- d) Internal circulars and memoranda (e.g. DH circulars, GPS circulars and hospital circulars) on various issues concerning policies and procedures, issued through the Director General (Health Division) or through Directors within the public health care sector, have provided limited guidance to staff on specific issues.
- e) According to the departments concerned (IHD and PHCD), support from the National Medicine Policy and Audit Unit (NMPAU) within the Health Division on policies and guidelines to pharmacies was negligible. Since its inception in 2001, the NMPAU has also not carried out monitoring or audit activities in government pharmacies, as its name implies. The Health Division has,



however, indicated that there are plans to strengthen the Unit by absorbing it into a Department of Pharmaceutical Affairs to be set up within the Health Division.

- f) Training offered to pharmacy staff in this field has been limited. Apart from the training of a hospital pharmacist on quality systems, the respective departments have indicated that over the past years the only planned training activity for pharmacy staff was a course on stores management in September and October 2002. This course was attended by managing pharmacists and stores officers from hospital pharmacies but was not extended to staff in pharmacies at health centres due to lack of allocated funding. Although the audit did not carry out a detailed analysis of the quality and the adequacy of the training provided, it was noted during fieldwork that there was need for more coordinated training on stock management and pharmacy practices in order to ensure that the skills and abilities of staff responsible for pharmacies and stocks are reinforced.
- g) There has been limited use of information technology to manage and control stocks in government pharmacies. Although there has been new investment in this field in four hospital pharmacies, other pharmacies (one hospital pharmacy and eight health centre pharmacies) are without dedicated software<sup>5</sup>. Moreover, software at two of the four hospital pharmacies (installed between 2002 and 2003) was found to be restrictive and there are plans to replace the packages in 2004 by a different system. This study did not undertake an in-depth assessment of the effectiveness of the new IT systems as the infrastructure was still being developed and introduced during the course of the audit. However, it was noted that:
  - i) The upgrading of information technology (including better infrastructure) should improve the overall control and efficiency in government pharmacies.
  - ii) New systems should interface with the wider environment, especially hospital

<sup>5</sup> In the case of health centres, discussions are in progress on the overall reforms required and this will have an impact on introduction of new systems.

operations (such as the wards) and the supplier (GPS), in order to ensure that data can be stored and accessed at all stages of the distribution process.

### D. Written standards and procedures

**3.20** In 2003, pharmacies visited by the NAO did not have written procedures that reasonably cover stock management and pharmacy activities.

**3.21** Since then, however, two out of twelve pharmacies have developed and established SOPs for activities within the pharmacy.<sup>6</sup> These documents were created independently of each other and standards adopted by the respective pharmacies were different and did not include the same specifications or level of detail. The procedures were created by the staff in each pharmacy and endorsed further up in the hierarchy.

**3.22** Although the audit did not assess in detail the technical and operational quality of these procedures, it was observed that the exchange of practices and procedures between the two pharmacies could have helped create a better set of SOPs for both.

**3.23** Overall, the two sets of SOPs cover various areas, including the organisation of stores, staff responsibilities, staff replacements in the absence of key personnel, the conditions for storage, monitoring of stock items, methods of stock rotation, handling of expired or damaged products, ordering procedures, delivery and checking of ordered stock, documentation and authorisation required, maintenance of bin cards and computer records, redistribution of items, keeping of records, filing system, reporting, ward orders and preparation and delivery of items to wards.

**3.24** As such, despite the inconsistencies, the newly introduced SOPs will serve as an important management and internal control tool. Risks remain, nonetheless, in ensuring that all the specified steps and practices are adequately communicated to the staff, implemented, managed and monitored.

<sup>6</sup> A separate visit was conducted by the NAO in April 2004 to measure progress in the compilation and / or implementation of written procedures (SOPs) in government pharmacies. The only pharmacies not visited or contacted were the pharmacies in St Vincent de Paule Residence, Zammit Clapp Hospital and in the new health centre in Cospicua. (Refer to Appendix A for more details).

## Part 3 - Stock Management in Government Pharmacies

3.25 Most of the pharmacies, however, remain without an overall policy framework as well as adequate or written procedures to manage stocks and other activities in pharmacies.<sup>7</sup>

3.26 By not having and / or enforcing uniform documented procedures on stock management and pharmacy practice in government pharmacies, the Departments are increasing their risks related to the following:

- a) the risk of middle management and pharmacy staff not knowing what is required for each activity or task, as well as the sequence in which to perform those steps;
- b) the risk that accountability and responsibility are not clearly defined (although this may be specified in detail in job descriptions);
- c) the risk that records and documents are not kept properly;
- d) the risk that the proper storage conditions are not maintained;
- e) the risk that precautions from deterioration, waste, pilferage and public health risks are not taken;
- f) the risk that the organisation and staff are not safeguarded against legal liability;
- g) the risk that the pharmacies will not be compliant with licensing and regulatory requirements; and
- h) the risk that traceability would be lost in the event of a product recall.

### Conclusions and Recommendations

3.27 The study carried out by NAO on the requisition, stock management and issue of pharmaceutical products in government pharmacies clearly demonstrates that the Departments concerned should continue to introduce new measures to strengthen the management of stocks in particular the development, coordination and monitoring of procedures.

<sup>7</sup> One of the pharmacies without adequate procedures has created a set of SOPs which, however, are not wide ranging enough to ensure a suitable control framework for the pharmacy and stores environment.

3.28 These measures should, however, be carried out with a wider commitment from all levels in the organisation and in a more coordinated and organised manner, in order to minimise the exposure to risks identified earlier in this section of the report.

3.29 More specifically, the management of the IHD and the PHCD should strengthen their systems by:

- a) Updating of the job description of the post of Principal Pharmacist within the organisational structure and defining how the post should support senior management and pharmacists managing pharmaceutical services.
- b) Ensuring that the post/s of Principal Pharmacist are supported with adequate resources.
- c) Improving the documentation and authorisation processes in order to ensure that a reliable audit trail can be established throughout the distribution process.
- d) Establishing and enforcing a uniform policy on the retention of records and documentation.
- e) Establishing the standards of good pharmacy practice and stock management procedures expected in all government pharmacies.
- f) Ensuring that clear and comprehensive written standard operating procedures are compiled, managed and enforced in all pharmacies, including official templates of stationery to be used by pharmacy staff.
- g) Liaising with the Licensing Authority and the Medicines Authority and taking coordinated steps to ensure compliance with regulations.
- h) Enhancing learning and communication amongst pharmacy staff on matters such as good pharmacy practice, new regulatory requirements and stock management processes.
- i) Expediting the installation of suitable management information systems in all government pharmacies, ensuring that the systems are holistic and integrative within the public health care sector.

- j) Preparing operational plans to ensure that measures to narrow gaps in the control systems are properly undertaken.
- k) Taking measures to ensure that new initiatives to improve standards do not fall on the wayside and are successful in the long-term (e.g. top management commitment, allocating adequate resources, selecting project champions, and forming task forces to promote, monitor and review progress).
- l) Ensuring that investigations and follow-up action are undertaken when stock discrepancies are found.
- m) Introducing a monitoring system that ensures that established controls and procedures are being fully and consistently implemented. This can also be enhanced with the development of an internal audit system that monitors stock management in the public health care system.

A blue-tinted photograph of a scientist in a lab coat and mask, wearing gloves and pouring liquid from a beaker into a test tube. The scene is set in a laboratory with various glassware visible in the background.

## Appendices

## Appendix A - Methodology

### Methodology

The National Audit Office adopted a variety of methods in the examination of:

- a) the inventory strategy currently in use at the Government Pharmaceutical Services (GPS); and
- b) the adequacy and reliability of stock management systems in government pharmacies.

The main methods adopted were:

#### A. Modelling Demand for Pharmaceuticals

NAO made use of computer simulations in order to test the performance of the current GPS inventory strategy. This exercise was based on the demand for a GPS stock item for the years 1996 to 2003. The results obtained provided a deeper insight into the workings of the current GPS inventory strategy. A stochastic model was defined and its parameters estimated from past records. Appendix B features a brief account of the model specification and estimation exercise conducted by the NAO.

#### B. Visits to government pharmacies

During 2003 and 2004, the NAO undertook visits to government pharmacies. A framework of questions was constructed to guide the fieldwork and during these visits pharmacy staff was asked several questions on systems and procedures.

#### C. The examination of a sample of records kept in nine government pharmacies

Tests were undertaken to assess the robustness and accuracy of records kept in a selection of nine government pharmacies in hospitals and health centres. The aim of these

tests was to establish the level of internal control and the quality of records kept in these pharmacies. However, at various stages in the requisition, stock management and issue process, the traceability of documents to bin cards and / or computer records was difficult or laborious to establish. As a result, some of the tests had to be aborted without the achievement of sufficient evidence.

Nine government pharmacies were included in this part of the study. These were the following:

#### Hospitals

1. In-Patient Dispensary, St. Luke's Hospital
2. Out-Patient Dispensary, St. Luke Hospital
3. Pharmacy, Mount Carmel Hospital
4. Pharmacy, Sir Paul Boffa Hospital
5. Pharmacy, Gozo General Hospital

#### Health Centres

6. Pharmacy, Paola Health Centre
7. Pharmacy, Floriana Health Centre
8. Pharmacy, Mosta Health Centre
9. Pharmacy, Birkirkara Health Centre

Wherever possible, a sample of documents and computer entries recording stock movements in government pharmacies were examined. The sample was made up of twenty stock items, selected from GPS's computer records on the basis of the most frequently ordered by individual pharmacies during 2002.

A spot check was also carried out in the nine pharmacies to test whether the physical count of the sampled items matched with the balances in the bin cards or the computer records, and to identify the causes of such discrepancies in the records.



### **D. Regular meetings and communication with key personnel**

NAO consulted with key personnel within Ministry of Health, the Elderly and Community Care and the Health Division through correspondence and meetings in order to obtain a broader perspective of the key factors affecting the management of the distribution processes, and to follow-up on issues raised during fieldwork and analyses.

### **E. Documentary Review and Data Analysis**

Forwarded data and documentation, such as reports, written procedures and copies of circulars and correspondence related to pharmacy operations and the procedural environment were also reviewed by NAO.

## Appendix B - Modelling Demand for Pharmaceuticals

### Modelling Demand for Pharmaceuticals

It might seem that the problem for determining how good ordering strategies in use are would be quickly solved by using the strategy guaranteeing the economic order quantity (EOQ) as the optimal one and measuring other strategies with reference to this. For such a method to work one needs to be able to use the formula:

$$EOQ = \sqrt{\frac{2OS}{H}}$$

where  $O$  is the ordering costs each time an order is delivered,  $S$  is the total (annual say) sales or demand,  $H$  is the holding cost.

Good estimates for  $O$ ,  $S$  and  $H$  are needed. It might well be that  $O$  and  $H$  could be estimated and assumed without too much divergence from reality to stay constant over a sufficiently long stretch of time.  $S$ , the demand, cannot be assumed to be constant over time. It is clearly random without a clear pattern. This means that the very first problem is to obtain some acceptable model for demand.

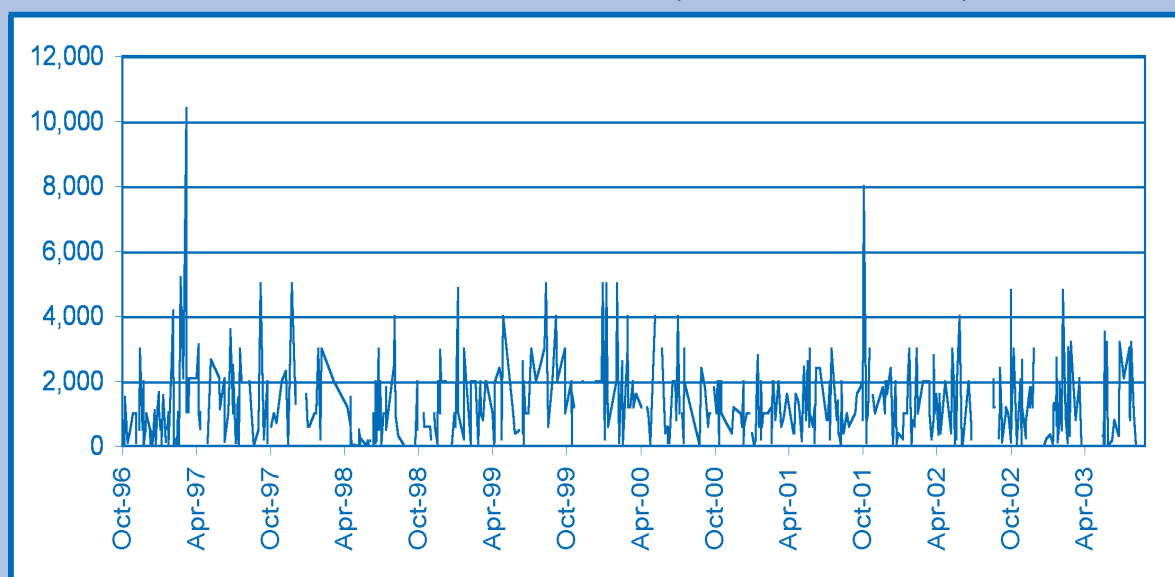
**Problem:** Given demand statistics covering the period 10 September 1996 till 9 April 2003, expressed as a numerical sequence of numbers  $Y_t$  of pills taken out on specific days arranged chronically, a statistical model needs to be constructed to represent in a mathematically compact and reasonably reliable manner the way demand for pharmaceuticals evolves over time. The exercise should strive to build a model which should be as parsimonious in parameter numbers and as low in complexity as possible. The exercise is started by using the more commonly used time series model, which will be shown to be unsuitable, necessitating progress to get a more appropriate model.

The first step would involve trying to fit a time series model:

$$Y_t = T_t + S_t + E_t \quad t = 1, 2, \dots$$

where  $Y_t$  is the number of pills dispensed at time  $t$ , and it is decomposed into a trend term  $T_t$ , into a seasonal component  $S_t$  and a disturbance term  $E_t$ .

A plot of the raw data, Graph 1 below:



Graph 1

## Appendices

reveals immediately that the model just proposed is not suitable because:

1. Delivery does not occur at regular intervals
2. There is no clear trend, the demand seems to be fairly stable over time
3. There is no seasonality in the data.

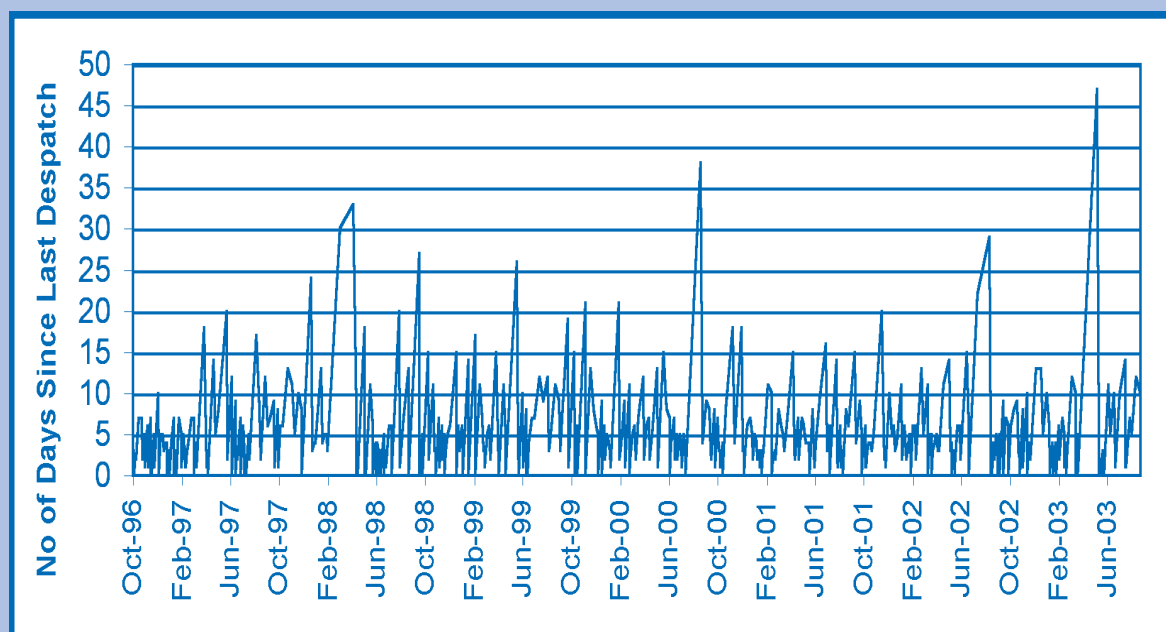
Point 1 is clarified by Graph 2 below where for each despatch date, the number of days elapsed since the last batch was sent is shown:

- The time interval separating deliveries in terms of days

- The size of each delivery

Two series of over 500 readings were derived from the original data. One series gave the sequence of the number of days separating each despatch from the succeeding one. This series is denoted by 'L'.

The other series consists of the size of each despatch. This series is denoted by 'D'.



Graph 2

Point 2, concerning the lack of a clear trend, comes out clearly from Graph 1 because the plot shows no upward or downward trend. The seasonal or cyclical component would need to be ferreted out by something more precise than just a graph. In fact the autocorrelation function was computed for the series and it shows clearly that there is no cyclical or seasonal pattern.

The problem has to be attacked differently. The data can be considered to come from a stochastic process, that is a process which is evolving over time according to probabilistic laws, rather than fixed deterministic laws. In technical jargon this is a renewal process. One needs to go into a basic analysis of the data.

Consider two random components:

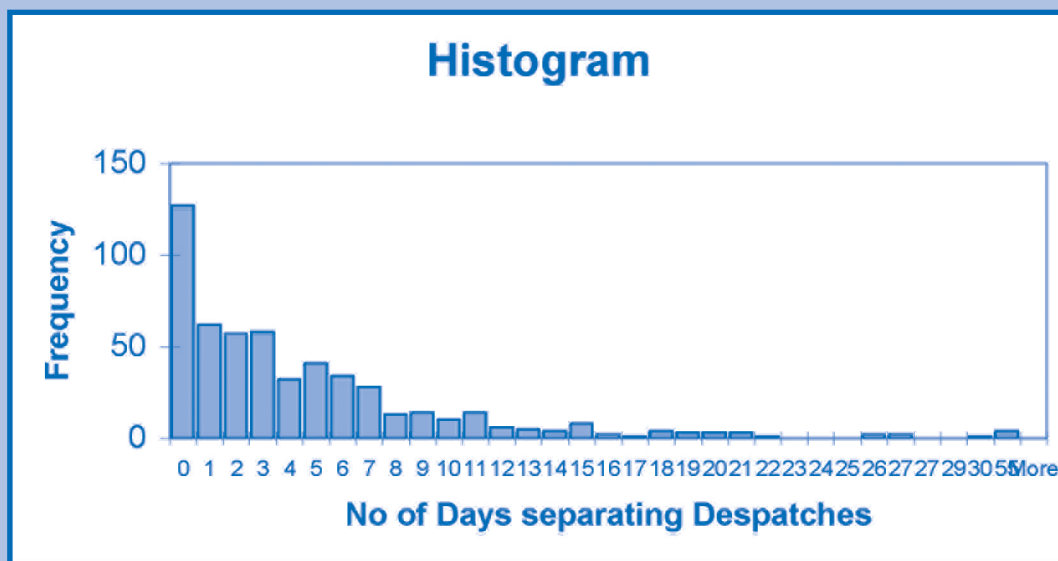
A statistical distribution needs to be fitted to each of the two series.

### The Series 'L'

There were 540 readings of dates when deliveries were effected. The number of days separating one order from the next then gave 539 inter-despatch times which were classified according to duration length. A frequency table and corresponding histogram were constructed and are displayed below. At this point, one should emphasize that in doing this one is assuming that the probabilities involved have been stationary over time, that is the process has maintained a probabilistic regularity from 1996 till 2003. This assumption might not be strictly speaking true but there is absolutely no evidence that it has been violated spectacularly.

## Inventory Strategy and Distribution of Pharmaceutical Products

<i>Duration</i>	<i>Frequency</i>	<i>Percentage</i>	<i>Duration</i>	<i>Frequency</i>	<i>Percentage</i>
0	127	23.56%	16	2	0.37%
1	62	11.50%	17	1	0.19%
2	57	10.58%	18	4	0.74%
3	58	10.76%	19	3	0.56%
4	32	5.94%	20	3	0.56%
5	41	7.61%	21	3	0.56%
6	34	6.31%	22	1	0.19%
7	28	5.19%	23	0	0.00%
8	13	2.41%	24	0	0.00%
9	14	2.60%	25	0	0.00%
10	10	1.86%	26	2	0.37%
11	14	2.60%	27	2	0.37%
12	6	1.11%	27	0	0.00%
13	5	0.93%	29	0	0.00%
14	4	0.74%	30	1	0.19%
15	8	1.48%	Over 30	4	0.74%



## Appendices

The main statistics regarding 'L' are the following:

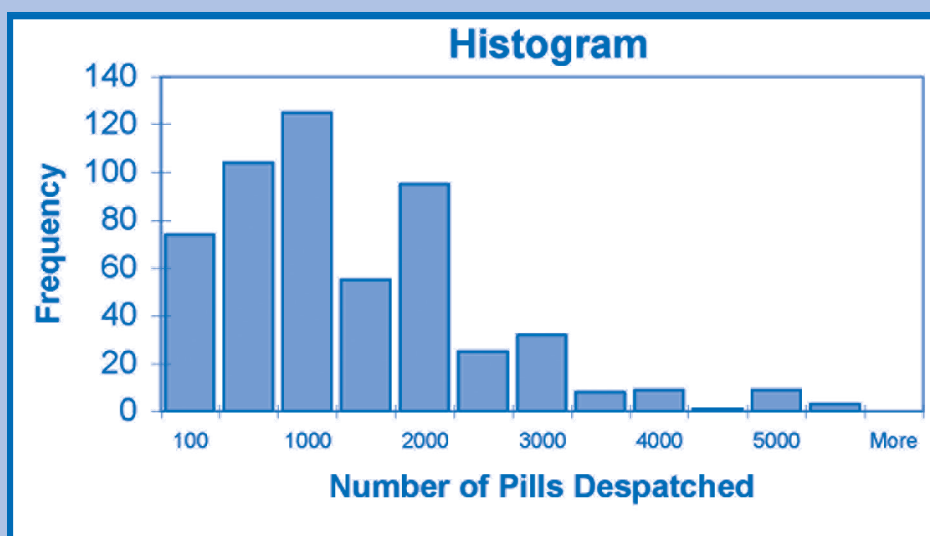
Mean [ L ] = 4.35    Variance [ L ] = 30.01    Standard Deviation [ L ] = 5.48

It is usual to assume that 'L' has the exponential distribution. The above statistics do not support very strongly this assumption. A gamma distribution was fitted using the method of moments and a gamma distribution with parameters  $\delta = 0.63$  and  $\beta = 6.89$  was obtained.

### The Series 'D'

A similar exercise was repeated for the data involving the quantities despatched on each of the 540 occasions. The frequency table is given below together with the histogram.

	<i>Quantity</i>		<i>Frequency</i>	<i>Percentage</i>
	<i>dispatched</i>	<i>range</i>		
1	100	74	13.70%	
100	500	104	19.26%	
500	1000	125	23.15%	
1000	1500	55	10.19%	
1500	2000	95	17.59%	
2000	2500	25	4.63%	
2500	3000	32	5.93%	
3000	3500	8	1.48%	
3500	4000	9	1.67%	
4000	4500	1	0.19%	
4500	5000	9	1.67%	
5000	10500	3	0.56%	





Clearly this is a bimodal distribution. One could go into identifying the source of the two modes, but on the other hand it would be wiser at this stage to settle for a normal approximation. Estimates for the mean and standard deviation are obtained for the data as 1251.59 and 1180.38 respectively. The standard deviation is too high to continue with the normal distribution. To correct

for the possibility of having negative values and for the skewness in the data one could use the lognormal distribution. This gives a mean of 6.46 and standard deviation of 1.54 for the natural logs of the number of pills.

These workings served as the demand engine for the simulations performed.

## Appendix C - Current setup of GPS and Government Pharmacies

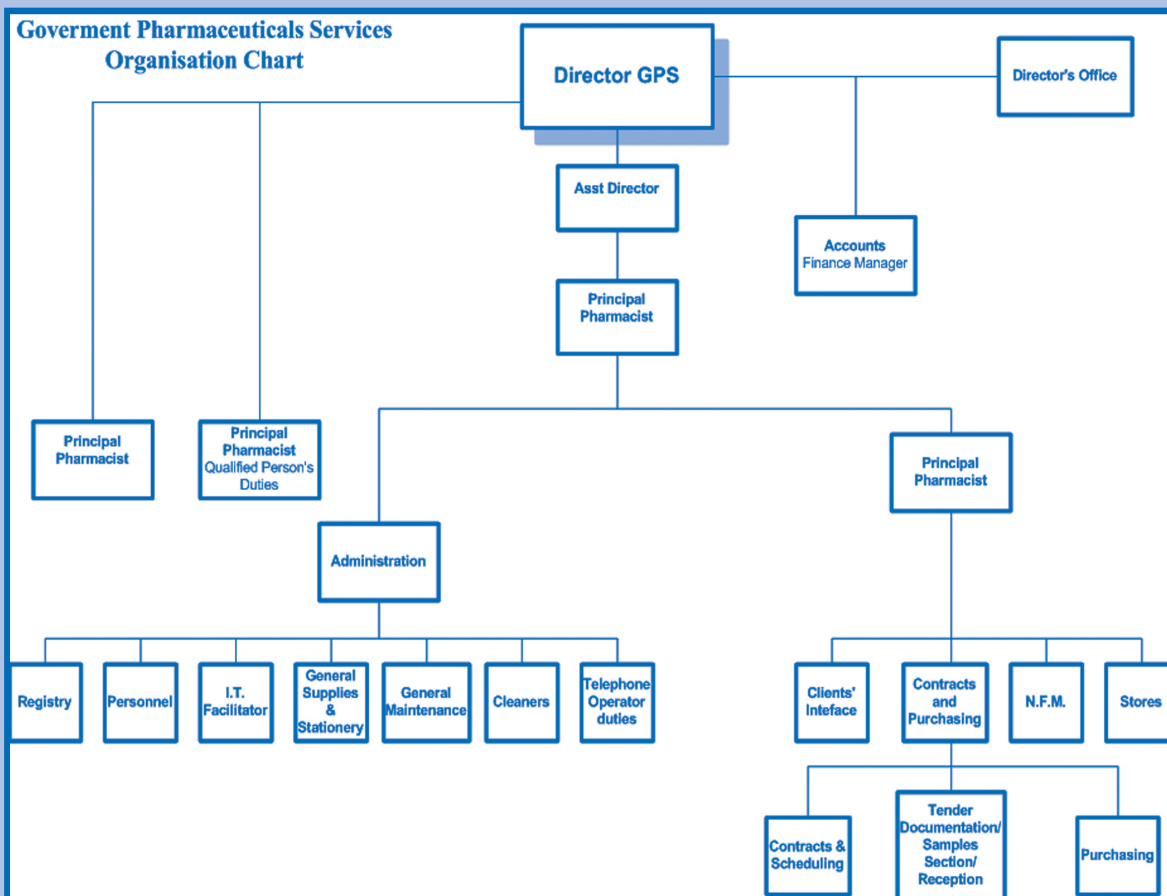
### The Government Pharmaceutical Services

GPS is responsible for procuring, storing and distributing pharmaceutical products and medical materials and devices to government pharmacies. During 2003, GPS employed 123 full-time employees and 10 outsourced employees. The main sections forming part of GPS are presented in the organisational chart in Figure C.1 below.

Since 2001, GPS has undergone major restructuring, mainly aimed at separating the

regulatory functions from the operational ones, improving efficiency and accountability in the entity, as well as preparing for compliance with the revised national legislation on the distribution of pharmaceutical products. GPS is also undertaking a Business Processing Re-engineering exercise with the assistance of a private consulting firm. The Health Division has indicated that this will require further internal restructuring.

**Figure C.1 Organisational Chart of the GPS**



Source: GPS January 2004

### Pharmacies operated by the Institutional Health Department

Pharmacies in government hospitals are currently managed by IHD which was created in 1993 as a result of a reform of the Health Division.

The Department's largest pharmacies are based at St. Luke's Hospital which has around 850 beds and provides a full range of secondary and tertiary medical services including transplant surgery and open heart surgery. The In-Patient pharmacy at St. Luke's Hospital operates on a twenty-four hour basis and provides services to wards and patients using the hospital. The Out-Patient pharmacy at St. Luke's Hospital offers a service to several outpatient categories, including residents of neighbouring areas, patients entitled to non-formulary items and narcotic drugs, Detox outpatients and patients who wish to buy medicines not available in retail pharmacies.

Other pharmacies falling under the Department of Institutional Health responsibility include those at Sir Paul Boffa Hospital, Mount Carmel Hospital, Zammit Clapp Hospital and St Vincent de Paule Residence.<sup>1</sup>

In May 2004, the Department's pharmacies were manned by a Principal Pharmacist, five Senior Pharmacists, forty-eight Pharmacists, three Senior Pharmacy Technicians, twenty-seven Pharmacy Technicians and eighteen minor staff.<sup>2</sup>

Presently, the Department is changing its role from being an operator of various hospital services to developing into its new mandate of regulator

of hospital care. The strategic direction of the Department is to eventually transfer the running of hospitals, including pharmacies operating within these hospitals, to autonomous entities.

### The Primary Health Care Department

PHCD currently operates eight community pharmacies in health centres in B'Kara, Cospicua, Floriana, Gzira, Qormi, Luqa, Mosta and Paola. The pharmacies supply medicinal products to patients residing in the eight different catchment areas. In addition, the health centres also operate a postal system to forty Government District Clinics. This service allows eligible patients to order and collect prescribed medicines from the District Clinic (*il-berga*) instead.

Apart from pharmaceutical services, the Department's mandate includes responsibility for the delivery of primary health care services such as general practitioner and nursing services, immunisation, speech therapy, dental services, antenatal and postnatal clinics, diabetes clinics, ophthalmic clinics, psychiatric clinics and paediatric clinics.

According to records kept by the Department, in 2003 pharmacies in government health centres served 376,788 patients, dispensing in the process 1,017,267 items and processing 505,447 prescriptions.

In May 2004, the health centre pharmacies were manned by a Senior Pharmacist, eighteen Pharmacists, four Senior Pharmacy Technicians and twenty-two Pharmacy Technicians.

<sup>1</sup> The hospital pharmacy in Gozo is managed by the Ministry for Gozo, with the technical support of the Department of Institutional Health.

<sup>2</sup> This figure excludes pharmacy staff employed with the Gozo General Hospital, namely a Senior Pharmacist, two Pharmacists, three Senior Pharmacy Technicians, two Pharmacy Technicians and three minor staff.



