Out of Stock Medicines/ Medical Materials/ Surgical Devices within the Government Sector
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Introduction of the Ombudsman

It is with great pleasure and a sense of satisfaction that I introduce the third own initiative report by Mr Charles Messina the Commissioner for Health in my Office. I immediately authorised him to conduct this enquiry on the prompt procurement and availability of medicines and medical supplies by the Health Authorities since this is an area of Public Health that has been and is still a matter of grave public concern.

The procurement of medicines, medical materials and surgical devices by the Health Authorities is the lifeline of an efficient, smooth and adequate health service that has, as its mission statement, the aim to provide a free public health service of excellence. That standard of excellence is prejudiced whenever medicines and other medical supplies are not available. More importantly, hardship and sometimes serious hardship is caused to those in urgent need of receiving prompt medical attention.

It is common knowledge that the provision of medical supplies, especially but not exclusively medicines, has always been problematic. It is not uncommon for supplies to be out of stock with the result that patients are constrained to purchase medicines required for their treatment elsewhere if they can afford it. There have been instances when operations and other interventions have had to be suspended until stocks are replenished. Such situations still occur even when the authorities have adequate, advanced projections and information on the supplies required in the foreseeable future.

This is unacceptable not only from the perspective of good public administration but also, and more importantly, considering the added responsibility the Authorities have to ensure sound and efficient
public health management. The Commissioner for Health did well to focus on this sensitive, problematic area soon after taking on his onerous functions.

His opinion contains a wealth of information that the public should know in order to be able to make a correct assessment of the difficult and complex processes involved in securing the procurement of medicines and medical supplies. Mr Messina analyses these problems after collecting the relevant data and makes useful recommendations for the consideration of the Health Authorities. These are intended to promote an efficient and transparent procurement process, to simplify procedures that reduce bureaucracy and to underline the responsibility that public officers have to take decisions within established time frames. These recommendations are meant to ensure that the incidence of out of stock in medicines and medicinal supplies are drastically reduced.

It is acknowledged that there are other players in this vital area of public health that have every interest to promote an efficient, workable and secure system of procurement of medicines and medical supplies. These include importers and suppliers, pharmacists and members of the medical professions. They can all make a valid contribution to the debate on ways and means how to improve procedures. Correctly and wisely, at this stage the Commissioner of Health focused on the need to have in place good administrative practices that fall strictly within the remit and responsibility of the Health Authorities.

On a final note, I would like to state that the appointment of Commissioners in my Office to focus on the investigation of complaints in specialised areas of the public administration has been a very positive experience. This and other reports, taken on their own initiative, are clear evidence that the system, now in place for almost a year, is working well to the benefit of citizens and the Public Administration alike.

J Said Pullicino
Chief Justice Emeritus
Parliamentary Ombudsman

2 July 2013
Foreword

In terms of Section 6(1) of Legal Notice No 250/2012, after consulting with the Ombudsman, I carried out an ‘Own Initiative’ investigation on the problem of out of stock Medicines, Medical Materials and Surgical Devices.

The problem of out of stock medicines is a recurrent one and it featured prominently in the local media besides attracting criticism from many quarters. In the year 2011 the Health Authorities acknowledged this problem and in fact appointed a Chief Executive Officer to lead the Unit that deals with the procurement of medicines, medical appliances, surgical devices, etc.

The problem seems to have aggravated by the increase from 38 to 79 of the diseases on the Fifth Schedule of the Social Security Act and by the introduction of the Pharmacy of Your Choice Scheme covering all localities in Malta and Gozo. Patients now find it easier and more convenient to go to the pharmacy nearer their home rather than having to go to the Health Centres or to Mater Dei Hospital to collect their medicines. Both these decisions therefore led to a substantial impact on the stocks situation.

This has also contributed to a greater expenditure which the Central Procurement Supplies Unit had to face and had to request for additional funds.
Members of the public, on the other hand, rightly expect to receive what they are entitled to by law and to be given free of charge the medicines they require for their ailments. When told that a particular medicine is out of stock, they have to dig into their own pockets to buy the medicines that they should have been given for free.

Through this report I strived to investigate the whole process involved and submitted recommendations which I think should go a long way towards finding a solution and reducing the problem to a minimum.

I am encouraged by the response already given by the Minister for Health who informed me that together with the management of CPSU, POYC and Mater Dei Hospital he views this report positively and all its recommendations on solutions have been accepted.

Charles Messina
Commissioner for Health

28 June 2013
Own-initiative investigation by the Commissioner for Health on Out of Stock Medicines/ Medical Materials/Surgical Devices within the Government Sector
Case No HM 0011

26 April 2013

Mr Joseph Rapa
Permanent Secretary
Ministry for Health
Palazzo Castellania
15 Merchants Street
Valletta

Dear Mr Rapa

Re: Out of Stock Medicines/Medical Materials/Surgical Devices

I attach a report following an ‘Own Initiative’ investigation, which I carried out in terms of paragraph 6 (1) of Legal Notice No: 250/2012, about out of stock medicines, medical materials and surgical devices.

It would be appreciated if you would kindly let me have feedback regarding my recommendations by not later than the 30 June 2013, please.

Regards

Charles Messina
Commissioner for Health

Encl.
1. Introduction

This Own Initiative investigation is being carried out in accordance with the provisions of Legal Notice No. 250/2012 which states that the Commissioners in the Office of the Ombudsman may carry out an “Own initiative investigations that fall within the functions of a Commissioner shall be carried out by such Commissioner following consultation with the Ombudsman”.

The investigation in respect of out of stock medicines was chosen in view of the repeated complaints on the matter by patients via the media. Similar complaints were also raised by Members of Parliament.

This exercise concerns only the administrative aspect of the problem vis-à-vis Government procedures.

2. The investigation

During preliminary informal meetings held in November 2012 with the Chief Executive and other officers at the Central Procurement and Supplies Unit (CPSU), within the Ministry for Health, I explained the purpose of this initiative and discussed what can be done to facilitate the process to ensure, as far as possible, that the problem of out-of-stock medicines be minimised and possibly solved.

I requested to be given detailed information about the procedure adopted for procurement including the issue of tenders.
3. Information provided by the Chief Executive Officer – Central Procurement and Supplies Unit

3.1 Procedure for procurement

3.1.1 There are over 1,300 different medicinal products on the Government Formulary List and these are therefore expected to be available at all times. A tender for each type of medicine is issued every 1 year/3 years.

3.1.2 There are three steps to be followed from the time a tender is initiated till its publication in the Government Gazette. Four other steps are taken following the closing period of the tender and further two steps from the award of the tender to the winning bidder. There is yet another step following the receipt of the stock till it is distributed to the respective pharmacies – in all up to ten (10) steps. The procedure is as follows -

(a) The first step is taken by the Procurement Officer (Medicines) who opens the file, prepares the tender documents and refers them to the Senior Pharmacist to check and consult with Directorate Pharmaceutical Affairs as to whether specifications need amendments;

(b) The file is then referred to the Accounts Officer within the Management Accounts Section for commitment of the estimated cost;

(c) The Principal Officer then refers the tender documents for publication in the Government Gazette. If it is a Department of Contracts tender, the file is referred to the latter Department for publication. The cost of the item determines whether it will be a Departmental Tender or Contracts Tender.

A Departmental Tender is in respect of values between €6,000 and €120,000 (Excluding VAT). Closing date is of four weeks.

A Contracts Tender is in respect of value between €120,000 and €2,000,000 (Excluding VAT). Closing date is of six weeks.

Contracts with a value of over €2,000,000 are also considered as a Contracts Tender and are submitted as, what is known, a Three Package Tender.

Calls for quotations for medicines, medical materials and surgical devices that are required urgently because of low or no stocks are also published in the Government Gazette and have a closing date of three weeks or one week depending on the urgency. This is especially so when there are cases of failure in delivery on the part of the contractor;

(d) After the closing date the quotations received are sent to the Scheduling Office for the preparation of the schedule whereby tenderers are listed in the order of price quoted. This schedule must be published on the Notice Board to ensure transparency of the process;

(e) The file (for medicines) is then sent to the Evaluation Pharmacists for adjudication;

(f) The file is then referred to the Adjudicating Committee for a final check of all the tender conditions and a recommendation is made depending on the most favourable offer;
(g) In the case of a Departmental Tender, the file is referred to the Department Contracts Committee (DCC) for the award recommendations. If it is a Department of Contracts Tender, then the file is sent to the General Contracts Committee (GCC) for the award recommendations;

(h) The letter of Acceptance of the Tender is then issued. However, there is a five working days objection period before the Letter of Acceptance is sent;

While, in the case of a Departmental Tender the relative papers are signed within days, when it comes to a Department of Contracts Tender, the relative papers may take up to a month for the issue of the Letter of Acceptance by the Department of Contracts;

(i) Before issuing the Confirmation of Order, the Procurement Officer refers the file to the Departmental Accounting System (DAS) office to effect a ‘hard’ commitment of funds. If, by that time, funds would not be available, the Confirmation of Order would be kept on hold;

(j) After the issue of the Confirmation of Order, supplies are delivered within six to eight weeks from the date when the first order is issued, or as agreed in the Letter of Acceptance.

From the time the procedure is initiated till the item is delivered, a period of between six to nine months elapses.

For urgent low cost medicines, (up to a maximum of €2,500 excluding VAT), direct quotations are requested from at least three suppliers. If the price exceeds €2,500 a call for quotations is published in the Government Gazette.
Further Enquiries

3.1.3 From further enquiries it resulted that:
(a) The Evaluation Pharmacists have to ensure that the Maximum Reference Price (MRP) was not exceeded. If the price is exceeded, authorisation to proceed with process is requested from the Director General, Finance through the Chief Medical Officer. When the Maximum Reference Price is not available at the Directorate Pharmaceutical Affairs, a Guidance Reference Price is indicated;

(b) If during the previous three years the estimated cost of a particular medicine would not have varied by more than 1%, the CEO would consider whether to issue the tender for a period of three years instead of one year so as to benefit from the economies of scale;

Since a significant amount of time elapses during the process, the funds might have been exhausted in the meantime and therefore, the Confirmation of Order, would have to be left on hold until funds are made available. In case of a lifesaving preparation this is processed immediately.

4. Main Reasons for shortages

4.1 The main reasons for shortages are:
(a) Increased consumption. Since there is no holistic IT system, and since medicines have to be supplied to all 209 pharmacies in the Pharmacy of Your Choice (POYC) system, it is extremely difficult to keep track of stock availability and consumption patterns which are dynamic and constantly changing;

(b) lack of funds;

(c) non delivery or delay by a tenderer. Although purchases will be made on Tenderer’s account, some time will elapse due to the fact that an urgent Call for Quotations will have to be issued before it is decided from which firm the purchase will be made;

(d) when specifications need to be updated;

(e) when the supplier is not known;

(f) when there are problems on the part of the manufacturers;

(g) in situations when the Maximum Reference Price is exceeded; and

(h) in the case of non-compliance with Tender conditions in respect of-
• delivery time;
• expiry date; and
• licensing status.
5. **Shortage of Funds**

Shortage of funds necessitates the prioritisation depending on the nature of the medicines required and as guided by the Director Pharmaceutical Affairs (DPA). Medicinals are usually classified into four categories i.e:

- Life Saving;
- Vital;
- Non-Critical High Impact; and
- Non-Critical Low Impact.

5.1 At one point (on 19 February 2013) there were a total of 130 medicines out of stock:

- 4 Life Saving;
- 59 Vital;
- 27 Non Critical High Impact; and
- 40 Non Critical Low Impact.

This means that over 10% of the medicines listed in the Formulary were not available.

6. **Introduction of New Medicines**

Requests for the introduction of new medicines in the Government Formulary List are normally made by:

(a) the Clinicians; and
(b) the Local Agents themselves.

6.1 The Director Pharmaceutical Affairs (DPA) then places the subject on the Agenda so that the Government Formulary List Advisory Committee which is chaired by the Chief Medical Officer will discuss and decide on the request.
Before approval, the advice of the Clinicians is sought regarding the expected annual consumption. The file is then sent to CPSU who decides the best way of procurement for that particular item.

7. **Named (non Formulary) Medicines**

7.1 There are situations when certain medicines which are not on the Government Formulary List need to be prescribed for a particular patient. Approval from DPA would first have to be obtained.

8. **Negotiated/Restricted Procedure**

8.1 For medicines which are approved by brand name, or are still under patent, a negotiating procedure will be initiated by the Negotiating Committee which recommends the approval to the CEO, CPSU. Discounts may also be asked for depending on the quantity of the order being made.

8.1.1 When supplies are limited, a call for a Request for Participation is published on the internet portal. If only one offer is received, a direct negotiation can take place. If more than one offer is received, the cheapest acceptable offer is confirmed. All the above procedures are authorised by the Ministry of Finance and the Department of Contracts.

9. **Purchasing of Medical Aids and Surgical Instruments**

The same procedure as mentioned above is used for the ordering and purchasing of medical aids and surgical instruments. There are about 2,000 devices and medical materials to be catered for. However the Procurement Officer will be the one who deals with Medical Devices. The Adjudicators will be the users at Mater Dei Hospital, Sir Paul
Boffa Hospital, Mount Carmel Hospital, Public Health Laboratory, etc... depending on the main area of usage.

10. Examination of Tender Documents

I have reviewed a copy of the tender documents and have asked the CEO, CPSU to clarify the following points:

(a) **Question** - Can a Tender be awarded (because of large quantities) to more than one Tenderer?

**Reply** – Clause 3 of the current tender documents – ‘Instructions to Tenderer’ states - that “The Government reserves the right to award the item/s requested to more than one contractor, unless otherwise specified in this tender document.” However the reasons for applying this clause do not relate to large quantities.

In the short term, through the use of the electronic public procurement system, CPSU shall start to make use of Framework Agreements whereby offers submitted are evaluated administratively and technically. Bidders whose respective offers are deemed to be administratively compliant with the specifications are then asked to enter into a mini competition every so often (e.g. 6 months) and compete financially only.

(b) **Question** - Are there any measures in place to ensure that a Tenderer is in a safe position to deliver?

**Reply** - At tendering stage bidders are asked to submit a list of principal deliveries they made during the previous five years of items of a similar nature to those being requested. Contractors who have supplied the Department of Health with supplies of similar nature in the previous three years are only asked to submit a declaration to this effect.

After the award of a contract, for contract agreements with a value greater than €10,000, a bank guarantee is requested. For firms with a turnover greater than 0.5 million Euros a year, CPSU holds a single bond as a form of performance guarantee.

The General Conditions for Supply Contracts provide further measures that safeguard the Contracting Authority, should the contractor fails to abide by the tender conditions.

(c) **Question** - Are any penalties imposed? If yes, when? Do they have any bearing on the Tender price quoted?

**Reply** - Article 21 of the General Conditions for Supply Contracts states as follows:

“21.1 If the Contractor fails under his own responsibility to deliver any or all of the goods or perform the services within the limit(s) specified in the contract, the Contracting Authority shall, without formal notice and without prejudice to its other remedies under the contract, be entitled, for every day which shall elapse between the expiry of the contractual period and the actual date of completion, to liquidate damages equal to 5/1000 of the value of the undelivered supplies to a maximum of 15% of the total value of the contract.”

“21.2 If the non-delivery of any of the goods prevents the normal use of the supplies as a whole, the liquidated damages provided for in paragraph 21.1 shall be calculated on the basis of the total contract value.”

“21.3 If the Contracting Authority has become entitled to claim at least 15% of the contract value, it may, after giving written notice to the...
Contractor, and after having obtained the prior approval of the Central Government Authority:

- seize the performance guarantee;
- terminate the contract, in which case the Contractor will have no right to compensation; and
- enter into a contract with a third party for the provision of the balance of the supplies. The Contractor shall not be paid for this part of the contract. The Contractor shall also be liable for the additional costs and damages caused by his failure."

“21.4 Besides the penalties for delay envisaged in these conditions and without prejudice to all his other liabilities arising out of the contract, the contractor shall also become liable to a penalty if the rate of progress of the work throughout the contract period is not satisfactory. The contractor shall be considered to be in default if he fails to carry out every month at least 70% of the estimated monthly average progress. For the purpose of assessing such average progress the value of the contract shall be divided by the number of months stipulated in the contract period. Within each month the contractor should complete works whose value is equivalent to the average progress obtained as above. However, in the case of contracts having a completion period of six or more months, no penalty shall be imposed in respect of the first month from the date of allocation of the contract. Should the contractor’s progress fall below the minimum percentage progress, he will become liable to a penalty equivalent to 2% of the value of the contract in respect of every month during which progress is below standard. If the contractor completes the whole contract within the stipulated period, the Government may consider the refund of any penalties the contractor may have incurred for slow monthly progress.”

(d) Question - If there is a decrease in consumption and the shelf life is due to expire, is the Tenderer obliged to change the product with an identical one with a longer shelf life?

Reply - Tenderer is obliged to change the product, with an identical one having a longer shelf life, only if at bidding stage the offer would have been submitted with a shelf life condition that was not in line with the specifications published in the tender.

One must note that through the current published tender document, if none of the offers received are compliant to the shelf life clause as required by the Contracting Authority (CA), the CA reserves the right to consider other means of supply, so that, if in the event of expired stock the latter is recollected by the Contractor and credited. This measure has led to a decrease in the number of calls for tenders that were being cancelled and ensured a more timely supply.

(e) Question - What is the reason for destroying medicines, medical aids, appliances etc...? Is this a frequent occurrence?

Reply - Supplies are destroyed in cases where either shelf life has expired or, although supplies have been returned, the storage conditions are unknown and thus the supplies cannot be redistributed...
due to safety measures and because good storage conditions at the client’s end cannot be ensured. Other supplies, such as appliances, are disposed once technically declared to be beyond economical use by a Board of Survey in accordance with the Government regulations.

(f) **Question** - If the Review Board upholds the Tenderer’s complaint, is the sum deposited refundable?

**Reply** - The decision on whether to refund an objection fee or not, is the prerogative of and rests entirely on the jurisdiction of the Public Contracts Review Board (PCRB). It might be considered adequate to increase such fees so that contractors would not raise objections unnecessarily.

**Interaction between the Commissioner and the CEO, CPSU during the investigation**

11. **Further clarifications were requested from the CEO, CPSU in respect of the Tender Documents** (the pages refer to those on the tender document).

During the course of the investigation, suggestions were made to the CEO, CPSU as shown hereunder -

(a) Page 11 – paragraph 28.3 line 2 – **Suggestion** – to read ‘directly or indirectly’ instead of directly.

**Reply** - Agreed, however this clause has been adopted from the Department of Contracts Templates.

**Comment** 2 – This suggestion was agreed to.

(b) Page 35 – Article 21 (3) line 3 – **Suggestion** – to add after the word objective ‘indicating detailed reasons’.

**Reply** - Agreed, however this clause has been adopted from Department of Contracts Templates.

**Comment** – This suggestion was agreed to.

(c) Page 35 – Article 21 (6) line 2 – **Suggestion** – after recourse add ‘because a Tenderer intends to appeal to the Public Contracts Review Board’.

**Reply** - This has been adopted from Doc Templates.

**Comment** – This suggestion was agreed to but has to be clarified with the Department of Contracts.

(d) Page 37 – Paragraph 5 line 1 – **Suggestion** – after option add ‘by CPSU’ and Page 40 – Article 18.2 line 3 – **Suggestion** - Delete ‘with the consent of contractor’

**Reply** - When extending the period of a contract agreement the consent of the contractor is required in order to confirm quoted rates and conditions. If the Department was to impose the extension, there would be the risk of either having contractors not aware of such change in the clause and will thereafter encounter difficulties upon order over an extended contract, or the Department would just not receive quotes.

**Comment** – This suggestion was agreed to but has to be clarified with the Department of Contracts.

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2. 'Comment' in this section is the Commissioner’s reaction and/or conclusion on the points discussed.
(e) Page 40 – Article 18.2 line 4 – **Suggestion** – to be 3 or 6 months (at the discretion of CPSU).

**Reply** - Is the reason for this so as to have more than one option available, in accordance to instant scenarios?

**Comment** - This suggestion was agreed to, but has to be clarified with the Department of Contracts.

(f) Page 46 – **Question** – Shouldn’t it read Dear Madam/Sir not Madame.

**Reply** – Agreed.

**Comment** – This suggestion was agreed to.

12. **Meeting with the Director General, Department of Contracts**

The Director General was very preoccupied by:

(a) the delay for tenders of both medicinals and non-pharmaceuticals to be collected after closing date (at times even one month later); and

(b) the great delay for tenders to be evaluated especially on new medicinal products.

Paragraph 11(d) (extension of the contract without the consent of the contractor) was discussed with the Director General who found no objection provided the tenderers would be informed of the change in the relative clause in the tender conditions.
13. Envisaged changes in the procedures adopted at Central Procurement Supplies Unit (CPSU)

From further discussions with the CEO, CPSU, it resulted that the Department of Health has invested in a Procurement Workflow System which at present is in the testing phase. The main objective is to eliminate the paper-based movements through files (which delay the processes) and to take overall control in all the procurement phases. This system will also include a Key Performance Indicator that will tie down all activities into a predefined period (days) for each activity. This system will alert the operators if there will be any delay. The system will thus be converted from a “pull” to “push” system.

The CEO together with the Director General Finance and the Chief Information Officer, Information Management Unit (Health) are considering the introduction of a Stock Control Management System to take control of the availability of all stock and visibility access entities. At the moment this arduous task is being done manually. CPSU has already issued a tender for a pilot project on stock control management cabinets.

The CEO added that when both systems are in place, integration would follow so that the databases will be linked to each other. The stock levels will therefore be maintained through an easy access so as to help reduce the risk of items falling below the minimum accepted levels. This Business Intelligence Software will eventually enable CPSU to obtain the best prices through forward buying and ascertain that safety stock levels are always maintained.

This Office is informed that the systems mentioned above are being actively considered by the Ministry for Health and the Ministry of Finance because approval of funds for capital expenditure is required.

The staff also needs to be appropriately trained to operate this system. This will be possible with goodwill and dedication.

14. Expected results from the new system

This new system should significantly shorten the present nine month long process with resultant improvement in stock management. However, it will take approximately about six months to implement the new procedures once the adequate system is identified.

15. Measures being presently adopted by CPSU

15.1 At present CPSU is endeavouring to maintain adequate stocks of the more than 1300 different types of medicines listed in the Government Formulary List, but most importantly those declared as life threatening, vital and non-critical high impact. Those classified as non-critical low impact are currently going through a process of evaluation of the need to continue to stock these items.

15.2 Measures are also being taken to appoint part-time clinical professionals to evaluate tenders regarding instruments, materials, etc rather than referring to individual clinicians with resultant delays.

16. Meeting with CEO, Pharmacy of your Choice (POYC) Unit

16.1 The CEO informed me that to date (6 March 2013) there are over 107,000 patients registered with the 209 pharmacies throughout Malta and Gozo.

16.2 Deliveries to all the pharmacies are made every week and, in case of urgency, deliveries are made as soon as possible.
16.3 The Unit knows exactly, what every pharmacy needs in respect of each type of medicine. The main problem is short or nil supplies from the Central Procurement Supplies Unit (CPSU). Otherwise the system is well organised and this has been acknowledged by the many awards it received and by the National Audit Office in its Report – An Analysis of the Pharmacy of Your Choice Scheme – Issued in May 2012. The Scheme reaches the scope for which it was set up i.e. eliminating the long queues in the Government pharmacies and serving the public as near as possible to their homes. In this way patients can also seek advice from their pharmacists.

16.4 It has been dismissed that some pharmacies may be over stocked while others have low stocks.

16.5 For more control, it was suggested that all the entitled patients in the Homes for the Elderly should be provided with a Schedule V (yellow) card.

16.6 It also transpired that the POYC Unit has great shortage of staff as declared by the National Audit Office.

16.7 Consideration should also be given to remove high cost medicines from the POYC system. Such medicines should be dispensed from the Mater Dei Hospital Pharmacy.

16.8 The POYC Unit do not accept any returned, unused medicines.

16.9 The agreement between the Ministry of Health, Elderly and Community Care (MHEC), the Ministry of Finance, the Economy and Investment, the Malta Chamber of Pharmacists and the Pharmacy Section of the Chamber of Small and Medium Enterprises within the General Retailers and Traders Union, provided two options for the delivery of pharmaceuticals.

The first option indicates that the participating pharmacies would receive the products already organised into customer packs and ready for dispensing.

The second option was to deliver pharmaceutical products in bulk to the participating pharmacies.

The second option was chosen apparently because of the great number of staff that would otherwise have been needed if the first option was adopted.

17. Funds

The funds approved in 2012 to supply outpatients and inpatients with medicines in all the Government hospitals (including Prosthesis) were €64,600,000 but an additional €7,500,000 were later made available. This vote is however not available only for the purchase of medicines but also to buy surgical instruments etc. Approximately 69% is spent on medicines and 31% on instruments etc.

18. Tenders/Quotations issued and Actual Expenditure

In the year 2012, 4,551 tenders/quotations were published in the Government Gazette. Of these 1,499 were for Drugs, and 3,052 for Equipment.
The actual expenditure for the year 2012 was –

€72,179,599 (+509,791 for Prosthesis) as follows –

€47,638,096  Drugs
€7,018,891    Equipment
€509,791      Prosthesis
€15,755,108   Specials
(items needed for heart operations, brain operations, heart procedures, etc…)
€1,767,504    Others
(chemicals, disinfectants, dressings, etc…)  

Including payments carried forward from previous year

i.e Only 69% is spent on drugs.

19. Appeals

The Public Contracts Review Board has to deal with all appeals against the Government and Local Councils. Therefore Appeals which concern the supply of medicines (both Departmental Tenders and Department of Contracts Tenders) might take quite some time to be decided.

20. Mater Dei Hospital

20.1 Mater Dei Hospital is by far the largest consumer of medicines, materials and other medical supplies. At present, requests for replenishment of stocks of medicines etc is made every week by the Nursing Officer of each ward. The room where medicines etc are kept is not used solely for their storage, but it is also accessible to all the staff in the ward.
Besides, pharmacists cannot do a physical check regarding the actual dispensing of such medicinal supplies to each and every patient.

The remedy to such a situation would be to introduce the system of Ward (including Operating Theatres etc) Pharmacists. If such a system is agreed to and implemented there would be more stringent checks with resultant saving of funds and easing of the out of stock problem.

The next best alternative would be to implement a top-up system to all the wards. Such a procedure has already been initiated but it is moving at a slow pace due to shortage of staff.

21. Considerations and comments

21.1. From the investigation it results that:

(a) the procedure for procurement is too long and cumbersome with too many steps which cannot but create delays between one step and the other. This procedure is being revised with the introduction of e-procurement and other procurement mechanisms that are being introduced by CPSU;

(b) the evaluation process of the tenders takes a considerable length of time – several months due to lack of dedicated expertise;

(c) since the procedure to check stocks is still done manually and at irregular intervals, it is not surprising that items will fall out of stock especially due to increase in demand;

(d) the approved funds are, year after year, exhausted much before the end of the year. This results in no funds being available for fresh procurement with the exception of medicines for life saving conditions. Although over €7,500,000 additional funds were provided in 2012, according to a recent Parliamentary Question another €21,000,000 would have been needed to settle all bills;

(e) the procedure for the procurement of new medicines takes too long. This system has however improved recently since CPSU was set up and if funds are available to sustain such procurement, then the situation should be resolved;

(f) a few but important amendments to the tender document as referred to in paragraph 11 of this report are suggested;

(g) the suggestion to delete “with the consent of contractor” in Article 18.2 page 40 of the Tender Document should have an additional positive effect on the outcome of the shortage situations as the contract can be automatically extended by a further 3 or 6 months at the discretion of the CEO, CPSU if he would need more time to finalise the next contract;

(h) the Central Procurement and Supplies Unit (CPSU) does not collect tenders immediately after the closing date/time for the submission of tenders mainly due to the time needed to identify external expertise since these are not available within CPSU;

(i) the Procurement Workflow System (paragraph 13), needs to come in place as soon as possible since this would significantly contribute to easing the problem;

(j) since staff have to become accustomed to a new computerised programme, training and co-operation in the introduction of the new systems would be required;

(k) since POYC Unit has to serve patients all over Malta and Gozo, it has to have all the stocks ready available whilst at the same time avoiding overstocking;
there is no doubt that a great amount of wastage occurs when unused medicines are disposed of. Perhaps consideration can be given by POYC Unit and the hospitals’ pharmacies to accept medicines that a patient or his/her relatives scrupulously confirm that the medicines had been properly stored in the recommended temperature;

according to the National Audit Office, the POYC has only 62% of the human resources needed (Paragraph 3.1.2 of the Report). Shortage of staff may delay the supply to pharmacies participating in the POYC scheme and this will lead to patients being told that the items are out of stock; and

prescribing habits need to be audited. It seems that a good number of doctors prescribe the quantities as dictated by the patients who seem to want to hoard just in case there would be an out of stock situation.

22. Conclusion

I feel it is of utmost importance that the Central Procurement Supplies Unit staff should have the mentality of availability stocks rather than “out of stock” and work towards that goal, so that, as far as can be achieved, no medication will be out of stock. It is however acknowledged that this is a mammoth task which requires finance, systems and resources.

There is no doubt that the system has to be completely electronic. I am confident that the staff are keen to adopt this system, but in case a few would not feel comfortable with electronic equipment or are reluctant to retrain, they should be offered alternative duties.

Until the time that the new electronic system is in place, the staff should continue to check stock levels manually as often as possible so that they would be in a position to switch on the red light well in time before the stocks would be reaching alarm levels.
23. Recommendations

In the light of the above conclusions, I recommend that action be taken so that –

(a) The Tender Documents as in paragraph 11(a), paragraph 11(d) and (f), paragraph 11(g) and (h) and paragraph 11(k) be amended. These were all agreed to by the CEO – CPSU as in replies given in paragraph 11. The most important amendments to avoid an out of stock situation are found in paragraph 11(g) of this report (To avoid any clashes, any significant amendments are to be brought to the attention of the Contractors);

(b) the new procedures as in paragraph 13 are to be introduced without delay. The workload is tremendous and this new procedure would greatly facilitate things;

(c) the staff be trained in advance so that the new procedures would be introduced without hiccups. It is hoped that the Unions will also cooperate towards this initiative;

(d) the funds are subdivided a *priori*, so that CPSU would know exactly what is available for medicines, surgical instruments, specials and other general items. However more funds need to be provided. It would be ideal if CPSU would begin the year with a clean sheet;

(e) since it is evident that the procedure being adopted at present to monitor stocks is manual and is not giving the desired results, and until the system is converted to an electronic one, the stock levels be checked as often as possible in order to ascertain whether the stocks would last until the new tender is awarded;

(f) in view of the time taken for Appeals to be heard, consideration is to be given to appoint more then one Public Contracts Review Board so that Appeals are decided in the shortest time possible;

(g) tenders are issued for a three year contract. They should be staggered so that about 440 tenders are issued yearly instead of the 1,300 a year as they are at present;

(h) a review of the system should be carried out in order to see whether any of the ten steps taken for the procurement and distribution of medicines as referred to in paragraph 3 of this report can be done away with;

(i) the appointment of an audit team of doctors (including retired doctors) to examine the prescribing habits should be considered;

(j) since almost all the residents in the Homes for the Elderly have a Schedule V Card, the same system should also be adopted at the Mtarfa Home which apparently brings its supplies of medicines from St Vincent de Paul Residence.

In view of the vastness of St Vincent de Paul Residence it might be difficult to give all the Residents a Schedule V card as well. Therefore consideration is to be given to adopt a ward pharmacy system for better control, more so, since the St Vincent de Paul Residence’s Pharmacy does not have an IT system. Alternatively a top-up system by the Pharmacists can be considered;

(k) since Mater Dei Hospital is the greatest consumer of medicines, materials etc, serious consideration should be given to introduce a ward pharmacy service or facilitate the process of a top-up system to obtain better control of consumptions;
(l) Staff levels at the POYC Unit should be improved. To make up for the 38% understaffing, the other 62% are working long hours of overtime which in the words of the Auditor General (paragraph 3.6.1 of the Report) “comes the increased probability of errors in processes being committed and remaining undetected, thereby reducing efficiency”.

(m) Consideration is to be given to remove high cost medicinals from the POYC system and that such medicinals be only given from the Mater Dei Hospital pharmacy;

(n) As regards medical materials and surgical devices, CPSU would need to have the expertise to prepare the specifications and evaluate such items in-house rather than having to resort to other clinical expertise from the various entities which are not readily available.

(o) Discussions should be held by the principal stakeholders namely CPSU, Mater Dei Hospital distribution pharmacists and POYC Unit to identify the main problems and suggests remedies.

It is hoped that the Department of Health finds this exercise useful to substantially minimise the long standing justified complaints.

Charles Messina
Commissioner for Health

26 April 2013
Out of Stock Medicines/Medical Materials/Surgical Devices within the Government Sector

Own-initiative investigation by the Commissioner for Health

Reply by Minister for Health dated 17 June 2013 to the own-initiative investigation by the Commissioner for Health
17 ta’ Ġunju 2013

L-Ombudsman
Prim Imhallef Emeritus
Dr. Joseph Said Pullicino

Qabelżejn iriringrazzjak tal-kontribut siewi li jkomplti jikkonferma dak li sab dan il-gvern fl-ewwel ġimgħat f’dan il-Ministeru. Ngħarfek li l-Ministeru fuq inżizzattiva tiegħu stess ukoll stharreq b’mod intern dan l-operat u l-analizi, u wara li ħejja r-rapport tiegħu ddeċedda li jitial ghal analizi esterna dettaljata minn awdituri li tiffokk u tindirizza b’mod partikolari is-CPSU, il-POYC, kampjun mis-swali u mit-teatri tal-operazzjonijiet kif ukoll kampjun minn spžeriji privati fi hdan l-operat tal-POYC.


Tislijiet

Onor. Dr. Godfrey Farrugia
Ministru għas-Sahha
Memorandum

From: Minister for Health
Hon. Dr. Godfrey Farrugia

To: Ombudsman,
Chief Justice
Emeritus Dr. Joseph Said Pullicino

Date: 10th June 2013

Subject: Comments on the Ombudsman Report on “Own Initiative on Out of Stock Medicine/Medical Materials/Surgical Devices within Government Sector”

The report, dated 26 April 2013 was commissioned by Commissioner of Health. Its intent was to identify the causes leading to the issue of out-of-stock medicines. The problem has persisted over a two-year period with repercussions on Malta’s National Healthcare. The issue concerns the list of the out-of-stock medicine items that is well above the threshold. This situation is impacting on patients, who are entitled for free medicine under Schedule II and Schedule V and depriving them of this medicine entitlement. Patients are thus left with no alternative but to pay for medicines out of their pockets or wait for overdue consignments to the detriment of their health.

Investigations were carried out through interviews with the CEO of three entities within the Health Department i.e. POYC, CPSU and Mater Dei Hospital, all appointed within Public Service in the last two years, and the Director of Contracts Committee. Although the problem seems to have a domino effect, issues are listed according to the entity from where they originate.

Ombudsman highlights various problems arising from CPSU. These include:

- tendering documents sometimes lack common guidelines and require amendments
- delays in the delivery of medicinal supplies by the supplier
- delays in the collection by the CPSU of tender bids from the DCC
- lack of stock visibility across dependent entities by CPSU
- lack of accountability
- lack of forecast for medicine consumption by item, which deprives procurement of a tangible projections in the ordering process
- the assigning of funds for medicine and medicinal devices in one budget

The problems identified by CEO of POYC are mainly attributed to lack of staff and the prescribing habits of a good number of doctors who are prescribing quantities as dictated by their patients. The aim of introducing POYC was to serve patients better with medicinal entitlement from the vicinity of their homes. According to a National Audit Office statement of May 2012, this scope has been achieved. Nevertheless because of the out-of-stock issue, the system is not really accommodating the patient because of a constantly rotating list of out-of-stock medicine.

Mater Dei is the largest consumer of the medicine/medicine devices budget. Through interviews with CEO Mater Dei Hospital, another major problem has emerged due to lack of wards’ monitoring, auditing, and accountability of medicine supply. Pharmacists cannot perform a physical check on the consumption of medicinal supplies up to patient level and subsequently the report recommends a system of weekly ward top-ups.

Moreover, a pivotal concern which has been missed by this report is that since the introduction of POYC, consumption of medicines has increased drastically, sometimes by more than a twice as much. This data has been extracted through an analysis in the CPSU Sage IT system. Considering the fact that free medicine subscribers have not increased, but have shifted from Health Centre Pharmacies to POYC, this constitutes an alarming factor in the out-of-stock situation. The Ombudsman report also does not mention that the medicine expenditure has increased by 313% with contractual expenses reaching 1.4 million Euros in 2012 when subscribers stood at 23,000. By May 2013 subscribers have gone up to 110,000 and one is expects these figures to continue increasing. Furthermore the report also failed to analyze the impact of the revised Social Security Act, Chapter 318, Article 23 Schedule V

Ministry for Health
provisions of February 2012 which increased the medicinal conditions from 38 to 79 under which patients receive free medicine.

The Ombudsman report proposes various positive recommendations and suggestions to remedy the situation. The report explicitly acknowledges the fact that the issue is "a mammoth task which requires finance, systems and resources". It recommends:

- the implementation of a Stock Control system as a high priority.
- the offering of alternative duties to staff who are reluctant or uncomfortable with electronic equipment
- manual checking of stock levels to be carried out until the IT systems are in place
- amendments to the format to the call for tender, establishing guidelines and conformity
- funds are to be sub-divided in advance, separating medicine from medical devices
- the introduction a weekly top-up system in all wards and operating theatres, and where possible up to patient level

Conclusions

The report presents major issues regarding the OOS situation. The incoming administration through its new Ministry for Health has immediately taken up the issue as a high priority and considers this challenge as pivotal to our National Healthcare. On taking office, the Minister initiated an analysis of the situation in order to take hold of the situation as early as possible and has highlighted the same problems as the Ombudsman with pretty similar solutions. The Ombudsman’s report recognizes the problem as a “mammoth” which could only be solved over a period of time. Certain measures can however be feasibly implemented in a short period of time. In fact a vigilant checking of stock levels and expiry dates of medicines as well as ward checks has already been initiated but more staff would be required to implement these across all points. The introduction of Stock and Inventory Control system has also been given the highest priority because stocks could be monitored accurately at real-time and include in automated auditing and accountability. A further autonomous audit is currently being carried out across stakeholders at POYC, CPSU and Mater Dei wards in order to attain an independent analysis of the situation.

On a final note, the Ministry together with the management of the CPSU, POYC and Mater Dei view this report positively and all its recommendations and solutions have been accepted. Once the presently ongoing independent audit is concluded, a final roadmap would be set to meet the challenges inherited from the previous government, in a bid at reducing the issue of out-of-stock medicine. However, as stated by Ombudsman, this challenge is a massive and requires finances, systems and resources.
Reply on 26 June 2013 by Parliamentary Ombudsman and Commissioner for Health to letter dated 17 June 2013 by Minister for Health
Każ Nru HM 0011

26 ta’ Ġunju 2013

L-Onorevoli Dr Godfrey Farrugia
Ministru għas-Saħħa
Palazzo Castellania
15 Triq Merkanti
Valletta

Onorevoli Ministru

Dwar: Rapport fuq Mediċini Out of Stock

Nirreferu ghall-ittra tiegħek tas-17 ta’ Ġunju 2013.

Ninnotaw b’sodisfazzjon li “the Ministry together with the management of CPSU, POYC and Mater Dei view this report positively and all its recommendations and solutions have been accepted”.


Letter to Director General, Department of Contracts, dated 16 May 2013

on own-initiative investigation by the Commissioner for Health
Case No HM 0011

16 May 2013

Mr Francis Attard  
Director General  
Department of Contracts  
Notre Dame Ravelin  
Floriana  
FRN 1600

Dear Mr Attard

Re: Out of Stock Medicines

In terms of paragraph 13(2) of the Ombudsman Act, XXI of 1995 and paragraph 6(1) of Legal Notice No 250/2012, I carried out an 'Own Initiative' investigation on the subject of Out of Stock Medicines.

One of the problems indicated in the report is the time taken by the Public Contracts Review Board to hear appeals. The main reason for the delay seems to be that the Board has to hear appeals against all the Government Departments and Local Councils awards of tenders.

I recommended that “consideration is to be given to appoint more than one Public Contracts Review Board ...”.

In terms of Section 22 (3) of the Ombudsman Act, XXI, 1995, I would appreciate to be informed whether any action would be taken in line with my recommendation please.

Regards

Charles Messina  
Commissioner for Health

Copy – Permanent Secretary - Ministry of Finance
Out of Stock Medicines/Medical Materials/Surgical Devices within the Government Sector

Reply on 21 May 2013
by Director General,
Department of Contracts
on own-initiative investigation
by the Commissioner for Health
OUT OF STOCK MEDICINES

Reference is made to the letter from the Ombudsman dated 16th May, 2013, addressed to this Department and copied to the Ministry for Finance.

This Department supports fully the recommendation being made by the Ombudsman. The Public Contracts Review Board is autonomous from this Department with this Office not involved in the operations of the Board. However, the feedback that this Department is receiving is that the number of appeals is always increasing and becoming more complex. It is being observed that it is taking quite some time before the PCRBM appoints a date for the hearing of appeals. In this Department’s view, these are clear indications that the Board is not coping with the volume of work.

The Public Contracts Review Board is set up in accordance with the Public Procurement Regulations. These regulations already provide for the setting up of different boards to hear and decide appeals on public tenders. In this regard, this Department would like to draw the attention of the Ministry to the following regulations within the PPR:

Reg 85 (7) (a) The Review Board shall be composed of a Chairman and two members who shall be appointed by the Prime Minister for a period of up to three years with the possibility of re-appointment.

(b) The Prime Minister may appoint a substitute, or such number of substitutes, as Chairman and as members of the Review Board to act on different Review Boards, in which case members shall serve for pre-determined periods of time, in accordance with such distribution of duties, including provisions for inability of members to serve and other circumstances, as the Prime Minister may establish.

Should the Ministry feels that there is the need for further consultation with this Department on the Ombudsman’s proposal, please do not hesitate to us.

Francis Attard
Director General (Contracts)

cc The Ombudsman
Reply on 28 May 2013
by Commissioner for Health
to letter dated 21 May 2013
by Director General,
Department of Contracts
Case No HM 0011
Your Ref. CT5008/2013

28 May 2013

Mr Francis Attard
Director General
Department of Contracts
Notre Dame Ravelin
Floriana

Dear Mr Attard

Re: Out of Stock Medicines

Reference is made to your letter dated 21 May 2013.

I appreciate the fact that your Department “supports fully the recommendation being made by the Ombudsman”.

I would be grateful if you would keep me informed of developments please.

Regards

Charles Mifsud
Commissioner for Health