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**PERFORMANCE AUDIT REPORT ON THE
DISTRIBUTION OF ESSENTIAL MEDICINES BY THE
PHARMACEUTICAL DEPARTMENT, MINISTRY OF
HEALTH**

Prishtin, 26 June 2009

TRANSMITTAL LETTER

Date:26/06/2009

Honoured, Minister of MH, Alush GASHI

I am pleased to introduce you to a new audit approach just recently put in practice by my office: Performance Audit. In carrying out a performance audit we examine the way in which an institution has used its resources in carrying out its duties. A performance audit focuses on a specific programme or function and seeks to determine the extent to which the programme objectives have been achieved (effectiveness) and whether this has been done economically and efficiently.

Please find attached my final Performance Audit Report on the Pharmaceutical program within the Ministry of Health covering the period 2008.

In accordance with the legal requirements this report will be published. I foresee a report from you within 30 days addressing the measures planned meeting the recommendations given in our report, including the measures you plan to undertake.

I appreciate the cooperation and courtesies extended to my staff during the audit. The Office of the Auditor General looks forward to cooperate with you also in the future.

Cc: Permanent Secretary, Haxhi KAMBERI

Cc: Chairperson of Budget and Finance Committee, Gani KOCI

Cc: Chairperson for Health, Work and Social Welfare Committee, Sadik IDRIZ

Cc: Director of PHD, Lutfi MULAKU

Yours Sincerely ,

Lars Lage OLOFSSON

Auditor General

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LIST OF ABBREVIATIONS

AI	Administrative Instruction
FCK	Pharmaceutical Corporation of Kosovo
MH	Ministry of Health
OAG	Office of Auditor General
PHD	Pharmaceutical Department
UCCK	University Clinical Centre of Kosovo

I. Executive Summary

The Pharmaceutical Department (PHD), within the Ministry of Health, is responsible for managing the supply and distribution of the 'essential list' of medicines to health institutions for onward dispensing to patients. The appropriated budget for the programme for 2008 was €15 million. The Office of the Auditor General (OAG) has conducted a performance audit of this programme with the objective of determining whether it has been managed in an efficient and effective manner. The audit focused on three main issues:

- whether hospitals' pharmacies receive and hold sufficient supplies (by type and quantity) of medicines from the essential list;
- whether adequate controls exist in hospital pharmacies over the receipt, storage, and distribution of other 'essential list' medicines;
- whether Ministry of Health officials investigate reported non-provision of 'essential list' medicines.

Main findings

The audit found weaknesses in all aspects of the program, raising the risk that essential medicines are not available to patients when needed. In particular:

- there are serious discrepancies between estimates of the amounts of essential medicines needed each year, the actual amounts made available, and the amounts actually requested by health institutions;
- pharmacies place orders direct with the private sector distribution company (KFK) rather than operating through Pharmaceutical Department, with the result that Pharmaceutical Department cannot properly manage and control the distribution process;
- pharmacies are not receiving the quantities of essential medicines ordered, apparently because of a shortage of medicines available in the central store;
- there is no systematic approach to ordering new supplies of medicines, raising the risk of medicines not being available for patients when needed;
- there are weaknesses in the control of medicines held in, and distributed from, the central store in that there is inadequate segregation of duties;
- Ministry of Health officials do not carry out periodic stock takes of medicines held in the central store;
- pharmaceutical storage facilities at UCKK are below standard, raising the risk of deterioration of medicines;
- there are insufficient controls over the physical distribution of medicines to patients.
- all in all these things create a risk prone environment, e.g. risks for leakage of medicines to patients outside the official health system; corruption and general mismanagement.

Recommendations:

We recommend the Minister of Health to initiate a more in depth analysis of the problems notified in this report and a development programme aiming to improve the distribution of medicines from the essential list and address the following recommendations:

1. The Ministry of Health, in conjunction with health institutions, should develop more robust and better informed estimates of the annual requirement of essential list medicines.
2. All requests made by health institutions for the supply of essential list medicines should be approved by the Pharmaceutical Department before being forwarded to the contracted distribution company for action.
3. The Pharmaceutical Department should investigate the reasons for the apparent failure in the supply chain of essential medicines.
4. The Pharmaceutical Department should issue guidelines for ordering medicines, including instructions for calculating a re-order level for each type of medicine based on average usage and lead time (processing order and delivery).
5. Pharmaceutical Department should ensure that a proper segregation of duties is introduced so that one individual does not have almost total control over the central storage operation.
6. The Pharmaceutical Department should ensure that independent stock takes of essential medicines held in the central store are carried out on a regular basis.
7. The authorities at University Clinical Centre of Kosovo (UCCK) should take action to bring the storage conditions up to an acceptable standard for the preservation of medicines.
8. We recommend that one point of departure in a strengthened process should be that records will be kept of which medicines, and quantities and prices, have been delivered to each patient.

II. Background

Law No. 03/L-075, Article 3.4 provides for the Auditor General to conduct a performance audit of the Ministry of Health (defined in Article 3.2 of the law as a Ministry of the Republic of Kosovo). In carrying out a performance audit, the Auditor General examines the way in which the Ministry has used its resources in discharging its duties. A performance audit focuses on a specific programme or function and seeks to determine the extent to which the programme objectives have been achieved (effectiveness) and whether this has been done economically and efficiently.

The Pharmaceutical Department, within the Ministry of Health, is responsible for managing the supply and distribution of ‘essential list’ medicines to health institutions for onward dispensing to patients. This activity is performed in accordance with Administrative Instruction No. 2007/11 (based on Law on Health No. 2004/4 promulgated with UNMIK Regulation No. 2004/31 effective from 27 December 2007). The appropriated budget for the programme for 2008 was 15 million euros. The essential list is compiled and approved on a regular basis by a commission within the Ministry of Health, and at the time of our audit it comprised 168 types of medicines.

III. Study objective and main issues

The objective of the performance audit was to determine whether the system for supplying and distributing ‘essential list’ medicines is sufficiently well managed and controlled to ensure that prescribed medicines are dispensed to patients as needed. Within this, we examined:

- whether hospitals’ pharmacies receive and hold sufficient supplies (by type and quantity) of medicines from the essential list;
- whether adequate controls exist in hospital pharmacies over the receipt, storage, and distribution of ‘essential list’ medicines;
- whether Ministry of Health officials investigate reported non-provision of ‘essential list’ medicines.

IV. Audit Scope

The scope of the study was limited to the arrangements put in place by Pharmaceutical Department to distribute medicines from the central storage facility to health institutions and for these institutions to hold and issue the medicines to patients. The study did not look at the arrangements for specifying medicines for inclusion on the ‘essential list’, nor did it examine the arrangements for purchasing medicines.

The study examined arrangements at two health institutions – Central University Clinic in Prishtina and Regional Hospital in Gjilan.

V. Methodology

The study methodology comprised a review of systems and controls, examining documents, testing a selection of transactions, and interviews with relevant staff. The specific audit tasks carried out were:

- reviewing existing regulation and practices for the administration and distribution of ‘essential list’ medicines;
- reconciling records relating to medicines issued from the central store and received by health institutions;
- tracking a limited selection of medicines through the distribution system;
- examining the storage premises in the two health institutions visited;
- reviewing procedures for issuing medicines from hospital pharmacies to patients and examining supporting records;
- interviewing relevant officials at the central storage depot and the two health institutions visited.

VI. Audit Findings

There are serious discrepancies between estimates of the amounts of essential medicines needed each year, the actual amounts made available, and the amounts actually requested by health institutions.

- We sought to establish from the Pharmaceutical Department whether the Commission that determines the estimated annual requirement for the specific ‘essential list’ medicines uses, as a basis for its planning exercise, the indicative needs prepared by each health institution. For a sample of 30 medicines, we compared the estimated annual requirement notified by the health institution with the amount recorded at the Ministry of Health. The results of this, testing revealed significant variances.

- We found cases, as set out in the table below, where the Pharmaceutical Department increased significantly increased the estimated annual requirement submitted by UCKK for fiscal year 2008.

Essential List Medicine	UCKK Estimate	PD Estimate for UCKK	Increase (%)
Adenosine ampoule 3mg/ml	1,940	80,000	4,123
Pancuronium Bromid nj. 2mg/ml	11,000	30,000	172
Oxytocin amp.10 IU/ml	26,220	40,000	53

There is a risk that this level of over-provision will have resulted in surplus stocks of these types of medicine, possibly resulting in wastage, while reducing the funds available for other medicines.

- We also found serious discrepancies at UCKK Central Pharmacy between the amounts of medicines estimated as required for 2008 and the amounts actually requested from central store during the year. The most serious discrepancies (for three types of medicine) are set out in the table below.

Essential List Medicine	Estimated requirement	Amount Requested	Shortfall (%)
Acetylsalicylic Acid 100mg tab	155,265	36,000	77
Amoxycilin 500mg	80,620	19,000	76
Gentamycin inj.80mg/2ml	142,325	50,200	65

- While there may be valid reasons for the shortfalls in the amounts of these types of medicines actually needed in 2008, the size of the shortfalls suggests that the estimated requirement was not based on reliable records of usage in previous years.,neither on “actual needs”

- The pharmacy’s management subsequently advised the audit team that they were aware that medicines were not available in the central store and that they therefore reduced the amount requested. This practice raises the risk of essential medicines not being available to patients and results in incorrect information being provided about the real physical need for medicines. It is essential that this situation be analysed in greater depth in order to find more effective mechanisms for the allocation.

- We also sought to establish whether the Commission’s annual planning exercise is carried out on a timely basis. Planning is carried out for each fiscal year, but the exercise is not completed until after the year has commenced. For example, planning the annual requirement for January to December 2008 was only completed in April 2008, some four months after the commencement of the year. As a result, there is a risk that supplies of essential medicines are not available in time to ensure continuity of supply by health institutions.

Conclusion: The estimates by Pharmaceutical Department and health institutions of the actual quantities of essential list medicines needed each year are unreliable and not based on any systematic analysis of usage and needs.

Recommendation no.1 The Ministry of Health, in conjunction with health institutions, should develop more robust and better informed estimates of the annual requirement of essential list medicines.

Pharmacies place orders direct with the distribution company (KFK) rather than operating through the Pharmaceutical Division

- The Pharmaceutical Department Administrative Instruction (No. 2007/11) sets out the steps to be followed for health institutions to order essential medicines. Specifically, according to Articles 11.3 and 11.4 of the Instruction, requests by health institutions for supply of medicines should be submitted to Pharmaceutical Department for approval. This enables the Department to monitor and control the volume of medicines being supplied to health institutions across Kosovo.

- We found, however, that requests for medicines are sometimes sent direct to the private contractor (KFK) at the central store in Mazgit. It was also clear, from discussions with officials and our review of relevant documents, that the quantities of medicines to be supplied to health institutions are approved by KFK and only countersigned by Pharmaceutical Department.

Conclusion: This practice prevents the Pharmaceutical Department from exercising effective management and control over the quantities of medicines being ordered by and delivered to individual health institutions. But it also indicates that the role of PD needs to be clarified by themselves in a dialogue with their stakeholders.

Recommendation no.2 All requests made by health institutions for the supply of essential list medicines should be approved by Pharmaceutical Department before being forwarded to the contracted distribution company for action.

Pharmacies are not receiving the quantities of essential medicines ordered

- We sought to establish to what extent the existing supply system is able to meet health institutions' requests for medicines.

- During discussions with the Director of Central Storage at UCKK we were told that the hospital's requests for medicines were rarely met in full – the quantities supplied were often below that requested.

- Based on monthly reports prepared by the central pharmacy of UCKK we compared the quantities requested with the quantities supplied for 30 (out of 168) requests over the period January-December 2008. In only 60 per cent of cases were all the medicines requested actually received. We were advised that the reason for these shortfalls was that there were insufficient supplies available at the central storage .

Conclusion: The current system for distributing essential medicines to health institutions does not ensure that they are provided with the amounts they request.

Recommendation no.3 Pharmaceutical Department should investigate the reasons for the apparent failure in the supply chain for essential medicines.

There is no systematic approach to ordering new supplies of medicines

- It is important that essential medicines are re-ordered before existing supplies are exhausted and that the order is made sufficiently in advance of this point to allow time for the order to be processed and medicines to be delivered to the health institution.

- From our discussions and review of existing guidance, it is clear that there are no instructions to assist health institutions determine at what point new supplies of medicines should be ordered. For a selection of orders, we analyzed the level of stock remaining at the point the order was made, and in each case it was zero.

Conclusion: Health institutions do not maintain a minimum stockholding (or buffer stock), raising the risk that essential medicines will not be available for patients as needed.

Recommendation no.4 The Pharmaceutical Department should issue guidelines for ordering medicines, including instructions for calculating a re-order level for each type of medicine based on average usage and lead time (processing order and delivery).

There are weaknesses in the control of medicines held in, and distributed from, the central store in that there is inadequate separation of duties.

- We examined the arrangements for distributing medicines from the central store to determine whether the activity is sufficiently well controlled (to prevent loss, theft etc). In particular, we reviewed the allocation of responsibilities to determine whether there is sufficient segregation of duties between the physical processes involved in storing and distributing medicines and the management oversight function.

- We found that there is inadequate segregation of duties because the same officer from within Pharmaceutical Department is responsible for overseeing receipt of medicines into the store, authorizing the dispersal of medicines from the store, and overseeing the whole distribution process.

Conclusion: This inadequate segregation of duties exposes the distribution of medicines to serious risks.

Recommendation no.5 Pharmaceutical Department should ensure that a proper segregation of duties is introduced so that just one individual does not have almost total control over the central storage operation.

Ministry of Health officials do not carry out periodic stocktaking of medicines held in central store

- Administrative Instruction (No. 11/2007) stipulates, in Article 22.2, that the Ministry of Health should carry out two stock takes each year of pharmaceutical products held in the central store.

- During discussions with relevant officials, we were advised that no stocktake was carried out by the Ministry of Health at the end of 2007. The private contractor (KFK) carried out a stock takes for its own purposes, but this was not witnessed by officials from the Ministry of Health. And at the time of our audit there had been no stocktake during 2008, though we were later advised that one had been carried out after our audit fieldwork had been completed.

Conclusion: The lack of regular stocktakes reduces the level of management control over medicines held in store and increases the risk of theft and misuse of medicines.

Recommendation no.6 Pharmaceutical Department should ensure that independent stocktakes of essential medicines held in the central store are carried out on a regular basis.

Pharmaceutical storage facilities at UCCK are not fully up to standard

- Medicines must be stored in a controlled environment to ensure that they remain usable for their indicated ‘shelf life’. Each storage facility should be secure (with restricted access), hygienic, waterproof, and temperature controlled.

- While at the central pharmacy at UCCK, we visited all the areas where medicines are kept and found that the condition of these storage areas is below the standard required for the preservation of medicines. While the stores were secure, the physical condition was poor, including a leaking roof, and the environment was humid and unhygienic.

- The central storage depot at Mazgit and the storage facility in Regional Hospital in Gjilan were in better condition.

Conclusion: Below standard storage conditions increases the risk that medicines will deteriorate and will have to be disposed of, resulting in a waste of resources.

Recommendation no.7 The authorities at UCCK should take action to bring the storage conditions up to an acceptable standard for the preservation of medicines.

There are insufficient controls over the physical distribution of medicines to patients

- It is important that the physical process of distributing medicines to patients is controlled and well documented.
- From conducting interviews with relevant officials and examining records, we found that the process of distributing medicines to patients is not sufficiently recorded.
- Tests carried out indicate that the process of distributing medicines from health units to patients is not recorded properly. Shortcomings noticed relates to identification and registration of medicines as well as the monitoring of the expenditures for the medicine..

Conclusion: Inadequate recording of medicines provided to patients raises the risk of improper use and waste of medicines. It also hinders any subsequent investigation by removing the ‘audit trail’ between the patient’s records and the medicines provided.

Recommendation no.8 The Minister of Health is recommended to initiate a thorough analyse of the process of distributing medicines to patients and based upon this take measures aimed at securing the quality in the distribution process. We recommend that one point of departure in a strengthened process should be that records will be kept of which medicines, and quantities and prices, have been delivered to each patient.

Our overall conclusion and recommendation is:

That the Minister of Health shall initiate a more in depth analysis of the problems notified in this report and a development programme aiming to improve the distribution of medicines from the essential list.