Republika e Kosovës
Republika Kosovo
Republic of Kosovo

Zyra Kombëtare e Auditimit
Nacionalna Kancelarija Revizije
National Audit Office

INFORMATION TECHNOLOGY AUDIT REPORT

Pharmaceutical Stock Information Management System

Prishtina, April 2024

The National Audit Office of the Republic of Kosovo is the highest economic and financial control institution vested by the Constitution and the Law[1] with functional, financial and operational independence

The National Audit Office is an independent institution that supports the Auditor General in carrying out his/her responsibilities. Our mission is to enhance public sector accountability through high-quality audits, promote transparency and good governance, and foster the economy, effectiveness, and efficiency of government programs for the benefit of all. We are thus building confidence in the spending of public funds and play an active role in securing the taxpayers' and other stakeholders' interest in increasing public accountability. The Auditor General is accountable to the Assembly for the exercise of duties and powers set forth in the Constitution, the Law, by-laws and in the public sector audit standards

This audit was conducted in accordance with the International Standards of Supreme Audit Institutions (ISSAI 3000[2]) and the Guidance on Audit of Information Systems (GUID 5100[3]).

The IT audits undertaken by the National Audit Office are an examination and review of IT systems and related controls to obtain assurance on the principles of legality, efficiency[4], economy[5], and effectiveness[6] of the information technology systems and related controls.

The Auditor General has decided on the IT audit reports on "Pharmaceutical Stock Information Management System" in consultation with the Assistant Auditor General Myrvete Gashi Morina who supervised the audit.

The audit team consisted of:

Samir Zymberi, Director of the Audit Department;
Shqipe Mujku Hajrizi, Team Leader; and
Kaltrina Sylejmani, Team Member

[1] Law no.05/L-055 on the Auditor General and the National Audit Office of the Republic of Kosovo
[2] ISSAI 3000 – Standards and guidelines for performance auditing based on INTOSAI's Auditing Standards and practical experience
[3] GUID 5100 – Guidance on Audit of Information Systems issued by INTOSAI
[4] Efficiency – The principle of efficiency involves maximising the output from available resources. It is about the relationship between the resources employed and the results given in terms of quantity, quality and time
[5] Economy - The principle of economy involves minimizing the cost of resources. The resources used should be available in a timely manner, in the right quantity and quality, and at the best price
[6] Effectiveness – The principle of effectiveness involves meeting predetermined objectives and achieving expected results

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List of abbreviations

FMA	Family Medicine Ambulance
KBRA	Kosovo Business Registration Agency
AIS	Agency for Information Society
BHIS	Basic Health Information System
CP	Central Pharmacy
PD	Pharmacy Division
DHIS	Department of Health Information System
NIPHK	National Institute of Public Health of Kosovo
HI	Health Institution
SHC	Secondary Health Care
PHC	Primary Health Care
PPRC	Public Procurement Regulatory Commission
THC	Tertiary Health Care
EML	Essential Medicines List
EL	Essential List
MH	Ministry of Health
EO	Economic Operator
SOP	Standard Operating Procedures
MFMC	Main Family Medicine Center
UCCK	University Clinical Center of Kosovo
FMC	Family Medicine Center
HUCSK	Hospital and University Clinic Service of Kosovo
PSMS	Pharmaceutical Stock Management System
IT	Information Technology
AI	Administrative Instruction
VPN	Virtual Private Network

Executive Summary

The Ministry of Health is responsible for developing and implementing healthcare policies to ensure an accessible and non-discriminatory system that adheres to high standards. This includes coordinating health initiatives, monitoring standards, improving public health awareness, disease prevention and supporting scientific research to guarantee quality and integrity in all health care services.

The National Audit Office has conducted an audit of the Information Technology to assess the management of the Pharmaceutical Stock System and the security of information related to this system at the Ministry of Health, as well as the system's utilization by public healthcare institutions in Kosovo.

Since 2013, the Ministry of Health has been investing in digitizing the management of pharmaceutical stock in healthcare institutions to supply medicines and disposable materials to patients from essential and non-essential lists. However, there are deficiencies in the system's scope and utilization, as well as in the management and governance of IT and data security.

The Ministry of Health has not fully implemented this system in all healthcare units, pharmacies in hospital wards and clinics, as well as Family Medicine Centers. This has led to inadequate management of pharmaceutical stock, lack of proper planning, and inefficient use of medicines and medical supplies. Additionally, there are weaknesses in information security and application controls within this system.

The Ministry lacks adequate mechanisms for IT governance despite significant investments in expanding systems. Over 6.1 million euros have been invested in expanding and improving hardware infrastructure across the territory of Kosovo, including healthcare systems and the Pharmaceutical Stock Management System. However, full implementation of the system has not been achieved by all pharmacies at various healthcare levels, up to the distribution of medicines to patients. There is a lack of clear responsibilities for managing the system, as well as IT policies and procedures. These shortcomings not only jeopardize the proper allocation of resources in investments, but also compromise the security of strategically important data for the Ministry of Health.

The Ministry of Health has not taken appropriate actions regarding the information security of the Pharmaceutical Stock Management System. There is a lack of a risk management plan for information systems and inadequate controls for information security. Additionally, the ministry has not properly managed logical access to the system, implemented a confidentiality statement, or established a dual hardware infrastructure for data recovery in case of system interruptions. These deficiencies increase the risk to patient privacy protection, data integrity, and pose a threat of data loss and service disruption for patients.

The Pharmaceutical Stock Management System has deficiencies in data registration and report generation. The lack of connection with central systems increases the risk of inaccurate data placement, while the failure to set expiration date limits for accepted items and not adjusting report generation according to officials' requests create extra work for officials and jeopardize the efficiency of medication use. Furthermore, the lack of technical measures in the system jeopardizes the protection of patients' personal data.

In order to address the identified issues related to the Pharmaceutical Stock Management System, we have provided 16 recommendations to the Ministry of Health, including the Hospital and University Clinic Service of Kosovo and Health Institutions.

Response from the Entities

The Ministry of Health, the Hospital and University Clinic Service of Kosovo, and the Municipality of Suhareka have agreed with the findings and conclusions of the audit, and have pledged to implement the recommendations provided.

Introduction

Healthcare in Kosovo is provided through a network of health institutions organized at three levels: primary (PHC)[7], secondary (SHC)[8] and tertiary (THC)[9], which includes the supply of medicines and disposable materials from the Essential Medicines List (EML), hereafter referred to as the Essential List (EL).

The Ministry of Health (MH), specifically the Pharmacy Division (PD), is responsible for supplying medicines and disposable materials from the Essential Medicines List (EML) to Primary Health Care (PHC) institutions based on the planning of those Institutions for 34 Main Family Medicine Centers (MFMCs). The MFMCs include Family Medicine Centers (FMCs) and Family Medicine Ambulances (FMAs). Additionally, it also supplies the National Institute of Public Health of Kosovo (NIPHK) with all types of vaccines according to the regular schedule, those with specific indications, flu vaccines, and specific products for the hospital level.

Meanwhile, the Central Pharmacy of the Hospital and University Clinic Service of Kosovo (HUCSK) supplies of medicines and medical materials from the Essential List (EL) as well as those not on the Essential List (through own revenues, donations) for the secondary and tertiary levels of health care.

The HUCSK provides supplies to 13 pharmacies of the University Clinical Center of Kosovo (UCCK): Pharmacies of the Oncology Clinic; Dermatology/Pulmonology; Surgery; Internal Medicine; Infectious Diseases; Neurology/Psychiatry; Pediatrics; Gynecology; Anesthesiology/Emergency Center; Orthopedics; ENT/Ophthalmology; Biochemistry and the Neonatology Clinic, as well as to seven (7) Regional Hospitals: the clinical pharmacies at Prizren, Gjakova, Peja, Gjilan, Ferizaj, Mitrovica and Vushtrri hospitals.

In order to improve the supply and management of pharmaceutical stock in healthcare institutions, the Ministry of Health began developing the Pharmaceutical Stock Management System (PSMS) in 2013. This centralized system is responsible for managing the supply of medicines and medical materials, both from the essential medicines list and those not on the essential medicines list, for all health care institutions. In 2018, the National Council of the Health Information System decided that this system should be further developed and utilized at all levels of healthcare in Kosovo.

The Pharmaceutical Stock Management System includes all processes related to registering and treating system users, managing the pharmaceutical warehouse resources of Health Institutions (HI) as easily and efficiently as possible, helping to facilitate the organization of

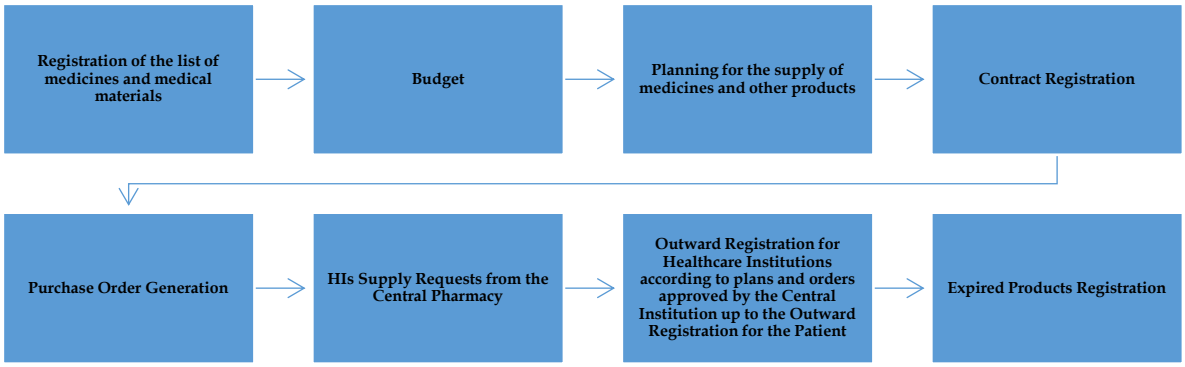
[7] The primary level includes Family Medicine Centers (FMCs) and Family Medicine Ambulances (FMAs).

[8] The secondary level includes the regional hospitals of Kosovo and the University Clinical Center of Kosovo (Pristina does not have a regional hospital, but instead uses the UCCK).

[9] The tertiary level includes the University Clinical Center of Kosovo.

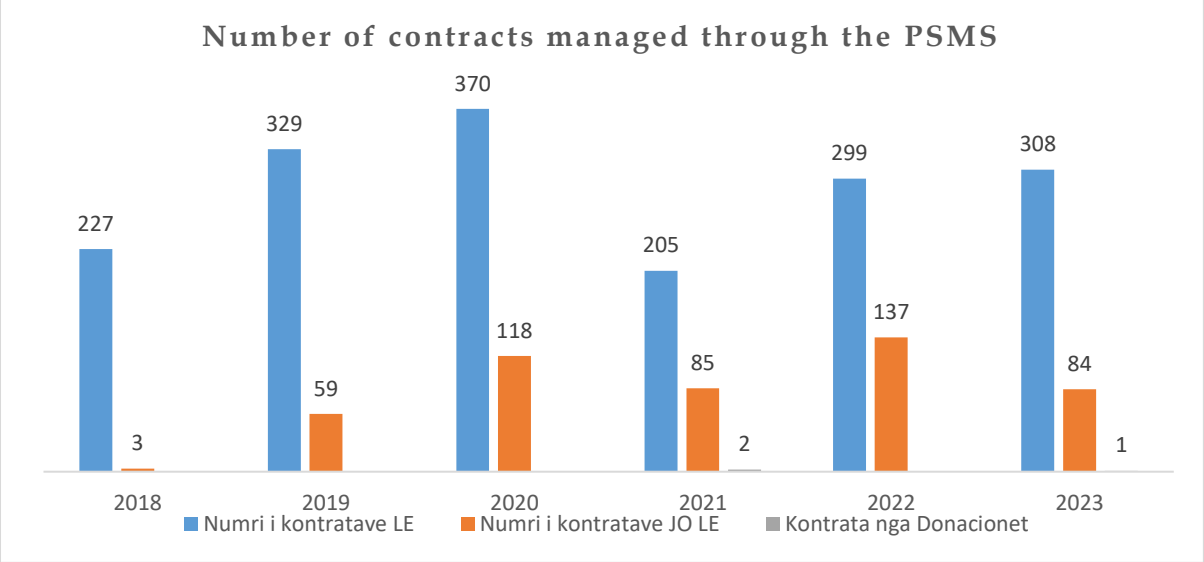
work within the institutions that use the system, from initial planning to patient discharge. Figure 1 shows the activities summarized in the Pharmaceutical Stock Management System.

Figure. 1 Activities summarized in the PSMS



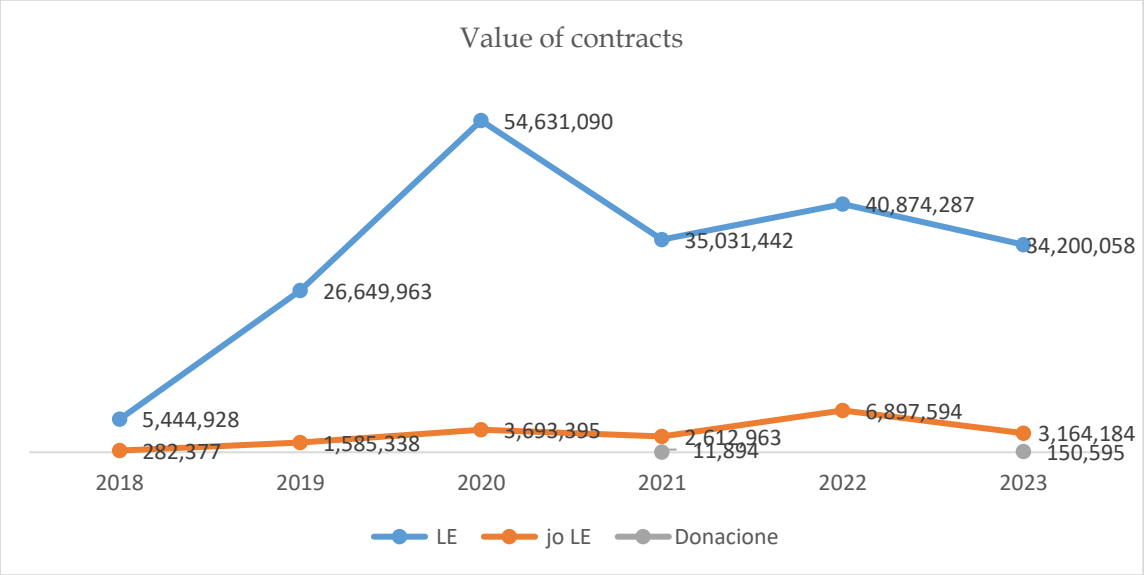
Through the Pharmaceutical Stock Management System (PSMS), a total of 2,228 contracts for the supply of medicines and medical materials from both the essential and non-essential list, as well as donations, were managed between 2018 and 2023. Figure 2 shows the number of contracts and that were registered and managed by the MH, the HUCSK, and HIs during the period 2018-2023 from the essential list (EL) and those not on the EL, with revenues coming from government grants, own revenues, and donations.

Figure 2. Number of contracts registered and managed in PSMS from EL and non-EL during 2018 - 2023



The total value of contracts registered in PSMS and managed by MH, HUCSK, and HIs during the period 2018-2023 is 215,230,107 euros.

Figure 3. Value of contracts managed in SMSF from EL and non-EL (own revenues, donations) during 2018 - 2023


Value of contracts
54,631,090
40,874,287
35,031,442
34,200,058
26,649,963
5,444,928
6,897,594
3,693,395
3,164,184
2,612,963
1,585,338
282,377
11,894
150,595
2018
2019
2020
2021
2022
2023
LE
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Objectives and Areas of Audit

The objective of this audit is to assess the management of the Pharmaceutical Stock System and the security of information related to this system at the Ministry of Health, as well as the system's utilization by public healthcare institutions in Kosovo.

Through this audit, our goal is to provide pertinent recommendations to the Ministry of Health and public healthcare institutions, in order to enhance the management of the information system.

Areas of audit - in order to achieve the audit objective, we have focused on IT governance, information security and application controls.

We have selected the following areas of audit:

Areas of audit	Audit issues
1. IT governance	1. IT organization structure
	2. IT policies and procedures
	3. Change development and management
	4. Monitoring
2. Information security	5. Risk assessment
	6. Security and confidentiality policies
	7. Access controls
	8. Disaster recovery plan
3. Application controls	9. Entry controls
	10. Exit controls

The focus of the audit is the Pharmaceutical Stock Management System, which has digitalized the process of managing medicines and disposable materials, encompassing stages from initial planning to distribution to patients. The audit covers the period from 2022 to 2023.

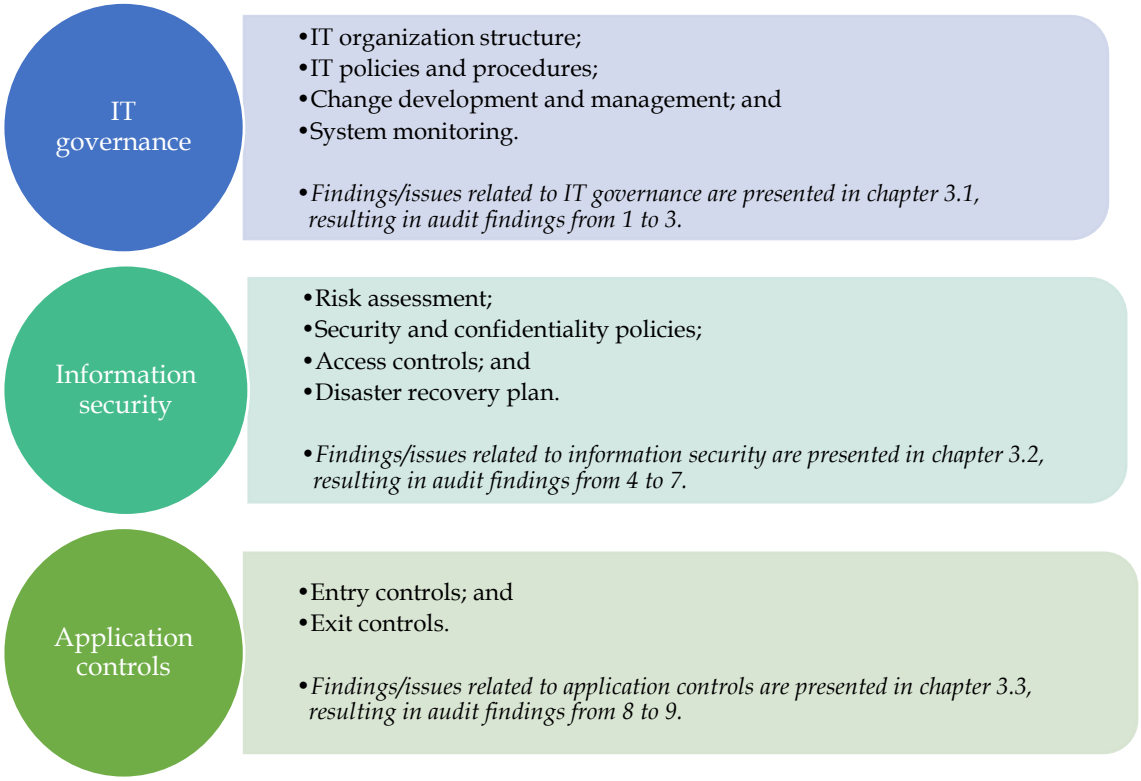
The methodology, questions, and criteria of the audit can be found in the appendix of this report[10]. The audit scope includes the Ministry of Health, specifically the Department of Health Information System and the Pharmacy Division, the Central Pharmacy of UCCK/HUCSK, the Oncology Clinic, the Neurological Clinic, the General Hospital in Gjilan, and the MFMC in Suhareka.

[10] Appendix I, methodology, questions, and criteria of the audit.

Findings of the Audit

This chapter presents the findings of the audit related to the activities of the parties responsible for managing the PSMS and the security of the system information in the MH and central pharmacies of: UCCK/HUCSK, the Oncology Clinic, the Neurological Clinic, the General Hospital in Gjilan, and the MFMC in Suhareka, all of which are PSMS users. The findings are structured into three parts, interconnected according to the audit issues as shown in Figure 4.

Figure 4. Structure of audit issues for the PSMS



3.1 Information Technology Governance

IT governance is the process that oversees information technology within an organization. This includes managing and supervising activities related to information technology such as the overall structure that guides the IT operations of an organization, developing and implementing IT policies and procedures, development and acquisition, monitoring, etc. These processes ensure that IT systems support and enable the achievement of the institution's objectives.[11]

Figure 5. Information technology governance

1. ***The PSMS is not used by all healthcare units***

Healthcare institutions should utilize the PSMS and manage all stocks of medicinal products (medicines and disposable materials) through this system[12]. The organization gathers and analysis performance data for the system/network regularly to better align with the organization's information systems monitoring and management needs.[13]

Health institutions have not been able to fully utilize the Pharmaceutical Stock Management System at all levels of healthcare. They have not provided the necessary physical and hardware infrastructure to enable the use of the PSMS, have not updated the Standard Operating Procedures (SOPs), not all system modules are used by all Healthcare Institutions, and patient exit transactions are not recorded in the system. Figure 6 shows the units of Healthcare Institutions and the level of PSMS utilization.

[11] Information Technology Audit Handbook, IT Governance.
[12] Information Circular 4/2023, Ministry of Health, Office of the Secretary General.
[13] Information Technology Audit Handbook, IT Operations.

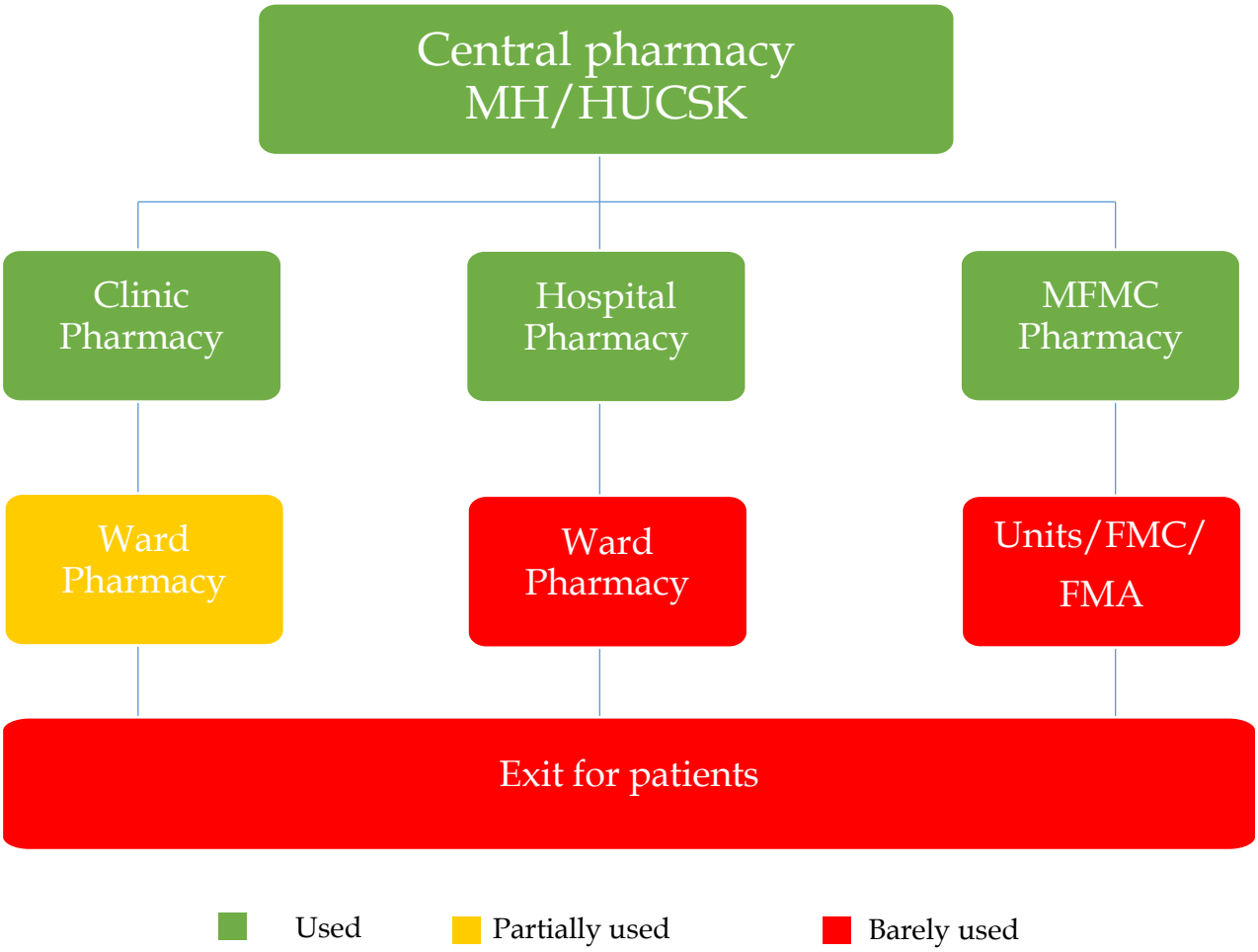


Figure 6. Units of Healthcare Institutions that utilize PSMS

From the figure, it can be seen that PSMS is utilized by pharmacies in clinics/hospitals or the MFMC, but it is barely utilized or only partially utilized in the pharmacies of clinic/hospital wards or FMC units, as well as partially utilized during the patient's exit (discharge).

Below, we have outlined the shortcomings in the audited entities responsible for administering the PSMS and managing pharmaceutical stock in healthcare units. These entities are responsible for managing pharmaceutical stock to the distribution of medicines and disposable materials to patients:

- **Ministry of Health**, specifically the DHIS, has not fully implemented the Pharmaceutical Stock Management System (PSMS) in all healthcare institutions for faster, safer, and more efficient management of pharmaceutical warehouses in primary, secondary and tertiary healthcare institutions.

The PSMS was initially developed in 2013 and then redesigned in 2019. However, the implementation of the system has been slow and incomplete. Currently, it has only been implemented in the central pharmacies of HUCSK, UCCK Clinics, all regional hospitals in Kosovo, and MFMCs.

The system is not used by all pharmacies in the wards of the UCCK clinics and regional hospitals, as well as by the Family Medicine Centers (FMCs) and Family Medicine Ambulances (FMAs) in the municipalities.
Overall, MFMCs utilize the Pharmaceutical Stock Management System (PSMS) until the patient's discharge, however, we have observed that the registration of "Insulin" for each patient in the system is incomplete. Planning for the supply of "Insulin" in the PSMS is consistently carried out and with specific quantities. The system communicates through the centralized GG[14] Platform with the Civil Registration System, where personal data of patients are collected and used for monthly insulin planning registration, verifying the patient's vital status (alive/deceased.

During the period from 2013 to 2018, the Ministry of Health has signed two contracts to expand the Health Information System infrastructure to cover 100% of the country's territory, with a total value of 6,158,884 euros. The goal of these two contracts was to guarantee the functionality of healthcare systems, including the Pharmaceutical Stock Management System (PSMS).[15]

However, during the audit process at General Hospital in Gjilan and at the MFMC in Suhareka, if was observed that the "Zero Client"[16] devices acquired through these contracts were not being utilized to connect to the Pharmaceutical Stock Management System (PSMS). This was because the devices could not be accessed on the virtual servers of the MH. Furthermore, the network extension in the facilities of the FMCs and FMAs in the Municipality of Suhareka was not carried out as planned. This was primarily due to the contracts not being enforced properly and the absence of a maintenance contract for the infrastructure of the Health Information System.

Therefore, the reason for not using the Pharmaceutical Stock Management System (PSMS) has been the lack of physical and IT infrastructure in all healthcare institutions, the inability of users to access the PSMS, and the staff's unwillingness to use the system.

[14] Government Getaway-The centralized platform that serves to interconnect the systems of institutions, of the public and private secto

[15] In 2013, the Ministry of Health (MH), co-funded by the Luxembourg Development Government Office-LuxDev invested in expanding the HIs network infrastructure in 30% of the territory of Kosovo, totaling 1,542,796 euros.
In 2018, the MH signed a framework contract for the expansion of the HIs network infrastructure in 70% of the territory of Kosovo, totaling 4,616,088 euros.

[16] Zero Client is a server-based computing model in which the end user's computing device has no local storage.

- **The Pharmaceutical Division at the Ministry of Health** oversees the central warehouse of the Ministry of Health that supplies medicines and medical supplies to all MFMCs in the municipalities from the Essential List (EL), as well as specific medicines to the UCCK and hospitals. The PD requires these institutions to establish annual and monthly supply planning for medicines and medical supplies from the Essential List (EL). The Pharmaceutical Division utilizes the Pharmaceutical Stock Management System (PSMS) for managing the pharmaceutical stock in all activities. However, the SOPs used by the PD have not been updated since 2015 and do not align with the work activities in the Pharmaceutical Stock Management System (PSMS). This is due to frequent changes in the management of the Division.

- **At the MFMC in Suhareka**, the Pharmaceutical Stock Management System (PSMS) is only used by the Central Pharmacy (CP) to set annual plans and request the supply of medicines and medical supplies from the Essential List (EL). Once the Ministry of Health supplies the items, the MFMC's Pharmacy does not record any transaction in the PSMS. The unit outputs in the pharmacies of the wards of the MFMC, FMC and FMA, and the outputs for patient supply with medicines and medical supplies are done manually using protocol books. Although the system has been operational in the Pharmacy of the MFMC since the beginning of its implementation, it has not been consistently utilized, resulting in no stock outputs recorded in the PSMS. As a result, there is stock imbalance in the PSMS. The Central Pharmacy (CP) of the MFMC has repeatedly asked the MH to adjust the previous stock to match the actual situation and to ensure that transactions for outputs are recorded through the PSMS, but no actions have been taken thus far.

  Furthermore, the MFMC does not record contracts for the supply of medicines and medical supplies in the Pharmaceutical Stock Management System (PSMS) using its own revenues. This is because there is a lack of knowledge about how to record in the PSMS, with the argument that the staff is new and has not received adequate training for using this system.

  Additionally, the lack of utilization of the system by six (6) FMCs and two (2) FMAs in the Municipality of Suhareka has been influenced by the absence of network infrastructure coverage in facilities, preventing them from connecting to the PSMS. The MFMC currently has 30 "Zero Client" devices in stock and has requested network expansion from DHIS for its units. The network expansion in the municipalities is currently underway. Two of the FMCs are undergoing renovation, while one has moved to a new facility.

  Furthermore, despite the lack of network extension, since 2020 AIS has been paying EO 20.40 euros per month FMC for VPN network service for five (5) FMCs. 4,488 euros have been paid unnecessarily until December 2023. However, MH has not informed AIS to discontinue the VPN services.

The municipality of Suharekë has entered a three-year contract with EO for the period of 2023-2025 to supply medicines and medical supplies for the Suhareka Main Family Medicine Center. However, within this contract there are products from the Essential List (EL) for which the responsibility of supply lies with MH. As a result, the Pharmacy Division at MH is unable to monitor the current stock at MFMCs and plan the institution's needs for supplying EL medicines.

- **The Central Pharmacy (CP) at HUCSK/UCCK,** is responsible for supplying medicines and medical supplies from the Essential List (EL) to the UCCK clinics and regional hospitals. The Central Pharmacy at HUCSK does not require the heads of regional hospital Central Pharmacies, the heads of clinical pharmacies, services and preclinical institutes of the UCCK to register the annual planning for medicines and medical supplies from the Essential List (EL) approved by HUCSK in the Pharmaceutical Stock Management System (PSMS). The HIs deliver the planning manually in Excel format. Due to not recording the planning into the system, HIs cannot make requests for the supply of medicines and medical supplies through the PSMS. These requests are carried out manually.

- Therefore, the officials at the Central Pharmacy (CP) manually follow the plans of the Healthcare Institutions (His) regarding supply requests. Additionally, the SOPs have not been updated since 2018, as a result they are not aligned with certain activities that can be performed in Pharmaceutical Stock Management System (PSMS) with the workflow in the Central Pharmacy at HUCSK and the Central Pharmacies of hospitals and clinics.

- **At the Neurology Clinic in UCCK,** the system is well implemented. The Clinic's pharmacy and ward pharmacies record all transactions related to the supply and distribution of medicines and medical supplies in the Pharmaceutical Stock Management System (PSMS) up to the patient's output transaction. However, the reconciliation of stock between the Clinic's wards is not done on the same day. The head nurse records the therapy that the patient received in the system under the field "output for patients" after the patient's history is closed. The delay in recording the therapy in the PSMS is due to staff shortage. However, for cases where patients receive monthly therapy prescribed by the doctor, the output for patients in the PSMS is registered immediately.

- **At the Oncology Clinic in UCCK**, the Pharmaceutical Stock Management System (PSMS) is utilized in the Clinic's Pharmacy, but not in the ward pharmacies. The Pharmacy receives supplies from the Central Pharmacy, which records outputs for the Oncology Clinic in PSMS. The Clinic's Pharmacy records all outputs for the ward pharmacies[17] in PSMS and reconciles the physical stock with electronic records daily.

[17] In this case, the designation "ward pharmacy" was used according to the designation in the PSMS.

The Clinic's Pharmacy manually processes supply requests from the Clinic's wards for each patient. Based on the requests, the Pharmacy dispenses medications to the ward pharmacies, where they are received by the head nurses. However, the PSMS is not utilized during the administration and distribution of medications to the patients.

The reasons for the delay in implementing the PSMS at this clinic until the patient is discharged are: firstly, the IT department at UCCK started training the staff at the Oncology Clinic late, and secondly, the staff was not prepared to implement the system. The training that was scheduled for September 2023 failed twice. In the first call, the staff did not have the current stock on hand to register in the PSMS, and during the second call, most of the designated staff were on annual leave. Currently, the Clinic is undergoing renovations and services are being provided from other clinics/centers.

- **The general hospital in Gjilan**, PSMS has only been utilized in the Central Pharmacy of the Hospital. The pharmacy currently accepts supply requests from hospital wards manually, while recording the outputs for distribution of products to the wards in the system. However, after the delivery of medicines and medical supplies to the wards and distribution to patients, the PSMS is not utilized. The staff's unwillingness and inability to access "Zero Client" devices on the virtual servers of the MH are the reasons for this situation. At the end of 2021, the hospital received hardware and network devices, including 160 "Zero Client" devices under the Ministry of Health's "Expansion of the HIs infrastructure" contract. However, since July 2023, users in GH Gjilan have been unable to use "Zero Client" devices because they could not connect to MH's virtual servers. This has forced them to go back to using old computer devices, causing problems with accessing, recording transaction, and generating reports in SMSF. There have even been instances where the Central Pharmacy of the Hospital could not connect to the PSMS for several days.

  Additionally, at Gjilan Hospital, contracts for the supply of medicines and medical supplies that are funded through their own revenues are not being registered in the PSMS. The justification given is that they were not aware that these contracts should be registered into the system. These contracts are not overseen by the Central Pharmacy of the Hospital and the products obtained through them are only recorded as inputs.

The lack of implementation of the Pharmaceutical Stock Management System (PSMS) by Health Institutions in all their activities, from planning to output for patients (discharge), has a significant impact on pharmaceutical stock management. These shortcomings lead to inadequate medication planning and improper allocation of resources. Consequently, this leads to inaccurate reporting of pharmaceutical stock levels and inefficient patient supply.

Moreover, the failure to utilize the Pharmaceutical PSMS makes it challenging to monitor HIs in terms of stock expenditure and the appropriate use inappropriate use of medicines and medical supplies.

2. *The roles and responsibilities of officials in managing the PSMS are not clearly defined*

The IT structure within the organization needs to be clearly defined, with its roles and responsibilities must be clearly outlined to effectively maintain the IT systems.[18]

The Department of Health Information System (DHIS) lacks a clearly defined IT structure, including roles and responsibilities for managing the PSMS. This department is in charge of maintaining and operating the PSMS, as well as providing authorizations for access to data sources and records as needed in the system. Furthermore, monitoring the operation of the PSMS falls under the responsibility of the Pharmacy Division (PD) at the Ministry of Health.

Users of the Pharmaceutical Stock Management System (PSMS) in Health Institutions are not informed by Ministry of Health about the designated official to contact for new requests or issues related to PSMS. Without this information, officials in HIs using PSMS end up communicating with various officials from the Department of Health Information System (DHIS), IT officials from the UCCK, or directly contacting the EO officials who maintain the system.

The management of PSMS was previously handled by the designated IT staff, but they have terminated their employment contract with the Ministry of HEalth. As a result, the current official assigned to this task now has conflicting responsibilities, as they are in charge of both the database and the PSMS application. This situation aros due to a shortage of IT staff and the frequent turnover of managerial staff within the Pharmacy Division acquiring the responsibility of managing users and data in the PSMS application. The Ministry of Health drafted a new regulation in 2023, that outlines the division of responsibilities for PSMS administration, and in early 2024, they announced a competition to recruit a new IT official.

The improper distribution of responsibilities causes delays in providing necessary services for PSMS, resulting in SMSF managers lacking knowledge to address issues identified by system users. Additionally, this leads to difficulties in managing PSMS, hidering the preservation of the integrity of health information.

3. *The Ministry lacks IT policies and procedures*

The organization should document, adopt and communicate the necessary policies and procedures to guide business and IT operations in order to achieve its mandate.[19] *In the change management*

[18] Information Technology Audit Handbook, IT Governance Audit Matrix.
[19] Information Technology Audit Handbook, IT Governance Audit Matrix.

process, change controls should be defined as follows: Change request - validation - acceptance - prioritization - design change - change testing - implementation - documentation.[20]

The Ministry of Health, respectively the Department of Health Information System (DHIS), is responsible for implementing work practices for IT activities. However, they do not have approved policies and procedures for IT. DHIS is tasked with drafting and implementing policies for the development, maintenance and operation of health information systems.

To date, DHIS has only drafted two SOPs in 2022, but they have not yet been approved. These SOPs are not sufficient to ensure a secure IT environment and to guarantee the safety and quality of data in health information systems. The Ministry of Health only adheres to the regulations and guidelines of the AIS for the services it receives from AIS.

The Ministry of Health, respectively the Department of Health Information System (DHIS), has failed to take action to review and approve SOPs, or to create additional policies and procedures to ensure information security in healthcare systems. There is no justification for not taking the necessary steps to develop IT policies and procedures.

Due to the lack of proper change management controls within information systems, change requests are submitted via emails, going directly to the Economic Operator (EO), without approval from a responsible official for system management and maintenance from the Ministry of Health. There are cases where change requests are made only through meetings and not always accompanied by formal supporting documents.

In 2019, the Ministry sent an email / letter warning the Economic Operator (EO) not to respond to any requests that had not been previously analyzed by DHIS officials. However, this practice was not followed during the years 2022/2023. Furthermore, DHIS officials have granted HIs officials the right to direct requests directly to the Economic Operator (EO), while keeping DHIS officials informed.

Officials from the Central Pharmacy at UCCK are makiing requests for changes in the system directly to the Economic Operator (EO), without informing the DHIS officials, who are the system owners. These changes are being applied directly to the live system instead of the test system, and there is no testing of the changes being done by the requesting unit. Additionally, these changes are not being documented, which makes it impossible to track the changes made in the system.

The absence of policies and procedures for IT administration poses a risk to employees and third parties in properly protecting information security and achieving the Ministry's objectives. This includes risks related to safeguarding personal data privacy, potential legal consequences, human resource management, and the efficient utilization of healthcare information systems, which are crucial strategically. Furthermore, the lack of a documented authorization process for changes made impedes proper accountability, raises the likelihood

[20] Information Technology Audit Handbook, IT Governance Audit Matrix.

of unauthorized changes, and compromises the ability to accurately identify errors that could affect other process changes within the system.

3.2 Information Security

Information security is a fundamental aspect of IT governance. In order to effectively manage information security, an organization must establish control mechanisms and adhere to them in order to protect information and minimize the risk of loss of confidentiality, integrity and availability of that information to an acceptable level.

Figure. Principles of information security

4. ***The Ministry of Health does not have a risk management plan for its information systems***

The organization should establish risk management policies and plans, as well as determine sufficient resources to identify and manage risks.[21]

The Ministry of Health has not developed a risk management plan for information systems, which includes identifying risks related to the systems, risk assessment, risk treatment, risk monitoring, and reporting on the security of information systems.

The Ministry has developed the "Institutional Integrity Plan 2023-2026", which includes a risk management plan for the Health Information System. However, this plan does not address specific risks related to the security and functionality of information systems. In this plan, the only identified risk is "Data and document storage and security", which only pertains to the system utilization. Additionally, the Department of Health Information System prepares the "Annual Work Plan of the Health Information Department" each year, where the only risk included is the non-implementation of projects in the procurement

[21] Information Technology Audit Handbook, IT Governance Audit Matrix.

procedures. This is due to the Department of Health Information System lacking work practices for managing information system risks.

The failure to identify and assess risks, along with the absence of a comprehensive risk management plan in information systems, puts resource allocation at risk of being directed towards inappropriate investments that may not effectively help in reducing risks and could lead to system failures. This situation could ultimately result in critical data loss, system disruptions, and financial damages for the institution.

5. ***The Ministry lacks adequate information security controls***

Information security policies address all operational risks and are capable of reasonably protecting all critical information assets from loss, damage and misuse. It is essential for personnel to comprehend and uphold information security measures. Employees, contractors and third-party users should be required to sign a confidentiality or non-disclosure agreement as part of their initial terms and conditions of employment.[22]

The Ministry has not taken any actions to address information security in order to protect assets and information from the potential loss of integrity, confidentiality and availability of data. However, the feasibility report does include recommendations regarding the aspect of data security and privacy that information systems should contain.

The Director of the Department of Health Information System explained that they intend to transfer the objective related to information security to the Agency for Information Society, but there is currently no agreement between the institutions. The draft organizational chart for DHIS includes a position for IT security, in accordance with the new draft regulation for internal organization and systematization of jobs.

In the Pharmaceutical Stock Management System (PSMS), there are no privacy protection measures in place to safeguard patient data. The PSMS database and application administrator can easily access personal data and the therapy received of patients, as this data is not encrypted and there are no restrictions within the application.

The requirement to sign the Confidentiality Declaration is not being enforced in the Ministry of Health for natural and legal persons when establishing contractual relationships (for the maintenance, development, and modification of information systems). This obligation is also specified in Administrative Instruction No. 11/2013 on Health Information System and Reporting of the Statistical Health Data.

Monitoring of activities in the information systems infrastructure is not being conducted, despite the MH investing in software for monitoring applications and the network under the contract "Expansion of Existing Infrastructure for HIS" in 2018. The Department of Health Information System does not offer awareness training for staff regarding information

[22] Information Technology audit handbook, information security audit matrix.

security. Furthermore, some officials at Health Instructions use their personal emails for communication. This is because there was no requirement from the MH that communication must be done solely through official e-mail.

Failure to implement information security controls can impact the protection of information from misuse, patient privacy breaches, data loss, and legal consequences.

6. The Ministry of Health does not have control over user access management in PSMS

Access procedures should establish a basis for intervention control in information. There should be divisions of responsibilities and controls to prevent unauthorized changes to information systems and system configurations. Access rights to the use of information systems for all employees, contractors or third parties must be suspended at the moment of contract termination, or adjusted to changes in responsibilities.[23]

The Ministry has the following shortcomings because of the lack of controls for information system access management and the implementation of information security standards:

- **Database administrators have full access to server administration where the Pharmaceutical Stock Management System is located, as well as application management**. This is due to the lack of proper task division. Additionally, the PSMS administrators, including the EO, use general shared accounts to administer the PSMS servers, database and application.
- **The Economic Operator has full access to the database and application**. User accounts in the Pharmaceutical Stock Management System (PSMS) are opened by the Economic Operator. Requests for account openings via e-mail from Health Institution officials are sent to the HIS coordinators of the relevant institutions. These requests are then forwarded to the Ministry of Health officials. The PSMS administrator in DHIS does not process account opening requests in the system, instead these requests are transferred to the Economic Operator.
  Additionally, any changes in the database are made by the Economic Operator. In the analysis of the records registered in the PSMS, there are cases where the sequential numbering (+1) was disrupted. This was due to technical errors during user registration, and the affected records have been deleted.
- **There are active non-personalized accounts in the Pharmaceutical Stock Management System (PSMS) application and database. T**he list of active users in the PSMS application shows that there are active non-personalized accounts. Additionally, there are non-personalized accounts with the role of "administrator" that have privileges to open and close user accounts, assig roles and responsibilities to user accounts, and edit or change data.
  Furthermore, even in the PSMS database, user accounts are not personalized. The same account is used by the database administrator and the Economic Operator. This

[23] ISACA-CISA Review Manual 27th Edition, 2019, Protection of Information Assets.

is because the database administrator and the application did not have officially personalized accounts set up in the database and application.
During the audit, the Department of Health Information System (DHIS) took steps to address this issue by deactivating non-personalized accounts in the PSMS application and creating personalized accounts for managing the PSMS database.

- **User access rights are not reviewed.** The Department of Health Information System (DHIS) does not deactivate the accounts of officials when their employment relationship with any health institution is terminated or when there is a change in position. It was found that there are active accounts of officials who terminated their employment relationship over a year ago but still have active accounts in the PSMS application and its infrastructure. During the audit, DHIS officials took action and deactivated these accounts.
In the Pharmaceutical Stock Management System (PSMS), there are up to three active accounts for the same official from the same institution, each with different roles. The system allows for additional privileges to be assigned to a user's role to carry out various work activities. This often results in officials having to log in and out of PSMS multiple times to complete work activities in the system.

Furthermore, in cases where an official responsible for managing a contract and either leaves their position or changes their employment status, their account remains active until the contract expires. The system does have the capability to transfer contracts to another user. However, users of PSMS at the Central Pharmacy have not been informed by the Ministry of Health about this feature, and as a result, they have not requested the transfer of contracts to the current responsible official.

There is a shortage of alternative (backup) officials in the Ministry of Health who can access the Pharmaceutical Stock Management System (PSMS) to perform specific tasks. As a result, there are user accounts that have carried out activities in the system during the annual leave period.

This is because the MH lacks a procedure for opening and closing user accounts, and the Department of Health Information System (DHIS) does not have a practice of periodically reviewing active accounts in information systems to verify that those accounts should be active or with those privileges. The Healthcare Institutions do not notify the coordinators of the HIS and the MH about the deactivation of accounts for officials who have terminated their employment relationship or have changed job position.

These deficiencies pose a risk of intentional and unauthorized transactions being conducted/modified/concealed. Likewise, transactions carried out in the PSMS may go unnoticed, compromising the integrity of data and information processing infrastructure may not be maintained, jeopardizing the protection of personal data, unauthorized access to information, information disclosure, and could lead to reputation loss for institutions.

7. The Ministry lacks a plan for maintaining information systems in the event of disasters

The organization needs to have a plan in place to ensure the continuity of information system operations, allowing activities to continue uninterrupted. To establish this plan, the organization needs to identify its main processes, determine response and recovery times, and assess potential losses.[24]

The Ministry has not developed a plan for the continuity of information systems in case of disasters, including natural disasters, cyber-attacks, and other factors that may affect the operation of the system. There is no redundant hardware infrastructure for the quick recovery of information systems in case of primary infrastructure failure. The Ministry of Health has allocated a budget for establishing a data recovery center. However, in 2019, the Ministry of Health coordinated with the Agency for Information Society (AIS) with the aim of creating a single center that can be used by all institutions of the country, including the Ministry of Health. Unfortunately, the AIS has not yet established a data recovery center.

The Department of Health Information System backs up the Pharmaceutical Stock Management System (PSMS) at the primary infrastructure's geographical location. However, it does not create a backup in another geographic location to mitigate risks in case of natural disasters or other events. The PSMS administrator occasionally backs up data on their PC, when a storage medium for data backup is unavailable. The most recent backup was done on the PC in July 2023 and is not password protected or encrypted.

The Ministry of Health is concerned about the lack of necessary infrastructure, despite having invested in hardware infrastructure, backup systems, and equipment for storing backup copies on servers (tapes). These investments are outlined in contracts related to the expansion of the Health Information System infrastructure in the country.

Although backups of the Pharmaceutical Stock Management System (PSMS) are regularly conducted, there is a lack of periodic tests for data recovery to ensure the system's efficiency in case of a malfunction.

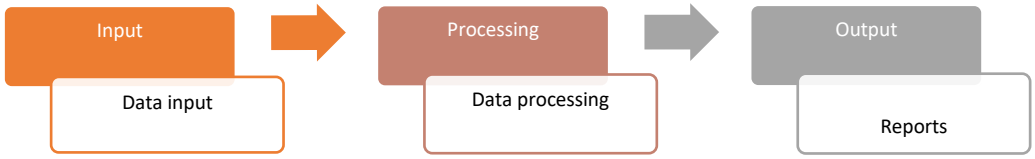
These identified deficiencies pose a risk of operational failure and impede the functioning of the Pharmaceutical Stock Management System (PSMS), as well as potentially leading to data loss.

[24] Information Technology audit handbook, audit matrix on BCP/DRP.

3.3 Application Controls

Application controls are controls to ensure and protect the accuracy, integrity, feasibility and confidentiality of information. They ensure proper initiation of authorized transactions, valid data processing, complete recording and accurate reporting.

Figure 8. Application controls



8. Some fields in the PSMS application lack validity controls for input data

Validaty rules shall be well designed, documented, and implemented in input interaction. The application shall have validation procedures in place to protect against data entry errors. Invalid data is properly rejected by the application[25]. The medicinal produkt shall have at least one (1) year of expiration date remaining. If the medicinal product has a defined total duration for use of one year or less after production, then import shall be allowed if the medicinal product has 2/3 of this period at the time it is imported into the Republic of Kosovo.[26]

PSMS lacks validation of fields for recording input data. This happened due to the lack of defined validation of the fields for data recording in the system. PSMS also has no connection with central information systems such as KBRA and PPRC which would enable only accurate data to be recorded in the system. As a result of the lack of connection with KBRA, there are cases where the same EO is recorded in the system more than once. Further, due to the lack of integration with PPRC, contract managers are obliged to record the same transactions in both systems.

When creating user accounts in PSMS, the personal number registration field is not linked to the Civil Registration System. The system communicates through the GG with the Civil Registration System, where the personal data of the patients are obtained for the registration of the output medications per patient. Whereas not using the connection of the "personal number" field in the creation of the official's account allows incorrect official data to be recorded in the system and allows a user to be registered twice.

The PSMS is not connected to BHIS (Basic Health Information System) where patients who receive outpatient services are recorded. The only connection is with the "Vaccines" module. Due to the lack of interconnection between these two systems, there are cases in the Suhareka MFHC when a patient is administered the same therapy twice a week. This happens because the medical staff checking the patient does not have the information and

[25] Information Technology audit manual, audit matrix on Application Controls.

[26] Law No. 04/L -190 on Medical Products and Medicinal Devices

history of the patient regarding the therapy that the patient has been administered and is using. While in the Pharmacy of the Oncology Clinic, in absence of patient information/history (patient file with all data, diagnosis, examinations, therapy), the responsible official of the Pharmacy creates a manual database through the system, to record the patient, diagnosis, prescribing doctor, and dose of therapy with the corresponding date.

In the PSMS, when recording the products received by the EO, the field of the item's expiration date is not limited. The system allows the receipt of items with an expiration date of less than a year or less than a month or even less than two days. This is because the MoH so far has not determined a minimum deadline for the received article. As a result of the invalidity of the "Expiry Date" field, responsible pharmacy officials may accept items with a short expiration date. This affects the delivery of therapy to patients who receive therapy on a monthly basis. Due to the short expiration date of the medication, patients are not supplied/administered the specified amount on time and are forced to go to the pharmacy several times to be supplied with the same therapy. Additionally, in cases of non-expenditure of items, pharmacies are obliged to return them to the CP and be replaced by EO, creating additional work.

9. ***Personal patient data in SMF are not protected and there are several gaps in the output reports***

Data output is addressed in accordance with the privacy protections applied, distribution of output/reports is well controlled.[27]

In the PSMS Application, the search mode for the patient in the "Administrator" role, is not limited for editing data according to the request. The administrator can see the output for all patients, including all their information. Searching by first name or last name only displays all patients with that first name/last name. That is, the method of searching by personal number is not limited. This limitation is in the "Patient output" report".

The report "On Current Stock" does not display groups of items with the same data (such as ATC Code[28], name, form, volume, serial number, price, etc.) grouped into a single stock quantity. These items appear several times in the report, but in separate quantities. The CP officials of the UCCK have requested for an improvement, but it was not performed by the EO.

PSMS also has problems with report generation. The CP officials at UCCK reported that the "Report on Current Stock by Types" and the "Verification of orders of contract managers" report were not developed according to the requests of offiials, and there are innacurate data in the second report. The pharmacies of clinics and hospitals cannot generate reports to be informed about the stock in clinics and regional hospitals in the event of item shortages. This would allow faster information, at what clinic/ward the request is to be made, and stocks

[27] Information Technology Audit Manual, Audit Matrix on Application Controls.

[28] The Anatomical Therapeutic Chemical (ATC) classification system is an alphanumeric code system designed by the WHO for the classification of drugs and other medical products.

would be exchanged where there is more, which would enable a rational use but also mitigate situations of potential shortages in relevant units.

There are cases when the responsible officials cannot generate reports and there are many delays until they are generated. This is because there is no continuous monitoring of the PSMS's infrastructure performance.

Failure to apply privacy protection violates the privacy of all citizens who receive services in healthcare institutions. Likewise, the lack of proper and accurate reporting of output data has meant that officials cannot use these reports directly from the system, but must do manual verification of these reports. This entails a large volume of work and increases the possibility of errors.

Conclusions

The Ministry of Health has not managed to fully implement the PSMS at all health levels even after investments of over EUR 6.1 million in the extension of the hardware infrastructure, to enable the implementation of health information systems, including the PSMS. The PSMS system is not used by all health units and most of the pharmacies of hospital and clinic departments and FMCs do not carry out transactions in the PSMS until patient release. Furthermore, the Ministry of Health and the Ministry of Education and Culture have not aligned the PSOs with the work processes in the PSMS. This results in poor management of the pharmaceutical stock and in poor planning for the allocation of resources in the purchase of drugs, difficulties in monitoring the HCIs for the expenditure of the stock and the most rational use of the drugs and medicinal material spent by all healthcare institutions.

The Ministry has deficiencies in the division of responsibilities for the administration of the PSMS, creating a conflict of responsibilities and difficulties in coordination and communication. This lack of separation of responsibilities has caused confusion for PSMS users, delays in the provision of timely services and jeopardizes the integrity of health information.

The MoH has failed to draft IT policies and procedures, risking the protection of IT assets, as well as the reliability and confidentiality of data in information systems of strategic importance for the MoH. Likewise, the MoH does not implement controls in the management of changes in information systems. As a result, changes were made without testing and without approval by authorized persons before implementation in the actual environment. This can lead to unauthorized or accidental changes which may have consequences in the operation of the system.

The MoH has not drawn up a risk management plan for information systems. The lack of risk analysis and assessment and plan drafting means that the Ministry is not prepared for unexpected situations and does not have mechanisms to mitigate risks and recover from potential incidents.

Information security controls are not implemented, thus risking the protection of patient privacy, protection of information assets, maintainence of integrity, confidentiality and availability in the PSMS. IT officers and EOs maintaining the system have been granted full access to the application and database with non-personalized PSMS accounts and the use of one account by more than one user. The signing of the confidentiality statement by natural and legal persons who have access to the PSMS and have not carried out staff awareness training regarding information security is not applicable.

The MoH does not have mechanisms to ensure the continuity of work in the PSMS. Lack of dual hardware infrastructure to restore the PSMS data as quickly as possible and failure to

maintain the backup copy in another geographical location, in case of natural disasters, cyber attacks or other factors that may cause disruptions in the system, presents a risk of data loss and stalling the provision of services to patients.

PSMS does not have connections in some modules with central systems and health systems. This has led to the recording of the same EOs and users in the system more than once, as well as consuming the time of officials by performing the same work in two systems. Further, there is no appropriate monitoring of patients who are supplied with the same therapy within a short period of time. This has allowed incorrect data to be entered, jeopardizing the quality of the recorded information.

The MoH has jeopardized the protection of patient privacy by not restricting PSMS access to the "Administrator" role to read patient data. Users cannot use all reports produced by PSMS for various analyses, due to inaccuracy of reports, inability to access reports and slow generation of reports. These shortcomings create additional work for officials for manual verification of reports and increase the risk of errors, while preventing the rational use of drugs by healthcare institutions and receiving reports on time.

Recommendations

We recommend the Ministry of Health in coordination with the Kosovo Clinical University Hospital Service as follows:

1. **Standard Operation Procedures.** Update and approve PSOs, and review user roles and responsibilities to ensure they align with the job position and work processes;

1.1 **Training Plan.** Design a training plan for system users and train all staff involved in stock management;

1.2 **Use of PSMS.** Extend the PSMS to all levels of IHs and register in the system all activities for the management of the pharmaceutical stock from the planning of CPs to the patient release from the ward pharmacies;

1.3 **Extension of network infrastructure.** Coordinate activities between institutions for VPN services and IT equipment, to ensure that investments and costs for services are reasonable;

2. **IT structure.** Define the roles and responsibilities for the administration of the PSMS, as well as divide duties for the administration of the PSMS application and database;

3. **IT policies and procedures.** Design, approve and implement IT policies and procedures and communicate them to all personnel to provide leadership and oversight of day-to-day operations for the administration of information systems and their security;

3.1 **Change management.** Design, approve and implement the change management procedure in information systems. Any change must be tested by the requesting unit on the test system and after confirmation applied to the actual system;

4. **Risk Management Plan.** Design and implement a detailed risk management plan for information systems. The plan should be updated and reviewed periodically to assess the effectiveness of the measures taken and to address new risks that may emerge;

5. **Information security**. Establish control mechanisms for information security. In the PSMS, the patient's personal data is encrypted. Implement a training programme to raise awareness of all staff on information security, use official e-mails/letters for communication and monitor activities on the network and in the PSMS system;

5.1 **Confidentiality statement.** Adopt the signing of confidentiality and non-disclosure statements with employees for contracting parties and external parties before allowing access to information systems;

6. **Privileged access.** Divide the duties for the administration of the PSMS application and database, and appoint the alternate officer for their administration. EO's access to the actual system should be cut off, except for read-only access, with special approval and supervision by the MoH;

6.1 **User accounts.** Create standardized and customized PSMS accounts. Deactivate duplicate user accounts in the PSMS application in cases where the user/official belongs to the same institution, and deactivate accounts of officials who have terminated the employment relationship;

6.2 **Access rights.** Review users' access rights to the PSMS at least on a semi-annual basis to ensure they are valid and appropriate for their job position.

7. **PSMS Continuity Plan.** Design and implement the continuity plan of information systems. Build redundant infrastructure (double hardware) to guarantee the functioning of the PSMS. Backup storage of PSMS data should be coded and encrypted, and a copy should also be stored in another geographical location.

8. **Validity of input data.** Link the PSMS with central information systems and health systems. In the PSMS application, it must implement field validation for input data and set the minimum deadline for item acceptance; dhe

9. **Report generation**. Limit the display of patient data to protect their privacy and adjust the reports for stocking items with the same specifications in stock and other reports according to the user's request. Adjust PSMS performance to enable timely report generation.

The recommendations are related to the findings presented and the issues identified therein, resulting in 16 recommendations.

Annex I. Audit design

Areas of risk and the purpose of the audit

The Pharmaceutical Stock Management System enables the management of the supply process of medicines and medicinal materials, starting from central level institutions (MoH and HUCSK) to health institutions and up to distribution to the patient.

The use of PSMS is important for monitoring the quantity of pharmaceutical products, expiration dates of products and to manage the procurement and distribution of medicinal products efficiently.

During the pre-study phase of the audit and the interviews conducted with the responsible officials in MH and HUCSK/UCCK, in order to assess the management of the PSMS and the security of information, as well as its use, we have identified the following risks:

- There are no procedures for managing changes in information systems;
- The economic operator has full access to the administration of the PSMS application and database;
- The division of responsibilities of officials within the information technology (IT) department is not clearly defined;
- The economic operator opens user accounts in the PSMS;
- User accounts are not personalized, there are users in the system who have more than one active account, and user accounts are not deactivated at the time their contract expires or their position changes;
- There is no risk management plan for information security;
- In the PSMS application, the patient's personal data is not fully protected;
- The performance of the system is slow when using it in UCCK;
- The PSMS is not used in all health institutions, and the patient exit module is not implemented by all levels of health care;
- There is no redundant infrastructure for data storage.

Reviewing the problem indicators identified by these sources as well as our assessments based on the Active IT Audit Manual[29] to identify the most risky areas related to the management of the PSMS and information security, leads us to the problem main which is PSMS administration.

[29] Active Audit Manual - is a platform developed by ITWG/EUROSAI and WGITA/INTOSAI, that it is used to identify the most risky areas, define questions, criteria and work methodology during the IT audit process.

System description

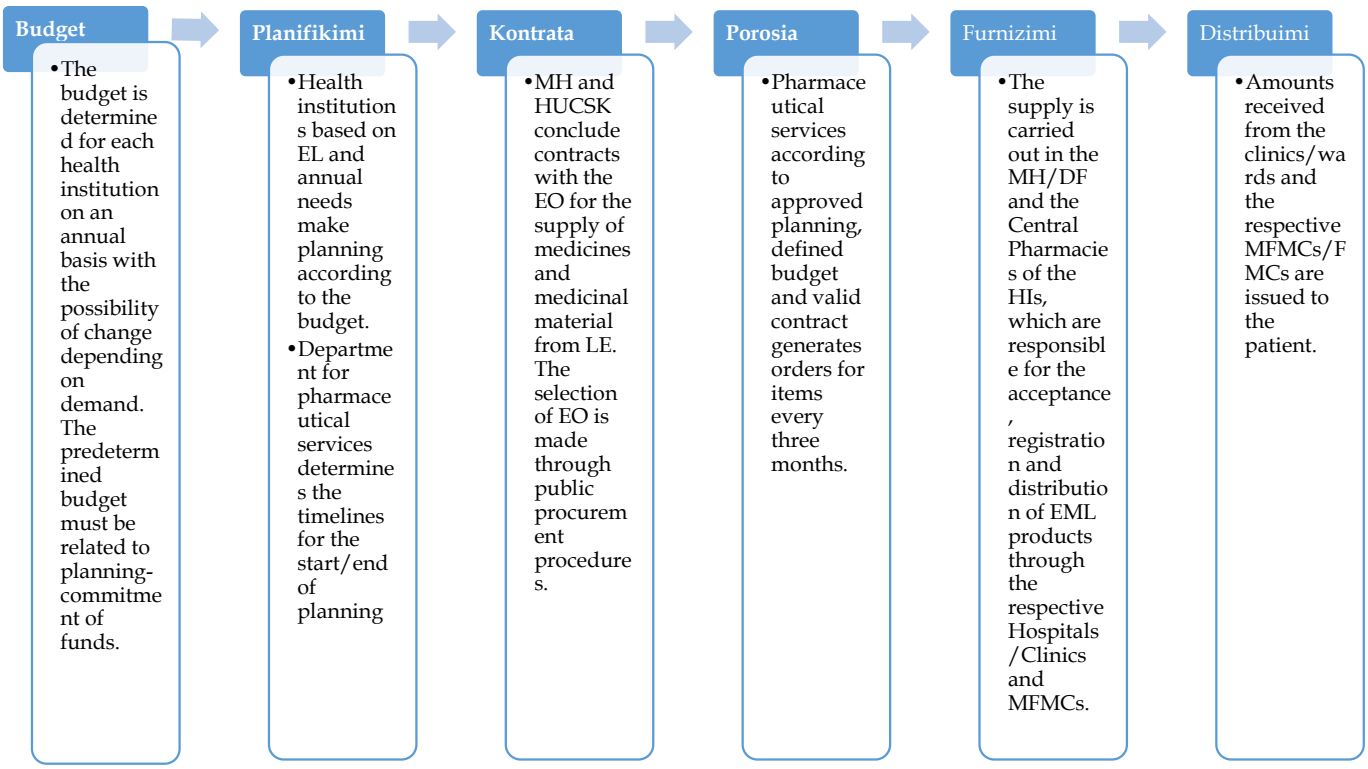
The Ministry of Health is an institution within the Government of the Republic of Kosovo and is responsible for drafting and implementing the Government's policies in the field of health services for all citizens of the Republic of Kosovo without distinction.

The implementation of development policies in healthcare is the responsibility of the Ministry, which through sectoral plans, organization, financing, standards, regulation, and management provides support for the improvement of healthcare by guiding the behavior of other governmental, municipal institutions, employees, employers, civil society, citizens, residents, and the health care system.

MH has developed PSMS to optimize medicine inventory management and improve pharmacy operations. This system includes various modules and functionalities that support efficient inventory tracking, stock management, medicine ordering and their transfer to health facilities.

Pharmaceutical stock management goes through the phases and supply procedures described as follows:

Figure 9. Phases of pharmaceutical stock management



Role and responsibilities of the parties

Within the Ministry of Health, the departments that administer PSMS are the Department of the Health Information System and the Division of Pharmacy, which report to the Secretary General.

Department of Health Information System

The duties and responsibilities of the Department of Health Information System who manage PSMS are to:

- Propose, draft and ensure the implementation of policy/strategy documents and legislation regarding the development of HIS;
- Monitor and report on a regular basis on the implementation of policies/strategies and legislation for HIS, including its maintenance and operation;
- Plan financial, human and technological resources for the regular operation of HIS;
- Contribute to the quality and safety of HIS data;
- Provide authorizations on access to data sources and registers, according to the request and relevant legislation for data protection.

The following Divisions are part of this Department:

- Division for Strategic Planning of HIS;
- Division of Oversight of the Operational Functioning of HIS.

Division of Pharmacy

The duties and responsibilities of the Pharmacy Division are to:

- Accept and analyze the requests of health institutions from the essential medicines list and consumables, including cost forecasts, for each fiscal year for Primary Health Care (PHC);
- Compile the annual plan of needs for the procurement of medicines and consumables from EML based on the analysis of the needs of the population, the requirements of health institutions, priorities and material possibilities of MH, for PHC;
- Coordinate and support the compilation and periodic review of the Essential Medicines List;
- Monitor and offer professional support in the execution of contracts for the supply of herbs and consumables;
- Monitor medicines stocks in the Ministry of Health's warehouses and ensure regular and uninterrupted supply of medicines and consumables available to PHC public health institutions;
- Supervise the operation and use the information of the Pharmaceutical module of the Health Information System until the full operationalization of the integrated HIS system.

Hospital and University Clinic Service of Kosovo

HUCSK is a unique health institution, consisting of secondary and tertiary level health care institutions in the public health sector as an organizational unit, and of Professional Services as its administrative and functional units, in accordance with the Law on Health.

The health institutions of the secondary and tertiary level of health care, which make up the HUCSK, are as follows:

- University Clinical Center of Kosovo (hereinafter "UCCK");
- University Dentistry Clinical Center of Kosovo;
- National Center of Occupational Medicine in Gjakova;
- National Center of Sports Medicine;
- National Blood Transfusion Center;
- National Telemedicine Center;
- General Hospital in Mitrovica;
- General Hospital in Gjilan;
- General Hospital in Peja;
- General Hospital in Gjakova;
- General Hospital in Prizren;
- General Hospital in Ferizaj;
- General Hospital in Vushtrri;
- Mental Health Centers with Homes for Community Integration;
- Center for Integration and Rehabilitation of Chronic Psychiatric Patients in Shtime.

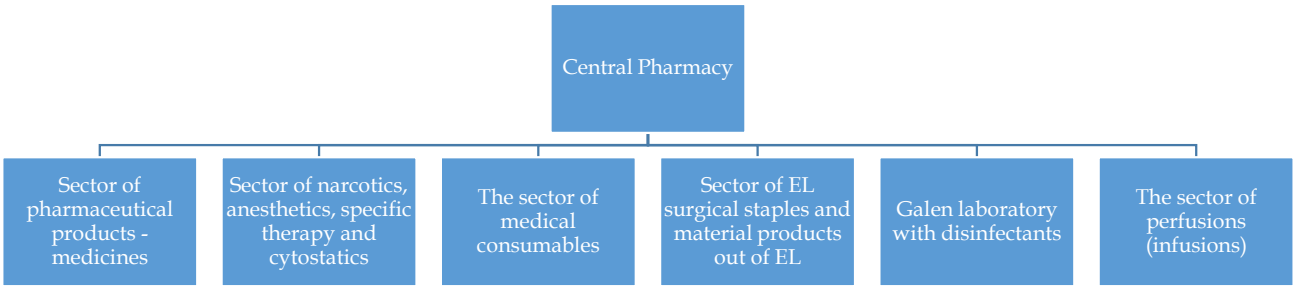
As an organizational unit of the HUCSK, there is also the Pharmaceutical Service, where pharmaceutical and professional services are offered, as well as the supply, storage, preparation, provision of medicine and information on its use, as well as other health care services, in accordance with the provisions of the law in force.

Central Pharmacy

The Central Pharmacy of HUCSK/UCCK is a pharmacy-specifically a pharmaceutical circulating warehouse, which currently, through the sectors in its composition and the Clinical Pharmacies operating within it, supplies all Clinics, Services and Preclinical Institutes of UCCK with pharmaceutical products-medicines and medical consumables necessary for the performance of health services.

The Central Pharmacy (CP) consists of six sectors as presented below:

Figure 10. Sectors of the Central Pharmacy



In the framework of the pharmaceutical service, the Central Pharmacy supplies all the Pharmacies of the Clinics within it as well as the Preclinical Institutes, the Emergency Clinic, the Central Anesthesiology and Intensive Care Medicine Clinic, the Medical Biochemistry Clinic as well as the Obstetrics-Gynecology Clinic with medicines and medical consumables, which shows that it is one of the most important organizational pillars of UCCK and HUCSK respectively.

Audit scope and questions

The scope of this audit is in:

- The Ministry of Health, namely the Department of the Health Information System, which is responsible for the administration of PSMS and the Division of Pharmacy, which performs the functions of managing medicines and consumables from the essential list for primary health care;
- The Central Pharmacy of UCCK/HUCSK, which is a pharmacy-respectively a pharmaceutical circulating warehouse, which supplies all Clinics, Services and Preclinical Institutes of UCCK with Pharmaceutical Products-Medicines and Medical consumables necessary for the performance of health services; and

The Oncology Clinic (does not record transactions in the patient exit module of the PSMS and the medicine used in this clinic have a high cost) and the Neurological Clinic (records all transactions, up to the "patient discharge) at UCCK, Gjilan Regional Hospital (The Central Pharmacy in UCCK carries out transactions in PSMS for this hospital) as well as in MFMC Suharekë (records very few transactions in PSMS). The focus of the audit will be in PSMS, through which the process of managing medicines and consumables has been digitized, including stages from planning to delivery to the patient. The audit will cover the period from 2022 to 2023.

Audit questions

To answer the audit objective, we have presented the main audit question and sub-questions as follows:

How does the MH administer the pharmaceutical stock management system and are health institutions effective in using this system?

Audit sub-questions:

1. *Is there an organizational structure, policies and procedures that enable the organization to achieve the mandate for the institution's goals?*
2. *Does the organization implement a standardized procedure for controlling all changes to key IT systems and applications?*
3. *Are health institutions able to use the Pharmaceutical Stock Management System (PSMS) effectively for monitoring and managing the stock of medicines and medicinal materials in their infrastructure?*
4. *How does MH manage information security risks?*
5. *Does the organization have an appropriate strategic direction and support for information security in terms of security policies, its coverage, awareness at the organizational level?*
6. *Has the organization ensured controls that only authorized users of the information have access?*
7. *Does the organization have a robust disaster recovery plan and procedures?*
8. *Does the application have adequate checks on the validity of input data?*
9. *Are the outgoing data handled in the right way for the protection of privacy?*

Audit criteria [30]

The criteria used in this audit are derived from the Active IT Audit Handbook [31], procedurave standard operating procedures and MH informative circulars.

In order to evaluate IT governance in MH, regarding organizational structures, IT policies and procedures that enable the organization to achieve the mandate for the institution's goals, the following criteria have been established:

- Health institutions through the PSMS must manage the entire stock of medicinal products (medicines and consumables). The organization collects and reviews system/network performance data on a real/periodic basis to better align with the organization's information systems monitoring and management needs;
- The IT structure within the organization is defined, its roles and responsibilities are clearly defined to properly maintain IT systems;
- The organization documents, approves, communicates appropriate policies and procedures to guide business and IT operations, in order to execute its mandate;
- The organization must have policies and procedures for managing changes in information systems. Change controls should be defined in the change management procedure: Change request - validation - acceptance - prioritization - design change - change testing - implementation - documentation.

In order to assess that MH has mechanisms for information and cyber security, the following criteria have been established:

- The organization has risk management policies and plans, and has determined sufficient resources to identify and manage risks;
- Information security policies cover all operational risks and are able to reasonably protect all critical information assets against loss, damage and abuse. Personnel must understand and maintain information security. Employees, contractors and third-party users should be required to sign a confidentiality or non-disclosure agreement as part of their initial terms and conditions of employment;
- The access procedures must provide a basis for the control of interference with information. Segregation of responsibilities and controls should be in place to prevent unauthorized changes to information systems and systems configuration. Access rights to the use of information systems for all employees, contractors or third parties must be terminated at the moment of termination of the contract, or adapted to the changes of responsibilities;

[30] The Information Technology Audit Handbook is a product of the EUROSAI Information Technology Working Groups (WGITA) as well as the INTOSAI Development Initiative (IDI) for the definition of Information Technology Audit standards. hereinafter Information Technology Audit Handbook.

[31] The Information Technology Audit Handbook is a product of the EUROSAI Information Technology Working Groups (WGITA) as well as the INTOSAI Development Initiative (IDI) for the definition of Information Technology Audit standards. hereinafter Information Technology Audit Handbook.

- The organization must have a plan on the continuity of the work of the information system, which enables the continuation of activities. For the realization of this plan, the main work processes of the organization must be identified, and the reaction time, the recovery time and the period of losses must be determined.

In order to assess that there are application control mechanisms in the PSMS, the following criteria have been established:

- Validation rules should be well designed, documented and implemented in input interaction. The application must have validation procedures in place to protect against data entry errors. Invalid data is properly rejected by the application;
- Data output is handled in accordance with the privacy protection applied, distribution of output/reports is well controlled.

Audit Methodology

In order to answer the audit question and sub-questions and in order to support the audit conclusions, we applied the following methodology:

- Analysis of legal and regulatory frameworks, SOPs of MH and HUCSK which are determining criteria for the management of the supply and distribution of medicines and medicinal material;
- Review of the organization structure of the IT sector;
- Analysis of policies and procedures designed for information systems;
- Checks if the mechanisms for information security are well defined;
- Analysis of controls for the protection of privacy and confidentiality;
- Analysis of the workflow documentation that is implemented in the PSMS, as well as the system user manual;
- Assessment of information security and logical access to applications and databases;
- Evaluation of input and output controls of the application;
- Analysis of the tables obtained from the PSMS database with CAAT tools (Idea, SQL, Excel) to evaluate the data sequences;
- Analysis of policies and processes to evaluate the continuity of information systems; and
- Conducting interviews with responsible officials.

Relevant documents

List of laws and regulations relevant to this audit:

- Law No. 04/L-125 on Health;
- Law No. 06/L-082 on Protection of Personal Data;

- Regulation (Grk) No. 07/2015 on Internal Organization and Systematization of Jobs of the Ministry of Health;
- Regulation (MPA) No. 01/2018 on Electronic Databases;
- Administrative Instruction (MH) no. 11/2013 on Health Information System and Reporting of Health Statistical Data;
- Statute of the University Hospital and Clinic Service of Kosovo;
- Development of the feasibility study for eHealth in Kosovo;
- Information Circular (MH) No. 4/2023.

Annex II. Confirmation letters

REPUBLIKA E KOSOVËS-REPUBLIKA KOSOVA-REPUBLIC OF KOSOVO
ZYRA KOMBËTARE E AUDITIMIT
NACIONALNA KANCELARIJA REVIZIJE / NATIONAL AUDIT OFFICE
17-04-2024

Njësia Org. Org. Jedin. Org. Unit	Shif.klasif. Klasif. Kod Class. Code	Nr.Prot. Br. Prot. Prot. No.	Nr.i faqeve Br. Stranica No. Pages
06	47	418	1

REPUBLIKA E KOSOVËS-REPUBLIKA KOSOVA-REPUBLIC OF KOSOVA
QEVERIA E KOSOVËS-VLADA KOSOVA-GOVERNMENT OF KOSOVA
MINISTRIA E SHËNDETËSISË-MINISTARSTVO ZDRAVLJA-MINISTRY OF HEALTH
Njësia Org. Org. Jedinica Org Unit 02
Nr. Prot: Broj Prot. Prot.No 05-2938
Nr.i faqeve Br.stranica No.pages -1-
Data: Datum: Date: 17/04/2024
Prishtinë / a

Republika e Kosovës
Republika Kosova - Republic of Kosovo
Ministria e Shëndetësisë / Ministarstvo Zdravsta / Ministry of Health

LETËR E KONFIRMIMIT

Për pajtueshmërinë me të gjeturat e Auditorit të Përgjithshëm për raportin e auditimit të teknologjisë së informacionit **"Sistemi Informativ për Menaxhimin e Stokut Farmaceutik",** dhe për zbatimin e rekomandimeve.

Për: Zyrën Kombëtare të Auditimit

Ptishtinë
15.04.2024

I nderuar,

Përmes kësaj shkrese, konfirmoj se:

- Kam pranuar draft raportin e Zyrës Kombëtare të Auditimit **"Sistemi Informativ për Menaxhimin e Stokut Farmaceutik"** (në tekstin e mëtejmë "Raporti");
- Pajtohem me të gjeturat dhe rekomandimet dhe nuk kam ndonjë koment për përmbajtjen e Raportit; si dhe
- Brenda 30 ditëve nga pranimi i Raportit final, do t'ju dorëzoj një plan të veprimit për implementimin e rekomandimeve, i cili do të përfshijë afatet kohore dhe stafin përgjegjës për implementimin e tyre.

Dr. Naim Bardiqi, Sekretar i Përgjithshëm në MSH

REPUBLIKA E KOSOVËS - QEVERIA E KOSOVËS - VLADA KOSOVA - GOVERNMENT OF KOSOVA - MINISTRIA E SHËNDETËSISË - MINISTARSTVO ZDRAVLJA - MINISTRY OF HEALTH
Prishtinë / a

Republika e Kosovës
Republika Kosova – Republic of Kosovo
Qeveria – Vlada - Government

Ministria e Shëndetësisë - Ministarstva Zdravstva - Ministry of Health

Shërbimi Spitalor dhe Klinik Universitar i Kosovës (SHSKUK)
Bolnička i Klinička Univerzitetska Sluzba Kosova (BKUSK)
The Hospital and University Clinical Service of Kosovo (HUCSK)

LETËR E KONFIRMIMIT

Për pajtueshmërinë me të gjeturat e Auditorit të Përgjithshëm për raportin e auditimit të teknologjisë së informacionit **"Sistemi Informativ për Menaxhimin e Stokut Farmaceutik"**, dhe për zbatimin e rekomandimeve.

Për: Zyrën Kombëtare të Auditimit

Vendi dhe data:Prishtinë17.04.2024

I nderuar,

Përmes kësaj shkrese, konfirmoj se:

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Drejtori i Përgjithshëm
Z. Elvir Azizi

REPUBLIKA E KOSOVËS
REPUBLIC OF KOSOVO-REPUBLIKA KOSOVA
KOMUNA E SUHAREKËS
MUNICIPALITY OF SUHAREKA-OPSTINE SUVA REKA

LETËR E KONFIRMIMIT

Për pajtueshmërinë me të gjeturat e Auditorit të Përgjithshëm për raportin e auditimit të teknologjisë së informacionit **"Sistemi Informativ për Menaxhimin e Stokut Farmaceutik"**, dhe për zbatimin e rekomandimeve.

Për: Zyrën Kombëtare të Auditimit

I nderuar,

Përmes kësaj shkrese, konfirmoj se:

- kam pranuar draft raportin e Zyrës Kombëtare të Auditimit **"Sistemi Informativ për Menaxhimin e Stokut Farmaceutik"** (në tekstin e mëtejmë "Raporti");
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Kryetari i Komunës

Bali MUHARREMAJ

Suharekë

18.04.2024

Adresa:
Zyra Kombëtare e Auditimit
Lagjja Arbëria
Rr. Ahmet Krasniqi, 210
10000 Prishtina
Republika e Kosovës